

# Beglaubigte Abschrift



Urkunde des Notars

**Eckart Maaß**

Jena

Die wörtliche Übereinstimmung nachstehender Abschrift mit der mir vorliegenden Urschrift beglaube ich hiermit.

I hereby certify that the above copy is a true copy of the original which has been produced to me.

Jena, den 13.04.2016

  
Maaß  
Notar

Technical File

# MeDioStar NeXT<sup>PRO</sup>

(Version 1591)



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## **1 Declaration on Conformity**

### ***1.1 Conformity assessment procedure***

This device has been assessed for conformity through the following procedure:

MDD 93/42/EWG Annex VI, Manufacturer's Self-Declaration

### ***1.2 Declaration of conformity***

The declaration of conformity for this device is appended to this file.

*CE MeDioStar 1591; 1592*

## 2 Device Description

### 2.1 Device description

The MeDioStar NeXT PRO is a pulsed diode laser (Class 4 laser product) that is used for the removal of unwanted hair, for the treatment of acne, for vascular treatments and for skin rejuvenation. Melanin and blood relatively strongly absorb the range of wavelengths of the radiation emitted by this laser, whereas the surrounding skin absorbs only a little bit of it. In this way, the radiation thermally destroys the target structure while protecting the surrounding skin.

For this medical device a compact design, maintenance-free usage and longevity is aspired. The Asclepion Laser Technologies GmbH uses it's long years of experience in the field of manufacturing laser emitted medical devices to offer a new, efficient medical device.

### 2.2 Intended use

- Hair removal
- Acne
- Vascular treatment
- Skin rejuvenation

### 2.3 Contraindications

- Light sensitivity
- Usage of preparations that increase sensitivity to light
- Cellulite therapies in the treatment area (wait a few weeks)
- Cancerous and pre-cancerous lesions in the treatment area
- Haired nevi in the treatment area
- Herpes simplex in the treatment area
- Tendency towards excessive scarring
- When using the ALX handpiece: Patients with skin type VI
- The laser must not be applied to the area near the eyes!
- Treatment of children, and women who are pregnant or nursing
- Tanned skin in the area to be treated, particularly when using the ALX handpiece.
- Tattoos in the area to be treated

Contraindications particularly for the treatment of spider leg veins

- Superficial varices with a diameter larger than 3 mm
- Branch and side branch varicose veins
- Ulcer
- Diabetes
- Vasculitis
- Stasis dermatitis
- Podedema
- Neuropathy of the legs
- Corticosteroids treatment in the last three months
- Thrombophlebitis



## 2.4 Functional description

### Technical description

#### Laser

The MeDioStar laser is a pulsed high power diode laser (laser class 4).

The emitted wavelength is in the near infrared (NIR) of between 755 nm and 950 nm.

The laser beam emission is activated by pressing the foot switch.

#### Power supply unit

The integrated power supply units transform the line voltage in rectified low voltage for the electrical supply of the device.

#### Control

The output parameters and the safety systems of the device are monitored and controlled by a microcontrol system.

#### Operating modes

The device operates in both single pulse mode and continuous mode.

The device is designed for continuous operation in the specified ambient conditions.

At high room temperature and high average power it is possible that, after longer treatments, the device goes into the cooling mode for a short time to guarantee the efficiency of the skin cooling.

#### Operation

The device is operated via a touchscreen. The data are output by an LCD with plain-text user guidance. Depending on the operating mode different parameters – such as fluence, pulse duration, pulse rate and others – can be set as described in the Operation chapter.

In addition to the parameters selected, other data such as the laser mode (STANDBY or READY), the handpiece used and, if necessary, error plain-text messages are displayed.

#### Cooling

The internal cooling system is required to prevent the component groups from being overheated. The lost heat is dissipated to the ambience via a water-air heat exchanger. A pump circulates the coolant through the component groups and the heat exchanger. In addition to this, integrated temperature and flow sensors provide safe operation.

The device cooling is ensured by the indoor air. External cooling water is not required

To maintain the cooling effect, the device should only be operated in the specified ambient conditions. The ambient air should be dustless. At the openings provided for cooling the device, a minimum distance should be kept to air-tight objects (e.g. the wall of the room). (See chapter Installation).

#### Skin Cooling

Next to the laser tip is a metal probe at the handpiece, which is cooled by an integrated Peltier element. Together with the procedure described in chapter Application it is guaranteed that the epi-dermis is cold before the laser pulse impinges. The temperature of the probe is monitored.

#### Safety units

The device is equipped with several safety units that have been provided to avoid maloperation and unintentional activation of the system:

Laser emergency STOP switch, Key switch, Power switch, Foot switch, STANDBY mode, Automatic shut-down Remote door interlock contact Acoustic signal



## 2.5 List of devices

| Designation                                                         | Description                                                                    |
|---------------------------------------------------------------------|--------------------------------------------------------------------------------|
| MeDioStar (NeXTPRO)<br>(item no.1591)                               | High power diode laser (main unit)                                             |
| MeDioStar Handpiece ST<br>(item no.4020)                            | Standard handpiece for hair removal                                            |
| MeDioStar Handpiece HP<br>(item no.4022)                            | High-power handpiece for hair removal                                          |
| MeDioStar Handpiece VAS<br>(Part no.4021)                           | Handpiece for vascular treatment                                               |
| MeDioStar handpiece with<br>XLS laser tip (item no. 4070<br>+ 4071) | Handpiece with large spot for anatomically difficult<br>areas (e.g. upper lip) |
| MeDioStar handpiece with<br>XLL laser tip (item no. 4070<br>+ 4072) | Handpiece with very large spot for large treatment<br>areas                    |

## 2.6 Materials

This device is made of typical materials used in electronic instruments. These includes PCB's, Liquid Cristal Display (LCD), electronic switches and wirings and a metal chassis.

## 2.7 Accessories

See the List of devices 2.5

## 2.8 Classification

Classification: 93/42/EEC Class IIb, Rule 9

UMDNS No.: 16-948 Laser, therapeutic

Laser classification according to EN 60825-1:2007: The MeDioStar is classified as class 4 laser.

Software safety classification acc. to EN 62304:2006: Class B

### 3 Design

The design history is founded under the following DHF number:

ALT-M 003/14 MeDioStar NeXT<sup>PRO</sup> 1591/1592

The summary of safety relevant material is documented in the following document:

FB 7331 LoCC MSPRO V03\_AWi/15/02/03-01

### 4 Testing

For a complete list of tests and testing protocols used to validate and verify the safety / effectiveness of this device is found in the following table:

| <b>Test and Testing protocols</b>                                                     | <b>document</b>                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Test Protocol IEC60601-1                                                              | 21215627_001_ IEC60601-1 Test report.pdf                                                                                                                                                                                  |
| Test Protocol EMC<br>EMC Evaluation                                                   | MSPRO EMC CB Test Report SLG - 1430-13-EE-14-PB002<br>CL 73532 Bewertung EMV MSPRO V01- MMo/14/08/25-01                                                                                                                   |
| Evaluation of software<br>development                                                 | CL 7365 IEC 62304 MSPRO - RH/14/07/01-01                                                                                                                                                                                  |
| Evaluation of laser safety                                                            | 21215627_001_attm#3_ IEC60601-2-22.pdf<br>CL 7355 IEC EN 60 825-1 MSPRO- IS/14/02/12-02                                                                                                                                   |
| Device Verification and Validation                                                    | FB 7351 Verifizierung MSPRO Vs.02 – AWi/14/11/10-01                                                                                                                                                                       |
| Validation Packaging                                                                  | FB 7351 Validierung Verpackung MSPRO Vs.02 – KL/14/11/06-01                                                                                                                                                               |
| Evaluation of Labeling                                                                | CL 7356 CL GA MeDioStar Vs.02 ZI/14/10/27-01<br>CL 7357 Geräteschilder MeDioStar Vs.05 AWi/15/01/20-01<br>CL 7363 EN 980 MeDioStar Vs.01 MMo/14/08/19-04<br>CL 7364 EN 1041 MSPRO MMo/14/07/04-01                         |
| Verification and Validation<br>Software (Listed in Traceability<br>Analysis document) | FB 7314 Traceability Analysis MSPRO Vs.04 – RH/15/02/03-04                                                                                                                                                                |
| Laser Verification                                                                    | FB 7351e Verification Report MSPRO Energy Adjustment rev 01-<br>MMo/14/08/19-01<br>FB 7351e Verification Stability of Laser output MSPRO<br>V01_MMo/14/08/19-02<br>FB 7351e Veri Energy Adjustment HS XL V01_MMo140819-01 |
| Verification Handpiece                                                                | FB7351e Veri MSPRO HP V01 IH141111-03.pdf<br>FB 7355 Laborbericht MSPRO Spotgröße Homogenität JE141204-<br>01.pdf                                                                                                         |
| Verification biocompatibility                                                         | FB 7351e Verification Biocompatibility Vs02 - IH/14/06/17-01<br>FB 7351e FB 7351e Verification Biocompatibility Vs02 -<br>IH/14/12/01-02                                                                                  |
| Verification electronic components                                                    | FB 7351_Verifizierung ACB3 Vs.01 – CB/14/07/01-01                                                                                                                                                                         |

## 5 Manufacture

The device is manufactured in the following location:

Asclepion Laser Technologies GmbH, Brüsseler Straße 10, 07747 Jena, Germany

## 6 Cleaning and Sterilization

### 6.1 *Cleaning and sterilization Process description*

The cleaning, disinfection should be performed according to the instructions in the User Manual:

1590 99 047\_V1 – 24March 2016 – UM-MSPRO RUS (en)

### 6.2 *Cleaning and sterilization process validation*

Sterilization is not possible and not required.

## 7 Packaging and Labeling

### 7.1 *Packaging description and validation*

The device packaging is illustrated in the following drawings:

159008004 Verpackungsvorschrift MS 159x V06.pdf

### 7.2 *Labeling description and validation*

The labels of the device are listed in the following drawings:

159099020 Labeling MSPRO

The labels were checked with final test report.



## 8 Risk Management

Risk analysis, risk management and post-market surveillance for this device is found in the Risk Management File:

*FB 7302 RAaC MSPRO V03 RH/14/11/10-01*

## 9 Usability

The usability engineering File and evidences of the Usability Engineering process can be found in the following document:

*CL 73523 EN 62366 / 60601-1-6 MeDioStar 1591, 1592 ZI/15/04/10-01*

*FB 7351e MeDioStar 1591, 1592 ZI/14/04/22-01-01*

## 10 Essential Requirement

### 10.1 ER checklist

The evidence of conformity with the Essential Requirements for this device is documented in the following document:

*CL 7351 Conformity MDD 93\_42\_EEC MeDioStar 1591/1592 CaM/14/11/12-01*

### 10.2 List of standards applied

The complete list of all standards that have been applied in the design/testing/Validation of the device can be found in the following document:

*CL 7321 Relevante Sicherheitsnormen MeDioStar NeXT<sup>PRO</sup> SE Vs. 02 MMo/14/08/21-01*

## 11 Clinical Data

Clinical data for this device is summarized in the following report:

*FB 7351e ClinEval MSPRO V01 ZI/14/03/27-01*



## 12 Quality Certificates

The facility and organization involved in the design and manufacturing of this device have obtained the following ISO certifications:

Asclepion Laser Technologies GmbH, Brüsseler Straße 10, 07747 Jena, Germany,

- EC Certificate Directive 93/42/EEC (Registration No.: HD 60105768 0001)
- Certificate EN ISO 13485:2012 / EN ISO 13485:2012/AC:2012 (Registration No.: SX 60105769 0001)

Die Übereinstimmung vorstehender Abschrift mit der Urschrift wird beglaubigt

Jena, den 11. AUG. 2018

Der Notar





Technical File

# MeDioStar NeXT<sup>PRO</sup>

(Version 1591)

Annexe:

| No. | Chapter                                                                          | Document                                                                                      |
|-----|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| 1   | 1.2 Declaration of Conformity                                                    | CE MeDioStar 1591, 1592                                                                       |
| 2   | 3 Design summary of safety relevant material                                     | FB 7331 LoCC MSPRO V03_AWi/15/02/03-01                                                        |
| 3   | 6.1 Cleaning and Sterilization<br>Cleaning and sterilization Process description | 159099002-V06-2.Sept.2014-GA-MSPRO-EN                                                         |
| 4   | 7.1 Packaging description and validation                                         | 1590 08 004 Verpackungsvorschrift MDS 159x Vs.06                                              |
| 5   | 7.2 Labeling description and validation                                          | 159099020 Labeling MSPRO                                                                      |
| 6   | 8 Risk Management                                                                | FB 7302 RAaC MSPRO V03 RH/14/11/10-01                                                         |
| 7   | 9 Usability                                                                      | CL 73523 EN 62366 / 60601-1-6 MeDioStar 1591, 1592 ZI/15/04/10-01                             |
| 8   | 9 Usability                                                                      | FB 7351e MeDioStar 1591, 1592 ZI/14/04/22-01-01                                               |
| 9   | 10.1 Essential Requirement ER checklist                                          | CL 7351 Conformity MDD 93_42_EEC MeDioStar 1591/1592 CaM/14/11/12-01                          |
| 10  | 10.2 Essential Requirement List of standards applied                             | CL 7321 Relevante Sicherheitsnormen MeDioStar NeXT <sup>PRO</sup> SE Vs. 02 MMo/14/08/21-01   |
| 11  | 11 Clinical Data                                                                 | FB 7351e ClinEval MSPRO V01 ZI/14/03/27-01                                                    |
| 12  | 12 Quality Certificates                                                          | EC Certificate Directive 93/42/EEC (Registration No.: HD 60105768 0001)                       |
| 13  | 12 Quality Certificates                                                          | Certificate EN ISO 13485:2012 / EN ISO 13485:2012/AC:2012 (Registration No.:SX 60105769 0001) |

## **EG-Konformitätserklärung** **EC Declaration of Conformity**

**Asclepion Laser Technologies GmbH**  
Brüsseler Straße 10  
07747 Jena  
Germany

Wir erklären hiermit die Übereinstimmung des Medizinproduktes

~~We declare the compliance of the medical device~~

### **MeDioStar**

ALT-Artikel-Nr./ALT-commodity no.: 1591; ~~1592~~

Klassifizierung/classification: Klasse II ~~b~~ gemäß 93/42/EWG Anhang IX  
Class II ~~b~~ according to 93/42/EEC Annex IX

mit der EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II  
(Benannte Stelle: „TÜV Rheinland LGA Products GmbH“, Tillystraße 2, 90431 Nürnberg, Nr. 0197;  
Registriernummer HD 60097279 0001 ).

Durch nicht von der Asclepion Laser Technologies GmbH autorisierte Änderungen an diesem Produkt  
verliert diese Erklärung ihre Gültigkeit.

with the requirements of the Medical Devices 93/42/EEC Annex II  
(notified body: „TÜV Rheinland LGA Products GmbH“, Tillystr. 2, 90431 Nürnberg, no. 0197;  
registration no. HD 60097279 0001).

Any modification to the product, not authorized by Asclepion Laser Technologies GmbH, will invalidate  
this declaration.

Zugrundeliegende Konformitätsakte/ underlying technical file: ALT M 03/14

Harmonisierte Normen/ Harmonized Standards:

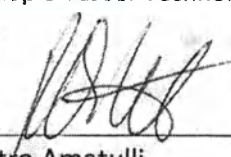
Grundlegende Anforderungen nach RL 93/42/EWG Anhang I mit allen zutreffenden harmonisierten  
Normen.

Essential requirements of Directive 93/42/EEC, Annex I with all relevant harmonized standards.

Jena, January 20<sup>th</sup> 2015

Asclepion Laser Technologies GmbH

i.V.

  
Pietro Amatulli  
Technical Director

Diese Erklärung ist gültig bis:

This declaration is valid until: 02.12.2015



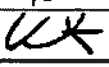
|                |                                                                                                        |                                                                                     |
|----------------|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| FB <b>7331</b> | List of safety relevant materials and components                                                       |  |
| Revision: A    | Identification No.: <b>AWi/15/02/12-01</b><br><small>Identification code/year/month/day-number</small> | Page 1 of 6<br>FB 7331 LoCC-MSPRO<br>V04_AWi150212-01.docx                          |

For:

|                               |                                                    |
|-------------------------------|----------------------------------------------------|
| Entwicklungsprojekt:          | MedioStar Weiterentwicklung                        |
| Projektnummer:                | 4800 93A 73 400                                    |
| Produktname:                  | MedioStar, Brandname MedioStar NeXT <sup>PRO</sup> |
| Artikelnummer <sup>1)</sup> : | 1591, 1592                                         |

Prepared:

| Vs. | Change short description                                                          | Date          | Name      | Sign                                                                                |
|-----|-----------------------------------------------------------------------------------|---------------|-----------|-------------------------------------------------------------------------------------|
| 04  | Update: No. 7.4: alternative Temperature Sensor                                   | Feb. 12, 2015 | A. Winter |  |
| 03  | Update: No. 4.4 alternative fan; No. 7.2.5 update Datasheet XL Laser Diode module | Feb. 02, 2015 | A. Winter | Sgd. Winter                                                                         |
| 02  | Update No. 1.5 (operating ratings of HPC825)                                      | May 19, 2014  | M.Möller  | Sgd. Möller                                                                         |
| 01  | First edition                                                                     | Feb. 18, 2014 | M.Möller  | Sgd. Möller                                                                         |

| Check and release: | Division                                                                            | Date          | Name       | Sign                                                                                  |
|--------------------|-------------------------------------------------------------------------------------|---------------|------------|---------------------------------------------------------------------------------------|
| Checked by         |  | Feb. 12, 2015 | Streit     |  |
| Released by        | QA R&D                                                                              | Feb. 13, 2015 | C. Kötting |  |

|                                                  |           |              |                                      |           |              |
|--------------------------------------------------|-----------|--------------|--------------------------------------|-----------|--------------|
| Grund für letzte Änderung des FB: Ersterstellung |           |              |                                      |           |              |
| FB erstellt durch Prozesseigner FuE:             |           |              | FB geprüft und freigegeben durch QM: |           |              |
| 17.07.05                                         | I. Streit | gez. Streit  | 10.09.05                             | R. Thieme | Gez. Thieme  |
| Datum                                            | Name      | Unterschrift | Datum                                | Name      | Unterschrift |

|                |                                                                                                        |                                                                                     |
|----------------|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| FB <b>7331</b> | <b>List of safety relevant materials and components</b>                                                |  |
| Revision: A    | <b>Identification No.: AWi/15/02/12-01</b><br><small>Identification code/year/month/day-number</small> | Page 2 of 6<br>FB 7331 LoCC MSPRO<br>V04_AWi150212-01.docx                          |

| no        | type and item number                                                                                                     | manufacturer                       | operating ratings                                                                                                                | nominal ratings                                                                                                                  | Standard No./, Edition                                                            | Mark(s) & Certificates of conformity                                            |
|-----------|--------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>1.</b> | <b>Electrical supply</b>                                                                                                 |                                    |                                                                                                                                  |                                                                                                                                  |                                                                                   |                                                                                 |
| 1.1       | Line cord<br>550704013                                                                                                   | Feller<br>Bürklin OHG              | 240 V<br>< 15 A                                                                                                                  | 250 V<br>16 A                                                                                                                    | IEC60884<br>VDE 0250<br>UL 817<br><br>CSA<br>GB17465.1<br>EN 60320/C19<br>ENEC 11 | •<br>107641<br>E42003<br>(ELBZ.E42003)<br>•<br>•<br>•<br>15-003<br>(28.02.2006) |
| 1.2       | Could apparatus<br>plug<br>550206080                                                                                     | Schurter /<br>O.Heil               | 240 V<br>< 15 A                                                                                                                  | 250 V<br>16 A                                                                                                                    | IEC 60320-1<br>VDE<br>CSA 22.2 No.42<br>UL 498<br>UL                              | 40026179<br>121440<br>27324<br>E45115<br>E96454                                 |
| 1.3       | Circuit Breaker<br>550901094                                                                                             | E-T-A<br>Elektrotechn.<br>Apparate | 240 Vac<br>< 15 A                                                                                                                | 240 Vac<br>16 A                                                                                                                  | IEC 60934<br>CSA C22.2<br>No.14<br>UL 1077<br>GB 17701                            | 40011839<br>QVNU8.E67320<br>QVNU2.E67320<br>-                                   |
| 1.4       | Line Filter<br>FN2060B-16-06<br>550301122                                                                                | Schaffner<br>Group                 | 240Vac<br>max. 12 A                                                                                                              | 250 Vac<br>30 A                                                                                                                  | IEC 60939<br>UL 1283<br>CSA 22.2 No.8<br>ENEC 14                                  | -<br>FOKY2.E64388<br>1059975<br>SE/0037-28C                                     |
| 1.5       | Power Supply<br>HPC825<br>A2-825-00<br>550399113                                                                         | PMB<br>Elektronik<br>Starnberg     | In<br>115Vac<br>50/60Hz<br>1400VA<br><br>220 -<br>240Vac<br>50/60Hz<br>1500VA<br><br>Out<br>24Vdc<br>400W<br><br>6-45V<br>0-130A | In<br>115Vac<br>50/60Hz<br>1400VA<br><br>220 -<br>240Vac<br>50/60Hz<br>1500VA<br><br>Out<br>24Vdc<br>400W<br><br>6-45V<br>0-130A | IEC 60601-1                                                                       | tested by LGA                                                                   |
| <b>2.</b> | <b>Switch-on circuit</b>                                                                                                 |                                    |                                                                                                                                  |                                                                                                                                  |                                                                                   |                                                                                 |
| 2.1       | Key Switch / Laser<br>Emergency Switch<br>Switch Element<br>Oktron BZOI_482<br>550101039<br>BZOO/1.000.7706<br>550101040 | Schlegel                           | 12 V DC<br>1 A                                                                                                                   | 250 VAC<br>6 A                                                                                                                   | EN 61058<br>IEC60947-5-1/-<br>5<br>UL 508<br>CSA 22.2 No.0-<br>M91 / No.14-95     | •<br>71363393<br>NKCR2.E72889<br>1107935                                        |

|                |                                                                                                        |                                                                                                                        |
|----------------|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| FB <b>7331</b> | List of safety relevant materials and components                                                       | <br>Asclepion<br>Light Technologies |
| Revision: A    | Identification No.: <b>AWi/15/02/12-01</b><br><small>Identification code/year/month/day-number</small> | Page 3 of 6<br>FB 7331 LoCC MSPRO<br>V04_AWi150212-01.docx                                                             |

| no        | type and item number                                                                                                     | manufacturer             | operating ratings         | nominal ratings                   | Standard No./, Edition                                                                                          | Mark(s) & Certificates of conformity                                    |
|-----------|--------------------------------------------------------------------------------------------------------------------------|--------------------------|---------------------------|-----------------------------------|-----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| 2.2       | Foot switch<br>KF1SD1S MED SK1<br>2<br>660806008                                                                         | Steute                   | 10 VAC<br>4..20 mA        | max.<br>25 VAC<br>max. 1 A        | IEC 60601-1<br>IEC 60601-2-2<br>IEC 60601-2-22<br>IEC 60529 (IPX8)<br>UL 60601-1<br>UL 94<br>CSA 22.2           | E9812309E01<br>•<br>110405 -<br>E178188A<br>E41871<br>E80168<br>1312657 |
| <b>3.</b> | <b>Control system</b>                                                                                                    |                          |                           |                                   |                                                                                                                 |                                                                         |
| 3.1       | ECD4 PCB<br>760106027                                                                                                    | ALT/ACD                  | +15 V<br>< 2 A            | +8-40 V<br>4 A                    | UL<br>Verified by ALT                                                                                           | E156885<br>•                                                            |
| 3.1.1     | Part of pos. 3.1:<br>Relais ALD 105<br>Relais ALD 112                                                                    | Panasonic                | +5 V<br>< 40 mA<br>1.5 kV | 277VAC/3<br>A<br>30VDC/3A<br>4 kV | IEC 61810-1<br>UL 508<br>CSA 22.2 No.14-<br>10                                                                  | 40014384<br>E43028                                                      |
| 3.1.2     | Part of pos. 3.1:<br>DC_DC Converter<br>NMV0512                                                                          | Murata                   | 1.5 KV                    | 3 kV                              | RoHS<br>tested and<br>verified by ALT                                                                           | •<br>•                                                                  |
| <b>4.</b> | <b>Cooling system</b>                                                                                                    |                          |                           |                                   |                                                                                                                 |                                                                         |
| 4.1       | Part of pos. 4:<br>Micro Pressure<br>switch<br>580067<br>Alternativ:<br>18575: HR30211B3<br>HP<br>19732: HR10611B3<br>HP | Wilspec                  | 12 - 15 Bar<br>24V / <1 A | 17,7 Bar<br>28V / 3A              | UL 873<br>CSA 22.2 No.24-<br>93<br>EN 12263                                                                     | E196928<br>D 23 2005 T1                                                 |
| 4.2       | Part of pos. 4:<br>Compressor<br>Aspen 19-24                                                                             | Aspen<br>Compressor<br>s | 24 V<br>9,5 A             | 24 V<br>10 A                      | Directive<br>2006/42/EC<br>(ISO12100-1/-2,<br>60204-1)<br>2004/108/EC<br>(EMC)<br>tested and<br>verified by ALT | 960107902<br>•                                                          |
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|                |                                                                                                        |                                                                                    |
|----------------|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| FB <b>7331</b> | <b>List of safety relevant materials and components</b>                                                |  |
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| no        | type and item number                                                                                                       | manufacturer      | operating ratings           | nominal ratings      | Standard No./, Edition                                                                         | Mark(s) & Certificates of conformity |
|-----------|----------------------------------------------------------------------------------------------------------------------------|-------------------|-----------------------------|----------------------|------------------------------------------------------------------------------------------------|--------------------------------------|
| 4.4       | Part of pos. 4:<br>1x Condenser Fan<br>SanAce<br>9GV1224P1H03                                                              | Sanyo Denki       | <24 V<br><0,8 A             | 20,4-27,6V<br>0,8 A  | TÜV<br><br>UL<br><br>CSA                                                                       | R 50145867<br><br>GPWV2.E46810       |
|           | Alternativ:<br>2x Condenser Fan<br>SanAce<br>9G0924A202                                                                    | Sanyo Denki       | <24 V<br><0,3 A             | 20,4-27,6V<br>0,3 A  | UL<br><br>CSA                                                                                  | GPWV2.E46810                         |
| 4.5       | Part of pos. 4:<br>Temperature Sensor<br>LM35 (TO-92)<br>661203011<br>LM35 (TO-220)<br>661203010                           | National Semic.   | 5 V<br>0,05 A               | 5 V<br>0,05 A        | tested and verified by ALT                                                                     | -                                    |
| 4.6       | Flow Sensor<br>FS-380P Series<br>661201017                                                                                 | Gems Sensors Inc. | 15V<br><0,1A<br>3 KV        | 30V<br>0,3A<br>4 KV* | tested and verified by ALT                                                                     | -                                    |
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| 5.2       | Braid Wire H05V-K<br>550701116<br>550701120<br>550701147                                                                   | U.I. Lapp         | 240V                        | 500V                 | HAR: H05V-K<br>IEC60332-1-2<br>HD 21/VDE 0281<br><br>VDE 0298 Teil4<br><br>HD 516/VDE 0298-300 | -<br>-<br>•<br>-<br>-                |
| 5.3       | Protective tubing<br>PVC<br>550806040                                                                                      | Alpha Wire        | N.A.                        | N.A.                 | UL 224<br><br>CSA 198                                                                          | E38155<br>•                          |
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|                |                                                                                                        |                                                                                     |
|----------------|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| FB <b>7331</b> | List of safety relevant materials and components                                                       |  |
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| no        | type and item number                                                                                     | manufacturer       | operating ratings                            | nominal ratings                              | Standard No./, Edition             | Mark(s) & Certificates of conformity |
|-----------|----------------------------------------------------------------------------------------------------------|--------------------|----------------------------------------------|----------------------------------------------|------------------------------------|--------------------------------------|
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| 7.2       | <u>alternative to part 7.1:</u><br>Plastic Handpiece cover 400106035<br>Bayblend T65<br>Allruna W55 E203 | Bayer Allod        | Device inside<br>< 50 °C                     | 70°C                                         | RoHS, REACH<br><br>Verified by ALT | -<br>-                               |
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| 7.3.2     | <u>alternative to part 7.2.1:</u><br>Laser Diode Module<br>JOLD-580-QA-8A<br>for handpiece ST<br>and HP  | Jenoptik GmbH      | U≤16 V<br>Ip≤100 A<br>Pp≤700 W<br>Pm≤126 W   | U ≤16 V<br>Ip ≤130 A<br>Pp≤840 W<br>Pm≤126W  | Tested and<br>verified by ALT      | -                                    |
| 7.3.3     | <u>Part of Pos.7:</u><br>Laser Diode<br>DILAS_C3N-<br>VO68.5-940nm<br>for handpiece VAS                  | Dilas GmbH         | U ≤ 6 V<br>Ip ≤90 A<br>Pp≤250 W<br>Pm≤44W    | U ≤ 6 V<br>Ip ≤100 A<br>Pp≤250 W<br>Pm≤44W   | Tested and<br>verified by ALT      | -                                    |
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|                |                                                                                                        |                                                                                    |
|----------------|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| FB <b>7331</b> | List of safety relevant materials and components                                                       |  |
| Revision: A    | <b>Identification No.: AWi/15/02/12-01</b><br><small>Identification code/year/month/day-number</small> | Page 6 of 6<br>FB 7331 LoCC MSPRO<br>V04_AWi150212-01.docx                         |

| no  | type and item number                                              | manufacturer    | operating ratings | nominal ratings | Standard No./, Edition     | Mark(s) & Certificates of conformity |
|-----|-------------------------------------------------------------------|-----------------|-------------------|-----------------|----------------------------|--------------------------------------|
| 7.5 | Part of Pos.7:<br>Temperature Sensor<br>LM35 (TO-92)<br>661203009 | National Semic. | 5 V<br>0,05 A     | 5 V<br>0,05 A   | Tested and verified by ALT | -                                    |
|     | Alternative:<br>Temperature Sensor<br>LTS LM45<br>760106097       | ALT/ACD         | 5 V<br>0,05 A     | 5 V<br>0,05 A   | Tested and verified by ALT | -                                    |



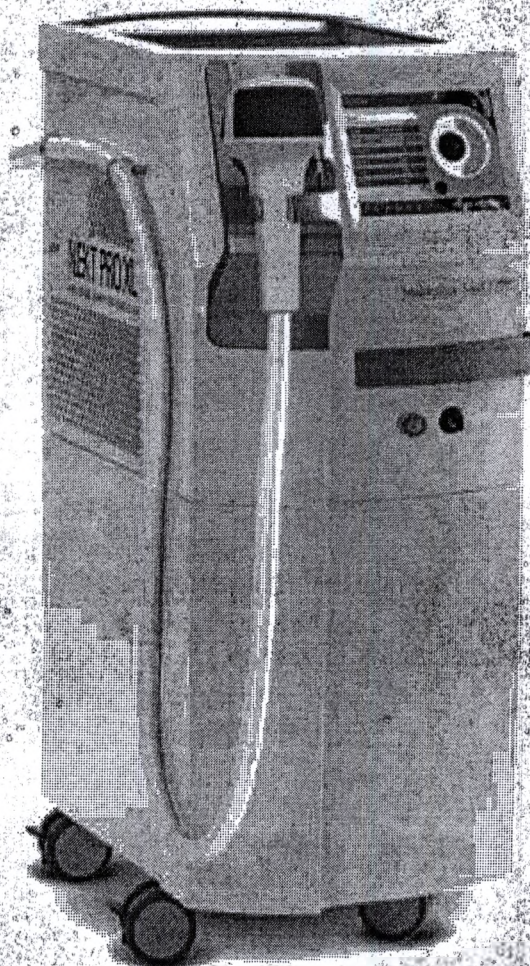
User manual

# MeDioStar

Brand names:

## MeDioStar NeXT

## MeDioStar NeXT<sup>PRO</sup>





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## 1 Introduction

All versions of the device are referred to as MeDioStar or device hereinafter.

### 1.1 General information

- This user manual contains the information required for the intended use of the device.
- It corresponds to the applicable national, European and international directives and laws on product liability of an integral component of the complete product.
- The most important objective is to protect persons against dangerous situations and the device against damages caused by improper use.

The information from this user manual is absolutely required to operate the devices. Therefore, please familiarize yourself with the contents and pay special attention to information concerning safe operation of the device.



#### WARNING

Incorrect use of this device can lead to severe health damage.

Unintended use of the device is understood as failure to observe the warnings, notes and information for this user manual, the improper use or maintenance and modification to the device!

### 1.2 Symbols in the user manual

The following symbols are used to draw your attention to residual risks, which could not be covered by appropriate safeguards, or to other possible dangers.



#### WARNING

This symbol indicates a potential danger to the life and health of persons.

Failure to follow these instructions can lead to severe health damage and life-threatening injuries.



#### CAUTION

This symbol indicates a potentially hazardous situation.

Failure to follow these instructions can lead to injuries.

The following symbols are used to give instructions on operating the device:



#### Important information

This symbol indicates important information about proper handling of the device. Failure to follow these instructions can lead to property damage, device malfunctions or interference in the surrounding area.



#### Tip

This symbol indicates application tips and particularly useful information. This information allows for optimal use of all functions on the device.



### 1.3 Changes and copyright

Subject to change based on further technical development.

For the latest information, contact customer service at Asclepion Laser Technologies GmbH or your Asclepion Laser Technologies distributor.

- © Duplication or distribution of this document, or use or disclosure of its contents, is prohibited unless expressly authorized. Any infringement shall incur liability for damages.

All rights reserved in the event of the grant of a patent, utility model or design.

## 2 Intended use

### 2.1 Intended application

MeDioStar is a pulsed diode laser (laser class 4) used for removing unwanted hair, treating acne, vascular treatments and for skin rejuvenation. Melanin and blood absorb a significant portion of the laser radiation in the wavelength range emitted by the laser, whereas the surrounding skin only absorbs a little. This destroys the target structure with heat while protecting the surrounding skin.

More specific, detailed information about application can be found in the chapter *Application*.

### 2.2 Contraindications



#### CAUTION

Intensive laser light in the infrared range can cause thermal damage to skin structures. The contraindications listed below stem from approximately 15 years of clinical experience with laser devices for this intended use. They do not claim to be complete or to have unlimited validity.

- Light sensitivity
- Intake of preparations that increase sensitivity to light
- Cellulite therapies in the treatment area (wait a few weeks)
- Cancerous and pre-cancerous lesions in the treatment area
- Haired nevi in the treatment area
- Herpes simplex in the treatment area
- Tendency towards excessive scarring
- The laser must not be applied to the area near the eyes!  
(There have been occasional reports of ophthalmitis and sight impairment despite the eyes being protected by intraocular shields!)
- Treatment of children, and women who are pregnant or nursing  
(There are no clinical studies for these patients)
- Tanned skin in the area to be treated.  
(Postpone treatment, use sun protection cream!)
- Tattoos in the area to be treated (avoid during treatment)

#### Contraindications specifically for the treatment of spider veins on legs:

- Surface varicose veins with a diameter larger than 3 mm
- Branch and secondary varicose veins
- Ulcers
- Diabetes
- Vasculitis
- Stasis dermatitis
- Podedema
- Neuropathy of the legs
- Intake of corticosteroids in the last three months
- Thrombophlebitis

## 2.3 Possible side effects

Please see chapters *Application/ Epilation/ Possible side effects* and *Application/ Vascular treatments/ Possible side effects*.

## 2.4 Requirements for the user



### WARNING

Laser radiation from the device can lead to thermal changes in tissue structures.

Treatment must only be carried out by a doctor or under the supervision of a doctor (simply referred to as the user in the following).

Furthermore, only users who demonstrate applicable technical knowledge based on their education, skills and practical experience may use active medical devices.

It must be expressly noted that only users who receive training for the device and have confirmed such training by signing the medical device book may use the device.

Corresponding courses on laser safety for medical applications are also offered by Asclepion Laser Technologies GmbH.

## 2.5 Classification of the medical device



MeDioStar meets the EU Medical Devices Directive 93/42/EEC.

Device class in accordance with Directive 93/42/EEC: II b

UMDNS No.: 16-948 laser, therapeutic



## 3 Safety

### 3.1 General safety information

The MeDioStar device complies with the requirements of the EU Medical Devices Directive (93/42/EEC) and the German Medical Product Act (MPG).

The MeDioStar is a class IIb medical product in accordance with appendix IX of the directive (i.e. surgically invasive product intended to cause a biological effect; this is not to be confused with the laser class!).

As with any device, operation of the MeDioStar may lead to potential dangers, of which the user should be aware before using the device. These risks include optical, electrical and biological dangers and fire hazards.

Observe the national regulations for using a medical device.

Applicable law may require that device operators and users follow a specific series of safety precautions when using class IIb devices. Such devices may be operated only in accordance with the generally recognized rules of the technology and occupational safety and accident prevention regulations.

Furthermore, you may be required to maintain a medical device book. A corresponding copy is provided in the User manual.

#### WARNING

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Furthermore, there is also a risk of electrical and biological hazards as well as hazards caused by radio interference.

The instructions specified below must be observed:

- No modification of this equipment is allowed.
- The equipment and procedures for operation, configuration, maintenance, inspection and calibration specified in this user manual must be observed.
- Note that regular (annual) safety checks must be carried out for this device in order to ensure the safety of personnel and patients. Failure to regularly carry out the checks can lead to severe health damage.  
The results of the checks are to be documented in the medical device book.

- Note that, in order to ensure the safety of personnel and patients, service and repairs on or changes to this device may only be carried out by Asclepion Laser Technologies GmbH or by those authorized to do so.

Service and repairs on or changes to the device carried out by non-authorized persons can lead to severe health damage.



#### WARNING

In the US or Canada this device should be installed and operated according to the US standard ANSI Z136.3 or the Canadian standard CAN/CSA-Z386: "Safe Use of Lasers in Health Care" in its current version.

### 3.2 Electric dangers



#### WARNING

The device is operated using line voltage.

To avoid the risk of electric shock, the following must be observed:

- This equipment must only be connected to a supply mains with protective earth.
- Never open the device if you are not trained or authorized to do so.
- Never set up the device such that disconnection from the power supply may be difficult.
- The device adheres to the specified limit values for leakage currents. Nevertheless, ensure that contact with the patient and device does not occur simultaneously when the device is switched on.
- The device is designed to prevent the ingress of liquids over the course of normal use. If, in exceptional cases, liquid enters into the device housing or handpiece, you must turn the power off and unplug the main power plug. Please contact our Technical Service.

### 3.3 Biological hazards

The device is developed and manufactured in a way that a safe use is ensured also with regard to compatibility of materials. The contact with materials of the device or with outgoing media (liquids, gases etc.) in normal use is not dangerous.



#### WARNING

The contact surface of the handpiece comes into contact with the patient when treating the skin. There is the risk of transmitting microorganisms.

The handpiece used must be thoroughly cleaned and disinfected immediately after each application; sterilization is not possible.

### 3.4 Radio interference

The device fulfills the requirements of the EN 60601-1-2 standard. The system is not affected by electromagnetic radiation from other devices that conform to the same standard. In addition, the system does not generate any electromagnetic radiation that exceeds the limit values of EN 60601-1-2. The manufacturer's declaration about electromagnetic compatibility in accordance with EN 60601-1-2 is included as an appendix to this user manual.



#### WARNING

Medical electrical equipment needs specific precautions regarding the electromagnetic compatibility (EMC). The instructions specified below must be observed:

- The equipment needs to be installed and put into service according to the EMC information provided in the Appendix.
- Portable and mobile RF communications equipment can affect medical electrical equipment. The same applies to other equipment that does not meet the standards listed above. This may result in unintended settings. Switch off cellular phones and similar devices before using the laser device!
- The use of accessories, handpieces and cables other than those specified, with the exception of handpieces and cables sold by the manufacturer of the device as replacement parts for internal components, may result in increased emissions or decreased immunity of the device. Only use accessories, handpieces and cables that are specified for use with this device by Asclepion Laser Technologies.





#### WARNING

- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories, handpieces or cables with other medical electrical devices that are not authorized by the manufacturer can lead to increased transmission or to reduced interference immunity of the device with the above mentioned effects.  
Only use accessories, handpieces and cables that are specified for use with the intended device by Asclepion Laser Technologies.
- The device emits small amounts of electromagnetic radiation that can potentially influence devices that do not fulfill the standards listed above. This may result in unintended settings on those devices.

## 3.5 Laser

### 3.5.1 Optical danger due to laser radiation

The lasers are classified according to their potential for danger. The most dangerous laser class is class 4 (the least dangerous is class 1). This device is a class 4 laser.

The fundamental rules for handling laser devices are derived from the EN 60825 international standard "Safety of laser products" including part 8 "Guidelines for the safe use of laser beams on humans".

In addition, national regulations are intended to protect against dangerous laser radiation. For medical applications, these measures are intended to protect both the personnel and the patients.

Also observe the specific national regulations for your location.



#### WARNING

Caution – The use equipment and procedures for operation, maintenance, inspection or calibration other than those specified in this user manual can lead to hazardous irradiation by laser radiation.

The protective measures specified below must be strictly observed. In particular, everyone in the room where the laser is being used ("laser area") must wear suitable protective eyewear while the laser is active.

The following protective measures are a few essential requirements that must be supplemented further for the specific circumstances with the help of a laser safety officer.

1. A **laser safety officer** with expertise regarding laser applications in medicine must be commissioned in writing and carry out at least the following tasks:
  - Supporting the operator with respect to safe operation and necessary protective measures
  - Monitoring safe operation of the laser
  - Collaborating with specialists for workplace safety for fulfilling their duties, including training for important matters concerning protection from laser beams.

### 2. Laser area

During operation, the area where the maximum permitted radiation level can be exceeded—called the "laser area"—must be cordoned off and marked by a laser warning sign. The laser area is the room in which the laser is being used. Use of the laser must be indicated by **warning lights** and the triangular yellow **laser warning sign** at all entrance points.



Figure 1: Laser warning sign

### 3. Personal eye protection

Everyone present in the laser room during a treatment session must wear laser safety glasses eye or shields for patients!

The laser safety glasses and eye shields for patients must comply with the specifications defined in the technical data section!

### 4. Additional safety precautions

- Cover up windows and other openings to the treatment room to prevent emission of laser radiation.
- Restrict access to the treatment room so that only people assisting with treatment and those trained to handle the laser device have access (besides the patient to be treated).
- Make sure that trained personnel assisting with treatment know how to switch off the laser in an emergency.
- Remove all metallic objects such as watches, rings, necklaces and similar objects from the working area and do not use any reflective tools or other reflective materials if at all possible.  
(Reflective objects could interrupt the laser beam and deflect it towards areas other than the intended treatment area. Many surfaces, even those that appear to be dull, can easily reflect the emission wavelength of the laser.)
- Only point the activated laser at the intended area to be treated.
- Never look directly into the outlet opening of the handpiece or the optical fiber, even if you are wearing laser safety glasses.
- Switch the laser into the STANDBY state when not in use (the laser cannot be activated accidentally while in the STANDBY state).
- Always remove the key from the key switch when the device is switched off and store the key in a secure place.

### 5. Responsibility

The user who triggers the laser emission is responsible for the safety of the laser. This user must ensure that all safety measures are being followed **before** activating the laser. Specifically, everyone present in the room—including the patient—must wear proper protective eyewear or eye protection for patient.



### 3.5.2 Laser-induced fire hazard



#### WARNING

A risk of fire and/or explosion exists when the laser output is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment

The device must, therefore, never be used in potentially explosive areas (in accordance with the AP and APG classification in accordance with EN 60 601-1).

The following protective measures must be followed for this reason.

- Some materials, for example cotton wool when saturated with oxygen may be ignited by the high temperatures produced in normal use of the laser equipment.  
Keep clothing as far away from the treatment area as possible.
- The solvents of adhesives\* and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.
- Attention should also be drawn to the danger of ignition of endogenous gases.\*
- Do not use any inflammable substances to cool the skin (such as inflammable cooling spray, but e.g. CoolPacks) directly before or during treatment.
- If possible, do not use any inflammable substances for anesthesia if at all necessary.
- Avoid the use of oxidizing gases such as nitrogen oxide (N<sub>2</sub>O) and oxygen. Be especially careful when using oxygen. Oxygen increases both the intensity and extent of fire.
- Keep combustible materials in the treatment room to a minimum. If treatment requires the use of combustible materials, moisten the materials.
- Only expose the surfaces of the body required for treatment to the laser emission.
- Always have a small amount of water ready in the treatment room and have a fire extinguisher for electric devices nearby.

\*not applicable for treatments with MeDioStar

## 4 Technical data

### 4.1 Device models

| Designation*                                                             | Description                                                                  |
|--------------------------------------------------------------------------|------------------------------------------------------------------------------|
| MeDioStar, item no. 1590<br>(Brand name: MeDioStar NeXT)                 | High-power diode laser (base unit)<br>Comment: Only suitable for ST, HP, VAS |
| MeDioStar, item no. 1591<br>(Brand name: MeDioStar NeXT <sup>PRO</sup> ) | High-power diode laser (base unit)<br>Comment: Suitable for all handpieces   |
| MeDioStar ST Handpiece<br>(item no. 4020)                                | Standard handpiece                                                           |
| MeDioStar HP Handpiece<br>(item no. 4022)                                | High-power handpiece (e.g. for finer hair)                                   |
| MeDioStar VAS Handpiece<br>(item no. 4021)                               | Handpiece for vascular treatment                                             |
| MeDioStar handpiece with XLS laser tip<br>(item no. 4070 + 4071)         | Handpiece with large spot for anatomically difficult areas (e.g. upper lip)  |
| MeDioStar handpiece with XLL laser tip<br>(item no. 4070 + 4072)         | Handpiece with very large spot for large treatment areas                     |

\*The item no. of the device can be found at the type plate. The item no. of the handpieces are on the tube near the handpiece. The item no. of the laser tips of the handpiece XL are engraved inside.

One base unit and one handpiece are included in the scope of delivery.

### 4.2 Specifications

| Specification                              | MeDioStar                                                                                                                                                                             |
|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Display                                    | 8.4" LCD display                                                                                                                                                                      |
| User interface                             | Touchscreen                                                                                                                                                                           |
| Cooling                                    | Internal cooling circuit                                                                                                                                                              |
| Door interlock connector                   | 12 V DC/max. 20 mA                                                                                                                                                                    |
| Laser warning lamp                         | Isolated relay contact<br>max. 24 V/1 A (normally open contact)                                                                                                                       |
| Permitted ambient conditions               | Temperature: 15 °C to 30 °C<br>Rel. air humidity: max. 85% (non-condensing)<br>Altitude: max. 2000 m above sea level<br>The device is not permitted for use inside an operating room. |
| Permitted transport and storage conditions | Upright standing position (do not lay it on its side!)<br>Temperature: 5 °C to +50 °C<br>Rel. air humidity: 10% to 90% (non-condensing)<br>Air pressure: 700 – 1070 hPa               |
| Dimensions                                 | 365 x 560 x 920 mm (W x D x H)<br>without handles or handpiece holder                                                                                                                 |



| Specification                                        | MeDioStar                                                    |
|------------------------------------------------------|--------------------------------------------------------------|
| Weight                                               | approx. 45 kg                                                |
| Power grid connection                                | 115 VAC, 50/60 Hz, 1400 VA<br>220–240 VAC, 50/60 Hz, 1500 VA |
| Main fuse                                            | 16A overcurrent trip, medium time lag                        |
| Overvoltage category                                 | II (IEC 60664-1)                                             |
| Max. line voltage peaks<br>Max. nominal line voltage | V MT peak = 2500 V peak<br>V MN r.m.s. = 300V r.m.s.         |
| Protection class                                     | I                                                            |
| Classification according to Directive 93/42/EEC      | II b                                                         |
| Degree of protection of the application parts        | B                                                            |
| Accessories                                          | See Chapter <i>Accessories</i>                               |
| Type of operation                                    | The device is designed for continuous operation*             |

\* At high room temperatures and high average power, the device may switch to cooling mode for a short period of time during longer treatments to ensure that the skin cools.

| Specification                                             | Laser                                                                                                                                                                                                                                            |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Laser type                                                | High-power diode laser array                                                                                                                                                                                                                     |
| Wavelength                                                | 810 - 950 nm (depending on handpiece)                                                                                                                                                                                                            |
| Laser class                                               | 4                                                                                                                                                                                                                                                |
| Required laser safety glasses (according to EN 207: 2009) | 810 - 950 nm D LB5                                                                                                                                                                                                                               |
| Pulse length                                              | Max. 400 ms (depending on mode and handpiece)                                                                                                                                                                                                    |
| Pulse energy                                              | Max. 200 J (depending on mode and handpiece)                                                                                                                                                                                                     |
| Pulse frequency                                           | Max. 12 Hz (depending on mode and handpiece)                                                                                                                                                                                                     |
| Spot sizes (handpieces)                                   | ST handpiece: 14 x 10 mm <sup>2</sup><br>HP handpiece: 8 x 6 mm <sup>2</sup><br>VAS handpiece: 4 x 3 mm <sup>2</sup><br>Handpiece (XL) with XLL laser tip: 38 x 24 mm <sup>2</sup><br>Handpiece (XL) with XLS laser tip: 30 x 10 mm <sup>2</sup> |
| Tolerance of the output energy                            | +/- 20%                                                                                                                                                                                                                                          |
| Laser beam mode                                           | Multimode                                                                                                                                                                                                                                        |
| Laser beam diameter at the handpiece output               | See spot sizes                                                                                                                                                                                                                                   |



| Specification                                                               | Laser                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Energy density (fluence)                                                    | Max. 47 J/cm <sup>2</sup> * @ ST handpiece<br>Max. 90 J/cm <sup>2</sup> @ HP handpiece<br>Max. 210 J/cm <sup>2</sup> @ VAS handpiece<br>Max. 20 J/cm <sup>2</sup> @ Handpiece with XLL laser tip<br>Max. 60 J/cm <sup>2</sup> @ Handpiece with XLS laser tip |
| Beam divergence at the handpiece output<br>(round angle, 1/e <sup>2</sup> ) | Typically 0.12 x 0.97 rad @ ST handpiece<br>Typically 0.19 x 1.66 rad @ HP handpiece<br>Typically 0.12 x 1.62 rad @ VAS Handpiece<br>Typically 0.11 x 0.68 rad @ XLS handpiece<br>Typically 0.06 x 0.51 rad @ XLL handpiece                                  |
| Nominal distance for danger to the eyes (with handpiece)                    | 35 m                                                                                                                                                                                                                                                         |

\*available in Professional mode

## 4.3 Technical description

### 4.3.1 Handpieces (with integrated laser source and skin cooling)

Note:

Normally one handpiece with a specific spot size is included in delivery. Additional handpieces can be purchased optionally (other spot sizes/wavelengths) (see chapter *Technical data/ Device models*).

The size of the laser spot (see chapter *Technical data/ Specifications*) can vary by changing handpieces or, on the XL handpiece, by changing the laser tip as well. The device automatically detects the new handpiece or the new laser tip and indicates this on the display.

#### Structure of the handpiece

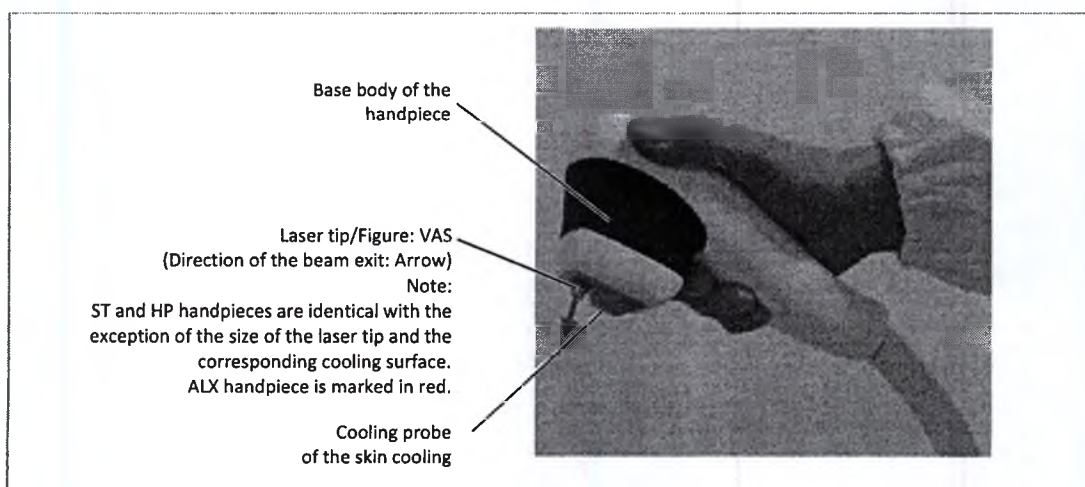


Figure 2: Handpiece (example VAS)

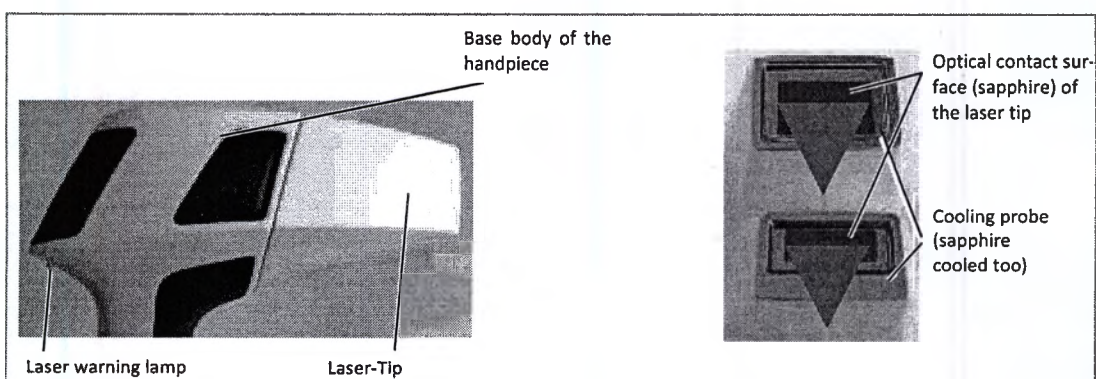


Figure 3: Handpiece (left) with XLL laser tip (top) or XLS (bottom)

#### Laser source

The MeDioStar laser is a pulsed high-output diode laser (laser class 4); its diode stack is located in the base body of the handpiece. The emitted wavelength is in the near infrared range (NIR) and is dependent on the handpiece (see chapter *Technical data/ Specifications*).

The laser beam emission is triggered by a foot switch.

## Beam path

The radiation of the pulsed high-output diode laser is led through optical elements in the handpiece to the laser tip. During this, a "Flat Top" beam profile is created; this means that the fluence (intensity of the laser beam) is evenly distributed over the treatment spot. As a result, no "hot" spots develop that would increase the side effects.

## Skin cooling

The metal probe of the handpiece is cooled by an integrated Peltier element. Additionally, the sapphire of the XL handpiece is cooled. This ensures (using the procedure described in the application section) that the epidermis is cooled before the laser pulse makes contact. The temperature of the probe is automatically monitored. When treating larger areas at high average power, the device can switch to cooling mode for a short period of time to ensure that the skin is cooled safely.

### 4.3.2 Base unit

#### Power supply

The integrated power supply converts the supply voltage into rectified extra-low voltage for the electric power supply of the device.

#### Control

Checking and controlling all output parameters and the safety equipment of the device is completed via a central processor unit (CPU).

#### Operating modes

The device works in both single-shot mode and continuous pulse mode.

The device is designed for continuous operation in the specified environmental conditions.



#### Important information

The maximum application time using the handpiece HP (item no. 4022) in uninterrupted pulse operation is limited to 10 minutes. Subsequently a break of application of 5 minutes is necessary.

When treating larger areas at high average power, the device can switch to cooling mode for a short period of time to ensure that the skin is cooled safely.

#### Operation

The device is operated via touchscreen. The display is in plain text on a LCD display. Various parameters, such as fluence, pulse duration, pulse sequence and others, as described in the *Operation* section, can be configured depending on the operation mode.

Along with the selected parameters, the operating state (STANDBY or READY), the handpiece used and, if necessary, error messages are also displayed in plain text.

The device contains a database in which the users can save treatment protocols with the parameters that they typically use for different types of treatment.

#### Cooling

The internal coolant circuit is required to prevent the modules from overheating. The lost heat is given off to the environment by a water-air-heat exchanger. A pump pumps coolant through the modules and heat exchangers to be cooled. Temperature and flow sensors also ensure safe and reliable operation.

The device is cooled by room air. External cooling water is not necessary.

To maintain cooling, the device should only be operated in the defined environmental conditions. The air in the environment should be subject to low quantities of dust. The cooling openings of the device should be maintained a minimum distance from obstacles impermeable to air (i.e. wall of the room) (see chapter *Installation*).



#### 4.4 Safety equipment

The device is equipped with different safety units that have been provided to prevent incorrect operation and unintentional activation of the system. All persons who operate the laser or assist during the treatment should be familiar with these units.

##### Laser emergency STOP switch

The purpose of the red laser emergency STOP switch on the front of the device (see Figure below) is to immediately switch off the laser emission system in an emergency. It should only be used in emergency situations, i.e. when it is necessary to immediately interrupt laser emission.

To immediately switch off the system, press this switch. After resolving the emergency situation, the switch unlocks by turning to the left until it jumps out again.



##### Important information

Do not use the laser emergency STOP switch to switch the device on and off in its normal state.

##### Key switch

The system is activated with the key switch. Only authorized persons who have access to the key can start the system. The key switch can only switch on the system if the laser emergency STOP switch is not depressed.



##### WARNING

The laser device emits strong radiation in the infrared range. This radiation can lead to severe eye damage if the device is used improperly.

The device must not be switched on or used by unauthorized persons.

Always take out the key after you have switched off the device and only allow authorized personnel to store it.

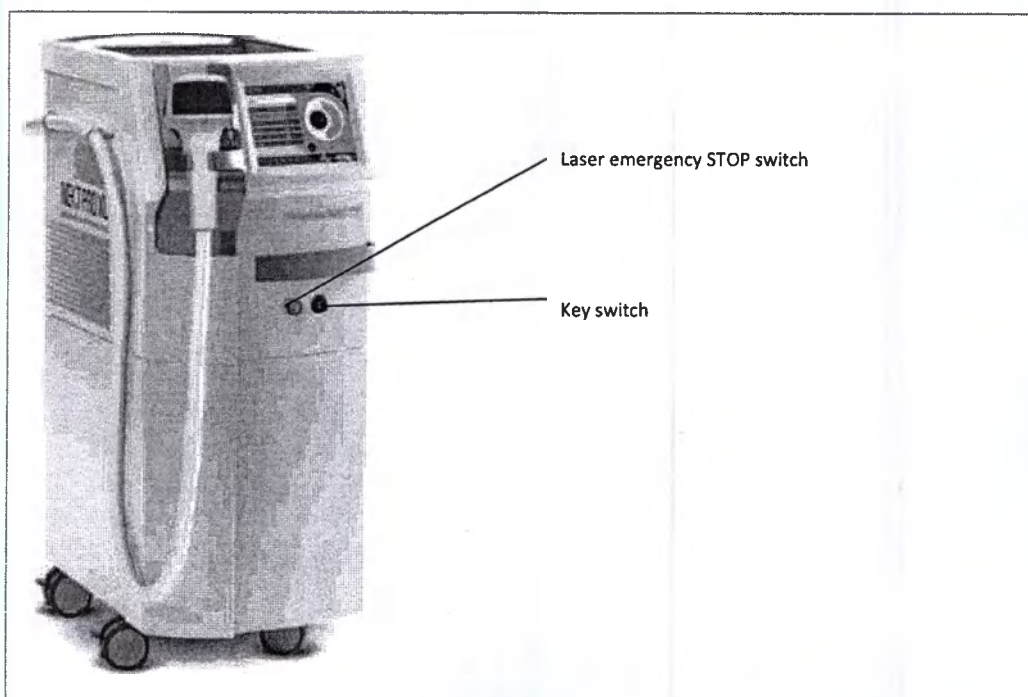


Figure 4: Safety equipment on the front side of the device (example MeDioStar NeXT<sup>PRO</sup>, MeDioStar NeXT equally)

## Power switch

The power switch separates the device from all poles of the supply voltage. When the device is not being used, the switch should be in the OFF (O) position.

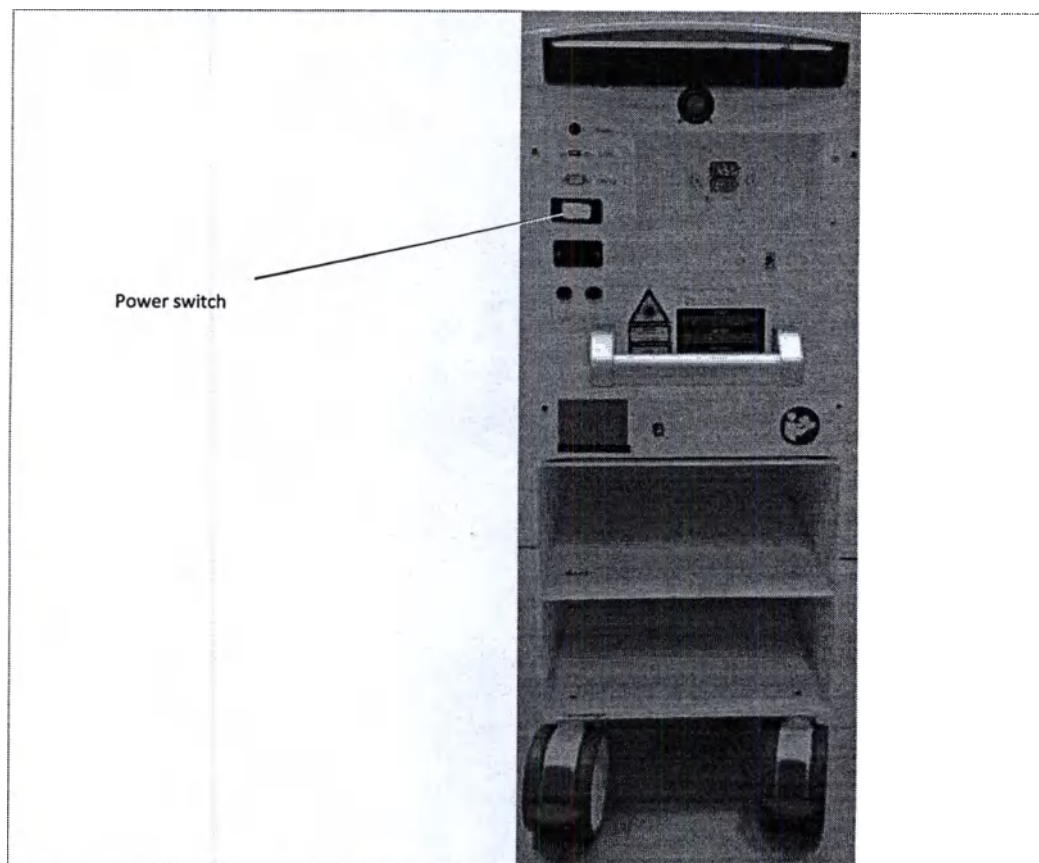


Figure 5: Power switch on the rear side of the device (example MeDioStar NeXT, MeDioStar NeXT<sup>PRO</sup> equally)

## Foot switch

The foot switch is equipped internally with two redundant switch elements to ensure safety. This does not affect how it is used. Additionally, accidental actuation of the switch is prevented by a protective flap. This flap (when closed) is opened by stepping on it.

The foot switch is an electric button that activates laser emission when pressed if the device is in the READY state.

Always set up the foot switch near the treatment area.

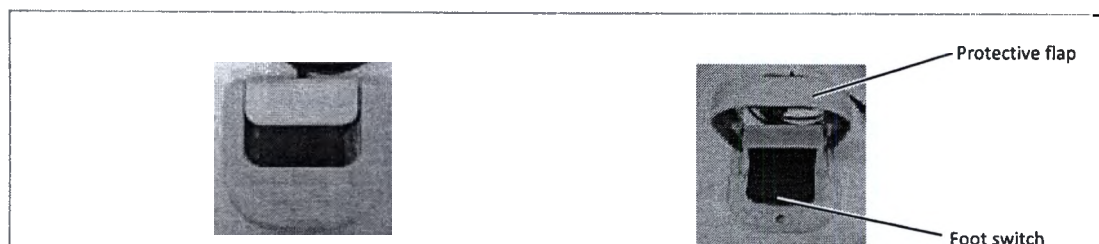


Figure 6: Foot switch (left: Protective flap closed; right: Protective flap opened)

## Operating state STANDBY

The STANDBY operating state prevents the laser from being unintentionally or accidentally activated. Laser emission is not possible if the system is in STANDBY. The operator can only activate emission after the READY button has been pressed.

The system goes into STANDBY in the following situations:

- After starting the system for the first time
- If the operator presses one of the buttons to select the laser parameters
- If the system has been in the READY state for a long period of time without the laser being initiated
- If the operator has pressed the STANDBY button while the system was in the READY mode.

## Automatic shutoff

The device has an automatic shutoff. If a specific problem occurs, the system switches automatically to the following safe state:

The electronic laser lock is closed, the laser emission is immediately interrupted and the foot switch is deactivated. An error message appears on the display that identifies the specific error (see chapter *Error messages and trouble shooting*).

## Remote interlock contact

The system is equipped with a remote interlock contact that can be connected at the entryways to the laser room. If the remote interlock contact is open (e.g. if the door is open), laser emission is automatically interrupted and the device goes into STANDBY.

## Additional potential equalization

The additional potential equalization forms a basic protective measure in accordance with IEC/EN 60601-1 in the areas of group 1 used for medical purposes (e.g. doctor's offices) and 2 (e.g. operating rooms; additional connections for the additional potential equalization are attached in the rooms for group 2).

This fulfills the purpose of equalizing potential differences between different devices in the patient's environment, to prevent the dropout of the ground wire of devices of protection class I (single-fault protection) and to ensure compliance of the required contact voltage with the housing of protection class I devices.

The potential equalization line can be connected to the potential equalization connection at the back of the device, to the corresponding connector of other devices and to the fixed installed system (of the room). The potential equalization does not replace the ground wire of the device.



### Important Information

Observe the requirements of IEC/EN 60601-1 regarding ME systems.

## Acoustic signal

Laser emission is displayed by an acoustic signal during emission.

## Warning signs

The device has various warning labels (see chapter *Start-up/ Installation/ Labels on the device*). These labels must be clearly visible at all times and must be immediately replaced if damaged.

For more information about this, contact our technical customer service.



**The manufacturer is only liable for safety, reliability and power of the device if:**

1. The device is used in agreement with all instructions in this handbook (on safety measures and system application).
2. Installation, assembly, expansions, modifications, repair and maintenance work carried out by qualified and skilled persons.
3. The electrical system at the installation location that fulfills the requirements of IEC/ EN 60601-1 and of local regulations.

## 5 Start-up

### 5.1 Delivery



#### Important information

Please check with the transport company whether all of the components listed below that are necessary for safe operation of the device are available and are not damaged. Claims for incomplete and/or damaged deliveries are to be filed with the supplier immediately. Asclepion Laser Technologies does not accept any liability unless another agreement has expressly been made. Please keep the packaging to safely ship the device.



#### CAUTION

If you detect mechanical damage on the device or accessories, the device is not to be operated. Operating the device under these circumstances could result in injury. Please contact the Service team of Asclepion Laser Technologies GmbH.

The basic equipment comprises the following device parts:

- Base unit
- Power cable
- Foot switch
- Handpiece
- Warning lamp/door interlock connector
- Keys (x2 for key switch)
- Laser safety glasses, blackout glasses for patients
- User manual
- Laser warning sign

## 5.2 Installation



### WARNING

The device is operated using line voltage and emits infrared radiation. There is a risk of electric shock and injury to the eyes!

The installation and the mandatory functional test may not be performed by anyone other than our service technicians or other technicians trained and authorized by us.

### 5.2.1 Device design

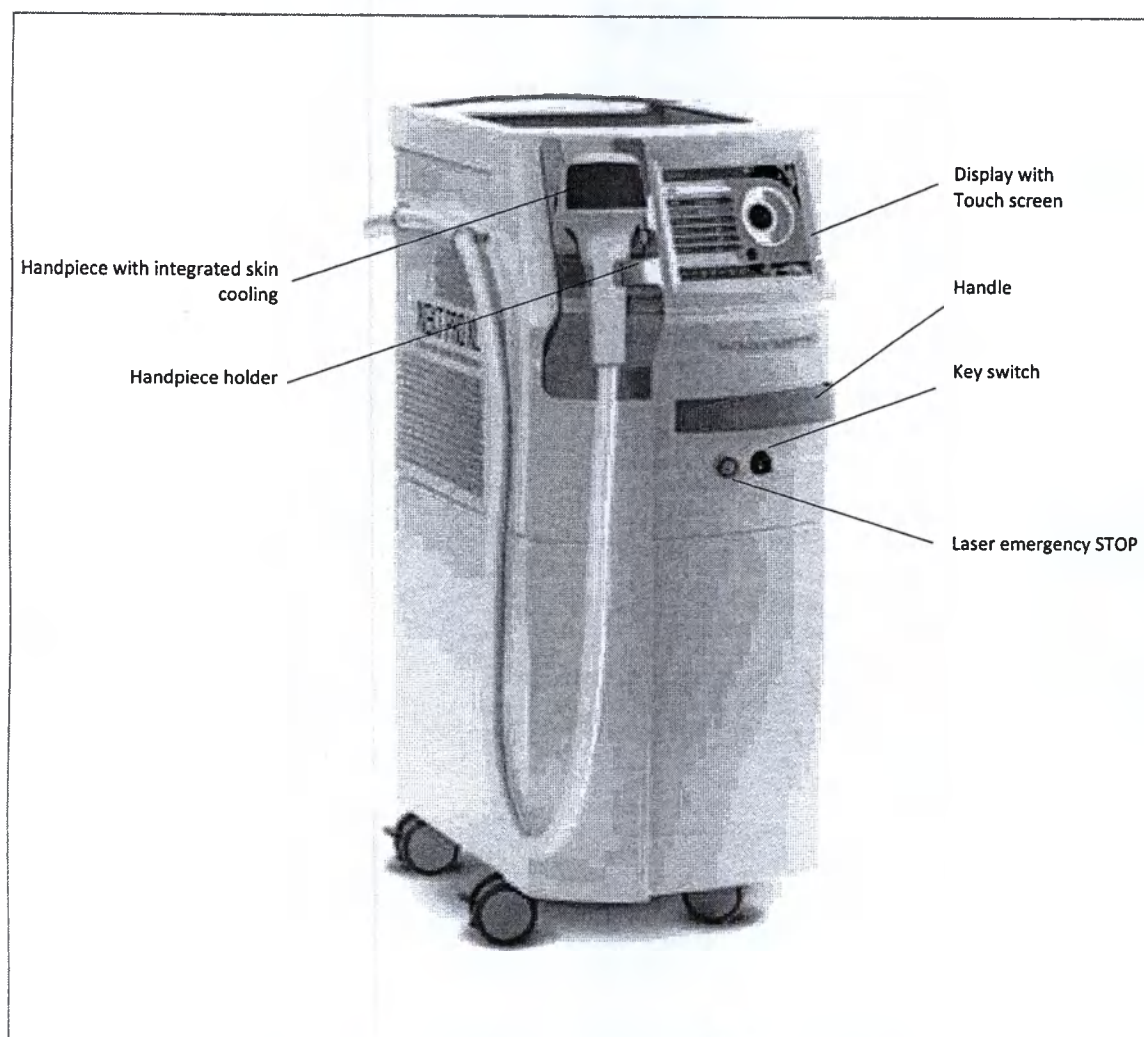


Figure 7: Front control panel (example MeDioStar NeXT<sup>PRO</sup>, MeDioStar NeXT equally)



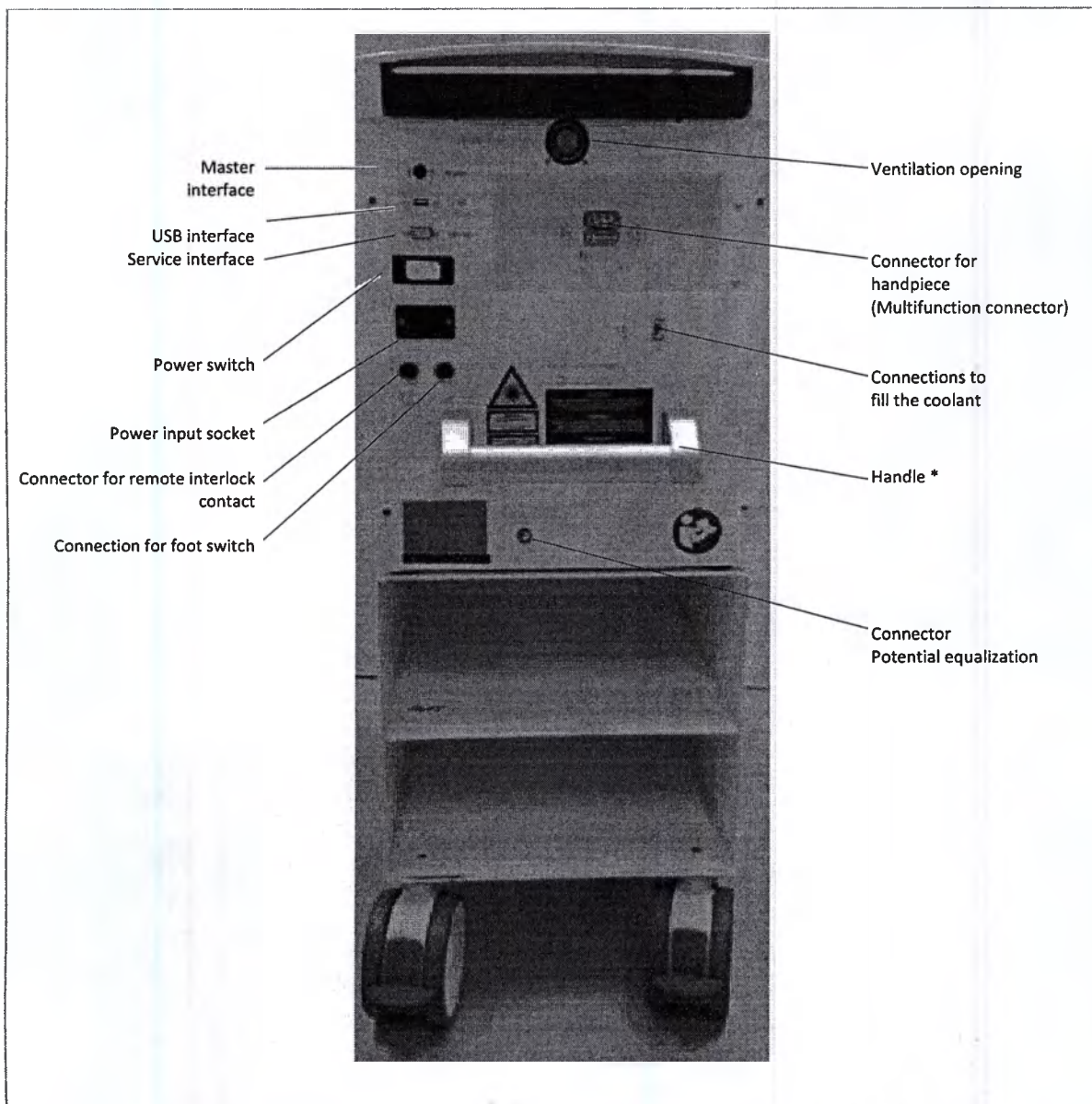


Figure 8: Connections on the rear side of the device (example MeDioStar NeXT, MeDioStar NeXT<sup>PRO</sup> equally)

\*please use the handles at front and rear side for transportation

### 5.2.2 Labels on the device



#### WARNING

The laser device emits strong radiation in the infrared range. This radiation can lead to severe eye damage if the device is used improperly.

Therefore, there are warning and information labels on the appropriate places on the device. The entire personnel must know these labels and their meaning to ensure proper use of the device.

All labels must remain in their respective positions and in good condition. Replace damaged labels immediately to ensure proper use of the device.



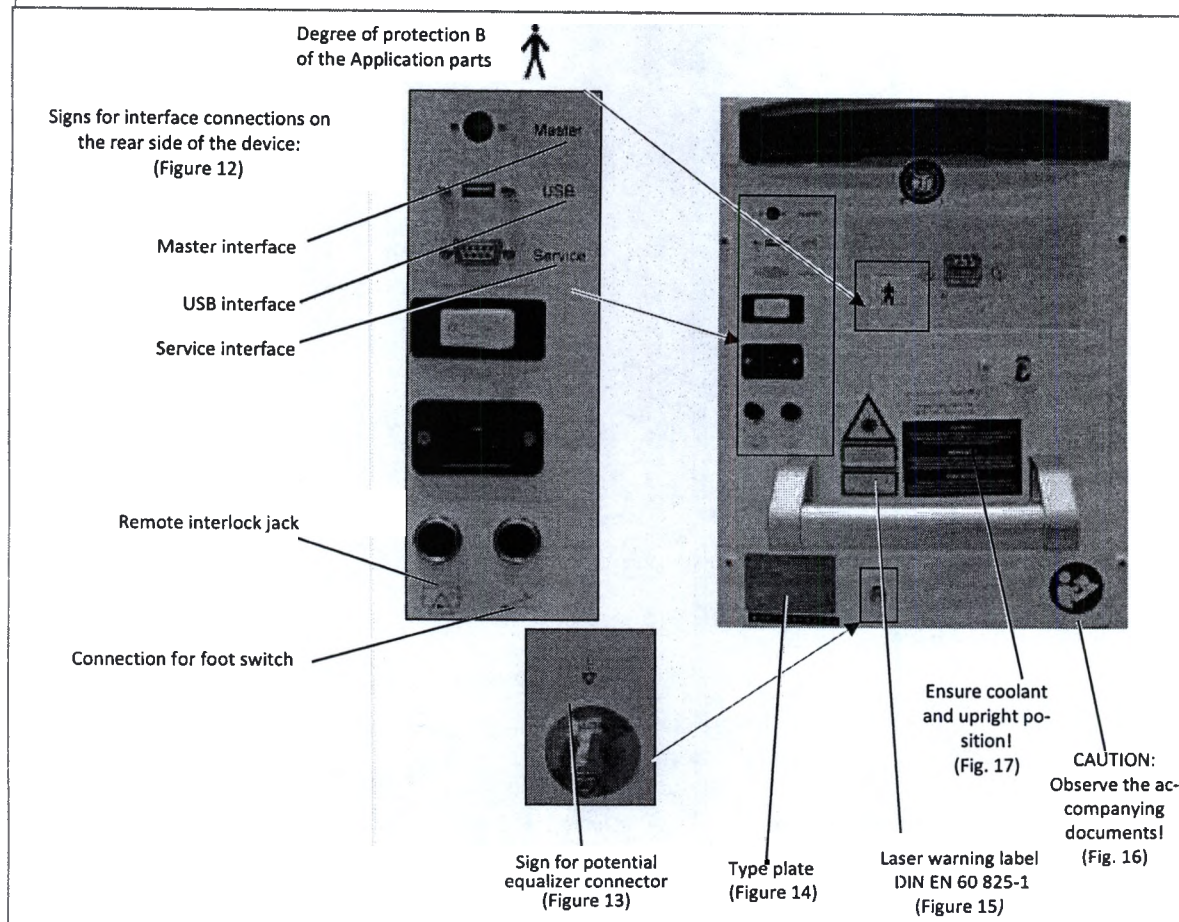
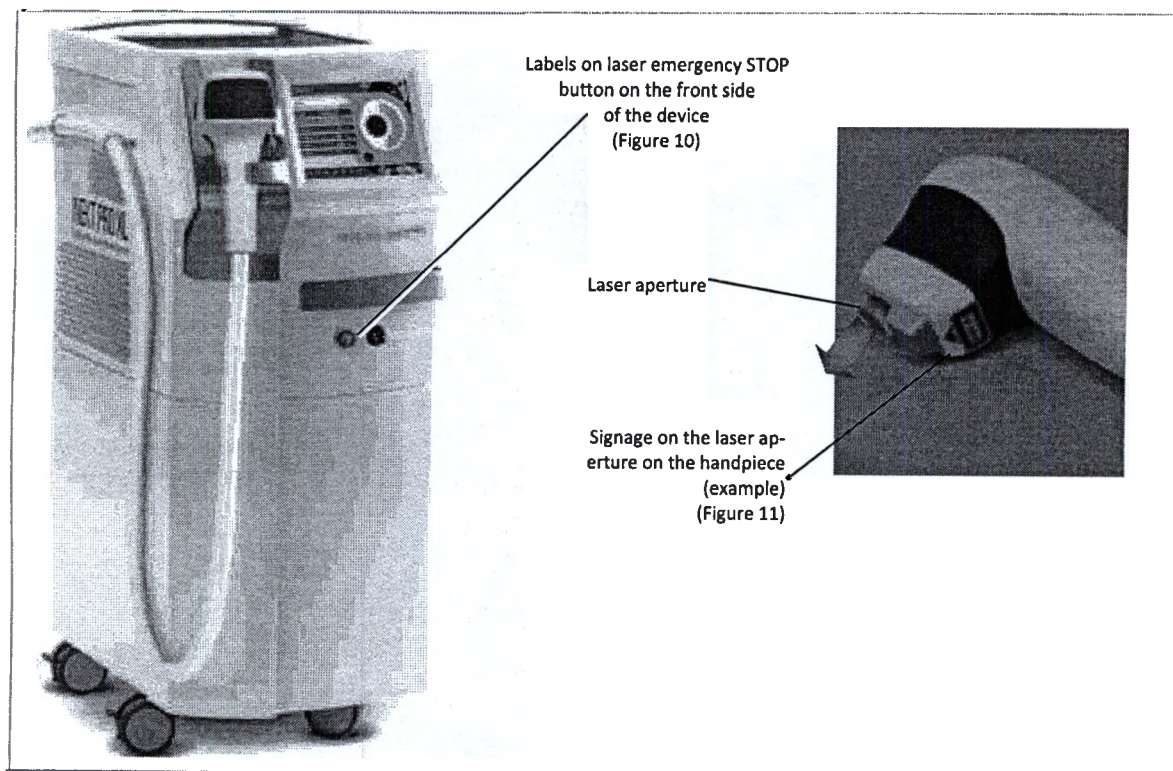


Figure 9: Labels on the MeDioStar device



Figure 10: Laser emergency STOP button

This sign marks the laser emergency STOP button for switching off the laser radiation in an emergency.



Figure 11: Beam exit aperture

This label marks the place where the laser beam exits the transmission system.

- ① Master
- ② USB
- ③ Service
- ④ 
- ⑤ 

Figure 12: Interface connections

**Warning:**  
No other accessory parts other than those approved by Asclepion Laser Technologies are to be connected to these connections. Master, service and USB are intended exclusively for use by authorized service personnel.

- ① Master interface
- ② USB interface
- ③ Service interface
- ④ Connection for remote interlock contact
- ⑤ Connection for foot switch



Figure 13: Potential equalization connection

This contact is used for the additional connection of the device to a potential equalization system

Model

Serial number

Manufacturing date (YYYY-MM)

CAUTION:  
Observe the accompanying documents!

**Asclepion Laser Technologies GmbH**  
07747 Jena, Brüsseler Straße 10, Germany

**Model: 159X**

|    |   |   |   |   |   |   |   |   |   |
|----|---|---|---|---|---|---|---|---|---|
| 1  | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| XX |   |   |   |   |   |   |   |   |   |

S/N: 159X03000

**MeDioStar**

115 V ~ 50/60Hz 1400VA  
220-240V ~ 50/60Hz 1500VA

2015-07






Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007

Figure 14: MeDioStar type plate – Example for model 1591

Type plates with type-specific data for the device, including the serial number and the manufacturing date.



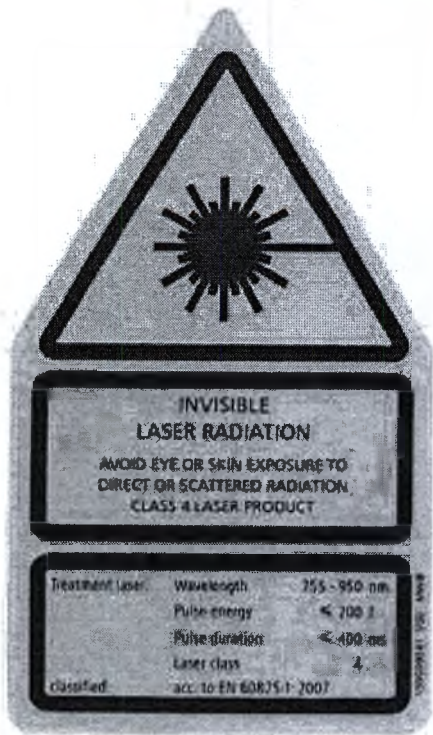


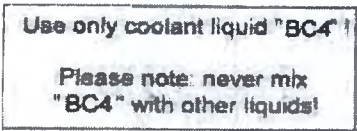
Figure 15: EN 60 825-1 laser warning label

This label provides information on the dangers, maximum value of energy emission and classification of the laser source.



Figure 16; CAUTION: Observe the accompanying documents!

This label informs the user that the device may not be used before the accompanying documents have been read.



and

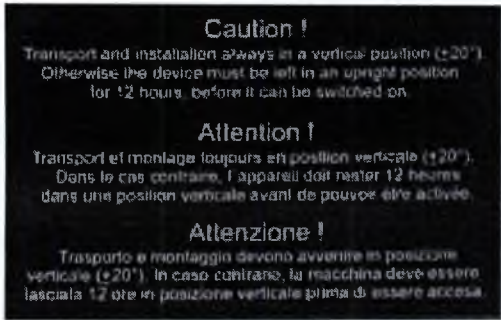


Figure 17: Ensure availability of coolant and upright transport position!

This label informs the user that the coolant specially developed by Asclepion for the device must be used (corrosion protection, antibacterial, antifreeze, effective cooling)!  
Never mix this coolant with distilled water!

This label indicates that the device must remain in an upright position (tilting angle less than 20°).

### 5.2.3 General notes on installation



#### WARNING

The laser device emits strong radiation in the infrared range and is operated using line voltage. It needs specific precautions regarding the electromagnetic compatibility (EMC). It can lead to severe injuries to patients and users if the device is set up and installed improperly.

The equipment needs to be set up and installed in a way that all instructions given in the chapters *Safety*, *Technical data/ Specifications* and in appendix EMC are observed.



#### Important information

After installation and any relocation of the device from a cold to a warm environment with a temperature difference of more than 5 °C, allow the device to adjust to the room temperature in an unpacked condition before use. Allow it to adjust for at least:

2 hours at a temperature difference of up to 10 °C

4 hours at a temperature difference of up to 15 °C

8 hours at a temperature difference of more than 20 °C

Afterward, switch on the device without connecting a handpiece and allow the device to warm up for at least 30 minutes.

Make sure that the environment in which the device is to be installed and operated complies with the permitted ambient conditions stated in chapter *Techn. Data/ Specifications*.

Failure to observe this information can lead to destruction of the device.

To cool the device efficiently, maintain a minimum distance of 20 cm between the side and back panels of the device and the wall.



#### WARNING

The laser device emits strong radiation in the infrared range. This radiation can lead to severe eye damage if the device is used improperly.

Warning lamps that light up (or flash) while the laser is in use must be installed at all entrance points into the laser area (the room where the laser is being used). This warns people before they enter the room.

### 5.2.4 Connection for door contact

There is a socket on the rear side of the device that allows the device to be connected to a remote interlock contact (see figure below).

This requires the use of a circular connector that screws in place, type (x)V 40 in accordance with IEC 60130-9, such as the Lumberg WSV 40 (included).

(x): Depending on type, for example, WS for angled plugs, such as those provided

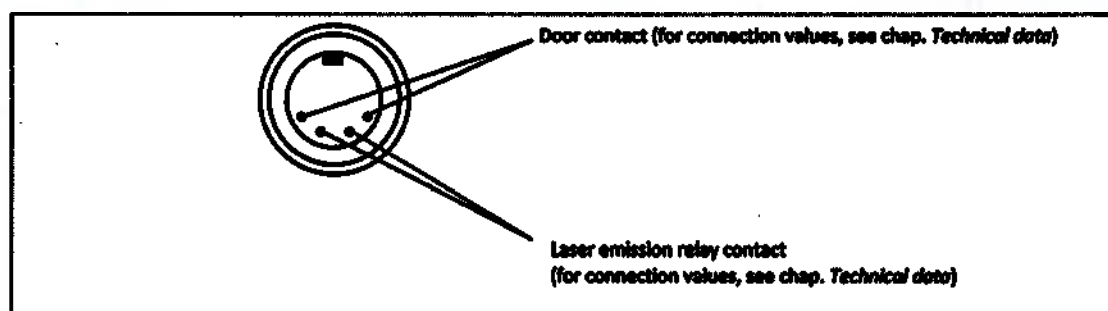


Figure 18: Connections for remote interlock contact and laser warning lamp



By connecting both *remote interlock contact* connections to an external door contact, you can prevent the laser radiation from being emitted if the door is opened.

This makes it possible to have the treatment beam of the laser switch off automatically if the entrance door to the laser area is opened, preventing hazards to the persons entering the room.

The included contact plug is equipped with a jumper at the factory. To connect a remote interlock contact, this jumper must be removed and your remote interlock contact must be connected to the same connectors. The external contact must be designed as a floating contact. If you do not want to use a remote interlock contact, the plug must be connected with the jumper provided at the factory.



#### Important information

The contact plug can only be connected if the device is switched off and disconnected from the power supply; otherwise the device could be damaged.

The contacts for the remote interlock and the foot switch must never be connected to the line voltage. Failure to observe this instruction could severely damage to the system. Only connect these connections as described in this section.



#### Tip

Please check that the laser cannot be switched to the READY state with this door open every day before starting treatment if you have connected a remote interlock contact to the entrance door. Please notify Technical Service in the event of a malfunction.

An external voltage source for a low-voltage warning lamp can be connected using two additional contacts of this plug connector. The switching relay inside the device is designed for the maximum voltage or maximum current as shown in the figure above. The safety requirements below must be followed when connecting an external warning lamp:



#### WARNING

Observe the following to prevent the risk of electric shock and associated severe health damage and the risk of fire in the transformer when operating the warning lamp using an external transformer:

A safety isolating transformer must be used in accordance with IEC/EN 61558-2-6.

The internal relay is closed if the device is in the *READY* state.

The prescribed warning lamp can be switched on and off using a normal light switch when the laser is in use.

### 5.2.5 Foot switch

Now connect the foot switch to the foot switch socket on the rear side of the device (see figure *Connections on the rear side of the device*). The plug must be inserted as far as it will go and then secured by turning the coupler clockwise. The foot switch should be positioned in the immediate vicinity of the device.

To be able to operate the foot switch later, first the protective cover must be pressed (see chapter *Techn. Data/ Safety equipment*). This opens the switch. This makes the actual switch (black) accessible; you can press it with your foot to activate emission of the laser radiation in the *READY* state.



## 5.2.6 Handpieces

The various handpieces all have the same multifunction plug (also see chapter *Technical description/ Handpieces*). This plug is carefully inserted into the connection on the rear side of the device and then pressed in until it locks (this can be heard; left and right). It connects both the power supply for the diodes and the water supply for the Peltier cooling (also see section *Operating the device/ Changing the handpiece*).

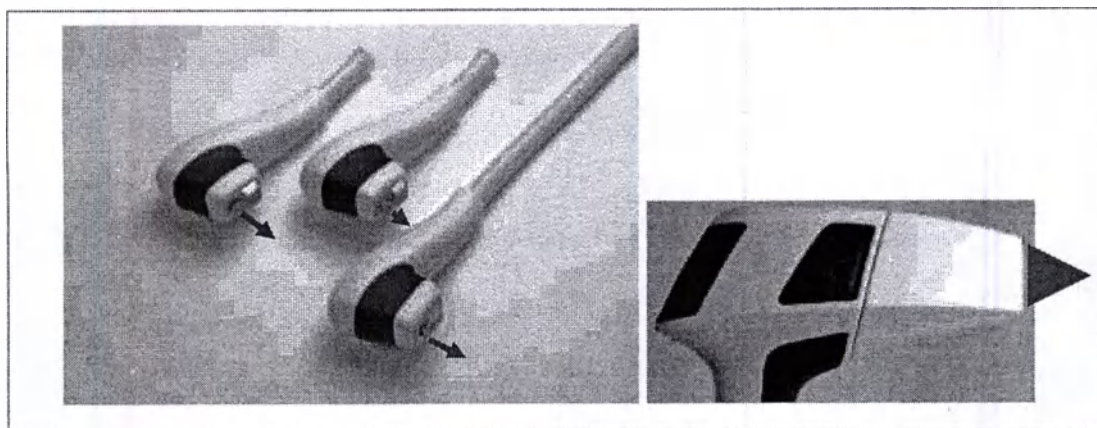


Figure 19: Handpieces with different spot sizes and indication of the beam output direction (red)  
Handpiece examples (starting from left): ST, HP, VAS and XLL/S

## 5.2.7 Power grid connection



### Important information

Observe all of the technical data for the local power supply and the device when selecting a power socket. First check that your power supply satisfies the previously mentioned connection requirements (supply voltage corresponding to type plate). Connecting the device to an unsuitable power supply can lead to damage to the device.

Please observe the requirements from regulations/standards in your country in their respective applicable versions.

Before connecting the device to the power grid, the shift paddle of the main switch must be on 0 (device de-energized). First plug the power cable into the power input on the rear side of the device before you connect the other side to the power socket. Operation of the laser requires that the device be connected to a single-phase power outlet protected by a **separate** fuse (delay-action fuse preferable) rated for at least 1500 VA.

## 5.2.8 Potential equalization line

The potential equalization line can be connected to the potential equalization connection at the back of the device, to the corresponding connector of other devices and to the fixed installed system. The potential equalization does not replace the ground wire of the device.



### Important information

Please observe the requirements of the IEC/EN 60601-1 regarding medical electric systems.

### 5.3 Switching on

Before switching on the device, make sure that the following requirements are fulfilled:

- The device is in proper condition (no damage).
- The voltage specified on the type plate is identical to the local supply voltage.
- The power plug of the device is connected to the correct power supply.
- The footswitch plug is properly connected and screwed to the footswitch socket on the rear side of the device.
- The plug for the remote interlock contact is properly connected and screwed to the rear side of the device.
- The handpiece is connected.
- Warning lamps are switched on at all entrance points.

Ensure that all safety measures have been met.

Then proceed as follows:

1. Switch the main switch on the rear side of the device to I (On).
2. Check whether the *Laser Emergency Stop* switch is deactivated (not pressed).
3. Then insert the key into the key switch and turn it clockwise as far as it will go.

The start screen appears on the display while the device is automatically testing essential and safety-relevant parts. The main menu appears on the screen.

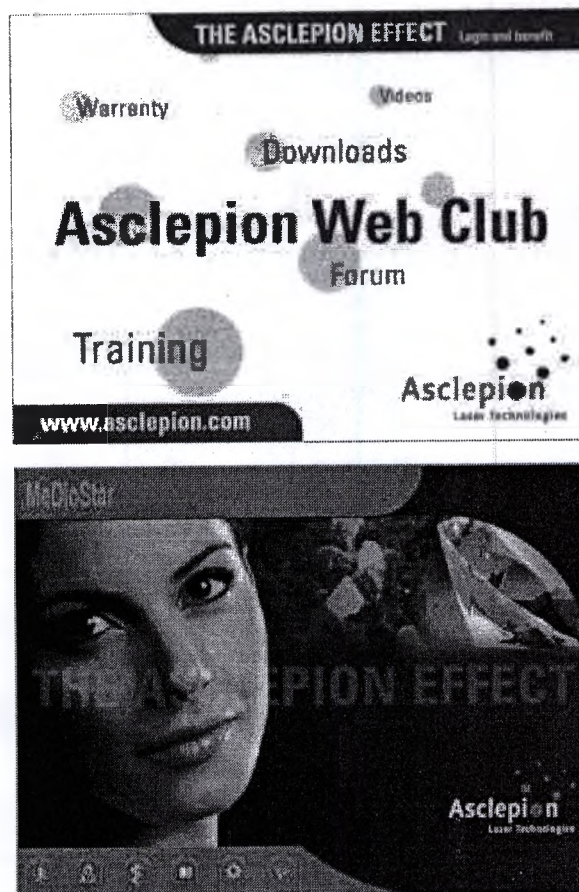


Figure 20: Start screen



## 6 Operating the device



### WARNING

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

The equipment and procedures for operation, maintenance, inspection and calibration specified in this user manual must be observed.

The device is operated using line voltage. There is risk of electric shock!

The device adheres to the specified limit values for leakage currents. Nevertheless, ensure that contact with the patient and device does not occur simultaneously when the device is switched on.

### 6.1 General notes on operation

The treatment parameters can be configured by using a touchscreen on the display on the front side of the device (see figure: *Front control panel*). Configuration is very easy and self-explanatory:

- The device software automatically detects and displays the currently connected handpiece, including the spot size. This spot size can be changed by replacing the laser tip when using the large XL handpiece; the spot size is fixed for all other handpieces.  
In the indication list, only the indications that are suitable for the connected handpiece can be enabled. However, it is possible to work with the handpiece using Quick-Start and adjust the parameters yourself.  
Only the modes permitted for the connected handpiece can be activated.
- Functions can be selected by tapping on the corresponding field on the display. Pressing the +/- buttons on the right side of the display lets you scroll through multi-page lists (e.g. indication lists)
- Parameters can be selected by pressing the corresponding parameter field.  
Parameter fields with dark backgrounds can be modified; fields with bright backgrounds (display fields) simply serve to provide information.  
Pressing the +/- buttons on the right side of the display lets you change the set parameters. The system scrolls through the parameters automatically if you hold the buttons down. The new parameters are applied by pressing OK.
- A short, audible signal indicates that the button press was successful.
- The laser can be activated by pressing the *STANDBY/READY* button. If the device is switched to the *READY* state, the yellow warning sign also appears on the display.

## Overview of important device function buttons

| Function/<br>Parameter      | Display                                                                             | Remarks                                                                                                    |
|-----------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| Switching off<br>the device |    | You can switch off the device by activating this switching element (analog key switch).                    |
| Quickstart                  |    | This brings you to the Quickstart menu. From here, the laser can be started directly.                      |
| Patient database            |    | Treatments and corresponding parameters can be retrieved and stored.                                       |
| Indications                 |    | All enabled indications are displayed and can be retrieved.                                                |
| Library                     |    | The library contains information including photos and videos.                                              |
| Setup                       |    | General settings for the device can be configured on the display.                                          |
| Asclepion                   |   | Experience the advantages of the Asclepion Web Club.                                                       |
| Tools                       |  | Stored special functions for the laser can be accessed here                                                |
| Save                        |  | Saving the settings for your treatment                                                                     |
| Start screen                |  | Returning to the start screen                                                                              |
| Setting keys                |  | Scrolling through lists and changing settings                                                              |
| Back                        |  | Returning to the last screen without applying any changed settings                                         |
| Cancel/<br>Delete           |  | Exiting the current indication/patient/favorite<br>Deleting                                                |
| OK                          |  | Applying changed settings                                                                                  |
| READY/<br>STANDBY           |  | The active state is shown in <u>white</u> . The yellow laser warning sign also appears in the READY state. |



## 6.2 Settings/Setup

You have the option to adjust general settings for your display, such as language and volume. Call up the *Setup* menu by pressing the *Setup* button on the main menu. The screen changes to the *Setup* screen (see figure below).

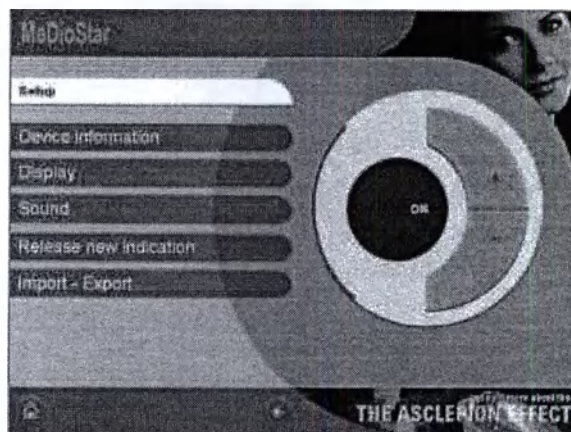


Figure 21: Setup

The following functions can be carried out by pressing the corresponding buttons:

| Function/<br>Parameter     | Display                | Remarks                                                                                                         |
|----------------------------|------------------------|-----------------------------------------------------------------------------------------------------------------|
| Information                | Device information     | Software version display                                                                                        |
| Language                   | Display                | Selecting between different languages                                                                           |
| Sound                      | Sound                  | Volume and sound choice settings                                                                                |
| Releasing an<br>indication | Release new indication | New treatment indications can be released.                                                                      |
| Import/Export              | Import - Export        | Allows the patient database, the indication list and the library to be imported from or exported to a USB stick |



### Tip

The USB interface may only be used in the STANDBY state and only for exporting data to and importing data from a suitable USB stick, for example, from Asclepion Laser Technologies.

Patient data is to be regularly saved to a suitable USB stick to prevent the loss of data in the event of a device defect.

The data can only be read on the device display.



### 6.3 Patient database

The patient database is used for obtaining information about treatments you have already performed and adding new patients to your database. To access the database, open it by pressing the *patient database* key in the main menu. The *Patient database* screen appears (see figure below).



Figure 22: Patient database screen

| Function/<br>Parameter | Display                                                                             | Remarks                                                                                                                                                      |
|------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| New patient            |  | You have the option to add new patients to your database. After pressing this button, a keyboard appears on the display that lets you input the new patient. |
| Information            |  | Here you can retrieve notes on a patient or enter additional information on a patient (e.g. allergies, reactions to treatment etc.).                         |



Figure 23: Screen for entering patient data

To write initial letters in uppercase, press the *Shift* button once; do not hold the button down. After typing a letter, the keyboard automatically shifts back to lowercase letters.

You can toggle the keyboard to writing uppercase letters by pressing the *Cap* button.

Activating the *Shift* or *Cap* button gives you the option to insert special characters.

The "äü" button gives you the option to insert special characters from foreign languages. *Shift* and *Cap* give you the option to write uppercase letters here as well. Press the "äü" button again to return to the original keyboard.



#### Important information

Ensure that the patient's birth date, specifically the year of birth, is entered **logically and has four-digits**. Saving the entries is not possible otherwise.

## 6.4 Library

The library contains information on individual indications, such as application and side effects as well as how to carry out the therapy. In addition to the respective therapies, there are also before and after photos and videos. To access the library, press the *Library* button in the main menu.



Figure 24: Library



You can retrieve the following information:

| Function/<br>Parameter | Display                                                                           | Remarks                                                                                            |
|------------------------|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| Indications            | Epilation BASIC                                                                   | Select the indication for which you want to display information (here, Epilation BASIC indication) |
| Photos                 |  | Before and after photos (if available)                                                             |
| Videos                 |  | Videos of treatment (if available)                                                                 |
| Application            | Indications                                                                       | Application areas for treatment                                                                    |
| Contraindications      | Contraindications                                                                 | Contraindications                                                                                  |
| Preparation            | Preparation                                                                       | Notes on treatment preparation                                                                     |
| Therapy                | Therapy Procedure                                                                 | Notes on carrying out the therapy                                                                  |
| Postoperative care     | Aftercare                                                                         | Notes on postoperative care                                                                        |
| Notes                  | Notes                                                                             | General information                                                                                |

Examples of available information:

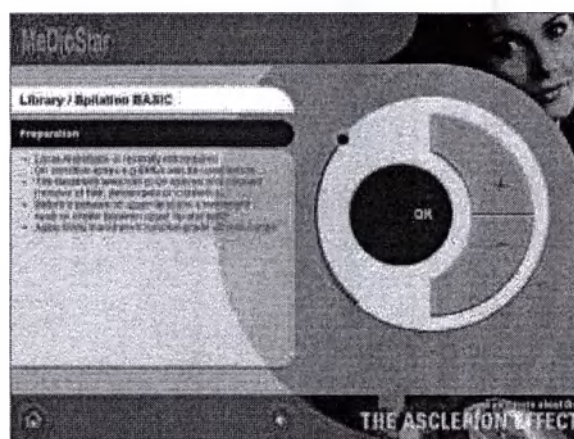


Figure 25: Therapy information



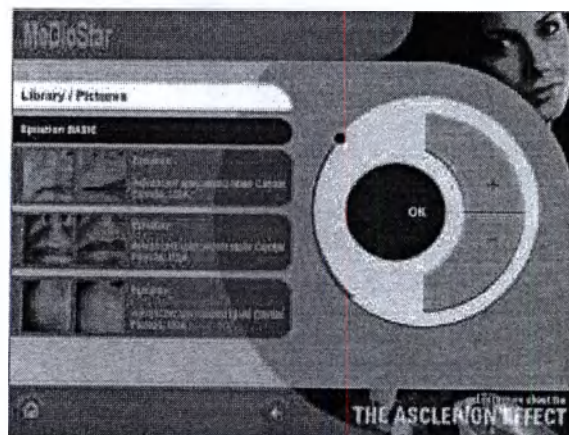


Figure 26: Library photos

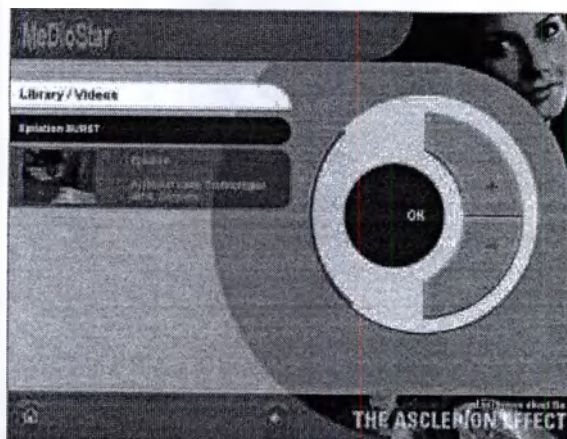


Figure 27: Library videos

To enlarge the photos or to start the video, simply touch the photo or video.

## 6.5 Asclepion Effect

The Asclepion Effect is a company philosophy that benefits both you as a customer and your patients.

The Asclepion Effect offers you information about Asclepion Laser Technologies, the company strategy and marketing tools.

Are you already a user of our exclusive Web Club? If not, you can find information on our offer here.



Figure 28: Asclepion Effect

## 6.6 Starting the treatment

Your device is suitable for a variety of applications.

In order to begin treatment, you have to switch to the treatment screen (see example below for starting through the indication list).

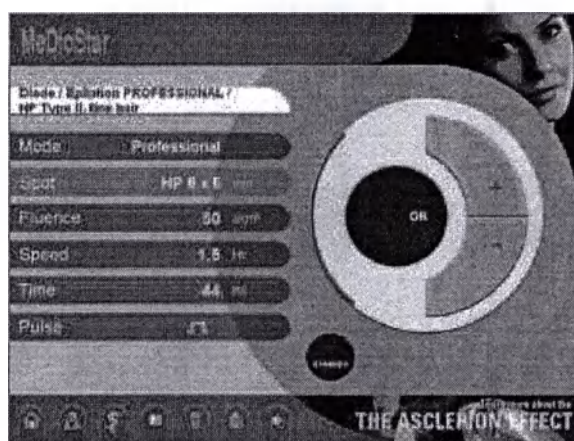


Figure 29: Treatment screen

Switching to the treatment screen via the indication list is only possible if the correct handpiece is connected. If no handpiece or if the incorrect handpiece is connected, a corresponding note appears on the display.

There are a variety of options for accessing the treatment screen from the main menu:

- Starting from Quickstart   
(Self-selected parameters can be adjusted directly on the display corresponding to the selected mode – Basic, Professional, SmoothPulse, Burst or Vascular.)
- Starting from the indication list   
(Corresponding to the selected indication, suitable parameters are already shown on the display for the **test treatment**, which are to be reduced or increased based on the response to the test treatment. See *Application* section.)
- Starting from the patient database   
(Recommend for continuing a treatment.)

#### 6.6.1 Starting from Quickstart

To get to the *Quickstart* screen, press the *Quickstart* button in the main menu.

It takes a few seconds before the Quickstart display appears.

You have the option to start your laser device using the Quickstart menu (see figure, *Basic* mode example).



Figure 30: Quickstart screen

Refer to the *Setting and saving parameters* section to configure parameters.

In the Quickstart menu on the display next to the parameters, you can also select different modes - Basic, Professional, SmoothPulse, Burst or Vascular, as long as these are enabled for the connected handpiece. (For application instructions see the *Application* section.)



### 6.6.2 Starting from the indication list

Pressing the *Indication list* button in the main menu takes you to the screen with the list of indications (see figure below).

All the treatment indications that are enabled for your device appear.



Figure 31: Indication list screen

Select your indication by pressing the corresponding field. You are taken to the treatment screen for the indication. Refer to the *Setting and saving parameters* section to configure parameters.

### 6.6.3 Starting from the patient database

Starting at the patient database option is useful when you have a patient who has already been treated before and you want to retrieve the parameters that were stored for that treatment. In order to do this, open the patient database by pressing the *Patient database* field. This takes you to the *Patient database* screen



Figure 32: Patient database screen

Pressing the patient's name and the respective treatment quickly takes you to the desired parameters.

The patient can be selected by pressing on the program name on the left side. The "+" and "-" buttons are for scrolling through the screen. Confirming with **OK** takes you to the *Treatment screen*. Refer to the section *Setting and saving parameters* to configure parameters.

## 6.7 Setting and saving parameters

This section describes how setting the parameters to the respective treatment is carried out and saved. First configure the treatment screen of the desired indication.

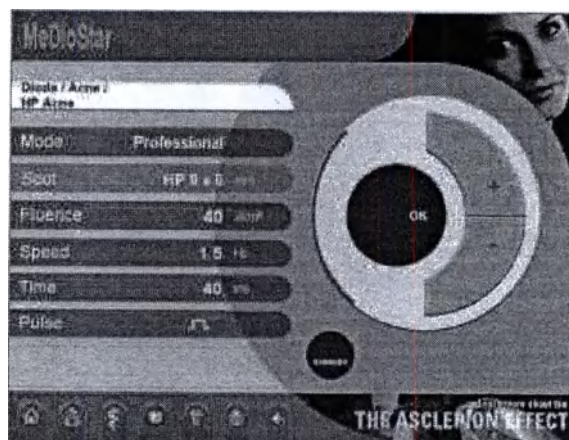


Figure 33: Treatment screen

Select the parameters to be changed by pressing the field. The selected parameter is visually accentuated (darker). To carry out changes, use the "+" and "-" adjustment buttons.

To load the modified settings, press **OK**.

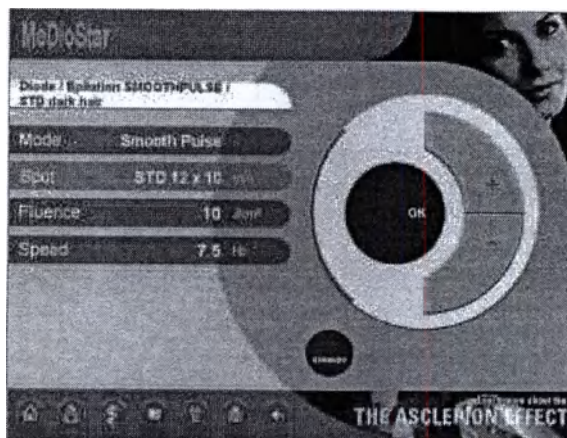


Figure 34: Standby screen

You can now save the changed settings by pressing the *Save* button. You have the option to save under a patient or an indication. Please press the *Patient database* or *Indication list* button accordingly.



Figure 35: Saving parameters

#### Saving under the patient database

If you would like to save the parameters in the patient database, you can choose between a new patient or a previously registered patient. If you decide to save the data for a previously registered patient, you have the option to create a new treatment or to configure a previously created treatment. If you wish to save it under a previously entered treatment, the stored values are overwritten.

Open the patient database to retrieve the stored parameters.  
(see section *Patient database*).

#### Saving under the indication list

If you have decided to save the data in the indication list, you can choose either a previously entered indication or a new favorite. If you pick a previously entered indication, the old data is overwritten.

Open the indication list to retrieve the stored parameters.  
(see section *Starting at the indication list*).

## 6.8 Settings for your laser device

The parameters that can be set depend on the **mode** and **handpiece**.

#### Basic mode:

Energy density (**Fluence**) and treatment speed (**Speed**) can be set

Note: In this mode, the shortest possible pulse time (**Time**) for the configured fluence is used and always using a double pulse.

For a double pulse, the fluence and time always refer to the sum of the two halves of the double pulse, e.g. it is the real laser emission (interruption of the pulse is ignored).

#### Professional mode:

The **Fluence**, **Speed**, **Time** and **Single or Double pulse** can be set

#### Vascular mode:

The **Fluence**, **Speed** and **Time** can be set.

Note: Always single pulse.



### Smooth Pulse mode:

The **Fluence** and **Speed** can be set

Note: Always single pulse, always the shortest possible time at the set fluence

Low fluence, high frequency

Unlike the other modes, multiple passes are always required (see *Application/Epilation*)

### Burst mode (pulse train):

The **Fluence**, **Speed**, **Time**, number of pulses (**Pulse**) and **Pause** in between can be set

Note: - The set fluence always refers to the sum of the pulse train (real laser emission, the complete pulse train is applied at the same place)

- Time refers to the pulse duration of one part of the pulse train (not the sum)

- Pause is the time between the respective parts of the pulse train (not the sum)

#### Tip

Please note:

- Only the modes feasible for a specific handpiece can be activated. This means that not every handpiece is configured for every mode.

- Most parameters are technically interdependent. This means that, for example, the highest fluence is not possible while using the shortest pulse duration.

The size of the spot can be changed by changing the handpiece or, on the XL handpiece, by changing the laser tip. This causes the system to detect the size automatically and to show it on the display.

Alongside the selected parameters, the device state (*STANDBY* or *READY*) and notes, where appropriate, are displayed in plain text in the event of errors.

The pulse energy, the number of pulses currently being emitted and the total number of pulses are also displayed (see section *Special function/Tools*).

The laser can be triggered using the foot switch.

## 6.8.1 Parameters

| Function/<br>Parameter | Display | Remarks                                                                                                                                                     |
|------------------------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Fluence                | Fluence | Fluence settings<br>(Total fluence in <i>Burst</i> mode)                                                                                                    |
| Treatment speed        | Speed   | Treatment speed setting (pulse frequency = repetition rate)                                                                                                 |
| Spot size              | Spot    | Display of the handpiece spot size                                                                                                                          |
| Pulse duration         | Time    | Pulse duration setting<br><i>Professional</i> : For double pulses, the sum of both pulse halves.<br><i>Burst</i> : Pulse duration of the parts of the pulse |
| Operating mode         | Mode    | Operating mode                                                                                                                                              |
| Pulses                 | Pulse   | <i>Professional</i> : Toggling between single/double pulse<br><i>Burst</i> : Number of pulses                                                               |
| Impulse break          | Pause   | Only in the <i>Burst</i> mode: Setting for the break between the parts of the pulse                                                                         |

## 6.8.2 Special function/Tools

Pressing the *Tools* button on your treatment screen takes you to the *Tools* screen.

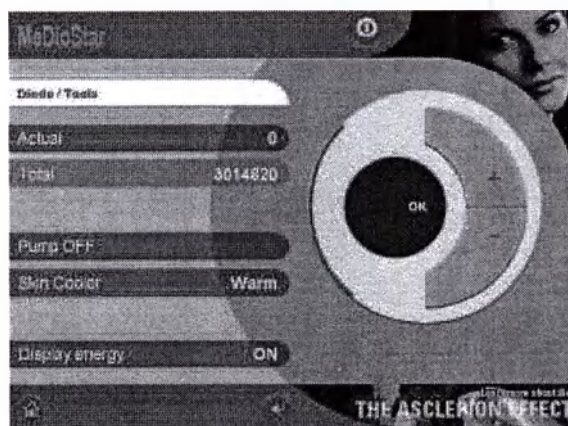


Figure 36: Tools screen

| Function/<br>Parameter      | Display        | Remarks                                                                                                                     |
|-----------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------|
| Pulse counter               | Actual         | Can be set to 0 by tapping on the field (until it beeps) and is set back to 0 automatically after switching off the device. |
| Pulse counter               | Total          | Total pulse counter                                                                                                         |
| Cooling water pump          | Pump OFF       | See information below                                                                                                       |
| Temperature<br>Skin cooling | Skin Cooler    | Cold/Medium/Warm<br>(Recommendation: Cold)                                                                                  |
| Energy display              | Display energy | Shows the energy in the display                                                                                             |



### Important information

Before changing the handpiece or the laser tip of the handpiece XL, the cooling water pump must always be switched off by switching off the device (recommended) or by pressing the "Pump off" button in the Tools menu. This prevents coolant from leaking except for a few drops. The pump automatically switches on again after changing the handpiece.



### Important information

Before the end of the connected handpiece's lifetime is reached (dependent on the handpiece), this information will appear on the display several times.



### 6.8.3 Establishing the laser ready state and activating emission of the laser beam

Also see chapter *Application*!

After activating the Quickstart button, an indication from the indication list or a former stored treatments of a patient, the laser is in the *STANDBY* state. Standby is highlighted in white on the *READY/STANDBY* button.

Check again to make sure that

- The handpiece is connected correctly and the laser tip is clean and disinfected
- All laser protection measures have been met
- Check the function of the door contact if you have it installed: Open the door; it must **not** be possible to switch the laser to the *READY* state (an error message is displayed and must be acknowledged).

Set the desired parameters according to the explanations given in the previous chapters.



#### WARNING

Direct and scattered laser radiation can cause severe eye injuries.

Everyone in the room where the laser is being used must wear protective eyewear or patient blackout glasses suitable for this laser while the laser is active, as specified in chapter *Technical data*. Other forms of protective eyewear may not ensure sufficient protection! The user must confirm this before pressing the *READY* button.

In the *READY* state, you can also activate a laser pulse by unintentionally pressing the foot switch! Therefore, the laser device must be switched to the *STANDBY* state immediately during breaks in treatment and at the end of treatment.

The laser beam may be triggered only if the handpiece is precisely directed onto the skin area to be treated.

Press the *Laser Emergency Stop* switch immediately in the event of a hazardous malfunction.

Pressing the *READY/ STANDBY* button lets you switch to the *READY* state. This causes the yellow laser warning sign to appear in the lower right of the display. First, a safety check of the hardware is carried out. This only takes a few seconds (see figure *READY state*).

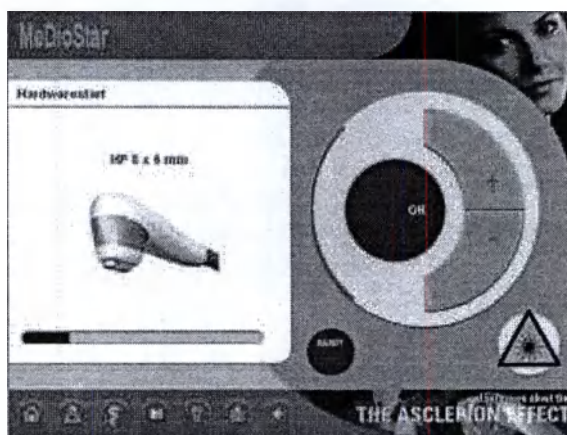


Figure 37: READY state



In addition, the system checks that the temperature of the handpiece's cooling probe is sufficiently cold. If the cooling temperature after the hardware start has not been reached yet, the Cooldown Handpiece screen is displayed. The progress bar on the Cooldown Handpiece screen indicates the cooling process for the cooling probe. The screen disappears once the cooling probe is cold enough. (The same applies for activating the device after 15 minutes of inactivity.)



Figure 38: Cooldown Handpiece

Pressing the foot switch releases the laser radiation from the laser tip of the handpiece with the set parameters. Releasing the foot switch immediately interrupts the laser emission.

The emission of the laser radiation is indicated audibly by a warning tone and visually by the flashing laser emission indicator on the handpiece.

If a parameter is changed in the *READY* state, the device automatically reverts to the *STANDBY* state. This means that the *READY/STANDBY* button must be pressed again to return to the ready state.

It is completely normal for the temperature of the cooling probe of the handpiece to become somewhat heated during treatment of larger surfaces. If the upper limit value of the cooling temperature is reached, emission of laser radiation is interrupted and the "Cooldown Handpiece" screen appears. Treatment can continue once the cooling probe temperature has been reached.

The MeDioStar is equipped with an *Laser Emergency Stop* button that is easy to operate. This button is on the front of the device. In an emergency, forcefully pressing this switch immediately deactivates the laser. This eliminates any danger to the operator and patient from the laser.

Once the emergency situation has been corrected, gently turn the *Laser Emergency Stop* button clockwise by hand until it is in its normal position to restore the proper device functionality.



#### CAUTION

If the symbols " $\triangle$ " or " $\nabla$ " appear in the Fluence field while using the laser, this means the device has detected a deviation from the starting values that is more than 20% too high or too low.

An upward deviation can lead to unwanted side effects; a downward deviation makes the treatment less effective.

Reduce or increase the parameter accordingly and if this occurs frequently, please notify technical support.

Once treatment is finished, switch the laser to the secure *STANDBY* state by pressing the *READY/STANDBY* button. Also switch the laser to the *STANDBY* state if you temporarily interrupt treatment. Unintentional activation is not possible in this operating state.

After prolonged inactivity in the *READY* state, the device automatically switches to the *STANDBY* state.

## 6.9 Changing the handpiece and changing the spot size on the XL handpiece

Changing the handpiece must always take place when the device is switched off. If this is not possible—and when changing the laser tip of the XL handpiece, you must make sure to deactivate the coolant pump before the handpiece is disconnected from the device or the laser tip is disconnected from the base body of the XL handpiece. To do so, press the "Pump off" button in the Tools menu (see *Special function/Tools*). This turns the pump off and the LED on the handpiece goes out. Only after this can the handpiece plug or laser tip (of the XL handpiece) be disconnected. The pump switches on automatically when the laser tip is re-engaged again.



### Important Information

Frequent changing of the laser tips of the XL handpiece leads to leakage of some coolant from the connectors. This can eventually lead to an information on the display, that coolant has to be refilled. Observe the procedure described above to restrict the leakage to a few drops.

It is recommended to hold the XL handpiece vertically with the tip down to let the drops fall out of the handpiece when the tip is changed. In case there are residues on the diode window inside, these must be cleaned using a microfiber cloth (see chapter *Cleaning and disinfection*).

The refilling of the coolant can easily be done by the user (see chapter *Routine maintenance*).

**Changing the handpiece** requires gripping the multifunction plug of the handpiece so that you can press both metal pressure points on the left and right sides inwards. You can do this with your thumb and forefinger or using both hands together. The multifunction plug is located on the rear side of the device; it connects both the power supply for the diodes and the water supply. The plug can then be pulled out. You can insert the plug by first correctly pressing it onto the connector and then pressing it more onto one side with a quick jerk and then repeating the motion on the other side. You can clearly hear the connector click into place two times.

**Changing the spot size on the XL handpiece** also requires pressing down the two pressure points on both sides of the handpiece at the same time (see figure below) to remove the laser tip. The other tip then clicks into place as described above. It is important to ensure that the handpiece remains clean inside, especially the optics (also see the *Cleaning and disinfecting* section).

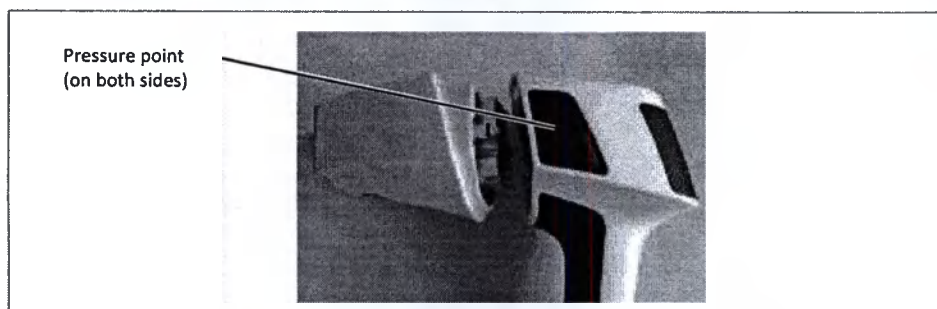


Figure 39: XL handpiece, after pressing the pressure points opened to change the laser-tips

## 6.10 Switching off the device

Exit the *READY* state and switch to the *STANDBY* state by pressing the *STANDBY/READY* button.

The laser is switched off by turning the key switch counterclockwise as far as it will go. Only then should you switch off the power switch at the rear panel of the device (see Figure: *Connectors on the rear side of the device*). Switching the device main switch to "0" (OFF) completely disconnects the device from the line voltage.



### WARNING

Direct and scattered laser radiation can cause severe eye injuries.

Never leave the laser device unattended while it is switched on. Completely disconnect the device from the line voltage with the main device switch. After switching off the device, ensure that the key is removed and kept in a secure place to prevent unauthorized use of the device.



## 7 Application

### 7.1 General information

Specific information for application is provided in this application section. The instructions provided can never replace expert knowledge for the medical application of lasers, extensive studies of relevant literature, personal experience gained under supervision and critical assessment of the current situation.

However, these instructions serve as useful support for beginners and as a memory aid.

Therefore, we recommend studying current medical literature and contacting physicians in private practices using such equipment in order to familiarize yourself with the methods of laser treatment before you start to treat patients yourself.

We would be happy to assist you in mediating contact with other users. Your responsible sales Representative would be happy to provide detailed information.

### User requirements

Please observe the chapter *Intended use/ Requirements for the user*.

Users must have sufficient knowledge of safe and efficient operation of this product before operating the device described in this User manual. Training is carried out by employees or authorized persons from Asclepion Laser Technologies GmbH based on the User manual and is documented in the device book. The user must be trained on the following points:

- Instruction on operation and the intended use of the device with practical exercises
- Operating and functional principle of the device and the energies applied
- Settings for all control parts
- Indications for device use
- Contraindications and side effects
- Warnings in all operating states
- Carrying out functional tests

Additional training requirements differs by country. It is the responsibility of the operator to ensure that training corresponds to the requirements of all applicable regional laws and provisions.



#### WARNING

Laser radiation from the device can lead to thermal changes in tissue structures.

Make sure you have understood the principles of laser-tissue interaction as summarized below, the correlations between the individual application parameters, the application techniques as well as the basics of laser safety.

If you are even the slightest bit unsure of any aspect, consult one or more colleagues with practical experience and/or the application specialists from your distributor authorized by Asclepion Laser Technologies GmbH before you start performing laser treatment.

## 7.2 General notes on treatment



### CAUTION

The application of laser radiation on skin can cause thermal damage to tissue structures. This may be intentional or unintentional depending on the indication.

The user is responsible for correctly determining the indication, the treatment zone and the treatment parameters. The user is also responsible for the correct positioning of the handpiece.

Before and during treatment, the set parameters must be checked on the display as well as the temperature of the skin cooling by hand.



### CAUTION

During and after treatment, the effect of the laser beam can cause side effects in the treatment area. These side effects are individually very distinctive, but usually very slight.

Therefore, a test treatment must always be carried out in a small area as described below. This is intended to minimize side effects while keeping treatment effective.

It is important to consider that the side effects can be more severe when treating larger areas than when treating a small test area.

In addition, the test treatment gives patients a better impression of the treatment and allows them to make a better decision before consenting to treatment.



### Tip

As part of the informed consent discussion, patients must be informed of all risks resulting from the actual treatment and from pre and post operative care. The discussion must also explain the operating mechanism behind laser treatment, alternative methods, the time required, the treatment prospects and information about patient behaviour after laser treatment.

A log of this discussion and a signed declaration of consent should be retained. Before and after photos are also recommend.



### WARNING

The contact surface of the handpiece comes into contact with the patient when treating the skin. There is the risk of transmitting microorganisms.

The handpiece must be disinfected before each treatment and must be cleaned and disinfected after each treatment according to the procedure described in Chapter *Cleaning and disinfecting*.



### CAUTION

Any absorbent dirt on the laser tip of the handpiece generates localized overheating, which can lead to increased side effects and defects on the handpiece!

Make sure that the laser tip of the handpiece is clean and remains clean during treatment!



### 7.2.1 Interaction between laser beam and tissue

The goal, specifically for dermatological and aesthetic treatments, is to eliminate lesions that are bothersome or require therapy without any side effects. The **selective photothermolysis** method, which was introduced by Anderson and Parrish in 1983 with this goal in mind, ensures effective damage to the target whilst protecting the surrounding skin.

With this in mind, the following issues must be observed for successful treatment:

#### Absorption of the laser beam - wavelength

The absorption of the laser beam in the target (e.g. melanin in the hair or blood in blood vessels) must be higher than in the surrounding skin, which primarily contains water. The higher the absorption in the target, the hotter it becomes; the lower the absorption in the surrounding skin, the lower the unwanted heat is.

The wavelength range of the MeDioStar in the near infrared (IR) range is absorbed relatively easily by melanin and blood, depending on the handpiece. The wavelengths of the various handpieces are optimally adjusted within the range for each intended indication.

However, the absorption by melanin in the epidermis needs to be taken into account for people with dark skin tones. This additional absorption is generally unwanted (except when treating benign pigmented lesions) and can cause side effects such as increased paresthesia, hyperpigmentation or hypopigmentation. This means that wavelengths under 800 nm are not as well-suited for treating dark skin types due to the higher melanin absorption and not suited at all for skin type VI (see *Contraindications*). The handpieces with 800 – 950 nm are better suited for dark skin. Due to the higher absorption by melanin, in contrast, the lower wavelength is also better suited for lighter hair for patients with light skin types I and II.

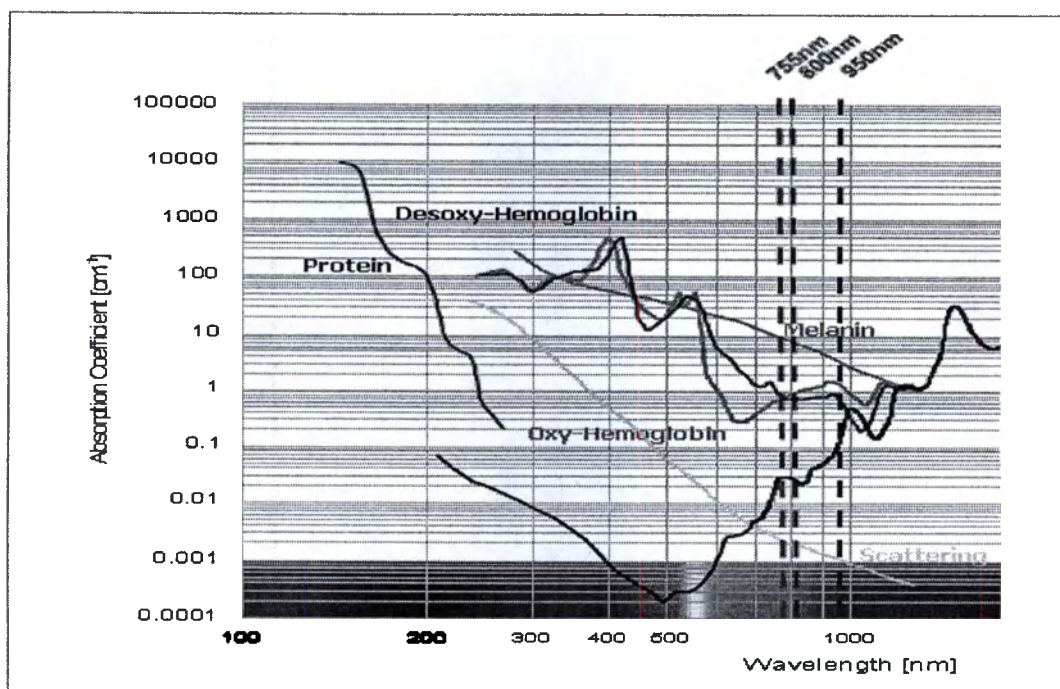


Figure 40: Absorption coefficients in relation to the wavelength of the laser beam

#### Spot size

The spot must be large enough so that the target located a few millimeters deep in the skin (e.g. root of a hair or blood vessel) is reached with sufficient energy density (FLUENCE). This is assured with the MeDioStar.

In general, it is important to note that a larger spot heats a larger volume of skin. Therefore, the required fluence is lower for larger spots.



### Pulse duration

The pulse duration should be shorter than, or at least not significantly longer than, the 'thermal relaxation time' of the target (e.g. hair or blood vessel). The thermal relaxation time is the time in which the target emits 50% of the heat into the environment.

Thin structures (hairs, vessels) emit heat considerably faster than thick structures. Thus, to reach the desired high temperature in thin targets, the required energy has to be delivered as quickly as possible. If the pulse is too long, the heat loss has to be compensated for in the surrounding skin by a higher fluence, which tends to lead to more side effects.

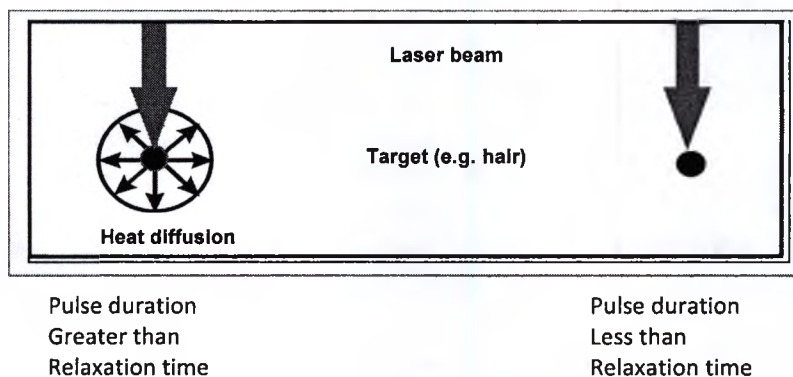


Figure 41: Thermal relaxation time and pulse duration of the laser beam

| Target         | Diameter                            | Therm. relaxation time       |
|----------------|-------------------------------------|------------------------------|
| Dilated vessel | 10 $\mu\text{m}$ – 50 $\mu\text{m}$ | 50 $\mu\text{sec}$ - 1 msec  |
|                | 100 $\mu\text{m}$                   | 5 msec                       |
|                | 300 $\mu\text{m}$                   | 45 msec                      |
|                | 500 $\mu\text{m}$                   | 125 msec                     |
|                | 1 mm                                | (500 msec)                   |
| Hair follicle  | approx. 300 $\mu\text{m}$           | approx. 45 msec              |
| Melanosomes    | approx. 0.5 – 1 $\mu\text{m}$       | approx. 0.05 $\mu\text{sec}$ |

Figure 42: Thermal relaxation time for various target diameters (examples)

For effective treatment, the required fluence and spot size are defined first. Then, for thin structures and light skin, the shortest possible pulse is set.

For the treatment of fine hair in small areas, e.g. in the face, the handpiece HP (item no. 4022) is particularly well suited. Due to the smaller spot it is able to emit shorter pulses with the necessary fluence – compared to the standard handpiece ST. The emission time of the laser is therefore shorter, too.

For dark skin, however, it is important to consider that the melanin in the epidermis is not to be heated. This means that the pulse duration would have to be set as long as possible, which does not present a problem for thick structures.

A compromise has to be found for treating thin hairs/vessels for dark skin. The pulse is set longer than for light skin and a thin target but shorter than for dark skin and thicker structures. The latter is still reasonable since heat generation for thin targets is still considerably lower than for thick targets. Also, the MeDio-Star still guarantees effective cooling of the epidermis (see below).

The epidermis can also be preserved by interrupting the pulse (double pulse). In BASIC mode, only a double pulse is emitted; in PROFESSIONAL mode, this can be configured on the display.

### Cooling the epidermis

Effective cooling of the epidermis is required for preventing unwanted side effects (particularly important for dark skin types due to their melanin absorption).

The MeDioStar's skin cooling mechanism is integrated into the handpiece. Contact between the epidermis and the cold metal probe is extremely effective due to the high heat conduction (eight-times better than sapphire cooling). For the XL handpiece, the sapphire (optical contact surface) is also cooled. The cooling temperature of the skin cooling mechanism is constantly monitored automatically as well.

### 7.2.2 Classification of skin types

| Skin type                            |                                                                  |                                     |
|--------------------------------------|------------------------------------------------------------------|-------------------------------------|
| I<br>("Irish" skin type)             | Pale white skin, blond or red hair, freckles, blue or green eyes | Always burns, never tans            |
| II<br>(frequent in Central Europe)   | Fair skin, blond hair, freckles, blue or green eyes              | Usually burns, tans minimally       |
| III                                  | Light brown or brown hair, brown eyes                            | Sometimes mild burn, tans uniformly |
| IV<br>(Mediterranean type)           | Light brown skin, dark or black hair, brown eyes                 | Rarely burns, tans quickly          |
| V<br>(Some Indians, South Americans) | Dark skin, black hair, dark eyes                                 | Rarely burns, tans very quickly     |
| VI<br>(some Africans, Indians)       | Very dark or black skin, black hair, black eyes                  | Never burns, tans very quickly      |

Figure 43: Classification of the skin types according to Fitzpatrick

### 7.2.3 Overview of areas sensitive to pain



Figure 44: Pain zones on the face

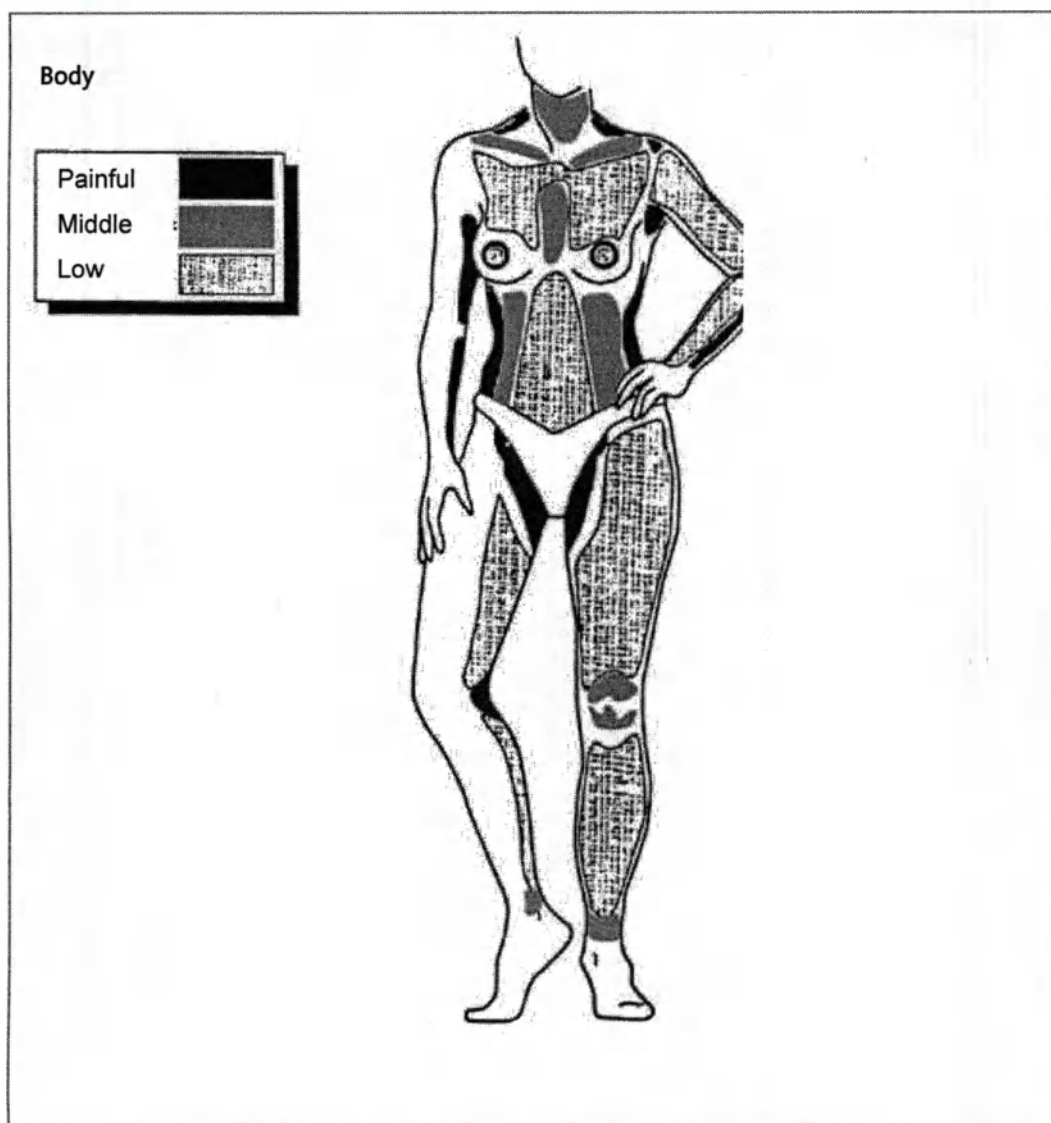


Figure 45: Pain zones on the body

#### 7.2.4 Application parameters

The **fluence** is very important for treatment using a pulse laser device such as the MeDioStar. It can be configured directly on the display in all modes. The higher the fluence, the more effective the treatment is; however, increased side effects are also possible. Therefore, test treatments must be carried out if the fluence is increased.

The mathematical relationships are as follows:

|                                   |                                              |
|-----------------------------------|----------------------------------------------|
| Fluence [joules/cm <sup>2</sup> ] | = energy [J]/spot surface [cm <sup>2</sup> ] |
| Power [watts]                     | = energy [J]/pulse duration [sec]            |



The device automatically takes the **spot size** used (depending on the handpiece) into account. As described above, a larger fluence tends to be required for smaller spots.

The **pulse duration** can be set in the modes *Professional*, *Vascular* and *Burst* as described above: Shortest possible (at sufficient fluence) for thin hair, vessels and lentigines, longer for protecting darker skin. Breaks between the pulse parts (**double pulse, burst**) are also more gentle on the melanin in the epidermis.

The *Basic* and *Professional* modes are intended for epilation; *Professional* is also used for rejuvenation (except for lentigines). *Vascular* is intended for vascular treatments and benign lentigines (with the small VAS handpiece spot). *Burst* mode can also be used for vascular treatments.

The *Smooth Pulse* mode can be used for the epilation of larger areas. This mode is recommended if it can be used since it is more comfortable and causes fewer side effects. In this mode, unlike all other treatments, the handpiece quickly moves over the surface to be treated at the set speed and lower fluence. However, in this case, multiple passes are required until erythema can be seen.

For all treatments (except lentigines), in order to guarantee that the epidermis is sufficiently **cooled**, the handpiece is always moved toward the cold metal probe so that the laser pulse always hits pre-cooled skin. The only exception is the treatment of lentigines, since the intention is to damage the melanin in the epidermis in this case.

The set **speed** in Hz (pulses per second) determines the speed of the treatment and has no implications on the effect of the treatment. In sensitive areas, a reduction can be less painful.

### 7.3 Typical indications - Overview

- Epilation
- Vascular treatments
- Acne inversa
- Acne
- Actinic elastosis (skin rejuvenation)

The following contains treatment instructions for individual indications.

## 7.4 Epilation

Removing unwanted hair is probably one of the oldest cosmetic surgeries/treatments and has experienced increased prevalence in recent years. Methods for this range from shaving, which must constantly be repeated, to waxing, which lasts longer, but is very painful, and hair removal using electrolysis needles, which is extremely time-consuming but has rather long-lasting success.

The goal of all of these methods—and, of course, laser epilation as well, which is considerably more comfortable in comparison—is to remove hair with the most long-lasting effects possible.

### 7.4.1 The target: Anatomy of the hair

As we all know from experience, merely plucking hair is not a permanent solution for hair removal. The hair grows back. This means, the structures responsible for the hair growing back also have to be destroyed.

Research today is largely in agreement that both the bulge with the germinative cells and the papilla contribute to hair growth and, accordingly, both must be damaged or destroyed.

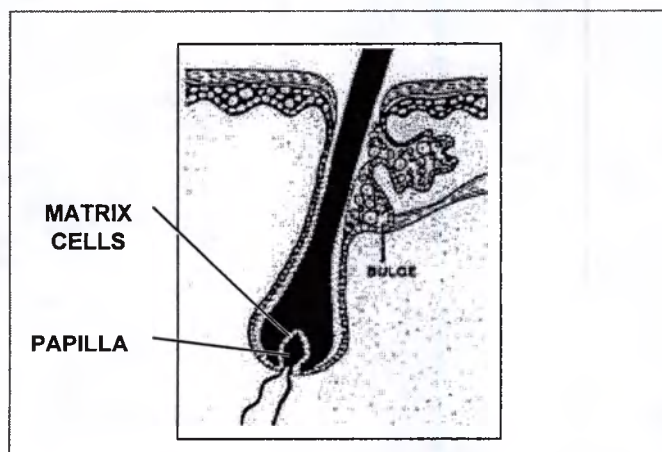


Figure 46: Anatomy of the hair follicle

Depending on the body region, the roots of the hair are up to 5 mm under the surface of the skin, sometimes even deeper. Therefore, the laser spot should be as large as possible to guarantee a sufficient effective depth for the laser radiation.

A clinical study\* (20 patients; direct comparison, test area on the leg) with the MeDioStar showed that a spot size of 12 mm was sufficient to treat leg hair effectively. Enlarging the spot to 14 mm did not yield any better results. The smaller spot sizes of 8 mm achieved approximately 10% lower effectiveness, even at a higher fluence.

\*Bäumler et al.: *The effect of different spot sizes on the efficacy of hair removal using a long-pulsed diode laser; DermatolSurg 2002: 28; 118-121*

However, it is important here to consider that in other areas, such as on the upper lip, the hair roots are not as deep in the skin and a smaller spot size can be effective and useful. Using smaller spots is specifically particularly recommended for finer hair since shorter pulses can be set with the smaller spot.

## 7.4.2 The growth phases of hair

Human hair begins growing even while we are still embryos, although it is very fine until toddlerhood. These lanugo hairs grow from the lower epidermis, successively moves to the dermis and does not have any papilla. Influenced by hormones, terminal hairs with papilla form later. The number is determined by genetics. The hair then grows in a cycle that repeats itself at intervals ranging from months to years (depending on the body region).

The active growth phase is called the anagen phase; the phase with very slow hair growth or none at all is called the telogen phase. The early anagen phase appears to be efficient for laser treatment.

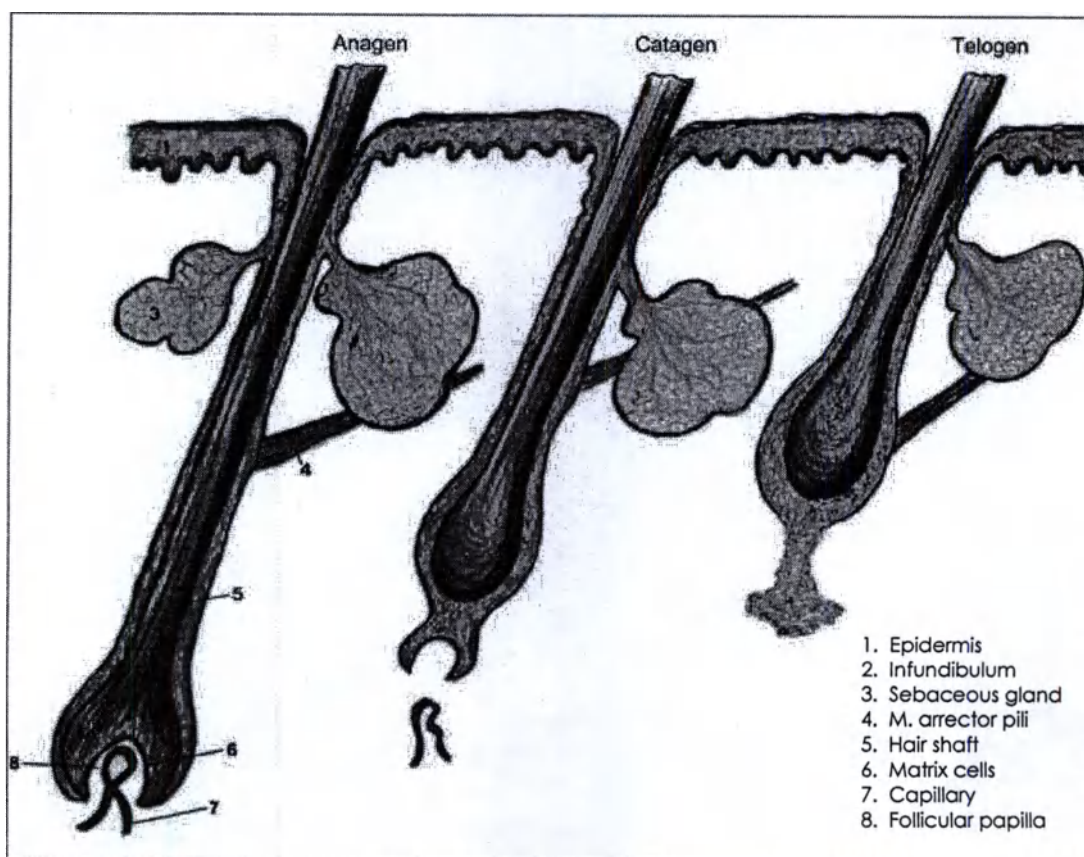


Figure 47: Hair growth cycle

In humans, the phases of various hairs are not synchronized, which means various hairs are found in various growth phases. Only a certain percentage of hair ever reacts to laser treatment in a respective area. Therefore, a series of treatments is always required.

The shorter the telogen phase in comparison to the anagen phase, the faster the hair grows back in a certain area. This is why the beard area has to be shaved more often than body hair. Accordingly, shorter intervals between the follow-up treatments with a laser have to be selected as well.



|              | Depth of the terminal anagen follicle | Duration of the telogen phase | Duration of the anagen phase | Number of follicles/cm <sup>2</sup> | Total number of follicles | Growth per day |
|--------------|---------------------------------------|-------------------------------|------------------------------|-------------------------------------|---------------------------|----------------|
| <b>HEAD</b>  |                                       |                               |                              |                                     | 1 million                 |                |
| Upper lip    | 1-2.5 mm                              | 6 weeks                       | 4 months                     | 500                                 |                           |                |
| Chin/beard   | 2-4 mm                                | 10 weeks                      | 1 year                       | 500                                 |                           | 0.38 mm        |
| Cheeks       | 2-4 mm                                |                               |                              | 880                                 |                           | 0.32 mm        |
| Eyebrows     | 2-2.5 mm                              | 3 months                      | 4-8 weeks                    |                                     |                           | 0.16 mm        |
| Ear          |                                       | 3 months                      | 4-8 weeks                    |                                     |                           |                |
| Head hair    | 3-5 mm                                | 3-4 months                    | 2-6 years                    | 350                                 |                           | 0.35 mm        |
| <b>BODY</b>  |                                       |                               |                              |                                     |                           |                |
| Armpits      | 3.5-4.5 mm                            | 3 months                      | 4 months                     | 65                                  |                           | 0.3 mm         |
| Legs         | 2.5-4 mm                              | 5 months                      | 4 months                     | 60                                  | 370 000                   | 0.21 mm        |
| Pubic region | 3.5-5 mm                              | 3 months                      | 4 months                     | 70                                  |                           |                |
| Arms         |                                       | 4 months                      | 3 months                     | 80                                  | 220 000                   | 0.3 mm         |
| Chest        | 3-4.5 mm                              |                               |                              | 65                                  |                           | 0.35 mm        |
| Torso        | 2-4.5 mm                              |                               |                              | 70                                  | 425 000                   | 0.3 mm         |

Figure 48: Hair growth (excerpt from Richards-Meharg table)

### 7.4.3 Selection of patients

Both women and men have successfully delayed hair growth in the long-term using laser treatment. For dark hair, laser epilation is particularly effective due to the high eumelanin content in the hair. Lighter hair usually requires higher fluence, which is tolerated because the skin is normally lighter as well. Using the handpiece with the shorter wavelength range starting at 755 nm is recommended for lighter hair. However, it is impossible to predict the success of treatment for individual cases. Surprisingly good results have also already been observed with blond hair. Conversely, there are also exceptions with particularly stubborn dark hair.

Light-blond hair, red hair (containing phaeomelanin) and gray hair usually respond very poorly or not at all to laser treatment. The same applies to thin hair.

The handpiece with a shorter wavelength range starting at 755 nm requires particular caution, see *Test treatment*.

Women with very strong hair growth should have their hormone status checked before treatment. Hormone treatment must be carried out first before treating transsexual men (male to female).

Achieving complete hair removal is not possible; fine light hair usually remains. Patients must be made aware of this!

#### Areas suited for epilation:

- Mustache/Upper lip
- Facial hair
- Chin/Upper neck
- Thigh
- Bikini line
- Lower leg
- Upper arm
- Lower arm
- Chest
- Back
- Hands
- Nose/Ears (treat cautiously)

#### 7.4.4 Contraindications

The contraindications from the *Intended use* section must be observed (except for spider veins).

In the event that epilation processes such as waxing or plucking have been carried out previously, you should wait 4 – 6 weeks since the hair shaft, the 'target', is no longer present and the laser treatment will have no effect as a result.

Any tattoos in the treatment area must be left out of the treatment! Otherwise, the tattoo may be damaged and the risk of side effects is very high (high absorption by dark ink particles)!

#### 7.4.5 Possible side effects

All side effects are less pronounced with light skin and lighter hair and become stronger with darker and thicker hair and darker skin. The effects also become stronger for handpieces with shorter wavelengths starting at 755 nm and, of course, if the fluence used for the individual situation is too high (test treatment!).

This means that the darker the skin is (which usually entails a darker hair color as well!), the lower the start values for the test treatment have to be.

During treatment, patients feel a pricking sensation accompanied by a feeling of warmth.

After treatment, there will be a slight erythema, particularly perifollicular erythema. For dark, thick hair, perifollicular edema can also develop. If *SmoothPulse* mode is used, the slight erythema will be less perifollicular and more general instead.

These effects are normal and only last a few hours, rarely up to 2 days, and very rarely a few weeks.

If the patient follows the proper procedure and compliance, blisters, scabs and temporary alterations in pigment (light protection!) are rare. Blisters and scabs normally heal without any side effects within one week. Alterations in pigment can last up to a few months.

Persisting alterations in pigment and scars are extremely rare.

In rare cases, dark hair can become discolored and can then no longer be removed with a laser/light due to the lack of absorption.

Paradoxical hair growth also occurs in rare cases, more often in clients with dark skin. This is where treatment stimulates hair growth (also see the tip in chapter *Treatment*).

#### 7.4.6 Preparation for laser epilation

The area to be treated must be healthy, shaved and cleaned; even deodorant or other cosmetic products must not be present.

Before treating the upper lip, a moistened gauze swab or the like should be placed between the upper lip and teeth to catch the small portion of laser radiation that can pass through the upper lip. This prevents the area around the teeth from heating up (can sometimes be painful).

Photos should be taken to document the success of the treatment.

Anesthetic is not normally required since laser epilation using the MeDioStar is relatively painless due to the handpiece's integrated skin cooling. Especially using the *SmoothPulse* mode, hardly anything is felt.

For sensitive areas or very widespread treatment areas, a topical anesthetic such as EMLA can be used depending on the tolerance and form of application (skin cooling!). However, anesthetic should not be used during the test treatment or first treatment if at all possible, since feeling during treatment allows for a fairly good estimation of the side effects to be expected.

Clinically tested **colorless** ultrasound gel optimizes the coupling of the laser beam into the skin by reducing reflections and scattering of the laser beam. This causes higher efficiency. A thin layer of the ultrasound gel is applied to the surface to be treated with the laser. This also reduces the formation of smoke and odors.



#### 7.4.7 Test treatment

If, after the informed consent discussion, the patient decides for laser epilation, a test treatment should always be carried out in the area to later be treated with the laser. The patient's reaction in terms of skin reaction and perception of pain can differ from person to person. Apart from particularly sensitive or particularly pain-tolerant patients, the sensation of pain is a good indicator for the side effects to be expected.

Test treatment is started on a small area with the start parameters recommended for the respective skin type in a treatment area thought to be non-sensitive. If sensitive areas are to be treated as well (e.g. bikini area or above the shin), the test must be repeated in this area.

The darker the skin type is, the lower the start fluence must be (and the longer the pulse duration must be in *Professional* mode). The latter is not an issue for thicker hair. For thin hair, as a compromise, the pulse must not be as long to ensure that the treatment remains efficient. Conveniently, the lower absorption rate for thin hair also tends to result in fewer side effects.

**The handpiece with the wavelength starting at 755 nm is only recommended for skin types I and II** since the most important advantage is the slightly higher effectiveness for lighter hair, which is normally associated with light skin and the melanin in the epidermis in dark skin causes more side effects. If this handpiece does get used for dark skin, the fluence has to be even lower than that used with the standard handpiece. Treating patients with skin type IV and skin type V should only be done (if at all) in *SmoothPulse* mode and only if the therapist has sufficient experience with skin type III (and skin type IV, if skin type V is being treated). Treatment for skin type VI and tanned skin are contraindications!

For the test treatment, the exact same application process has to be used as for later treatment.

The handpiece is always moved on the skin with light pressure, which reduces the distance to the root of the hair (more effective). Make sure that the cold metal skin cooling probe remains in contact with the skin during treatment to guarantee pre-cooling of the epidermis. For practical purposes, the handpiece should remain in contact and not be re-applied each time. The location of the next series of spots to be applied can be detected easily using the ultrasound gel.



#### WARNING

Laser radiation can cause severe eye injuries.

Before starting laser treatment, all personnel in the room must put on the laser safety glasses (including patient eye protection) in compliance with the information in chapter *Technical data!*

The configured/displayed data on the display must be checked before and during treatment!  
The skin cooling must also be inspected to ensure that it is cold!

At the desired FLUENCE, switch the MeDioStar to the *READY* state, place the handpiece on the area to be treated and, if necessary, wait briefly until the *READY* state is reached (skin cooling has reached specified temperature – information on the display).

Using ***SmoothPulse* mode** (low FLUENCE, high SPEED, multiple passes) **is generally recommended, if use is possible from an anatomical perspective with respect to the handpiece spot size used – but in particular for dark skin. This process is more gentle but still effective.** (The time required is approximately the same. The handpiece moves faster in *SmoothPulse* mode, but multiple passes have to be made.)

For the test treatment in ***SmoothPulse* mode**, an area of approximately 10 cm<sup>2</sup> is treated by moving the handpiece quickly (approx. 10 cm per second). During this process, avoid leaving any gaps if possible and always move the handpiece in the direction of the skin cooling.



For light skin, this must be repeated four times, three times for dark skin ( 3-4 passes). Stop if it becomes painful, otherwise increase the number of passes by a reasonable amount.  
End point: Slight erythema.

The **Basic and Professional** modes are well-suited for anatomically difficult areas, but, in principle, are also suited for all other areas. When using these modes, at least 4-6 spots must be set by the test FLUENCE as a square since individual spots can cause less of a reaction (surrounding skin provides improved cooling).

To start, briefly place the cold handpiece probe onto the first area to be treated with the laser. Next, move the handpiece the distance of the spot size so that the laser tip reaches the pre-cooled area (and the next spot is being pre-cooled simultaneously). Then, emit the laser radiation by pressing the foot switch.

Move the handpiece toward the cold skin cooling probe by the distance of the spot each time in the cycle of the configured SPEED. The warning signal sounds with the same cycle and can be used for guidance.

If nothing is felt and no skin reaction can be detected after a few minutes, the fluence can be gradually increased (test an adjacent area).

End point: Perifollicular erythema

If the treatment becomes painful, the fluence must be reduced again. Do not use any anesthetic creme for this reason.

Once the treatment of the small test area is complete, switch the laser to the *STANDBY* state.

#### 7.4.8 Treatment

After the treatment area has been prepared, the border of the area to be treated can be marked with a white pencil (e.g. eyeliner pencil). It may be useful to divide larger areas into sections. (Apply ultrasound gel section by section to prevent it from drying.)

This ensures that the laser is evenly applied to the surface to be treated.

Tattoos and pigmented lesions not clearly diagnosed as benign must be left out of the treatment!

Proceed as described in the previous section.

##### Tip

If the laser is to be applied to large areas, the area must be scanned lengthwise whenever possible to reduce the "escalation" of the pain, particularly for dark, thick hair close together. When larger areas are treated the **foot switch must be released after each "line"** (interruption of the laser emission) and restarted next to the starting point. The "line" can also be 10 cm wide in *SmoothPulse* mode, for example, if a spiral-shaped procedure is used as shown in the figure. This process is not only more comfortable for the patients, but also less of a strain on the device's skin cooling mechanism. The mechanism can cool better in the few seconds during the interruption so that treatment does not have to be suspended, even during prolonged treatment periods.

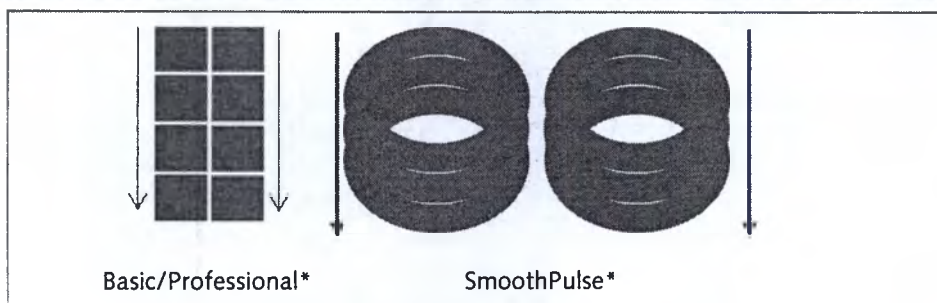


Figure 49: Direction of treatment – application restarts back at the top

\*During treatment, avoid leaving gaps between the spots and "lines" whenever possible. Instead, slightly overlap them so that no hair "lines" remain.

The spiral-shaped treatment process (right) described above is recommended for **SmoothPulse** mode. Moving in a line or in a meandering pattern is also possible if moving quickly (approx. 10 cm per second). For the XL handpiece, the easiest way is to move fast in lines due to the large spot size.

The number of passes determined in the test treatment must be applied. If the treatment is painful despite this, interrupt treatment and cool the skin.

When using **Basic** or **Professional** mode for treatment, set the FLUENCE that was well tolerated during the test treatment.

Then, scan the area as described above and always move the handpiece in the direction of the skin cooling mechanism. The first spot must be pre-cooled again at each newly started line.

If the treatment is still painful, reduce the fluence, stop treatment if necessary and cool the skin immediately.

If treatment is interrupted for a short period or if the treatment of the area is complete, switch the laser to the **STANDBY** state.



#### CAUTION

Dirt deposits on the laser tip can burn in due to the laser radiation and cause side effects such as redness, potential formation of blisters or scabs, and scars in rare cases! Make sure that the laser tip is clean and remains clean during treatment.

The easiest way to keep the laser tip clean even during treatment is to wipe off the tip with a moistened swab or similar once a "line" has been treated with the laser. Audible crackling noises when treating dark, thick hair with a laser usually mean there is hair residue on the tip. The tip must be wiped off immediately. If the laser continues to be used anyway, the hair can potentially burn onto the tip and cannot be simply wiped off.



#### Tip

New hair develops in some cases adjacent to the treatment area (paradoxical hair growth). A study\* determined that this effect can be prevented by providing adequate cooling around the treatment area before and during treatment, for instance, with CoolPacks, and by treating very aggressively in the treatment area, i.e. with 2 passes (in **Basic** or **Professional**). The authors hypothesize that paradoxical hair growth is caused by sub-therapeutic thermal energy.

### 7.4.9 Post-treatment

The skin should be cooled for an extended period as soon as possible after treating an area with the laser, particularly in cases of dark hair and dark skin. Extended cooling can reduce the side effects considerably! Flexible cooling compresses that can be handled by the patients themselves as needed are well-suited for this.

An anti-inflammatory ointment can be applied after the skin has been sufficiently cooled. If overtreatment occurs, skin cooling is very important, a topical antibiotic is indicated and the healing process must be monitored.



#### CAUTION

Radiation on the treated area from the sun and tanning beds after treatment causes increased side effects, particularly alterations in pigment. Therefore, this type of exposure must be avoided for a period of 6 weeks or sunscreen of at least SPF 20 must be worn. Traumatizing the laser-treated area must also be avoided for 2-3 days.

\* Willey et al: Hair stimulation following laser and IPL photo-epilation: review of 543 cases and ways to manage it / Lasers In Surgery and Medicine 39: 297-301 (2007)

Exfoliation can be supported by using lotion.

Patients should be aware that they may have thick secretions from their hair ducts up to two days after treatment. The scabs that may develop should not be touched and should only be removed by normal growth and the use of lotion.

#### 7.4.10 Follow-up treatment

Particularly for thick hair, it may take up to two weeks after treatment until the hair reemerges. Patients must be made aware of this.

If the previous session has been well tolerated, number of passes (*SmoothPulse*) or fluence (*Basic/ Professional*) can be increased gradually in follow-up treatments. This is also advisable since the remaining hair becomes less and less dense and thinner. Therefore, a higher fluence is required and usually tolerated as well.

The number of required treatments depends on multiple factors:

- Genetic disposition
- Hormone status
- The body region to be treated (amount of hair in the anagen phase)
- Hair and skin type
- Result desired by the patient (remaining fine hair is often tolerated)
- Time between treatments

On average, four to seven treatments are required to reach a satisfactory result. The number of treatments required can also be higher, particularly in the beard area and for people whose hair grows very quickly.

The same applies for men whose chest or back hair has just started to develop. In these cases, it may seem as if the laser treatment has had little success, but the eventual hair density would have become much greater without treatment. Here, it is very useful to ask the father or an uncle how hair-growth developed at the respective age.

The time between sessions should not be too short (at 4 - 6 weeks or even longer, hardly any hair has grown back) so that as much hair as possible has switched from the resting phase into the growth phase.

In general, the time between treatments in the beard area should be short (approx. 4 weeks) and longer for other treatments (approx. 6 weeks), as explained in section *The growth phases of hair*.

Normally, the time is extended after multiple treatments since less hair grows back.

However, if strong growth becomes apparent after laser treatment, we advise applying the laser treatment again after a short period since a lot of hairs are now in the anagen phase and will react well to the treatment in this case.

For patients with normal hair growth, the result achieved can remain stable for several years. For patients with strong hereditary hair growth, take into account that the patient must be re-treated each year, though fewer treatments are then necessary.



#### 7.4.11 Expected treatment outcome

Expected treatment outcome for Hair Removal:

| Study | Skin type | Hair color           | Fluence [J/cm <sup>2</sup> ] | Body area                             | Spot size & Pulse length                          | Number of treatments In study* | Effectiveness                                                                                                                                                                                               |
|-------|-----------|----------------------|------------------------------|---------------------------------------|---------------------------------------------------|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A     | I - III   |                      | 35 (I/II)<br>30 (III)        | Axilla                                | MedioStar miXT: 12mm<br>MedioStar NeXT: 10 x 14mm | 3                              | % average hair reduction:<br>Skin type I/II:<br>MedioStar NeXT: 64.3%<br>MedioStar miXT: 50.1%<br>Skin type III:<br>MedioStar NeXT: 65.1%<br>MedioStar miXT: 61.6%<br>SmoothPulse:<br>MedioStar NeXT: 67.1% |
| B     | I - III   | Fair, brown to black | 33 - 44                      | Lower or upper legs                   | 8 - 14mm<br>2 x 60msec                            | 3                              | % average hair regrowth (after 3 month):<br>67% with 8mm<br>54% with 12 mm<br>55% with 14mm<br>11% black hair<br>26% brown hair<br>31% fair hair<br>Hair thickness reduced to 85%                           |
| C     | II - IV   | Light brown to black | 35                           | Upper lip                             | 12 mm<br>2 x 45 msec                              | 3                              | % average hair reduction after 6 months: 49%                                                                                                                                                                |
| D     | II -IV    | Light to dark brown  | 25-35                        | Face, axilla, moustache, chin, bikini | 12 mm<br>50 msec                                  | 3                              | % average hair removal after 6 months: 70 %<br>Histology:<br>reduction anagen(growth) phase to other: at least 1:1 (versus normal 8:2)                                                                      |
| E     | I - VI    |                      | 10 - 36                      | Plethora of body locations            | 12 mm                                             | 3 - 11                         | % of hair reduction after mean 5.4 months:<br>26% after 1 treatment<br>47% after 2 treatments<br>64% after 3 treatments                                                                                     |

\* As explained above, one cannot expect long term epilation after 3 treatment sessions only (see also effectiveness of E).

#### Reference:

- A: Steps, A.: Diode laser hair removal: a study with a new high power system; White paper 2013
- B: W. Bäuml, PhD; K. Scherer, MD; C. Abels, MD; S. Neff, MD; M. Landthaler, MD and R.-M. Szeimies, MD. The Effect of Different Spot Sizes on the Efficacy of Hair Removal Using a Long-Pulsed Diode Laser. *Dermatol Surg* 2002; 28: 118-121
- C: E. J. Fiskerstrand, MD, PhD; L.O. Svaasand, PhD; J.S. Nelson, MD, PhD. Hair Removal with Long Pulsed Diode Lasers: A Comparison Between Two Systems With Different Pulse Structures. *Lasers in Surgery and Medicine* 32: 399-404 (2003)
- D: N.S. Sadick, MD, FACP, FAACS; V.G. Prieto, MD, PhD. The Use of a New Diode Laser for Hair Removal. *Dermatol Surg* 2003; 29: 30-34
- E: Albert J. Nemeth MD, FAAD, FASLMS, FASDS, FISHS. Impressive Laser Hair Removal with an 810 nm Powerpulsed Diode Laser: Safety and Efficacy. Presentation EADV 2004

## 7.5 Vascular treatments

Telangiectasias are treated using a smaller spot adapted for blood vessels (optional handpiece).

The laser treatment of superficial dilated blood vessels, primarily on the face but also in other locations, has been carried out very successfully for more than 20 years, primarily with lasers that emit in the yellow and green range (argon, dye, KTP and copper-bromide lasers).

These lasers are very well suited for the coagulation of very small vessels since blood readily absorbs their wavelengths while the water in the surrounding skin does not (see Absorption curve). Selective photothermolysis ensures effective damage to the blood vessel, while protecting the surrounding skin at the same time. The penetration depth of this laser radiation is sufficient for the very fine vessels.

Due to the higher penetration depth of laser light, lasers with **wavelengths in the infrared range**, such as the MeDioStar diode laser, are more suitable for treating vessels with slightly larger diameters. For example, this pertains to typical leg veins, which are usually larger and located slightly deeper in the skin, and also hemangiomas. In this case, the lower water absorption compared to a Nd:YAG laser (1064 nm) is advantageous since fewer side effects tend to occur.

Recent reports also describe the successful treatment of port-wine stains (which had previously not reacted well to treatment with green or yellow lasers) by using lasers in the near infrared range.

The relatively large spot diameter (made possible by the high power of the MeDioStar) plays a role in this. The larger the spot is, the greater the effective depth of the laser radiation.

Leg veins remain one of the cosmetic problems where treatment is sought very frequently. The method of choice is sclerosing. Its effectiveness has been proven for decades. However, many patients prefer laser treatment.

Generally, the success rate of laser treatment for spider veins on legs is lower than, for example, laser treating telangiectasias on the face since they are under hydrostatic pressure and are very different with respect to the vessel diameter and oxygen saturation. A success rate of approximately 70% can be achieved.

The absorption of laser light in the melanin of patients with dark skin types is lower at the wavelength of the MeDioStar than in lasers in the green-yellow range (see Absorption curve). To minimize undesired side effects, they must nevertheless be taken into consideration during treatment by sufficiently cooling the skin surface.

In addition to the wavelength, the **FLUENCE** and exposure time of the laser radiation (pulse length) are important parameters for the success of treatment. The fluence must be selected so that the vessel is sealed, but no unwanted side effects result (therapeutic window).

The pulse time should be the same or shorter than the **thermal relaxation time** of the vessel (this is the time the target needs to emit 50% of the heat produced through absorption) to follow the treatment concept of selective photo-thermolysis mentioned above. If the pulse duration is too long, the skin surrounding the vessel will be heated up further, the effectiveness will be reduced and the risk of side effects will increase.

### 7.5.1 Selection of patients

Patients with skin type I through III who are not tanned in the area to be treated can be treated with the following restrictions.

The MeDioStar is best suited for treating dilated vessels with a diameter between 0.5 and 2 mm. Treating hemangiomas is also possible.

A distinction is made between red and blue leg veins. The red vessels are smaller, closer to the surface of the skin and have higher oxygen saturation (dilations of the arterial loop of the capillaries).



The blue vessels, on the other hand, are a dilation of the venous capillaries with a lower flow speed. The larger vessels respond to the treatment with this laser better than the smaller vessels.

Before laser treating spider veins on the legs, existing varicose veins—particularly lateral saphenous branches varicosis—must either be ruled out using Doppler sonography or be surgically treated or sclerosed beforehand.

Reticular varicose veins may undergo laser treatment only if they occur separately or the deeper veins are healthy.

### 7.5.2 Contraindications

The contraindications from the *Intended use* section must be observed (including those for spider veins).



#### CAUTION

The higher fluence required for treating dilated vessels and the stronger absorption due to the size of the vessel's diameter can cause more severe side effects (e.g. compared to hair removal), also specifically including subsequent alterations in pigment.

Therefore, never treat patients with skin type IV, V or VI or tanned areas (postpone treatment).



#### Tip

Smoking heavily and/or obesity can impede the results of treatment.

### 7.5.3 Possible side effects

The higher fluence required for treating dilated vessels and the stronger absorption due to the size of the vessel's diameter can cause more severe side effects (e.g. compared to hair removal).

Therefore, the skin must be sufficiently cooled as described below. This is more important here than for hair removal.

All side effects are less pronounced with light skin and thinner vessels and become stronger with thicker vessels. The effects also become stronger if the fluence used for the individual situation is too high (test treatment!).

Therefore, the start values for the test treatment must be lower for skin type III (avoid treatment on darker skin types).

During treatment, patients feel a pricking sensation accompanied by a feeling of warmth. This can become a strong burning feeling for thick vessels.

After treatment, there will be erythema along the path of the vessels. For thicker vessels, edema can also develop along the vessels. These effects are normal and only last a few hours up to 2 days, and rarely a few weeks. Small blisters, scabs and temporary alterations in pigment occasionally occur, more frequently in comparison to epilation (light protection!).

Blisters and scabs normally heal without any side effects within one week. Alterations in pigment can last up to a few months.

Persisting alterations in pigment and scars are very uncommon if the proper procedure is used and the patient is compliant.



#### 7.5.4 Preparation for the laser treatment

The surface to be treated must be cleaned; cosmetic products must also not be present. Hair must be removed carefully, if present.

Photos should be taken of the initial situation to document the success of the treatment.

The treatment can be particularly painful for thicker vessels. However, anesthesia is not normally required if sufficient pre-cooling and post-cooling occurs. The use of topical anesthetics such as EMLA does not reduce the sensation of pain.

A thin layer of transparent, **colorless** ultrasound gel is to be applied to the treatment area.

Cold CoolPacks (from the refrigerator, not frozen!) are to be laid out.

#### 7.5.5 Test treatment

If, after the informed consent discussion, the patient decides for laser treatment, a test treatment should always be carried out.

Due to the wide variety of blood vessel calibers that are possible, optimum amount fluence in real-world use can only be found empirically by treating test areas and must be redefined for each area that has a different vessel diameter (color/structure change).



##### CAUTION

The higher fluence required for treating dilated vessels and the stronger absorption due to the size of the vessel's diameter can cause more severe side effects compared to hair removal. Sufficient pre-cooling and post-cooling are very important to minimize the side effects!

After the treatment area has been prepared, the test area to be treated with the laser is pre-cooled with a CoolPack (approx. 4-8 °C) for a few seconds. Then, the cooling probe of the handpiece is moved back and forth lengthwise over the vessel to be treated without applying the laser.

The same mode has to be used for the test treatment as planned for the treatment: *Vascular* mode (always single pulses) or *Burst* mode (total fluence is divided into multiple partial pulses). This process is more gentle due to the pauses between the pulses (similar to double pulses during epilation).

The test fluence must be set lower for skin type III than for light skin. For smaller vessels, the set pulse duration should be as short as possible for the adjusted fluence and longer for larger vessels and skin type III. The treatment speed is always initially set to 0.5 Hz (SPEED). This setting makes it possible to evaluate the situation after a single pulse without problems since it is possible to deactivate the foot switch again after one pulse. Also, the next area to be treated with the laser is pre-cooled longer at a lower treatment speed.



##### WARNING

Laser radiation can cause severe eye injuries.

Before starting laser treatment, all personnel in the room must put on the laser safety glasses or eye protection for patient in compliance with the information in Chapter *Technical data*!

The configured/displayed data on the display must be checked before and during treatment!

The skin cooling must also be inspected to ensure that it is cold!

At the desired FLUENCE, the MeDioStar is switched to the *READY* state.



#### Tip

Unlike epilation treatment, NO pressure is applied with the handpiece.

A distance of about 1 mm between laser tip and skin is recommended. At the same time, the cold probe of the skin cooling mechanism has to be in contact to the skin (slightly tilt the handpiece).

Apply 2-3 pulses to the vessel to be tested; move the laser tip towards the skin cooling mechanism. Then, the area treated with the laser is evaluated.

If the vessel is faded (more likely with smaller vessels) or changes to a dark discoloration (more likely with larger vessels), the fluence is kept and spot by spot is applied along the vessel.

Immediately after treating with the laser, the area is cooled again for a few seconds with the cooling probe.

If no reaction is identified, wait a few minutes to see if an inflammation reaction develops. In the meantime, you can start testing another vessel size using the same process.

The larger the vessel, the lower the required fluence normally is.

If, after waiting, there is still no reaction to be seen, pre-cool the NEW (!) test area again with the cooling probe and apply the laser to it in an overlapping manner or two times at the same location before increasing the fluence if required. The risk of side effects when overlapping is lower than when the fluence is too high!

Here, always pre-cool and post-cool each of the test areas with the cooling probe.

After treatment, the laser is switched to the *STANDBY* state.

A test treatment can also be used to assess the danger of alterations in the pigment, the healing process and the risk of subsequent scarring. The patient can also get an idea of how the lesion will be treated.

### 7.5.6 Course of treatment

The first area to be treated is pre-cooled for a few seconds with CoolPacks. Then, the first vessel is pre-cooled with the cooling probe as described above.

Using the parameters found during the test (potentially different for various vessels), the first vessel is treated with the laser and then the treated vessel is post-cooled with the probe.

After an area was treated completely, a CoolPack is placed on it for post-cooling and then the next area is started using the same method.

Make sure that the cooling probe always remains in contact with the skin during treatment (without applying pressure) and that the handpiece is always moved toward the cooling probe.

After treatment, the laser is switched to the *STANDBY* state.

The entire treated area continues to be cooled for at least 10 minutes.

This procedure causes a significant reduction in pain and side effects by providing consistent cooling.

### 7.5.7 Post-treatment

After the skin has been sufficiently cooled, an anti-inflammatory ointment must be applied and left on until the next day.

In the case of overtreatment, a topical antibiotic is indicated and monitoring the healing process is absolutely necessary.





#### CAUTION

Radiation on the treated area from the sun and tanning beds after treatment causes increased side effects, particularly alterations in pigment.

Therefore, this type of exposure must be avoided for a period of 6 weeks or sunscreen of at least SPF 20 must be worn.

Traumatizing the laser-treated area must also be avoided for 2-3 days.

Furthermore, patients have to temporarily forgo activities involving extreme physical strain or strain on the vessel, such as jogging, visits to the gym or sauna, hot baths and the like.

#### 7.5.8 Follow-up treatment

To evaluate the result if the vessels are not directly faded, you can run your finger along the vessel to see if blood is flowing back or not.

Depending on the result of the treatment, the individual skin reaction and the interests of the patient, further treatment with higher fluence can be scheduled, if required.

The interval between sessions should be at least 12 weeks. Reports indicate that vessels sometimes take several months to disappear. Until then, some vessels are even darker than before (coagulation of the blood). Patients must be made aware of this.

More than three treatments are not worthwhile for spider veins. As previously mentioned, a success rate of approximately 70% can be achieved.

#### 7.5.9 Expected treatment outcome

Expected treatment outcome for vascular treatments.

| Study                                                                                                                                                                                  | Methods                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Results                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| K. Kykalova:<br>Vascular treatments with<br>MeDioStar high power di-<br>ode laser from Asclepion<br>Laser Technologies<br>Institute of Aesthetic Medi-<br>cine,<br>Prague, Czech, 2002 | Application study, case report<br><b>Patients:</b><br>Group 1 (2001): 9 patients aged 33 – 65<br>Group 2 (2002): 24 patients, aged 27 – 60<br>Skin type I-III<br>leg veins 1 – 4mm at thighs and lower<br>legs (no combination with sclerotherapy<br>or surgery)<br><b>Parameters:</b><br>MeDioStar 810nm, spot size 6mm (vascu-<br>lar tip)<br>Fluence group 1: 130 – 150J/cm <sup>2</sup><br>Fluence group 2: 90 – 100J/cm <sup>2</sup><br>Number of treatments : 2 – 5, interval 2<br>months<br><b>Method:</b><br>Treatment up to clinical endpoint – dis-<br>appearance of vessel or coagulation of<br>blood (darker appearance of vessel)<br>Next treatment, if there was no result af-<br>ter 2 months (individually different) | <b>The lower fluence used for group<br/>2 causes less side effects by keep-<br/>ing the result!</b><br><u>Small veins : 1-2mm</u> diameter af-<br>ter third treatment almost 70%<br>completely healed without coming<br>back (last control 2months after<br>last treatment)<br><u>Medium vessels: 2-3mm</u><br>after third treatment 50% com-<br>pletely healed without coming<br>back (last control 2months after<br>last treatment)<br><u>Big vessels: 4mm*</u><br>need more than 3 treatments and<br>reccurency after third is about<br>70% so need more treatments and<br>higher energy<br>* Please note:<br>In the intended use of this manu-<br>al the treatment of vessels more<br>than 3mm in diameter is stated<br>as contraindication! |



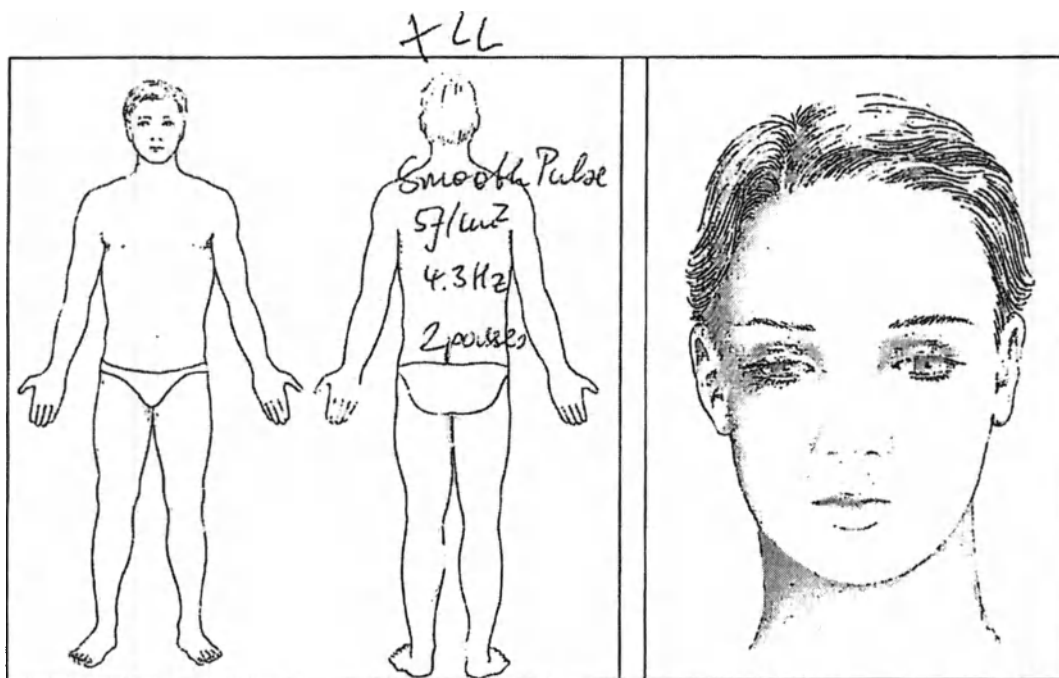
Behandlungsprotokoll

Datum: 24.6.14

Name Patient: Michael Höller

Behandlung/Folgebehandlung: 4 beh. auf MS NEXT für 3 Jahre

Indikation: Epilation (Test)



Verwendetes Gerät: MS PRO 1591 00 726 (Vierströmpistol), Handst XLL

Verwendete Parameter: 5.0.

Anmerkungen: nicht gemacht

Behandlungsprotokoll

Datum: 24.6.14

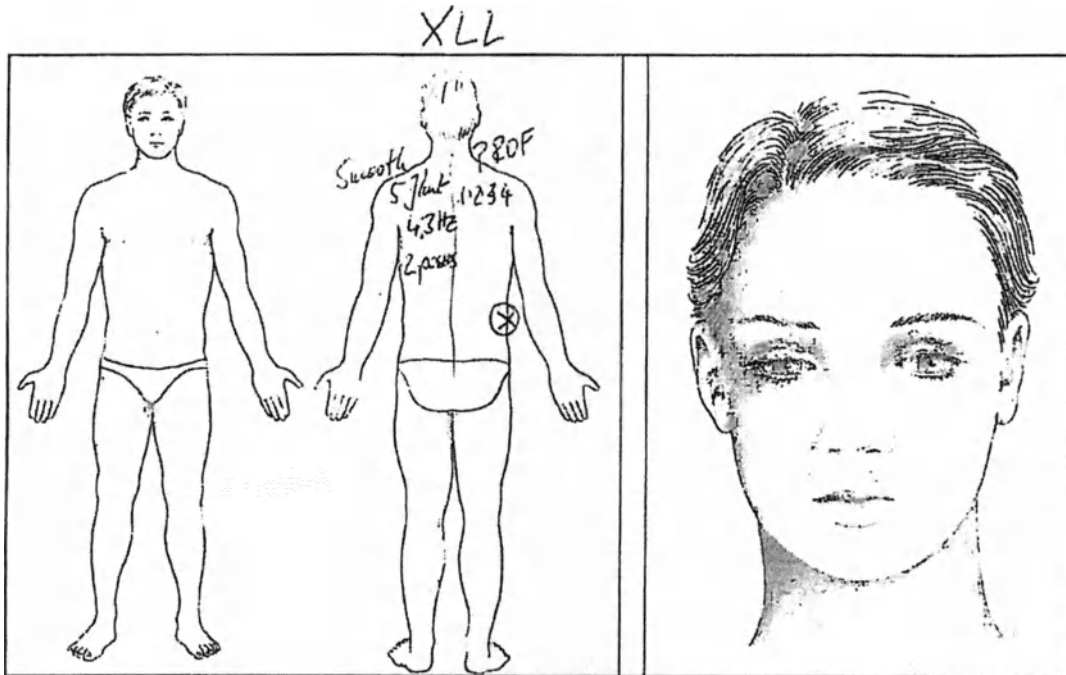
Name Patient:

Roberto Mancarelli

Behandlung/Folgebehandlung:

Indikation:

Epilation (Test)



Verwendetes Gerät: MS PRO 1591 00 726 (Varrimpot)

Verwendete Parameter: s.o. / s.z. Handstück XLL

Anmerkungen:

rechts PROFESSIONAL 2.1 Hz, kürzeste Zeit

1 | 7 J/cm²

2 | 8 J/cm²

3 | 9 J/cm²

4 | 10 J/cm²

etwas schmerzhaft an der Seite  
↓  
gekühlt mit CoolPacks ⊕  
starker perif. Ödem, aber nur  
in einem Teil des Spots (Mitte?)

|                             |                                                                                                          |                                                                                      |
|-----------------------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| FB <b>7351e</b>             | <b>Verification / Validation Report</b>                                                                  |   |
| Revision Index:<br><b>B</b> | <b>Identification number: ZI/14/04/22-01</b><br><small>Member Code/year/month/day-sequential no.</small> | Page 7 of 8<br><small>FB 7351e UsabilityValid MSPRO<br/>Vs01 ZI140422-01.doc</small> |

## 2.5 Validation of usability for practical treatment by persons not involved in development, but experts for treatment

This evaluation was realized with the new handpiece and both spots: XLL (9cm<sup>2</sup>) and XLS (3cm<sup>2</sup>), because all other handpieces are already used with the current device.

Serial number of device: 159100726 (pre-series device) with new XL handpiece

Date: June 24, 2014

Participants: G.Zimmermann, Product Manager, involved in development  
R.Mancarelli, Head of German Sales, not involved in development (volunteer)  
T.Bauer, Head of German Sales, not involved in development  
H.Prüfer, international Sales, not involved in development  
Ch.Kurscheid, German Sales, not involved in development  
T.Unger, Marketing, not involved in development  
M.Möller, Development, involved (volunteer)

Protocols see next pages (7a and 7b).

For this evaluation two volunteers were treated at the back for epilation. Both modes, PROFESSIONAL and SmoothPulse, were used for one volunteer side by side and for the other only SmoothPulse was applied.

Both volunteers could tolerate the treatment very well.

The handling with the new handpiece, which is larger and heavier due to the necessary higher diode power, is convenient and as easy as with the other handpieces. The higher weight is not critical, because

1. The handpiece is in contact to the skin during treatment – therefore it is not 'carried' by the hand all the time
2. The treatment time is very short – only about 2 minutes for the whole men's back

One issue, which is not yet perfect, is the handpiece holder at the front of the device. So far it is the holder for the current handpieces, which are smaller. The requirement 1.6 of the RS matrix (see chapter 2.3 above) is not yet ready and has to be realized before devices are sold.

The second was the change of the laser tip of the new handpiece XL, which needed some pressure for connection to the basic body of the handpiece and does not meet the requirement 1.5 of the RS matrix that this connection has to be easy done.

The reason is that this new handpiece XL is not yet a serial product and it is clear, that pre-serial parts are not yet perfect due to higher tolerances. As with the issue one, it has to be checked once more that this deviation is fixed with the series.

All participants - not involved in the development - evaluated the new handpiece to be a very good tool for treatments of large areas – given that the 2 deviations above are fixed. Even with the larger handpiece the treatment is convenient to apply and it is very fast.

## 2.6 Validation of user manual

The new user manual is based on the user manual of the current device. There were never problems caused by the manual. The description for the new handpiece was added (including photos):

- Technical data
- Technical description of the handpiece
- How to change the laser tips
- Cleaning and disinfection

The manual was checked using the check list CL 7356 GA MeDioStar V01\_ZI140205-01 (includes measures raised from risk analysis) to guarantee the safe use of the device.



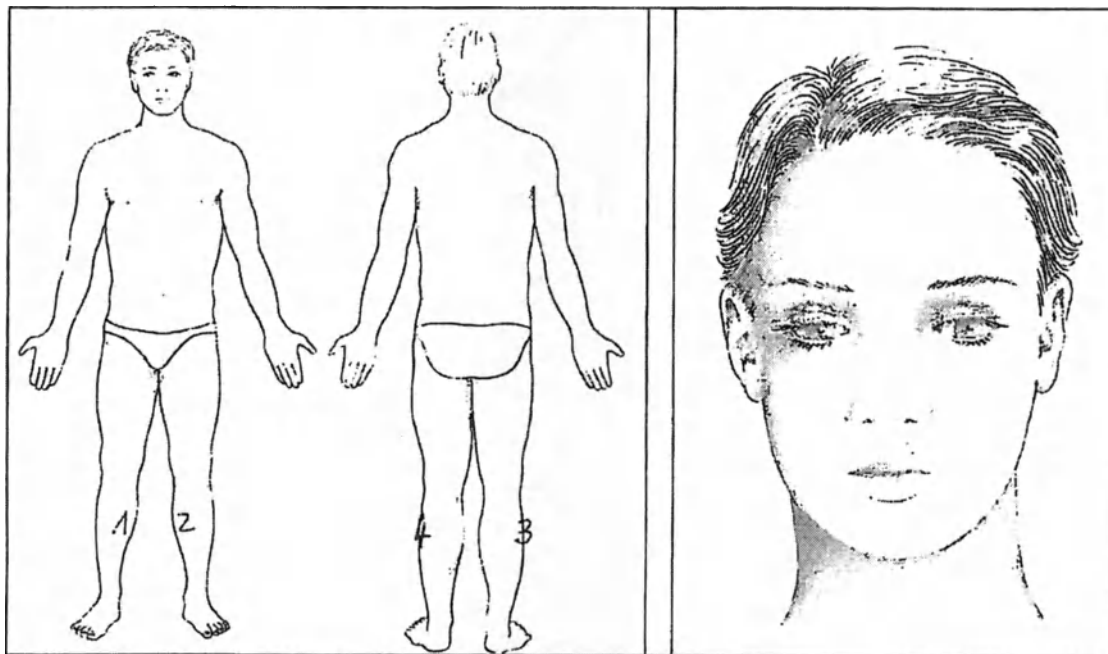
Labar Zuberhies  
FE, 1H, 2  
Datum: 16.6.14

# Behandlungsprotokoll

Name Patient: Zimmermann, Gabi

Behandlung/Folgebehandlung: Test MS-PRO Einw. Gerät NetT test. NT

Indikation: (Epilation) Test



Verwendetes Gerät: 1591 00 726 (Verschönerung)

Verwendete Parameter: 5. 21.

1/ Gephir  
steht vor

XLS 30x10  
Anmerkungen:

① rechts innen  
Smooth Pulse

② links innen  
Short, 35 f/cm<sup>2</sup> → zu schwach  
30  
25 kleine Fläche gerade  
ausarbeiten

XLL 24x38 ③ rechts außen  
Smooth Pulse  
5 f/cm<sup>2</sup>; 5,3 Hz  
einzige Einstellung  
3 passes i.d.  
4. abbrechen

④ PROFESSIONAL  
links außen  
12 f/cm<sup>2</sup> @ 60 ms ok  
↓  
15 zu schwach  
13 noch weniger Imp. zu schwach

|                      |                                                                                                          |                                                                                       |
|----------------------|----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| FB 7351e             | <b>Verification / Validation Report</b>                                                                  |    |
| Revision Index:<br>B | <b>Identification number: ZI/14/04/22-01</b><br><small>Member Code/year/month/day-sequential no.</small> | Page 6 of 8<br><small>FB 7351e Usability/Valid MSPRO<br/>Vs01 ZI140422-01.doc</small> |

| Nr. | Kundenforderung                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Acceptance<br>(acceptance) |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| 3.  | Bedienung / Software<br>Details siehe Anforderungen an die Software (Software requirement specification/ SRS)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ok                         |
| 4.  | Applikationsparameter<br>- for details of parameter setting please see validation report FB 7351e Vali SW MSPRO V01 CaM140520-01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |
| 4.2 | Folgende Modi werden für die angegebenen Handstücke definiert:<br>BASIC: einstellbar: Fluence, Folgefrequenz (Speed),<br>autom. kürzest mögliche Impulsdauer bei gewählter Fluence, Doppelpuls,<br>möglich mit ST, HP, ALX, XLS, XLL<br>PROF: einstellbar: Fluence, Pulsdauer, Speed, Einzel- oder Doppelpuls<br>möglich mit ST, HP, ALX, XLS, XLL<br>SmoothPulse: einstellbar: Fluence, Speed<br>möglich mit ST, HP, ALX, XLS, XLL<br>BURST: einstellbar: Fluence, Pulsdauer, Speed, Anzahl der Pulse im Impulszug (Burst), Pause<br>Pulsdauer, Anzahl Impulse<br>Eingestellte Fluence wird durch Anzahl geteilt<br>Pause einstellbar<br>wenn Pulsdauer verändert wird, Pause notfalls mitändern und anzeigen<br>analog Speed mitändern<br>möglich mit allen Handstücken<br>VASCU: einstellbar: Fluence, Pulsdauer, Speed, immer Einzelpuls<br>möglich mit VAS | ok                         |
| 4.3 | Folgefrequenz abhängig von Handstück, Modus, Pulsdauer und mittlerer Leistung<br>Modus BASIC, PROFESSIONAL, BURST, VASCULAR<br>Modus SmoothPulse                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | ok                         |
| 4.4 | Fluence und Pulsdauer abh. von Handstück und Modus einstellbar bei Handstück                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | ok                         |
| 4.6 | Hautkühlung: Kontaktkühlung mit Metall bzw. Saphir (Handstücke ST, ALX, XLS/L)<br>Erreichen der Kühltemperatur max. 15 sec. nachdem Stecker gewechselt wurde bzw. Gerät länger in<br>Standby war (Anzeige auf Display) – 30 sec. nachkühlen, damit schnelle Rückkehr von Standby in Ready.<br>Wasserfluss anzeigen durch ständig leuchtende LED.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | ok                         |

## 2.4 Validation of usability for practical treatment by persons involved in development, but experts for treatment also

This evaluation was realized with the new handpiece and both spots: XLL (9cm²) and XLS (3cm²), because all other handpieces are already used with the current device.

Serial number of device: 159100726 (pre-series device) with new XL handpiece

Date: June 16, 2014

Participants: G.Zimmermann, Product Manager  
J.Elbrecht, Head of development of accessories  
I.Harrass, development of accessories

Protocol see next page (6a).

This was a first test only by the product manager herself. The handling was checked for usability of the new handpiece with larger spots during treatment.

The handpiece was applied at the lower legs with different modes (PROFESSIONAL, Smooth-Pulse) with XL handpiece and both spot sizes without problems.

The test treatment was evaluated to be well acceptable. There were no disturbing aspects for the treatment with the new handpiece.

|                      |                                                                                                   |                                                                                     |
|----------------------|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| FB 7351e             | Verification / Validation Report                                                                  |  |
| Revision Index:<br>B | Identification number: ZI/14/04/22-01<br><small>Member Code/year/month/day-sequential no.</small> | Page 5 of 8<br>FB 7351e Usability/Valid MSPRO<br>Vs01 ZI140422-01.doc               |

## 2.2 Validation of requirements of RS, chapter 3.1: functions related to safety

| Sicherheits-Funktion<br>(safety function)                                                                             | Anforderung für sichere Benutzung<br>(requirement for safe use)                    | Akzeptanz<br>(acceptance) |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------|
| 12. Laser NOTAUS (Betätigen in Not-situation)                                                                         | Vorn am Gerät, einfach zu bedienen, klar sichtbar                                  | ok                        |
| 13. Schlüsselschalter<br>(gegen missbräuchliche Nutzung des Gerätes durch nicht autorisiertes Personal)               | Schlüsselschalter abziehbar                                                        | ok                        |
| 14. Bestätigen der geänderten Be-handlungsparameter                                                                   | Geänderter Parameter darf nur übernommen werden, wenn Bestätigung erfolgt          | ok                        |
| 15. Bewußtes Herstellen der Laser-Bereitschaft<br>(Warnlampe an der Tür, Schutzbrille aller Anwesenden kontrollieren) | Extra Betätigen der READY-Taste; zusätzlich gelbes Warnsignal auf dem Display      | ok                        |
| 16. Bewußtes Auslösen der Emission                                                                                    | Schalter muss so ausgeführt sein, dass ein unbeabsichtigtes Auslösen unmöglich ist | ok                        |
| 17. Automatische Türverriegelung                                                                                      | Anschluss muss an Rückseite des Gerätes sein                                       | ok                        |

## 2.3 Validation of requirements of RS, chapter 3.2: requirement matrix

| Nr. | Zu validierende Kundenforderung (customer requirement to be validated)*<br>* some numbers are not cited, because these requirements are verified by measurements                                                                                                                                                                                                                                                                                                                                                 | Akzeptanz<br>(acceptance) |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| 1   | <p>Design:</p>                                                                                                                                                                                                                                                                                                                                                                                                                | ok                        |
| 1.1 | Tischgerät 365 x 560 x 465 mm (B x T x H) ohne Griffe u. Handstückhalter; Max. 40kg, Griffe zum Tragen, widerstandsfähigere Lackierung – weiß Hochglanz; Oberfläche desinfizierbar<br>Display 8,4"; Touchscreen, leicht nach hinten geneigt; gut erkennbar bei heller Beleuchtung<br>Stift zur Bedienung vorsehen mit geeigneter Ablage<br>Handstück-Stecker, Hauptschalter, Netzstecker, Anschlüsse Fußschalter, Warnlampe, Fernverriegelung der Tür, Service-Schnittstellen gut zugänglich an Geräte-Rückseite |                           |
| 1.3 | Aktuelle Handstücke im äußeren Design beibehalten, und zukünftig weißer oder spiegelnden Aufkleber direkt hinter dem Laser-Tip auf dem Handstück-Gehäuse<br>Ergonomische Gestaltung der neuen Handstücke; keine scharfen Kanten/ Ecken; desinfizierbar                                                                                                                                                                                                                                                           | ok                        |
| 1.4 | Neue Handstücke mit gekühltem Saphir als Hautkühlung; desinfizierbar                                                                                                                                                                                                                                                                                                                                                                                                                                             | ok                        |
| 1.5 | Alle Handstücke und die Tips am neuen Handstück XL müssen einfach und zuverlässig wechselbar sein                                                                                                                                                                                                                                                                                                                                                                                                                | ok                        |
| 1.6 | Gute Gestaltung der 'Ablage' für Handstücke, muss für alle Handstücke geeignet sein                                                                                                                                                                                                                                                                                                                                                                                                                              | ok                        |

\* Connection of laser tip to base body of handpiece XL needs to be checked previously due to the fact that it is not yet a serial part. To be checked once more with serial part.



|                             |                                                                                                          |                                                                                              |
|-----------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| FB <b>7351e</b>             | <b>Verification / Validation Report</b>                                                                  |           |
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### 1.3 Validation of usability by international physicians

Additional there is an actual survey of some international physicians for all our devices including MeDioStar. These customers evaluated the main operational functions of the device (see App.4). So far it was a small group of 6 doctors only, but this survey will be continued.

The acceptance of the functions was rated between 1 (very good/ easy to understand) and 5 (very bad/ complicated).

The mean value for functionality was 1.25, which is really good. There were no proposals for improvement in this survey.

The result of this small survey was very positive and confirms with the positive result of all reviews of market surveillance in the past.

## 2. VALIDATION OF THE NEW DEVICE VERSION

Serial number of device: 1591 00 726 (pre-series device) incl. new handpiece

Date: April 25, 2014

Participants: G.Zimmermann, Product Manager

### 2.1 Validation of requirements of RS, chapter 3.1: often used functions

| Häufig benutzte Funktion<br>(often used functions)                       | Anforderung für sichere Benutzung<br>(requirements for safe use)                                                                                                                                                                      | Akzeptanz<br>(acceptance) |
|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| 1. An-/Ausschalten des Gerätes mit Hauptschalter                         | Hauptschalter muss gut zugänglich sein und leicht bedienbar (Kippschalter an der Rückseite des Gerätes)                                                                                                                               | ok                        |
| 2. An-/Ausschalten des Gerätes mit Schlüsselschalter                     | Schlüsselschalter muss gut zugänglich sein und leicht bedienbar (vorn am Gerät)                                                                                                                                                       | ok                        |
| 3. Aufrufen des Behandlungs-Displays                                     | Muss unkompliziert möglich sein                                                                                                                                                                                                       | ok                        |
| 4. Auswählen der Behandlungsparameter zum Einstellen                     | Muss unkompliziert möglich und eindeutig zu sehen sein, welcher Parameter geändert wird                                                                                                                                               | ok                        |
| 5. Jeweils Bestätigen der geänderten Behandlungsparameter                | Geänderter Parameter darf nur übernommen werden, wenn Bestätigung erfolgt                                                                                                                                                             | ok                        |
| 6. Herstellen der Laser-Bereitschaft: Wechsel zwischen STANDBY und READY | Im Zustand READY (Emissionsauslöser „scharf“) muss das gelbe Warnzeichen auf Display erscheinen                                                                                                                                       | ok                        |
| 7. Herausnehmen/ Ablegen des Handstücks aus der / in die Halterung       | Muss unkompliziert möglich sein; Halterung darf keine scharfen Kanten/ Ecken haben                                                                                                                                                    | ok*                       |
| 8. Betätigen des Fußschalters                                            | Schalter muss so ausgeführt sein, dass ein unbeabsichtigtes Auslösen unmöglich ist                                                                                                                                                    | ok                        |
| 9. Bewegen des Handstücks auf der Haut des Patienten                     | -Muss unkompliziert möglich sein,<br>-alle Körperstellen müssen erreichbar sein und<br>-darf keine Ermüdung verursachen<br>-Griff gerade oder nach hinten gebogen<br>-optische Kontaktfläche: Saphir, keine scharfen Kanten und Ecken | ok                        |
| 10. Reinigen und Desinfizieren der Oberfläche des Handstücks             | Oberflächen müssen glatt sein ohne schwer zugängliche Löcher o.ä., da wegen der Optik und Elektronik nur feuchtes Wischen erlaubt                                                                                                     | ok                        |
| 11. Wechsel der Handstücke                                               | Stecker muss gut zugänglich sein (an der Rückseite des Gerätes), leicht bedienbar und zuverlässig                                                                                                                                     | ok                        |

\* the holder is possible, but not perfect → modification before series

|                      |                                                                                                          |                                                                                      |
|----------------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| FB <b>7351e</b>      | <b>Verification / Validation Report</b>                                                                  |   |
| Revision Index:<br>B | <b>Identification number: ZI/14/04/22-01</b><br><small>Member Code/year/month/day-sequential no.</small> | Page 3 of 8<br><small>FB 7351e UsabilityValid MSPRO<br/>Vs01 ZI140422-01.doc</small> |

### **PRELIMINARY IMPORTANT NOTE:**

The intention for the development of this advanced version of the MeDioStar was to reduce the treatment time (especially of extended body areas, e.g. men's back) for the customers and patients. This is possible with larger spot sizes in a way that with one laser pulse a larger area of skin is simultaneously treated. Nowadays more laser power for a reasonable price is available, which is necessary for realization of large spots. Technical changes were necessary, e.g. more diodes in a new hand-piece and a more powerful power supply internally in the basic unit.

At the same time complete functionality and intended use of the current MeDioStar version (including all handpieces) shall be maintained:

Due to the big success (nearly 1000 devices sold for the actual MeDioStar versions since 2011 and more than 2500 for all versions since 1999) and the effective and safe use of the device, which in all these years didn't cause more side effects than stated in the manual, it was the clear demand in the RS for this device in question, that the changes to the current device have to be as minor as possible:

- The intended use including operator profile, principle of action to the tissue, physical functionality and the handling etc. (please see App.1) are identical to the current version of MeDioStar as required in the RS.
- The POFs including safety measures are identical to the current version of MeDioStar as required in the RS (please see App.2 and RS).

The basic unit is not changed for the customer. All handpieces, which are available today, keep unchanged.

For the customer the only difference is the (optional) new, larger handpiece for faster treatments.

## **1. VALIDATION BASED ON THE CURRENT DEVICE**

### **1.1 Evaluation of reports about events with related devices**

The advices of German BfArM (Bundesamt für Arzneimittel und Medizinprodukte) and the reports to the BfArM about events were evaluated for relevance for the device in question (and all our other devices) regularly once a year. There were never advices or recalls relevant for the MeDioStar. For last evaluation please see App. 3.

Additionally the website of the FDA (Food and Drug Administration of the U.S.) was evaluated for recalls of medical devices. No recalls could be found, relevant for the MeDioStar (see App.3 also).

### **1.2 Evaluation of our MeDioStar devices so far**

In all these years since 1999 there were never accidents or injuries with the MeDioStar devices. The side effects were not more than stated in the user manual. Yearly reviews were done regularly for market surveillance. Most of the our own studies were reviewed in 2010 for the MeDioStar XT/ miXT (see Review 2010).

As an example:

The most comprehensive prospective application study was realized by Dr. A. Nemeth, Florida (lecture at EADV 2004, Florence, Italy).

He treated 200 patients of all skin types with 978 total treatment sessions. He had in all these treatments 5 cases of transient hyperpigmentations only (0.5%), no scarring or other permanent side effects.

The number of treatments necessary was between 3 and 11, which is normal for hair reduction. The result was: 26% hair reduction after 1<sup>st</sup>, 47% after 2<sup>nd</sup> and 64% after 3<sup>rd</sup> treatment.

|                      |                                                                                                          |                                                                                            |
|----------------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| FB 7351e             | <b>Verification / Validation Report</b>                                                                  |         |
| Revision Index:<br>B | <b>Identification number: ZI/14/04/22-01</b><br><small>Member Code/year/month/day-sequential no.</small> | <b>Page 2 of 8</b><br><small>FB 7351e UsabilityValid MSPRO<br/>V01 ZI140422-01.doc</small> |

**History:**

| Rev | Brief description of change | Date           | Name       | Signature         |
|-----|-----------------------------|----------------|------------|-------------------|
| 01  | First edition               | April 22, 2014 | Zimmermann | <i>Zimmermann</i> |
|     |                             |                |            |                   |
|     |                             |                |            |                   |
|     |                             |                |            |                   |

**Linked documents:**

| document                           | abbreviation | file name                                             |
|------------------------------------|--------------|-------------------------------------------------------|
| Requirement specification          | RS           | FB 7321_LH-MSPRO-V01_ZI140127-01                      |
| Review 2010 for MeDioStar XT/ miXT | Review 2010  | FB 73511Review 2010 MeDioStar XT-miXT ZI-2010-03-12-1 |
| Check list for user manual         | n/a          | CL 7356 GA MeDioStar V01_ZI140205-01                  |
| Risk analysis                      | n/a          | FB 7302 RAaC MSPRO V01_MM0140204-01                   |



|                      |                                                                                                          |                                                                                             |
|----------------------|----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| FB 7351e             | <b>Verification / Validation Report</b>                                                                  |          |
| Revision Index:<br>B | <b>Identification number: ZI/14/04/22-01</b><br><small>Member Code/year/month/day-sequential no.</small> | <b>Page 1 of 8</b><br><small>FB 7351e UsabilityValid MSPRO<br/>Vs01 ZI140422-01.doc</small> |

|                                 |                                                                                                                                                                                                                                    |                                                    |                                                      |
|---------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|------------------------------------------------------|
| <b>Verification</b>             | <input type="checkbox"/>                                                                                                                                                                                                           | <b>Validation</b>                                  | <input checked="" type="checkbox"/> <b>Usability</b> |
| <b>Product / part:</b>          | <b>MeDioStar</b>                                                                                                                                                                                                                   | <b>Material number:</b>                            | <b>1591, 1592</b>                                    |
| <b>Cause:</b>                   | <input type="checkbox"/> Product development                                                                                                                                                                                       | <input checked="" type="checkbox"/> Product change | <input type="checkbox"/>                             |
| <b>Original document:</b>       | <input checked="" type="checkbox"/> Requirement specification of:<br>FB 7321_LH-MSPRO-<br>V01_ZI140127-01 in KA 5.1<br><input checked="" type="checkbox"/> Risk analysis of:<br>FB 7302 RAaC MSPRO<br>V01_MM0140204-01 in KA 7.2.2 |                                                    |                                                      |
| <b>Design specification of:</b> | <input type="checkbox"/>                                                                                                                                                                                                           |                                                    |                                                      |
| <b>Change-application no.:</b>  | <input type="checkbox"/>                                                                                                                                                                                                           |                                                    |                                                      |
| <b>Serial number:</b>           | 1591 00 726                                                                                                                                                                                                                        |                                                    |                                                      |

#### Brief description:

This validation of usability of this advanced, new MeDioStar version in question is based on the current device MeDioStar, which is for the user almost identical to the new version, and on the validation of the requirement specification for this new version of the MeDioStar including application tests.

The difference and advantage for the user is the new handpiece with larger spots to reduce the treatment time. This new handpiece shall be sold additionally (optional) to the handpieces currently available. Besides the new handpiece, technical changes inside the basic device were also necessary, which are not relevant for the user.

The intended use, parameter setting, display, operation including safety measures and treatment procedure are not changed compared to the current device.

The current device version (and the forerunner devices also) never caused problems more than the side effects stated in the manual and the treatments with the device are very effective.

**Selected measuring and test equipment:** MeDioStar, device no. 1591 00 726

#### Documents of the enclosure:

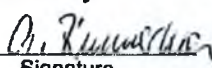
- App.1: Specification of application (TP 7342 Usab-App1SpecifAppl MSPRO Vs01\_ZI140422-02)
- App.2: Specification of primary operational functions incl. safety measures  
(TP 7342 Usab-App2POFs MSPRO Vs01\_ZI140422-03)
- App.3: Protocol of search reports about events with related devices incl. results  
(TP 7342 Usab-App3-BfArM+FDA-Vs1-ZI130827-1)
- App.4: Protocol of user evaluation (TP 7342 Usab-App4-AuswertgFragenVs01\_ZI140425-01)

#### Final assessment of results:

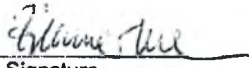
Summarizing, it can be assessed that the usability for the advanced new MeDioStar version is even better than that of the current device, because the treatment time is shorter by keeping safety and effectiveness of the current device.

☐ VERIFICATION / VALIDATION NEGATIVE ☒ VERIFICATION / VALIDATION POSITIVE  
 if negative, derived measures:

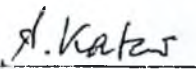
**Plan Ident-No. ZI/14/04/22/-01 drawn by:**

|                |            |                                                                                     |
|----------------|------------|-------------------------------------------------------------------------------------|
| April 22, 2014 | Zimmermann |  |
| Date           | Name       | Signature                                                                           |

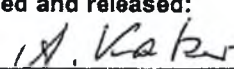
**Verification/Validation performed:**

|               |            |                                                                                       |
|---------------|------------|---------------------------------------------------------------------------------------|
| June 25, 2014 | Zimmermann |  |
| Date          | Name       | Signature                                                                             |

**Plan checked and released:**

|                |        |                                                                                     |
|----------------|--------|-------------------------------------------------------------------------------------|
| April 23, 2014 | Katzer |  |
| Date           | Name   | Signature                                                                           |

**Verification/Validation checked and released:**

|               |        |                                                                                       |
|---------------|--------|---------------------------------------------------------------------------------------|
| June 26, 2014 | Katzer |  |
| Date          | Name   | Signature                                                                             |

|                                         |           |             |                                |           |             |
|-----------------------------------------|-----------|-------------|--------------------------------|-----------|-------------|
| Cause of latest modification FB: review |           |             | FB checked and released by QA: |           |             |
| FB drawn by process owner R&D:          |           |             |                                |           |             |
| 05.07.2012                              | I. Streit | sdg. Streit | 06.07.2012                     | R. Thieme | sdg. Thieme |
| Date                                    | Name      | Signature   | Date                           | Name      | Signature   |

|                      |                                                                                            |                                                                                                                       |
|----------------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| CL <b>73523</b>      | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                  | <br>Asclepion<br>Laser Technologies |
| Revision index:<br>B | <b>Identification number: ZI/15/04/10-01</b><br>Identification code/year/month/day-number. | page 15 of 15<br>CL 73523 Usab MSPRO<br>Vs02_ZI150410-01.doc                                                          |

| Par., Description, Requirement                                                                                                                                                                                                                                                                                              | Results, Comments                                                               | Compliance                          |                          |                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|
|                                                                                                                                                                                                                                                                                                                             |                                                                                 | Yes                                 | No                       | N.A.                     |
| Der Hersteller hat notwendiges Schulungsmaterial zur Verfügung gestellt;<br><i>The manufacturer has provided the necessary training material;</i>                                                                                                                                                                           | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 4.2 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Der Hersteller hat sichergestellt, dass dieses Material verfügbar ist (oder);<br><i>the manufacturer has ensured, that the material is available (or);</i>                                                                                                                                                                  | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 4.2 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| der Hersteller hat eine Schulung angeboten.<br><i>the manufacturer has offered a training.</i>                                                                                                                                                                                                                              | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 4.2 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| In den Begleitpapieren sind vorhandene Schulungsmöglichkeiten beschrieben und es sind Richtwerte für Dauer und Häufigkeit der Schulung angegeben<br><i>The Accompanying document describes the available training options and the accompanying document includes the suggested duration and frequency of such training.</i> | User manuals, chapter 2 and 7.1                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Der Bestimmungsgemäße Gebrauch und die Benutzer-Profile bilden die Grundlage der Schulung und des Schulungsmaterials.<br><i>Intended use and user profile(s) are the basis for training and training material</i>                                                                                                           |                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|                      |                                                                                            |                                                                                     |
|----------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| CL <b>73523</b>      | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                  |  |
| Revision index:<br>B | <b>Identification number: ZI/15/04/10-01</b><br>Identification code/year/month/day-number. | page 14 of 15<br>CL 73523 Usab MSPRO<br>Va02_ZI150410-01.doc                        |

| Par., Description, Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Results, Comments                                                               | Compliance                          |                                     |                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                 | Yes                                 | No                                  | N.A.                                |
| <b>6. Begleitpapiere/ Accompanying documents</b><br><br>Die Begleitpapiere enthalten eine Zusammenfassung der Spezifikation der Anwendung.<br><i>The Accompanying document includes a summary of the Medical Device application specification</i><br><br>Eine knappe Beschreibung der Funktionsweise, der wesentlichen physischen Merkmale, wesentlicher Leistungsmerkmale und vorgesehener Benutzer-Profil des Medizinprodukts sind in den Begleitpapieren enthalten.<br><i>A concise description of the Medical Device, its operating principles, significant physical and performance characteristics and intended User Profile are included in the Accompanying document</i><br><br>Begleitpapiere sind auf einem Niveau geschrieben, das mit dem beabsichtigten Anwender-Profil (Benutzer-Profil) vereinbar ist.<br><i>The accompanying papers are conformable written with the intended operators-profile.</i><br><br>Die Begleitpapiere sind optional in elektronischer Form verfügbar.<br><i>The Accompanying document for equipment are, optionally, provided electronically</i><br><br>Wenn Ja/ if Yes:<br><br>Informationen in Papierform oder als Kennzeichnung auf dem Gerät sind ausreichend vorhanden und decken den Notfallbetrieb ab.<br><i>Information on paper or as label on the equipment is enough available and satisfy emergency handling.</i> | User manuals, chapter 2                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | User manuals, chapter 4.3, 4.2 and 2                                            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 4.1 | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |
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| <b>7. Schulung und Schulungsmaterial/ Training and materials for training</b><br><br>Eine spezielle Schulung für die Hauptfunktion des Gerätes ist erforderlich.<br><i>A special training for the main function of equipment is necessary</i><br><br>Wenn ja / if Yes:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |
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| CL <b>73523</b>      | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                                 | <br><b>Asclepion</b><br><small>Medical Technology</small> |
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| Par., Description, Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Results, Comments                                                                                                                                                                                                                                               | Compliance                                                                                                                                                                                      |                                                                                                                                                                           |                                                                                                                                                                                      |
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| <b>5.8 Verifizierung der Gebrauchstauglichkeit/ Usability verification</b><br><br>Die Bediener-Geräte-Schnittstelle wurde gemäß der Spezifikation der Gebrauchstauglichkeit verifiziert und in der Ergonomie-Akte dokumentiert.<br><br><i>User-equipment interface was verified according to the specification of the usability and documented in the Usability file</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.13                                                                                                                                                                                | <input checked="" type="checkbox"/>                                                                                                                                                             | <input type="checkbox"/>                                                                                                                                                  | <input type="checkbox"/>                                                                                                                                                             |
| <b>5.9 Validierung der Gebrauchstauglichkeit/ Usability validation</b><br><br>Der Hersteller hat die Gestaltung der Benutzer-Gerät-Schnittstelle gemäß dem Validierungsplan für Gebrauchstauglichkeit validiert.<br><i>The manufacturer has validated the design of operator-equipment interface in accordance to the validation plan for usability.</i><br><br>Die Ergebnisse der Verifizierung sind in der Gebrauchstauglichkeits-Akte aufgezeichnet<br><i>The results are recorded in the usability engineering file</i><br><br>Wenn die im Validierungs-Plan für Gebrauchstauglichkeit festgelegten Akzeptanzkriterien nicht erfüllt sind:<br><i>For the acceptance criteria documented in the usability validation plan that are not met:</i><br>Wurden weitere Arbeiten zur Gestaltung und Verwirklichung der Benutzer-Produkt-Schnittstelle ausgeführt; oder<br><i>further User Interface design and implementation activities are performed; or</i><br><br>Wenn eine weitere Verbesserung nicht praktikabel ist, muss der Hersteller Literatur und Daten sammeln, um festzustellen ob der medizinische Nutzen der Zweckbestimmung größer ist als die aus den Problemen mit der Gebrauchstauglichkeit resultierenden Risiken.<br><i>if further improvement is not practicable, the MANUFACTURER may gather and review data and literature to determine if the medical benefits of the INTENDED USE outweigh the RISK arising from USABILITY problems</i> | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.13<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.13<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 4.3 | <input checked="" type="checkbox"/><br><br><br><input checked="" type="checkbox"/><br><br><br><div style="border: 1px solid black; height: 100px; width: 100%;"></div> <input type="checkbox"/> | <input type="checkbox"/><br><br><br><input type="checkbox"/><br><br><br><div style="border: 1px solid black; height: 100px; width: 100%;"></div> <input type="checkbox"/> | <input type="checkbox"/><br><br><br><input type="checkbox"/><br><br><br><div style="border: 1px solid black; height: 100px; width: 100%;"></div> <input checked="" type="checkbox"/> |

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| CL <b>73523</b>             | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                                 | <br><b>Asclepion</b><br><small>Medical Technologies</small> |
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| Par., Description, Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Results, Comments                                                                                                                                                                                                                                                                                                                                                | Compliance                                                                                                                                                                                           |                                                                                                                                                                     |                                                                                                                                                          |
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| Die Validierung der Gebrauchstauglichkeit wurde in einer simulierten Gebrauchsumgebung durchgeführt:<br><i>usability validation performed in a simulated use environment:</i><br>Die Validierung der Gebrauchstauglichkeit wurde in der wirklichen Gebrauchsumgebung durchgeführt:<br><i>usability validation performed in the actual use environment:</i><br><br>Der Validierungsplan für die Gebrauchstauglichkeit behandelt folgendes:<br><i>The usability validation plan addresses:</i><br>Benutzungs-Szenarien, die häufige Anwendungssituationen repräsentieren, und<br><i>frequent Use Scenarios, and</i><br>Vernünftigerweise vorhersehbare Benutzungs-Szenarien für den ungünstigsten Fall, die in der Spezifikation der Gebrauchstauglichkeit ermittelt wurde<br><i>reasonably foreseeable worst case use scenarios that are identified in the usability specification</i><br>Der Validierungs-Plan für Gebrauchstauglichkeit ist in der Gebrauchstauglichkeits-Akte aufgezeichnet<br><i>The usability validation plan recorded in the usability engineering file</i> | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.12<br><br><br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.12<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.12<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.12 | <input checked="" type="checkbox"/><br><br><input type="checkbox"/><br><br><input checked="" type="checkbox"/><br><br><input checked="" type="checkbox"/><br><br><input checked="" type="checkbox"/> | <input type="checkbox"/><br><br><input checked="" type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/> | <input type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/> |
| <b>5.7 Gestaltung und technische Umsetzung der Benutzer-Produkt-Schnittstelle/ User interface design and implementation</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                      |                                                                                                                                                                     |                                                                                                                                                          |
| Vom Hersteller wurde die Benutzer-Produkt-Schnittstelle gemäß der Spezifikationen der Gebrauchstauglichkeit gestaltet und technisch umgesetzt und dabei geeignete Methoden und Techniken der Gebrauchstauglichkeitsorientierten Entwicklung eingesetzt<br><i>MANUFACTURER designed and implemented the USER INTERFACE as described in the USABILITY SPECIFICATION utilizing, as appropriate, USABILITY ENGINEERING methods and techniques</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.13                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/>                                                                                                                                                                  | <input type="checkbox"/>                                                                                                                                            | <input type="checkbox"/>                                                                                                                                 |

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| CL <b>73523</b>      | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                                 |  |
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| Par., Description, Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Results, Comments                                                                                                                                                                                                                                                                                                                                                                                                                                | Compliance                          |                          |                          |
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| Forderungen an die Benutzer-Produkt-Schnittstelle für die Hauptbedienfunktionen, eingeschlossen jene zur Risiko-Entschärfung;<br><i>User Interface requirements for the primary operating functions equipment including those to mitigate Risk;</i><br>Forderungen, um entscheiden zu können, ob Hauptbedienfunktionen vom Benutzer leicht zu erkennen sind<br><i>Requirements for determining whether primary operating functions are easily recognizable by the User.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.11.4<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.11.5                                                                                                                                                                                                                                                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>5.6 Validierungsplan für Gebrauchstauglichkeit/ usability validation plan</b><br><br>Der Hersteller hat einen Plan für die Validierung der Gebrauchstauglichkeit entwickelt<br><i>The manufacturer has developed and maintains a usability validation plan</i><br><br>Der Validierungsplan spezifiziert folgendes:<br><i>The validation plan verifies the following:</i><br>die Methode für die Validierung der Gebrauchstauglichkeit für die Hauptbedienfunktionen;<br><i>the method for validation of usability for primary operating functions;</i><br>Kriterien zur Festlegung einer erfolgreichen Validierung der Gebrauchstauglichkeit der Hauptbedienfunktionen auf der Grundlage der Spezifikation der Gebrauchstauglichkeit; und<br><i>criteria to the determination for successful validation of usability of primary operating functions based on the usability specification; and</i><br>die Beteiligung einer repräsentativen Gruppe vorgesehener Benutzern<br><i>the involvement of representative intended users</i><br><br>Die Validierung der Gebrauchstauglichkeit wurde in einer Laboreinrichtung durchgeführt:<br><i>usability validation performed in a laboratory setting:</i> | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.12<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.12<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.12<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.12<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.12 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |





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| Par., Description, Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Results, Comments                                                                                                                                                                    | Compliance                          |                          |                          |
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| <p>Ergebnisse der Überprüfung der Benutzer-Produkt-Schnittstelle<br/><i>results of the review of the USER INTERFACE</i></p> <p>Die Ergebnisse der Ermittlung von Gefährdungen, Gefährdungssituationen und Schweregrade sind in der Gebrauchstauglichkeits-Akte aufgezeichnet.<br/><i>The results of this identification of HAZARDS, HAZARDOUS SITUATIONS and SEVERITY are recorded in the USABILITY ENGINEERING FILE.</i></p>                                                                                                                                                                                                                                                                                                            | <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.2</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.15</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p><b>5.4 Hauptbedienfunktionen/ primary operating functions</b></p> <p>Die Hauptbedienfunktion ist vom Hersteller festgelegt und in der Ergonomieakte dokumentiert.<br/><i>The primary operating functions are specified by the manufacturer and documented in the usability-engineering file.</i></p> <p>In die Festlegung der Hauptbedienfunktionen gehen häufig benutzte Funktionen und sicherheits-bezogene Funktionen des Medizinprodukts ein<br/><i>The inputs to the primary operating functions include frequently used functions and functions related to Safety of the Medical Device</i></p>                                                                                                                                 | <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.10</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.10</p>  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p><b>5.5 Spezifikation der Gebrauchstauglichkeit/ usability specification</b></p> <p>Der Hersteller hat eine Spezifikation der Gebrauchstauglichkeit als Teil des Ergonomieprozesses entwickelt und dokumentiert;<br/><i>manufacturer developed a usability specification recorded in the usability engineering file as part of the usability engineering process</i></p> <p>Die Spezifikation der Gebrauchstauglichkeit ist in der Gebrauchstauglichkeits-Akte aufgezeichnet. Die Spezifikation der Gebrauchstauglichkeit kann in andere Spezifikationen integriert werden.<br/><i>The usability specification recorded in usability engineering file. The usability specification may be integrated into other specifications</i></p> | <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.11</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.11</p>  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| <p>Bei der Ermittlung der Gefährdungen und Gefährdungssituationen wurde folgendes berücksichtigt:</p> <p><i>During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered:</i></p> <p>die Spezifikation der Anwendung, einschließlich Benutzerprofile; und<br/><i>application specification, including user profile(s);</i></p> <p>mit Arbeitsaufgaben zusammenhängende Anforderungen;<br/><i>task related requirements;</i></p> <p>Der Benutzungskontext;<br/><i>context of use;</i></p> <p>verfügbare Informationen über bekannte Gefährdungen und Gefährdungssituationen für bestehende Benutzer-Produkt-Schnittstelle für Medizinprodukte eines ähnlichen Typs;<br/><i>information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTER-FACES of MEDICAL DEVICES of a similar type, if available;</i></p> <p>vorläufige Benutzungs-Szenarien;<br/><i>preliminary USE SCENARIOS;</i></p> <p>mögliche Benutzungsfehler;<br/><i>possible USE ERRORS;</i></p> <p>Ob ein falsches mentales Modell der Funktionsweise des Medizinprodukts einen Benutzungsfehler verursachen kann, der eine Gefährdungssituation hervorruft; und<br/><i>if an incorrect mental model of the operation of the MEDICAL DEVICE can cause a USE ERROR resulting in a HAZARDOUS SITUATION; and</i></p> | <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.2</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.2</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.2</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.2</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.2</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.2</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.2</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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| <p>die Spezifikation der Anwendung, einschließlich Benutzerprofile; und<br/><i>application specification, including user profile(s); and</i></p> <p>häufig benutzte Funktionen<br/><i>frequently used functions.</i></p> <p>Die Ergebnisse der Ermittlung der sicherheits-bezogenen Merkmale sind in der Gebrauchstauglichkeits-Akte aufgezeichnet.<br/><i>Results of this identification characteristics related to safety recorded in the usability engineering file</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.1</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.9.1</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.13</p>                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>5.3.2 Ermittlung bekannter oder vorhersehbarer Gefährdungen und Gefährdungssituationen/ Identification of known or foreseeable hazards and hazardous situations</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                 |                                     |                          |                          |
| <p>Der Hersteller hat gemäß der ISO 14971:2007, 4.3.bekannte oder vorhersehbare Gefährdungen ( im Rahmen einer Risikoanalyse) ermittelt.<br/><i>manufacturer has identified known or foreseeable hazards (part of a risk analysis) related to usability according to ISO 14971:2007, 4.3.</i></p> <p>Die Ermittlung von Gefährdungen berücksichtigt Gefährdungen für Patienten, Benutzer und andere Personen<br/><i>Identification of hazards considered hazards to patients, users and other persons</i></p> <p>Vernünftigerweise vorhersehbare Abfolgen oder Kombinationen von Ereignissen, in die die Benutzer-Produkt-Schnittstelle einbezogen ist und die in mit dem Medizinprodukt verbundene Gefährdungssituationen münden können, wurden ermittelt. Der Schweregrad des möglicherweise entstehenden Schadens wurde bestimmt.<br/><i>Reasonably foreseeable sequences or combinations of events involving the user INTERFACE that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE were identified. The SEVERITY of the resulting possible HARM is determined.</i></p> | <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.4 and 3.9.2</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.4 and 3.9.2</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.4, 3.9.1 and 3.9.2</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| CL <b>73523</b>      | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                                 |  |
| Revision index:<br>B | <b>Identification number: ZI/15/04/10-01</b><br><small>Identification code/year/month/day-number.</small> | page 6 of 15<br>CL 73523 Usab MSPRO<br>Vs02_ZI150410-01.doc                         |

| Par., Description, Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Results, Comments                                                                                                                                                          | Compliance                          |                          |                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                            | Yes                                 | No                       | N.A.                     |
| Vorgesehene Gebrauchsbedingungen (Umgebung einschließlich hygienischer Anforderung, Häufigkeit des Gebrauchs, Ort, Beweglichkeit) und<br><i>intended conditions of use (e.g.. environment including hygienic requirements, frequency of use, location, mobility); and</i><br><br>physikalische Funktionsweise<br><i>operating principle(s)</i>                                                                                                                                                                                                                                                                    | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.7.6<br><br>Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.7.7 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>5.2 Häufig benutzte Funktionen/ Frequently used functions</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                            |                                     |                          |                          |
| Sind die häufig benutzten Funktionen, die eine Interaktion zwischen dem Benutzer und dem Medizinprodukt einschließen bestimmt und in einer Gebrauchstauglichkeits-Akte aufgezeichnet?<br><i>Are frequently used functions that involve USER interaction with the MEDICAL DEVICE are determined and recorded in the USABILITY ENGINEERING FILE?</i>                                                                                                                                                                                                                                                                | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.8                                                                                            | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>5.3 Ermittlung von mit Gebrauchstauglichkeit zusammenhängenden Gefährdungen und Gefährdungssituationen/ Identification of hazards and hazardous situations related to usability</b>                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                            |                                     |                          |                          |
| <b>5.3.1 Ermittlung Sicherheits-bezogener Merkmale/ Identification of characteristics to safety</b><br><br>Eine Ermittlung sicherheits-bezogener Merkmale mit Schwerpunkt auf Gebrauchstauglichkeit wurde gemäß ISO 14971:2007, 4.2. durchgeführt<br><i>Identification of characteristics related to safety (part of a risk analysis) that focuses on usability performed according to ISO 14971:2007, 4.2.</i><br><br>Bei der Ermittlung der sicherheits-bezogenen Merkmale wurde folgendes berücksichtigt:<br><i>During the identification characteristics related to safety, the following are considered:</i> | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.9.1                                                                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| CL <b>73523</b>             | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                                 | <br><b>Asclepion</b><br><small>Laser Technologies</small> |
| Revision index:<br><b>B</b> | <b>Identification number: ZI/15/04/10-01</b><br><small>Identification code/year/month/day-number.</small> | <small>page 5 of 15</small><br><small>CL 73523 Usab MSPRO</small><br><small>Vs02_ZI150410-01.doc</small>                                   |

| Par., Description, Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Results, Comments                                                                                                                                                                                                                                                                                  | Compliance                                                                                                                        |                                                                                                  |                                                                                                  |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                    | Yes                                                                                                                               | No                                                                                               | N.A.                                                                                             |
| <b>4.3 Anpassen des Aufwands für Gebrauchstauglichkeitsorientierte Entwicklung/<br/>Scaling of the usability engineering effort</b> <p>Der Gebrauchstauglichkeits-Entwicklungs-Prozess stützt sich auf die Bedeutung von Modifizierungen abhängig von den Folgen der Risikoanalyse und wurde dokumentiert.<br/><i>The USABILITY ENGINEERING PROCESS is scaled based on the significance of any modifications depending on the results of the RISK ANALYSIS and documented</i></p>                                                                                                                                                                                                               | MeDioStar 1591/ 1592:<br>Usability file ZI/14/04/29-01;<br>chapter 1 (note)<br>MeDioStar 15912:<br>Usability plan ZI/15/02/01-12;<br>Preliminary important note                                                                                                                                    | <input checked="" type="checkbox"/>                                                                                               | <input type="checkbox"/>                                                                         | <input type="checkbox"/>                                                                         |
| <b>5. Gebrauchstauglichkeitsorientierter Entwicklungs-Prozess/ Usability engineering process</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                    |                                                                                                                                   |                                                                                                  |                                                                                                  |
| <b>5.1 Spezifikation der Anwendung/ Application specification</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                    |                                                                                                                                   |                                                                                                  |                                                                                                  |
| Der Hersteller des Gerätes hat die Anwendung in der Ergonomieakte spezifiziert.<br><i>The manufacturer has itemised the using in the usability-engineering file.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Usability file ZI/14/04/29-01;<br>Usability file ZI/15/04/01-01;<br>chapter 3.7                                                                                                                                                                                                                    | <input checked="" type="checkbox"/>                                                                                               | <input type="checkbox"/>                                                                         | <input type="checkbox"/>                                                                         |
| Die Spezifikation enthält:<br><i>The specification includes:</i> <p>Vorgesehene medizinische Indikation (z.B. Untersuchung, Beobachtung, Behandlung, Diagnose oder Vorbeugung von Leiden oder Krankheiten)<br/><i>intended medical indication (e.g., conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented);</i></p> <p>vorgesehene Patientengruppe (z.B. Alter, Gewicht, Gesundheit, Zustand)<br/><i>intended patient population (e.g., age, weight, health, condition);</i></p> <p>Körperteil oder Gewebetyp für den die Anwendung oder Behandlung vorgesehen ist<br/><i>intended part of the body or type of tissue applied to or interacted with;</i></p> | <div> Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.7.1 </div> <div> Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.7.3 </div> <div> Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.7.4 </div> | <input checked="" type="checkbox"/><br><br><br><input checked="" type="checkbox"/><br><br><br><input checked="" type="checkbox"/> | <input type="checkbox"/><br><br><br><input type="checkbox"/><br><br><br><input type="checkbox"/> | <input type="checkbox"/><br><br><br><input type="checkbox"/><br><br><br><input type="checkbox"/> |



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| CL <b>73523</b>      | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                  |  |
| Revision index:<br>B | <b>Identification number: ZI/15/04/10-01</b><br>Identification code/year/month/day-number. | page 4 of 15<br>CL 73523 Usab MSPRO<br>Vs02_ZI150410-01.doc                         |

| Par., Description, Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Results, Comments                                                                                                                                                                   | Compliance                          |                                     |                          |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                     | Yes                                 | No                                  | N.A.                     |
| <p><b>4.1.3 Sicherheits-Hinweise/ Information for Safety</b></p> <p>Der Hersteller unterwirft die Sicherheits-Hinweise dem gebrauchstauglichkeitsorientierten Entwicklungs-Prozess (z.B. Warnhinweise oder Nutzungseinschränkungen in den Begleitpapieren, Kennzeichnungen, usw.)</p> <p><i>MANUFACTURER subject the information for safety used as a RISK CONTROL to the USABILITY ENGINEERING PROCESS (e.g., warnings or limitation of use in the ACCOMPANYING DOCUMENTS, marking, etc.)</i></p> <p>Die Nichtbeachtung solcher Sicherheits-Hinweise liegt außerhalb der praktikablen Möglichkeiten der Risikobeherrschung</p> <p><i>Disregarding such information for SAFETY is considered beyond any further reasonable means of RISK CONTROL</i></p> | <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.14</p> <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.13</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> |
| <p><b>4.2 Gebrauchstauglichkeits-Akte/ Usability engineering file</b></p> <p>Die Ergebnisse des Gebrauchstauglichkeitsorientierten Entwicklungs-Prozesses sind in der Gebrauchstauglichkeits-Akte aufgezeichnet.</p> <p><i>The results of the USABILITY ENGINEERING PROCESS are recorded in the USABILITY ENGINEERING FILE</i></p> <p>Die Aufzeichnungen und andere Dokumente, die die Gebrauchstauglichkeits-Akte bilden, sind Teil anderer Dokumente und Akten.</p> <p><i>The records and other documents that make up the USABILITY ENGINEERING FILE form part of other documents and files (e.g., a MANUFACTURER'S product design file or RISK MANAGEMENT FILE),</i></p>                                                                             | <p>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 4</p>                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                     | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

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| CL <b>73523</b>      | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                                 |  |
| Revision index:<br>B | <b>Identification number: ZI/15/04/10-01</b><br><small>Identification code/year/month/day-number.</small> | page 3 of 15<br>CL 73523 Usab MSPRO<br>Vs02_ZI150410-01.doc                        |

| Par., Description, Requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Results, Comments                                                                                                                                                                                                                                    | Compliance                                                                                                             |                                                                                                             |                                                                                                             |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                      | Yes                                                                                                                    | No                                                                                                          | N.A.                                                                                                        |
| 4 Allgemeine Anforderungen / General requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                      |                                                                                                                        |                                                                                                             |                                                                                                             |
| 4.1 Allgemeine Anforderungen / General requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                      |                                                                                                                        |                                                                                                             |                                                                                                             |
| <b>4.1.1 Gebrauchstauglichkeitsorientierter Entwicklungs-Prozess / Usability engineering process</b><br><br>Hat der Hersteller einen Gebrauchstauglichkeitsorientierten Entwicklungs-Prozess eingerichtet, dokumentiert und eingehalten, um die Sicherheit für Patienten, Benutzer und andere Personen im Hinblick auf die Gebrauchstauglichkeit sicherzustellen?<br><i>Has the MANUFACTURER established, documented and maintained a USABILITY ENGINEERING PROCESS to provide SAFETY for the PATIENT, USER and others related to USABILITY for the product?</i><br><br>Behandelt der Prozess Benutzer-Interaktionen mit dem Medizinprodukt gemäß den Begleitpapieren, die Transport, Lagerung , Installation, Betrieb, Warnung, , Reparatur und Entsorgung einschließen aber sich nicht darauf beschränken.<br><i>Does the PROCESS addressed USER INTERActions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal?</i> | <div>MeDioStar 1591/ 1592:<br/>Usability file ZI/14/04/29-01 in KA 7.6</div> <div>MeDioStar 15912:<br/>Usability file ZI/15/04/01-01 in KA 7.6</div><br><div>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 4.1</div> | <div><input checked="" type="checkbox"/></div> <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> | <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> | <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> |
| <b>4.1.2 Restrisiko/ Residual Risk</b><br><br>Sind die mit der Gebrauchstauglichkeit des Medizinproduktes verbundenen Restrisiken akzeptabel, es sei denn, es gibt gelegentliche objektive Nachweise?<br><i>Are RESIDUAL RISKS associated with USABILITY of the MEDICAL DEVICE presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary and documented?</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <div>Usability file ZI/14/04/29-01;<br/>Usability file ZI/15/04/01-01;<br/>chapter 3.13<br/>chapter 4.3</div>                                                                                                                                        | <div><input checked="" type="checkbox"/></div> <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> | <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> | <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> <div><input type="checkbox"/></div> |

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| CL <b>73523</b>      | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                  |  |
| Revision index:<br>B | <b>Identification number: ZI/15/04/10-01</b><br>Identification code/year/month/day-number. | page 2 of 15<br>CL 73523 Usab MSPRO<br>Vs02_ZI150410-01                             |

### Identification

#### Details of examiner:

Identification of the person responsible for examining and classifying the product under inspection:

Name: Gabi Zimmermann  
print full name (block letters)

Position: Senior Product Manager  
print full title

If the above named person is not an employee of the manufacturer of the product to be examined, state the details of the examiner's employer or organization:

Organisation: n/a \_\_\_\_\_

Address: n/a \_\_\_\_\_

\_\_\_\_\_

#### Medical product

Details of product to be inspected: manuals

### Photos of the products:

#### MeDioStar 1591/ 1592:



#### MeDioStar 15912:





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| CL <b>73523</b>             | <b>Conformity Evaluation acc. to 62366 and 60 601-1-6</b>                                                 | <br><b>Asclepion</b><br>Laser Technologies |
| Revision index:<br><b>B</b> | <b>Identification number: ZI/15/04/10-01</b><br><small>Identification code/year/month/day-number.</small> | page 1 of 15<br><small>CL 73523 Usab MSPRO<br/>         Vs02_ZI150410-01.doc</small>                                         |

**Tested equipment:** *MeDioStar*  
**Name and/or model:** *1591, 1592 and 15912*  
**Manufacturer:** *Asclepion Laser Technologies GmbH*  
**Address:** *Brüsseler Str. 10, 07747 Jena, Germany*

**Applied standard:** **EN 62366: 2008 (IEC 62366: 2007)**  
 Medizinprodukte – Anwendung der Gebrauchstauglichkeit auf Medizinprodukte  
 Medical devices – Application of usability engineering to medical device  
**EN 60 601-1-6: 2010 (IEC 60 601-1-6: 2010)**  
 Medizinische elektrische Geräte – Allgemeine Festlegungen für die Sicherheit – Ergänzungsnorm: Gebrauchstauglichkeit  
 Medical electrical equipment – general requirements for safety - collateral standard: Usability

**Attachments:**

| <i>check and release:</i> | <i>department</i> | <i>date</i>          | <i>name</i>       | <i>signature</i>  |
|---------------------------|-------------------|----------------------|-------------------|-------------------|
| <i>checked by</i>         | <i>APM</i>        | <i>Apr. 16, 2015</i> | <i>Zimmermann</i> | <i>Zimmermann</i> |
| <i>released by</i>        | <i>f PM</i>       | <i>Apr. 17, 2015</i> | <i>A. Katzer</i>  | <i>Katzer</i>     |

|                                                                                                                                         |                     |                                       |                                                                              |                     |                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------------------------------------|------------------------------------------------------------------------------|---------------------|---------------------------------------|
| Grund für letzte Änderung des Formulars: neue Version der EN 60601-1-6<br>Cause of last modification form: new version of EN 60 601-1-6 |                     |                                       |                                                                              |                     |                                       |
| Formular erstellt durch FuE:<br>Form drawn by R&D:                                                                                      |                     |                                       | Formular geprüft und genehmigt durch QM:<br>Form checked and released by QA: |                     |                                       |
| 04. 06. 2013                                                                                                                            | I. Streit           | Gez. streit                           | 10.06.2013                                                                   | R. Thieme           | Gez. R. Thieme                        |
| <small>Datum/Date</small>                                                                                                               | <small>Name</small> | <small>Unterschrift/Signature</small> | <small>Datum/Date</small>                                                    | <small>Name</small> | <small>Unterschrift/Signature</small> |

|                                    |                                                                                                                                                    |                    |
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| Verification Biocompatibility      | FB 7336Bewertung MatVer Gerät_V01 AWi_141010-01<br>FB7351e Veri Biocom MS PRO HP V01 IH140710-01<br>FB7351e Veri Biocom MS NeXT HP V02 IH140617-01 | KA ALT 003/14 7.13 |
| Verification Device                | FB 7351 Veri Gesamtgerät MSPRO V02 AWi141110-01                                                                                                    | KA ALT 003/14 7.9  |
| Evaluation EN 980 / EN ISO 15223-1 | CL 7363 EN 980 EN 15223-1 MSPRO V01_MMo140819-04                                                                                                   | KA ALT 003/14 7.9  |
| Risk evaluation cooling probe      | TP 7342 Risikobetrachtung Unterkühlung V01 MMo111111-01                                                                                            | KA ALT 002/10 7.13 |

## List of Records

| Record                                           | Name of document                                                                                         | Design History file |
|--------------------------------------------------|----------------------------------------------------------------------------------------------------------|---------------------|
| Risk Management Concept                          | FB 7301 RMC MSPRO V02_MMo140519-02                                                                       | KA ALT 003/14 7.2.1 |
| Risk Management Report                           | FB 7301 RMR MSPRO V02 RH141110-02                                                                        | KA ALT 003/14 7.2.1 |
| Insulation diagram                               | Isolationsdiagramm MSPRO V02_MMo140708-02                                                                | KA ALT 003/14 7.3   |
| Test Report 60601-1                              | 21215627_001_ IEC60601-1 Test report                                                                     | KA ALT 003/14 7.3   |
| Test certificate power supply                    | HPC825 CB_Certificate DE2-018029                                                                         | KA ALT 003/14 7.3   |
| Test Report 60601-1-2                            | 1430-13-EE-14-PB001                                                                                      | KA ALT 003/14 7.4   |
| Test Report 60601-2-22                           | 21215627_001_attm#3_ IEC60601-2-22                                                                       | KA ALT 003/14 7.3   |
| User Manual                                      | 159099001-V06-2.Sept.2014-GA-MSPRO-DE<br>159099002-V06-2.Sept.2014-GA-MSPRO-EN                           | KA ALT 003/14 2.2   |
| Usability file                                   | FB 73513 UsabilityFile MSPRO Vs01 ZI 140429-01                                                           | KA ALT 003/14 7.6   |
| Software Requirement specification               | FB 73211 SRS MSPRO V01_CaM140205-01                                                                      | KA ALT 003/14 5.2   |
| Level of Concern                                 | FB 7354 Level of Concern MSPRO V01_RH140204-02                                                           | KA ALT 003/14 7.2.1 |
| Software Konfiguration Management                | FB 7332 SKM MSPRO V01 RH140204-01                                                                        | KA ALT 003/14 4.3   |
| Architecture DesignChart                         | ArchitectureDesignChart MSPRO V01_RH140206-23                                                            | KA ALT 003/14 5.4.1 |
| <b>Software Design specification:</b>            |                                                                                                          |                     |
| GUI Main Frame                                   | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| GUI Diode                                        | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| GUI Service                                      | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| Handpiece                                        | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| Slave Boot                                       | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| Slave Cooler                                     | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| Slave Diode                                      | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| Slave Hardware                                   | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| Slave Main                                       | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| Verification Software                            | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| Validation Software                              | look at Traceability Analysis                                                                            | KA ALT 003/14 5.4   |
| Labeling Drawing                                 | 159199020 Labeling MSPRO (BL1+BL2)                                                                       | KA ALT 003/14 2.3   |
| List of safety relevant materials and components | FB 7331 LoCC MSPRO V02_MMo140519-01                                                                      | KA ALT 003/14 2.4   |
| Checklist User Manual                            | CL7356 GA MSPRO V02_ZI141027-01                                                                          | KA ALT 003/14 7.9   |
| Checklist Device Labels                          | CL7357 Geräteschilder MSPRO V04_AWi141110-02                                                             | KA ALT 003/14 7.9   |
| Verification packaging                           | FB7351 Vali Verpackung MSPRO V02 KL141106-01                                                             | KA ALT 003/14 7.9   |
| Verification Spillage/Overflow/Leakage           | FB 7351 Veri Spillage_Overflow_Leakage MSPRO V01_MMo140710-03                                            | KA ALT 003/14 7.9   |
| Verification Cooling                             | FB 7351 Veri Kühlung MSPRO V01_MMo140522-01                                                              | KA ALT 003/14 7.15  |
| Verification Handpiece                           | FB7351e Veri MSPRO HP V01 IH141111-03                                                                    | KA ALT 003/14 7.12  |
| Verification Report Laser                        | FB 7351e Verification Report MDS SE Energy Adjustment rev 01-110608                                      | KA ALT 002/10 7.11  |
|                                                  | FB 7351e Verification Stability of Laser output MDS SE rev01                                             |                     |
|                                                  | FB 7351e Verification Stability of Laser output MSNeXT V01_MMo120516-03                                  |                     |
|                                                  | FB 7351e Veri Energy Adjustment HS ALX V01_MMo140619-04                                                  |                     |
|                                                  | FB 7351e Veri spotsize HP ALX V01_MMo140619-09                                                           |                     |
|                                                  | FB 7351e Veri Stability HS ALX V01_MMo140619-02                                                          |                     |
|                                                  | FB 7351e Veri Stability HS XL V01_MMo140819-02<br>FB 7351e Veri Energy Adjustment HS XL V01_MMo140819-01 | KA ALT 003/14 7.11  |



| Risikoanalyse / Risk Analysis      |                                                                |                                                     |                        |                                                                                                                  |                     | Rückführung / Risk Control                                                                                                                                                                                                                                                                                                                                                |                                                   |                                     |                            |                            |                            |                            |                            |                                                                |                            |                            |                            |
|------------------------------------|----------------------------------------------------------------|-----------------------------------------------------|------------------------|------------------------------------------------------------------------------------------------------------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------------------------------------------|----------------------------|----------------------------|----------------------------|
| HA                                 | Beschreibung<br>Description                                    | Wirkung / Effect                                    | Schweregrad / Severity | Ursache / Cause                                                                                                  | Folge / Consequence | Maßnahme / Measure                                                                                                                                                                                                                                                                                                                                                        | Normen / Standards                                | Zustand / Status                    | Überprüfung / Verification | Überprüfung / Verification | Überprüfung / Verification | Überprüfung / Verification | Überprüfung / Verification | Überprüfung / Verification                                     | Überprüfung / Verification | Überprüfung / Verification | Überprüfung / Verification |
|                                    |                                                                |                                                     |                        |                                                                                                                  |                     |                                                                                                                                                                                                                                                                                                                                                                           |                                                   |                                     |                            |                            |                            |                            |                            |                                                                |                            |                            |                            |
| HA1705                             | na                                                             | na                                                  | dispensable            | na                                                                                                               | inconceivable       | na, because there are no external supply connections.                                                                                                                                                                                                                                                                                                                     | IEC 60601-1:2005<br>7.2.5 [TRF]                   | IEC 60601-1:2005<br>EN 60601-1:2006 | na                         | na                         | na                         | na                         | na                         | na                                                             | na                         | na                         | na                         |
| HA1710                             | Hazards related to device labelling                            | Unwanted side effects (moderate)                    | minor                  | Missing/wrong placed safety sign on device                                                                       | inconceivable       | na, because all physiological effects are obvious for the OPERATOR, no safety sign is required general safety informations in user manual chapter 2                                                                                                                                                                                                                       | IEC 60601-1:2005<br>7.2.13 [TRF]<br>MDD 93/42/EEC | IEC 60601-1:2005<br>EN 60601-1:2006 | na                         | na                         | na                         | na                         | na                         | na                                                             | na                         | na                         | na                         |
| HA1720                             | Hazards related to device labelling                            | Unwanted side effects (moderate)                    | dispensable            | na                                                                                                               | inconceivable       | na, because no danger by interchanging of L and N.<br>no polarization dependent components<br>2 pole separation<br>final test report (PTR): electrical measurement (leakage current) with exchanged polarity                                                                                                                                                              | IEC 60601-1:2005<br>7.2.7 [TRF]                   | IEC 60601-1:2005<br>EN 60601-1:2006 | na                         | na                         | na                         | na                         | na                         | na                                                             | na                         | na                         | na                         |
| HA1730                             | Operational hazards                                            | Unwanted side effects (moderate)                    | minor                  | Wrong control settings due to missing wrong position indication or not clear visible status of control variable. | occasional          | - main switch<br>- key switch<br>- Laser stop button marked by rotation for unlocking<br>- Ready and standby mode<br>Declaration of control devices according to IEC60601-1, table D1<br>- No. 12 "ON" (mains switch)<br>- No. 13 "OFF" (mains switch)<br>- No. 16 "ON" for part of equipment (key switch)                                                                | IEC 60601-1:2005<br>7.4.2 [TRF]<br>MDD 93/42/EEC  | IEC 60601-1:2005<br>EN 60601-1:2006 | Yes                        | Yes                        | Yes                        | Yes                        | Yes                        | Drawings                                                       | na                         | na                         | na                         |
| HA1740                             | Operational hazards                                            | General injury (moderate)                           | minor                  | Poor indicator design                                                                                            | occasional          | The system states are visualized by the display.<br>The warm-up state (during system test) is visualized by a splash screen. Connection of handpiece is visualized in work screen and by indication light on hand piece.                                                                                                                                                  | IEC 60601-1:2005<br>15.4.4 [TRF]                  | IEC 60601-1:2005<br>EN 60601-1:2006 | Yes                        | Yes                        | Yes                        | Yes                        | Yes                        | Validation Software look at HA130(s)<br>Traceability: Analysis | na                         | na                         | na                         |
| 8.3 Hazards related to user manual |                                                                |                                                     |                        |                                                                                                                  |                     |                                                                                                                                                                                                                                                                                                                                                                           |                                                   |                                     |                            |                            |                            |                            |                            |                                                                |                            |                            |                            |
| HA1750                             | Hazards related to user manual                                 | General injury (moderate)                           | critical               | No information provided on residual risk due to poor accompanying information                                    | occasional          | Check the user manual in all relevant requirements of IEC 60601-1                                                                                                                                                                                                                                                                                                         | IEC 60601-1:2005<br>7.9.2 [TRF]<br>MDD 93/42/EEC  | IEC 60601-1:2005<br>EN 60601-1:2006 | Yes                        | Yes                        | Yes                        | Yes                        | Yes                        | Checklist User Manual                                          | ZI                         | na                         | na                         |
| HA1760                             | User's manual too complicated (Wrong handling and maintenance) | Faulty treatment                                    | minor                  | Wrong handling inadequate maintenance                                                                            | occasional          | User manual based on that for forerunner device, which never caused problems.<br>Testing of usability of user manual                                                                                                                                                                                                                                                      | MDD 93/42/EEC<br>EN 62368:2009<br>4.1, 5.3, 8     | EN 60601-1-6:2010                   | Yes                        | Yes                        | Yes                        | Yes                        | Yes                        | Usability-File                                                 | ZI                         | na                         | na                         |
| 9 Complaints/Market surveillance   |                                                                |                                                     |                        |                                                                                                                  |                     |                                                                                                                                                                                                                                                                                                                                                                           |                                                   |                                     |                            |                            |                            |                            |                            |                                                                |                            |                            |                            |
| 9.1 Complaint related hazards      |                                                                |                                                     |                        |                                                                                                                  |                     |                                                                                                                                                                                                                                                                                                                                                                           |                                                   |                                     |                            |                            |                            |                            |                            |                                                                |                            |                            |                            |
| HA1770                             | Use by unskilled / untrained personnel (Misuse of device)      | Insufficient therapeutic effect<br>Faulty treatment | minor                  | Missing requirements on the user misuse                                                                          | occasional          | Description of user profile for intended user<br>Training of personnel<br>Securing against unauthorized use by key switch                                                                                                                                                                                                                                                 | EN 62368:2008<br>4.1, 5.3, 8                      | EN 60601-1-6:2010                   | Yes                        | Yes                        | Yes                        | Yes                        | Yes                        | Usability-File<br>User manual                                  | ZI                         | na                         | na                         |
| HA1780                             | Complications / Abortion of treatment                          | Interruption of treatment                           | critical               | [SFC] Inaccurate values of controls and/or instruments                                                           | occasional          | Emitted radiation is within ±20% of displayed values (fluence).<br>Continuous monitoring and control of parameters.<br>Warning or error message on exceeding parameter tolerance limits (±20% deviation).<br>Continuous monitoring with aid of two independent measurement system (electrical sensors)<br>Switch off by more as 50 %<br>Specify DIN EN 60601-2-22 sec. 51 | IEC 60601-1:2005<br>12.1 [TRF]<br>4.7 [TRF]       | IEC 60601-1:2005<br>EN 60601-1:2006 | Yes                        | Yes                        | Yes                        | Yes                        | Yes                        | Verification Report Laser                                      | MfO                        | na                         | na                         |
| HA1790                             | Complications / Abortion of treatment                          | Interruption of treatment                           | critical               | [SFC] Inaccurate values of controls and/or instruments                                                           | occasional          | Use a watchdog which must be triggered regularly in the predefined timeframe                                                                                                                                                                                                                                                                                              | IEC 60601-1:2005<br>12.1 [TRF]<br>4.7 [TRF]       | IEC 60601-1:2005<br>EN 60601-1:2006 | Yes                        | Yes                        | Yes                        | Yes                        | Yes                        | Verification Software look at HA120<br>Traceability Analysis   | na                         | na                         | na                         |

FILE NUMBER: PB 7208 PACS WSPROD V02 041411 10-01 2000



[illegible]



| Risikoanalyse / Risk Analysis                                             |                                                                                                               |                                                                                     |                        |                                                                                                    |                       | Risikostrukturmatrike / Risk Control                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
|---------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-----------------------------------------|-----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|
| No.                                                                       | Beschreibung<br>Description                                                                                   | Art / Type of hazard                                                                | Schweregrad / Severity | Ursache der Fehlfunktion<br>Cause of the malfunction                                               | Folge / Consequence   | Maßnahme / Measure                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Normen / Standards                                             | Angeordnete Normen<br>Required measures | Sicherheits-<br>Funktion / Safety<br>Function | Sicherheits-<br>Maßnahme / Safety<br>Measure | Sicherheits-<br>Maßnahme / Safety<br>Measure | Sicherheits-<br>Maßnahme / Safety<br>Measure | Sicherheits-<br>Maßnahme / Safety<br>Measure | Sicherheits-<br>Maßnahme / Safety<br>Measure | Sicherheits-<br>Maßnahme / Safety<br>Measure | Sicherheits-<br>Maßnahme / Safety<br>Measure | Sicherheits-<br>Maßnahme / Safety<br>Measure | Sicherheits-<br>Maßnahme / Safety<br>Measure | Sicherheits-<br>Maßnahme / Safety<br>Measure |
|                                                                           |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| HA1350                                                                    | cooling circuit<br>(Pressure-relief device)                                                                   | General injury<br>(moderate)                                                        | critical               | [SFC] Loss of pressure                                                                             | hardly<br>conceivable | There is a pressure-relief device used<br>(see LoCC) with the following specifications:<br>open at 17,7bar ±0,7<br>proof pressure 41bar<br>burst pressure 345bar<br>- cycle life: min. 100'000<br>The pressure-relief device is installed on the<br>cooling unit, close to the pressure parts.<br>It could not adjusted or rendered operative without<br>the use of a tool and it is located inside the device.<br>There is no shut-off valve between the pressure-<br>relief device and the parts that it is intended to<br>protect. | IEC 60601-1:2005<br>9.7.7 [TRF]<br>MOD 9.7.42/IEC              | IEC 60601-1:2005<br>EN 60601-1:2006     | Yes                                           | -                                            | -                                            | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          |
|                                                                           |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| 6 Biological and chemical hazards                                         |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| 6.1 Biological hazards                                                    |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| HA1370                                                                    | Biological incompatibility<br>(material selection,<br>compatibility with<br>substances, tissue,<br>materials) | Injury to patient, users<br>or third parties                                        | critical               | Use of not allowed<br>materials for patient<br>relevant parts (tube,<br>hand piece, spacer)        | often                 | Compliance with ISO 10993-1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | IEC 60601-1:2005<br>11.7<br>ISO 11983-1:2009<br>MOD 9.7.42/IEC | IEC 60601-1:2005<br>EN 60601-1:2006     | -                                             | Yes                                          | -                                            | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          |
|                                                                           |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| 6.2 Chemical hazards                                                      |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| 6.2.1 Exposure of property                                                |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| HA1380                                                                    | Operational hazard                                                                                            | Unwanted side effects<br>(moderate)                                                 | dispensable            | use of incompatibility<br>substances                                                               | inconceivable         | Ultrasound gel used between sapphire of<br>handpiece and skin.<br>Description in user manual about use with US gel<br>and cleaning of the hand piece                                                                                                                                                                                                                                                                                                                                                                                  | IEC 60601-1:2005<br>11.6.8 [TRF]                               | IEC 60601-1:2005<br>EN 60601-1:2006     | Yes                                           | -                                            | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          |
|                                                                           |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| 7 Operational hazards                                                     |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| 7.1 Functionality hazards                                                 |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| HA1350                                                                    | na                                                                                                            | na                                                                                  | dispensable            | na                                                                                                 | inconceivable         | na, no battery and no additional power supply is<br>used in according to IEC 60601-1 clause 7.9.2.4                                                                                                                                                                                                                                                                                                                                                                                                                                   | IEC 60601-1:2005<br>7.9.2.4 [TRF]                              | IEC 60601-1:2005<br>EN 60601-1:2006     | na                                            | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           |
| HA1400                                                                    | na                                                                                                            | na                                                                                  | dispensable            | na                                                                                                 | inconceivable         | No indication lights according to IEC 60601-1<br>clause 7.8.1                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | IEC 60601-1:2005<br>7.8.1                                      | IEC 60601-1:2005<br>EN 60601-1:2006     | na                                            | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           | na                                           |
| HA1430                                                                    | Complex and confusing<br>control and operation<br>system<br>(Operating error)                                 | Wrong parameter<br>settings<br>Unattended stop of<br>treatment                      | minor                  | Too complex control<br>system/ User interface                                                      | occasional            | Testing of usability<br>(Clear LCD-Display with Touch Screen,<br>self-explaining Laser Emergency Stop at the<br>front, Beep when change of parameters, Ergonomic<br>arrangement of buttons)                                                                                                                                                                                                                                                                                                                                           | IEC 60601-1:2005<br>15.1 [TRF]<br>EN 62366:2008<br>4.1, 5.3, 6 | EN 60601-1:2005<br>EN 60601-1:2006      | Yes                                           | -                                            | -                                            | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          |
|                                                                           |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| 7.2 Hazards related to unwanted side effects and inadequate effectiveness |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| 7.2.1 Incorrect treatment output                                          |                                                                                                               |                                                                                     |                        |                                                                                                    |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |                                         |                                               |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |                                              |
| HA1440                                                                    | Incorrect treatment<br>output                                                                                 | General injury<br>(moderate)                                                        | critical               | Non standard<br>application may<br>resulted other than<br>preset controls                          | occasional            | Display of selected settings concerned laser<br>treatment:<br>- Fluence<br>- Pulse duration<br>- Repetition Frequency                                                                                                                                                                                                                                                                                                                                                                                                                 | IEC 60601-1:2005<br>13.4.5 [TRF]                               | IEC 60601-1:2005<br>EN 60601-1:2006     | Yes                                           | Yes                                          | -                                            | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          |
| HA1450                                                                    | Erroneous measurement<br>and other measurement<br>aspects                                                     | - Over treatment<br>- Vesicles and / or scars                                       | minor                  | wrong laser parameter<br>by wrong hand piece                                                       | occasional            | - Hand piece data, saved in EEPROM with hand<br>piece type display and/or spot size, shown at the<br>display<br>- Protection against hazardous initial value the high<br>displayed energy density is shown at the display                                                                                                                                                                                                                                                                                                             | IEC 60601-1:2005<br>14.6.1<br>(una-ailable data)               | EN 62304: 2008                          | Yes                                           | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          |
| HA1460                                                                    | Erroneous measurement<br>and other measurement<br>aspects                                                     | - Over treatment<br>- Vesicles and / or scars                                       | minor                  | wrong laser parameter<br>through wrong current<br>provided by<br>multifunctions In diode<br>driver | occasional            | - monitoring of drive value and pulse width<br>gate locking<br>redundant current measurement                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                | EN 62304: 2008                          | -                                             | Yes                                          | -                                            | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          |
| HA1470                                                                    | Erroneous measurement<br>and other measurement<br>aspects                                                     | - Over treatment<br>- Vesicles and / or scars                                       | minor                  | wrong laser parameters<br>because of wrong<br>display (master)                                     | occasional            | - Display communication with confirmation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | IEC 60601-1:2005<br>14.6.1<br>(lack of integrity of<br>data)   | EN 62304: 2008                          | -                                             | Yes                                          | -                                            | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          |
| HA1480                                                                    | Erroneous measurement<br>and other measurement<br>aspects                                                     | - Over treatment<br>- Vesicles and / or scars<br>- Third degree burns on<br>to skin | minor                  | wrong laser parameters<br>because of wrong pulse<br>length                                         | occasional            | - monitoring of the clock frequency<br>gate locking                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | IEC 60601-1:2005<br>14.6.1<br>(incorrect timing of<br>data)    | EN 62304: 2008                          | -                                             | Yes                                          | -                                            | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          | Yes                                          |

[illegible]



| Risk Analysis |                           |          |           | Risk Control                            |                                         |                                         |                                         | Residual Risk Evaluation                |                                         |                                         |                                         |
|---------------|---------------------------|----------|-----------|-----------------------------------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|-----------------------------------------|
| No            | Risk Category             | Severity | Frequency | Control Measure                         | Residual Risk                           | Residual Risk                           | Residual Risk                           | Residual Risk                           | Residual Risk                           | Residual Risk                           | Residual Risk                           |
|               |                           |          |           |                                         |                                         |                                         |                                         |                                         |                                         |                                         |                                         |
| HAT150        | Electrical energy hazards | Minor    | Minor     | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        |
| HAT160        | Mechanical energy hazards | Minor    | Minor     | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        |
| HAT170        | Mechanical energy hazards | Minor    | Minor     | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        | Insufficient mechanical strength        |
| HAT180        | Mechanical energy hazards | Critical | Critical  | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system |
| HAT190        | Mechanical energy hazards | Critical | Critical  | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system |
| HAT200        | Mechanical energy hazards | Critical | Critical  | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system | Insufficient dimension of liquid system |



| No.    | Produkt / Prod. description | Produktionsabgleich Prod. Control |                                                             |                                                    |                                                             | Reparaturanweisung<br>Repair instructions |
|--------|-----------------------------|-----------------------------------|-------------------------------------------------------------|----------------------------------------------------|-------------------------------------------------------------|-------------------------------------------|
|        |                             | Suche und<br>Find                 | Überprüfung der Schaltpläne<br>Circuit diagram verification | Überprüfung der Bauteile<br>Component verification | Überprüfung der Dokumentation<br>Documentation verification |                                           |
| HA1001 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1002 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1003 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1004 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1005 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1006 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1007 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1008 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1009 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1010 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1011 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1012 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1013 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1014 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1015 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1016 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1017 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1018 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1019 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1020 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1021 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1022 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1023 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1024 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1025 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1026 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1027 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1028 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1029 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1030 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1031 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1032 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1033 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1034 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1035 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1036 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1037 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1038 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1039 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1040 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1041 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1042 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1043 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1044 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1045 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1046 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1047 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1048 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1049 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1050 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1051 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1052 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1053 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1054 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1055 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1056 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1057 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1058 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1059 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1060 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1061 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1062 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1063 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1064 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1065 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1066 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1067 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1068 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1069 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1070 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1071 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1072 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1073 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1074 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1075 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1076 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1077 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1078 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1079 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1080 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1081 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1082 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1083 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1084 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1085 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1086 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1087 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1088 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1089 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1090 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1091 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1092 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1093 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1094 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1095 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1096 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1097 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1098 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1099 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1100 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1101 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1102 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1103 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1104 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1105 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1106 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1107 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1108 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1109 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1110 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1111 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1112 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1113 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1114 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1115 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1116 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1117 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1118 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1119 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1120 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1121 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1122 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1123 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1124 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1125 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1126 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1127 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1128 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1129 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1130 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1131 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1132 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1133 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1134 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1135 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1136 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1137 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1138 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1139 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1140 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1141 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1142 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1143 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1144 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1145 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1146 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1147 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1148 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1149 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1150 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1151 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1152 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1153 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1154 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1155 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1156 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1157 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1158 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1159 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1160 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1161 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1162 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1163 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1164 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1165 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1166 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1167 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1168 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1169 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1170 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1171 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1172 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1173 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1174 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1175 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1176 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1177 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1178 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1179 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1180 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1181 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1182 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1183 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1184 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1185 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1186 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1187 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1188 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1189 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1190 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1191 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1192 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1193 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1194 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1195 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1196 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1197 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1198 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1199 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1200 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1201 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1202 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1203 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1204 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1205 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1206 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1207 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1208 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1209 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1210 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1211 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1212 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1213 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1214 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1215 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1216 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1217 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1218 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1219 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1220 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1221 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1222 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1223 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1224 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1225 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1226 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1227 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1228 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1229 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1230 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1231 | Handheld power tool         | Yes                               | Yes                                                         | Yes                                                | Yes                                                         | Yes                                       |
| HA1232 | Handheld power tool         |                                   |                                                             |                                                    |                                                             |                                           |





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| Rückanalyse / Risk Analysis                               |                                         |                                                                 |             |                                                                                                                                            |               | Rücküberprüfung / Risk Control                                                                                                                                                                                                                                                                |                                                                          |                                   |            |            |                  |                  |                  |                  |                  |                  |                  |
|-----------------------------------------------------------|-----------------------------------------|-----------------------------------------------------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-----------------------------------|------------|------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| No.                                                       | Hazard                                  | Hazard / Failure Mode / Effect                                  | Severity    | Cause of Failure Mode                                                                                                                      | Frequency     | Mitigation Measure(s)                                                                                                                                                                                                                                                                         | Applicable Norm                                                          | Safety                            | Redundancy | Interlocks | Fail-safe design | Fail-safe design | Fail-safe design | Fail-safe design | Fail-safe design | Fail-safe design | Fail-safe design |
|                                                           |                                         |                                                                 |             |                                                                                                                                            |               |                                                                                                                                                                                                                                                                                               |                                                                          |                                   |            |            |                  |                  |                  |                  |                  |                  |                  |
| HA710                                                     | No ionising radiation - laser radiation | Eye damage / injury, injuries by light, injury of third persons | critical    | No interruption of laser radiation in case of footswitch release (in terms of footswitch malfunction and/or short circuit in signal lines) | occasional    | Redundant release for software and hardware (Two independent contacts) - Laser stop button                                                                                                                                                                                                    | IEC 60601-1:2005 14.8.1 (unintended interactions within and among PESS)  | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA720                                                     | No ionising radiation - laser radiation | Eye damage / injury, injuries by light, injury of third persons | critical    | Unintended release of laser radiation at ready activation because of active footswitch                                                     | occasional    | No release of laser radiation at ready activation if footswitch is activated.                                                                                                                                                                                                                 | IEC 60601-1:2005 14.8.1 (unintended interactions within and among PESS)  | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA730                                                     | No ionising radiation - laser radiation | Eye damage / injury, injury of third persons                    | critical    | People in the room without safety goggles during laser treatment                                                                           | often         | Acoustical and optical display of emission.<br>Ergo closing time at ready activation<br>1-Acoustical signal after ready state is activated<br>2-Activation of laser is possible two seconds after activation of ready state<br>Note in user manual to safety goggles (required use and specs) | IEC 60601-1:2005 14.8.1 (unintended interactions within and among PESS)  | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA750                                                     | No ionising radiation - laser radiation | Eye damage / injury, injury of third persons                    | critical    | Access of third persons during laser treatment                                                                                             | occasional    | Door interlock<br>Laser warning lamp                                                                                                                                                                                                                                                          | IEC 60601-1:2005 14.8.1 (incorrect data)                                 | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA760                                                     | No ionising radiation - laser radiation | Over treatment<br>Vesicles and / or scars                       | critical    | wrong laser parameter through faulty software and/or hardware (abnormal system end)                                                        | occasional    | Plausibility check of laser parameter by slave use of CRC in data transmission between master and slave<br>Using of watchdog                                                                                                                                                                  | IEC 60601-1:2005 14.8.1 (incorrect data)                                 | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA770                                                     | No ionising radiation - laser radiation | Eye damage<br>Over treatment<br>Vesicles and / or scars         | critical    | Unintentional switch-on of the laser system                                                                                                | occasional    | Key switch<br>Laser stop button<br>Ready and standby mode<br>Footswitch                                                                                                                                                                                                                       | IEC 60601-1:2005 14.8.1 (unintended interactions within and among PESS)  | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA780                                                     | No ionising radiation - laser radiation | Over treatment<br>Vesicles and / or scars                       | critical    | wrong laser parameter through wrong read data of non-volatile storage                                                                      | occasional    | Use of LRC                                                                                                                                                                                                                                                                                    | IEC 60601-1:2005 14.8.1 (incorrect data)                                 | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA790                                                     | No ionising radiation - laser radiation | Eye damage<br>Over treatment<br>Vesicles and / or scars         | critical    | wrong laser output parameter after change of the power supply mode driver                                                                  | occasional    | current adjustment<br>monitoring of output energy<br>Note in service manual:<br>Measurement of the laser energy                                                                                                                                                                               | IEC 60601-1:2005 14.8.1 (unknown aspects or quality of third-party PESS) | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA800                                                     | No ionising radiation - laser radiation | Eye damage<br>Over treatment<br>Vesicles and / or scars         | critical    | wrong laser parameter after change of the laser hand piece                                                                                 | occasional    | energy adjustment with initialization of handpiece and<br>Parameters displayed via GUI.<br>Fluence<br>type of handpiece                                                                                                                                                                       | IEC 60601-1:2005 14.8.1 (unknown aspects or quality of third-party PESS) | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA810                                                     | No ionising radiation - laser radiation | Eye damage<br>Over treatment<br>Vesicles and / or scars         | critical    | Malfunction of diode driver<br>wrong output parameter (incorrect current or pulse width)                                                   | occasional    | Supervision of pulse width by gate lock<br>Supervision of the laser energy                                                                                                                                                                                                                    | IEC 60601-1:2005 14.8.1 (incorrect data)                                 | EN 62304:2006                     | Yes        | Yes        | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              | Yes              |
| HA820                                                     | Radiation energy is too high            | General injury (moderate)                                       | critical    | Unintended infrared radiation from ME-Equipment                                                                                            | inconceivable | n.a., because there is only IR radiation from the Laser diode.<br>The Requirements of IEC 60825 and IEC 60601-2-22 of the IR radiation are met.                                                                                                                                               | IEC 60601-1:2005 10.6 (TRF)                                              | EN 60601-1:2005 / EN 60601-1:2006 | na         | na         | na               | na               | na               | na               | na               | na               | na               |
| 3.2.3 UV-Radiation hazards                                |                                         |                                                                 |             |                                                                                                                                            |               |                                                                                                                                                                                                                                                                                               |                                                                          |                                   |            |            |                  |                  |                  |                  |                  |                  |                  |
| HA830                                                     | na                                      | na                                                              | dispensable | na                                                                                                                                         | inconceivable | n.a. because there is no ultraviolet radiation.                                                                                                                                                                                                                                               | IEC 60601-1:2005 10.7 (TRF)                                              | EN 60601-1:2005 / EN 60601-1:2006 | na         | na         | na               | na               | na               | na               | na               | na               | na               |
| 3.2.4 Microwave radiation hazards                         |                                         |                                                                 |             |                                                                                                                                            |               |                                                                                                                                                                                                                                                                                               |                                                                          |                                   |            |            |                  |                  |                  |                  |                  |                  |                  |
| HA840                                                     | na                                      | na                                                              | dispensable | na                                                                                                                                         | inconceivable | n.a. because there is no microwave radiation from device.                                                                                                                                                                                                                                     | IEC 60601-1:2005 10.3 (TRF)                                              | EN 60601-1:2005 / EN 60601-1:2006 | na         | na         | na               | na               | na               | na               | na               | na               | na               |
| 4 Thermal energy hazards                                  |                                         |                                                                 |             |                                                                                                                                            |               |                                                                                                                                                                                                                                                                                               |                                                                          |                                   |            |            |                  |                  |                  |                  |                  |                  |                  |
| 4.1 Hazards from high temperatures                        |                                         |                                                                 |             |                                                                                                                                            |               |                                                                                                                                                                                                                                                                                               |                                                                          |                                   |            |            |                  |                  |                  |                  |                  |                  |                  |
| 4.1.1 Excessive temperature at mains circuit installation |                                         |                                                                 |             |                                                                                                                                            |               |                                                                                                                                                                                                                                                                                               |                                                                          |                                   |            |            |                  |                  |                  |                  |                  |                  |                  |

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| Manufacturer's Risk Analysis |                                                                                     |                                                                  |       |       |       |       |       |       |       | Manufacturer's Risk Control |       |       |       |       |       |       |                    |       |                               | Manufacturer's Risk Control |                          | Manufacturer's Risk Control |  |
|------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------|-------|-------|-------|-------|-------|-------|-------|-----------------------------|-------|-------|-------|-------|-------|-------|--------------------|-------|-------------------------------|-----------------------------|--------------------------|-----------------------------|--|
| No.                          |                                                                                     |                                                                  |       |       |       |       |       |       |       |                             |       |       |       |       |       |       | Control and Safety |       | Manufacturing and Maintenance |                             | Residual Risk Evaluation |                             |  |
|                              |                                                                                     |                                                                  |       |       |       |       |       |       |       |                             |       |       |       |       |       |       |                    |       |                               |                             |                          |                             |  |
| HA001                        | No definition<br>No hazard<br>No description<br>No impact<br>No effect<br>No result | How both<br>No definition<br>No hazard<br>No effect<br>No result |       |       |       |       |       |       |       |                             |       |       |       |       |       |       |                    |       |                               |                             |                          |                             |  |
| HA002                        | HA002                                                                               | HA002                                                            | HA002 | HA002 | HA002 | HA002 | HA002 | HA002 | HA002 | HA002                       | HA002 | HA002 | HA002 | HA002 | HA002 | HA002 | HA002              | HA002 | HA002                         | HA002                       | HA002                    | HA002                       |  |
| HA003                        | HA003                                                                               | HA003                                                            | HA003 | HA003 | HA003 | HA003 | HA003 | HA003 | HA003 | HA003                       | HA003 | HA003 | HA003 | HA003 | HA003 | HA003 | HA003              | HA003 | HA003                         | HA003                       | HA003                    | HA003                       |  |
| HA004                        | HA004                                                                               | HA004                                                            | HA004 | HA004 | HA004 | HA004 | HA004 | HA004 | HA004 | HA004                       | HA004 | HA004 | HA004 | HA004 | HA004 | HA004 | HA004              | HA004 | HA004                         | HA004                       | HA004                    | HA004                       |  |
| HA005                        | HA005                                                                               | HA005                                                            | HA005 | HA005 | HA005 | HA005 | HA005 | HA005 | HA005 | HA005                       | HA005 | HA005 | HA005 | HA005 | HA005 | HA005 | HA005              | HA005 | HA005                         | HA005                       | HA005                    | HA005                       |  |
| HA006                        | HA006                                                                               | HA006                                                            | HA006 | HA006 | HA006 | HA006 | HA006 | HA006 | HA006 | HA006                       | HA006 | HA006 | HA006 | HA006 | HA006 | HA006 | HA006              | HA006 | HA006                         | HA006                       | HA006                    | HA006                       |  |
| HA007                        | HA007                                                                               | HA007                                                            | HA007 | HA007 | HA007 | HA007 | HA007 | HA007 | HA007 | HA007                       | HA007 | HA007 | HA007 | HA007 | HA007 | HA007 | HA007              | HA007 | HA007                         | HA007                       | HA007                    | HA007                       |  |
| HA008                        | HA008                                                                               | HA008                                                            | HA008 | HA008 | HA008 | HA008 | HA008 | HA008 | HA008 | HA008                       | HA008 | HA008 | HA008 | HA008 | HA008 | HA008 | HA008              | HA008 | HA008                         | HA008                       | HA008                    | HA008                       |  |
| HA009                        | HA009                                                                               | HA009                                                            | HA009 | HA009 | HA009 | HA009 | HA009 | HA009 | HA009 | HA009                       | HA009 | HA009 | HA009 | HA009 | HA009 | HA009 | HA009              | HA009 | HA009                         | HA009                       | HA009                    | HA009                       |  |
| HA010                        | HA010                                                                               | HA010                                                            | HA010 | HA010 | HA010 | HA010 | HA010 | HA010 | HA010 | HA010                       | HA010 | HA010 | HA010 | HA010 | HA010 | HA010 | HA010              | HA010 | HA010                         | HA010                       | HA010                    | HA010                       |  |
| HA011                        | HA011                                                                               | HA011                                                            | HA011 | HA011 | HA011 | HA011 | HA011 | HA011 | HA011 | HA011                       | HA011 | HA011 | HA011 | HA011 | HA011 | HA011 | HA011              | HA011 | HA011                         | HA011                       | HA011                    | HA011                       |  |
| HA012                        | HA012                                                                               | HA012                                                            | HA012 | HA012 | HA012 | HA012 | HA012 | HA012 | HA012 | HA012                       | HA012 | HA012 | HA012 | HA012 | HA012 | HA012 | HA012              | HA012 | HA012                         | HA012                       | HA012                    | HA012                       |  |
| HA013                        | HA013                                                                               | HA013                                                            | HA013 | HA013 | HA013 | HA013 | HA013 | HA013 | HA013 | HA013                       | HA013 | HA013 | HA013 | HA013 | HA013 | HA013 | HA013              | HA013 | HA013                         | HA013                       | HA013                    | HA013                       |  |
| HA014                        | HA014                                                                               | HA014                                                            | HA014 | HA014 | HA014 | HA014 | HA014 | HA014 | HA014 | HA014                       | HA014 | HA014 | HA014 | HA014 | HA014 | HA014 | HA014              | HA014 | HA014                         | HA014                       | HA014                    | HA014                       |  |
| HA015                        | HA015                                                                               | HA015                                                            | HA015 | HA015 | HA015 | HA015 | HA015 | HA015 | HA015 | HA015                       | HA015 | HA015 | HA015 | HA015 | HA015 | HA015 | HA015              | HA015 | HA015                         | HA015                       | HA015                    | HA015                       |  |
| HA016                        | HA016                                                                               | HA016                                                            | HA016 | HA016 | HA016 | HA016 | HA016 | HA016 | HA016 | HA016                       | HA016 | HA016 | HA016 | HA016 | HA016 | HA016 | HA016              | HA016 | HA016                         | HA016                       | HA016                    | HA016                       |  |
| HA017                        | HA017                                                                               | HA017                                                            | HA017 | HA017 | HA017 | HA017 | HA017 | HA017 | HA017 | HA017                       | HA017 | HA017 | HA017 | HA017 | HA017 | HA017 | HA017              | HA017 | HA017                         | HA017                       | HA017                    | HA017                       |  |
| HA018                        | HA018                                                                               | HA018                                                            | HA018 | HA018 | HA018 | HA018 | HA018 | HA018 | HA018 | HA018                       | HA018 | HA018 | HA018 | HA018 | HA018 | HA018 | HA018              | HA018 | HA018                         | HA018                       | HA018                    | HA018                       |  |
| HA019                        | HA019                                                                               | HA019                                                            | HA019 | HA019 | HA019 | HA019 | HA019 | HA019 | HA019 | HA019                       | HA019 | HA019 | HA019 | HA019 | HA019 | HA019 | HA019              | HA019 | HA019                         | HA019                       | HA019                    | HA019                       |  |
| HA020                        | HA020                                                                               | HA020                                                            | HA020 | HA020 | HA020 | HA020 | HA020 | HA020 | HA020 | HA020                       | HA020 | HA020 | HA020 | HA020 | HA020 | HA020 | HA020              | HA020 | HA020                         | HA020                       | HA020                    | HA020                       |  |
| HA021                        | HA021                                                                               | HA021                                                            | HA021 | HA021 | HA021 | HA021 | HA021 | HA021 | HA021 | HA021                       | HA021 | HA021 | HA021 | HA021 | HA021 | HA021 | HA021              | HA021 | HA021                         | HA021                       | HA021                    | HA021                       |  |
| HA022                        | HA022                                                                               | HA022                                                            | HA022 | HA022 | HA022 | HA022 | HA022 | HA022 | HA022 | HA022                       | HA022 | HA022 | HA022 | HA022 | HA022 | HA022 | HA022              | HA022 | HA022                         | HA022                       | HA022                    | HA022                       |  |
| HA023                        | HA023                                                                               | HA023                                                            | HA023 | HA023 | HA023 | HA023 | HA023 | HA023 | HA023 | HA023                       | HA023 | HA023 | HA023 | HA023 | HA023 | HA023 | HA023              | HA023 | HA023                         | HA023                       | HA023                    | HA023                       |  |
| HA024                        | HA024                                                                               | HA024                                                            | HA024 | HA024 | HA024 | HA024 | HA024 | HA024 | HA024 | HA024                       | HA024 | HA024 | HA024 | HA024 | HA024 | HA024 | HA024              | HA024 | HA024                         | HA024                       | HA024                    | HA024                       |  |
| HA025                        | HA025                                                                               | HA025                                                            | HA025 | HA025 | HA025 | HA025 | HA025 | HA025 | HA025 | HA025                       | HA025 | HA025 | HA025 | HA025 | HA025 | HA025 | HA025              | HA025 | HA025                         | HA025                       | HA025                    | HA025                       |  |
| HA026                        | HA026                                                                               | HA026                                                            | HA026 | HA026 | HA026 | HA026 | HA026 | HA026 | HA026 | HA026                       | HA026 | HA026 | HA026 | HA026 | HA026 | HA026 | HA026              | HA026 | HA026                         | HA026                       | HA026                    | HA026                       |  |
| HA027                        | HA027                                                                               | HA027                                                            | HA027 | HA027 | HA027 | HA027 | HA027 | HA027 | HA027 | HA027                       | HA027 | HA027 | HA027 | HA027 | HA027 | HA027 | HA027              | HA027 | HA027                         | HA027                       | HA027                    | HA027                       |  |
| HA028                        | HA028                                                                               | HA028                                                            | HA028 | HA028 | HA028 | HA028 | HA028 | HA028 | HA028 | HA028                       | HA028 | HA028 | HA028 | HA028 | HA028 | HA028 | HA028              | HA028 | HA028                         | HA028                       | HA028                    | HA028                       |  |
| HA029                        | HA029                                                                               | HA029                                                            | HA029 | HA029 | HA029 | HA029 | HA029 | HA029 | HA029 | HA029                       | HA029 | HA029 | HA029 | HA029 | HA029 | HA029 | HA029              | HA029 | HA029                         | HA029                       | HA029                    | HA029                       |  |
| HA030                        | HA030                                                                               | HA030                                                            | HA030 | HA030 | HA030 | HA030 | HA030 | HA030 | HA030 | HA030                       | HA030 | HA030 | HA030 | HA030 | HA030 | HA030 | HA030              | HA030 | HA030                         | HA030                       | HA030                    | HA030                       |  |
| HA031                        | HA031                                                                               | HA031                                                            | HA031 | HA031 | HA031 | HA031 | HA031 | HA031 | HA031 | HA031                       | HA031 | HA031 | HA031 | HA031 | HA031 | HA031 | HA031              | HA031 | HA031                         | HA031                       | HA031                    | HA031                       |  |
| HA032                        | HA032                                                                               | HA032                                                            | HA032 | HA032 | HA032 | HA032 | HA032 | HA032 | HA032 | HA032                       | HA032 | HA032 | HA032 | HA032 | HA032 | HA032 | HA032              | HA032 | HA032                         | HA032                       | HA032                    | HA032                       |  |
| HA033                        | HA033                                                                               | HA033                                                            | HA033 | HA033 | HA033 | HA033 | HA033 | HA033 | HA033 | HA033                       | HA033 | HA033 | HA033 | HA033 | HA033 | HA033 | HA033              | HA033 | HA033                         | HA033                       | HA033                    | HA033                       |  |
| HA034                        | HA034                                                                               | HA034                                                            | HA034 | HA034 | HA034 | HA034 | HA034 | HA034 | HA034 | HA034                       | HA034 | HA034 | HA034 | HA034 | HA034 | HA034 | HA034              | HA034 | HA034                         | HA034                       | HA034                    | HA034                       |  |
| HA035                        | HA035                                                                               | HA035                                                            | HA035 | HA035 | HA035 | HA035 | HA035 | HA035 | HA035 | HA035                       | HA035 | HA035 | HA035 | HA035 | HA035 | HA035 | HA035              | HA035 | HA035                         | HA035                       | HA035                    | HA035                       |  |
| HA036                        | HA036                                                                               | HA036                                                            | HA036 | HA036 | HA036 | HA036 | HA036 | HA036 | HA036 | HA036                       | HA036 | HA036 | HA036 | HA036 | HA036 | HA036 | HA036              | HA036 | HA036                         | HA036                       | HA036                    | HA036                       |  |
| HA037                        | HA037                                                                               | HA037                                                            | HA037 | HA037 | HA037 | HA037 | HA037 | HA037 | HA037 | HA037                       | HA037 | HA037 | HA037 | HA037 | HA037 | HA037 | HA037              | HA037 | HA037                         | HA037                       | HA037                    | HA037                       |  |
| HA038                        | HA038                                                                               | HA038                                                            | HA038 | HA038 | HA038 | HA038 | HA038 | HA038 | HA038 | HA038                       | HA038 | HA038 | HA038 | HA038 | HA038 | HA038 | HA038              | HA038 | HA038                         | HA038                       | HA038                    | HA038                       |  |
| HA039                        | HA039                                                                               | HA039                                                            | HA039 | HA039 | HA039 | HA039 | HA039 | HA039 | HA039 | HA039                       | HA039 | HA039 | HA039 | HA039 | HA039 | HA039 | HA039              | HA039 | HA039                         | HA039                       | HA039                    | HA039                       |  |
| HA040                        | HA040                                                                               | HA040                                                            | HA040 | HA040 | HA040 | HA040 | HA040 | HA040 | HA040 | HA040                       | HA040 | HA040 | HA040 | HA040 | HA040 | HA040 | HA040              | HA040 | HA040                         | HA040                       | HA040                    | HA040                       |  |
| HA041                        | HA041                                                                               | HA041                                                            | HA041 | HA041 | HA041 | HA041 | HA041 | HA041 | HA041 | HA041                       | HA041 | HA041 | HA041 | HA041 | HA041 | HA041 | HA041              | HA041 | HA041                         | HA041                       | HA041                    | HA041                       |  |
| HA042                        | HA042                                                                               | HA042                                                            | HA042 | HA042 | HA042 | HA042 | HA042 | HA042 | HA042 | HA042                       | HA042 | HA042 | HA042 | HA042 | HA042 | HA042 | HA042              | HA042 | HA042                         | HA042                       | HA042                    | HA042                       |  |
| HA043                        | HA043                                                                               | HA043                                                            | HA043 | HA043 | HA043 | HA043 | HA043 | HA043 | HA043 | HA043                       | HA043 | HA043 | HA043 | HA043 | HA043 | HA043 | HA043              | HA043 | HA043                         | HA043                       | HA043                    | HA043                       |  |
| HA044                        | HA044                                                                               | HA044                                                            | HA044 | HA044 | HA044 | HA044 | HA044 | HA044 | HA044 | HA044                       | HA044 | HA044 | HA044 | HA044 | HA044 | HA044 | HA044              | HA044 | HA044                         | HA044                       | HA044                    | HA044                       |  |
| HA045                        | HA045                                                                               | HA045                                                            | HA045 | HA045 | HA045 | HA045 | HA045 | HA045 | HA045 | HA045                       | HA045 | HA045 | HA045 | HA045 | HA045 | HA045 | HA045              | HA045 | HA045                         | HA045                       | HA045                    | HA045                       |  |
| HA046                        | HA046                                                                               | HA046                                                            | HA046 | HA046 | HA046 | HA046 | HA046 | HA046 | HA046 | HA046                       | HA046 | HA046 | HA046 | HA046 | HA046 | HA046 | HA046              | HA046 | HA046                         | HA046                       | HA046                    | HA046                       |  |
| HA047                        | HA047                                                                               | HA047                                                            | HA047 | HA047 | HA047 | HA047 | HA047 | HA047 | HA047 | HA047                       | HA047 | HA047 | HA047 | HA047 | HA047 | HA047 | HA047              | HA047 | HA047                         | HA047                       | HA047                    | HA047                       |  |
| HA048                        | HA048                                                                               | HA048                                                            | HA048 | HA048 | HA048 | HA048 | HA048 | HA048 | HA048 | HA048                       | HA048 | HA048 | HA048 | HA048 | HA048 | HA048 | HA048              | HA048 | HA048                         | HA048                       | HA048                    | HA048                       |  |
| HA049                        | HA049                                                                               | HA049                                                            | HA049 | HA049 | HA049 | HA049 | HA049 | HA049 | HA049 | HA049                       | HA049 | HA049 | HA049 | HA049 | HA049 | HA049 | HA049              | HA049 | HA049                         | HA049                       | HA049                    | HA049                       |  |
| HA050                        | HA050                                                                               | HA050                                                            | HA050 | HA050 | HA050 | HA050 | HA050 | HA050 | HA050 | HA050                       | HA050 | HA050 | HA050 | HA050 | HA050 | HA050 | HA050              | HA050 | HA050                         | HA050                       | HA050                    | HA050                       |  |
| HA051                        | HA051                                                                               | HA051                                                            | HA051 | HA051 | HA051 | HA051 | HA051 | HA051 | HA051 | HA051                       | HA051 | HA051 | HA051 | HA051 | HA051 | HA051 | HA051              | HA051 | HA051                         | HA051                       | HA051                    | HA051                       |  |
| HA052                        | HA052                                                                               | HA052                                                            | HA052 | HA052 | HA052 | HA052 | HA052 | HA052 | HA052 | HA052                       | HA052 | HA052 | HA052 | HA052 | HA052 | HA052 | HA052              | HA052 | HA052                         | HA052                       | HA052                    | HA052                       |  |
| HA053                        | HA053                                                                               | HA053                                                            | HA053 | HA053 | HA053 | HA053 | HA053 | HA053 | HA053 | HA053                       | HA053 | HA053 | HA053 | HA053 | HA053 | HA053 | HA053              | HA053 | HA053                         | HA053                       | HA053                    | HA053                       |  |
| HA054                        | HA054                                                                               | HA054                                                            | HA054 | HA054 | HA054 | HA054 | HA054 | HA054 | HA054 | HA054                       | HA054 | HA054 | HA054 | HA054 | HA054 | HA054 | HA054              | HA054 | HA054                         | HA054                       | HA054                    | HA054                       |  |
| HA055                        | HA055                                                                               | HA055                                                            | HA055 | HA055 | HA055 | HA055 | HA055 | HA055 | HA055 | HA055                       | HA055 | HA055 | HA055 | HA055 | HA055 | HA055 | HA055              | HA055 | HA055                         | HA055                       | HA055                    | HA055                       |  |
| HA056                        | HA056                                                                               | HA056                                                            | HA056 | HA056 | HA056 | HA056 | HA056 | HA056 | HA056 | HA056                       | HA056 | HA056 | HA056 | HA056 | HA056 | HA056 | HA056              | HA056 | HA056                         | HA056                       | HA056                    | HA056                       |  |
| HA057                        | HA057                                                                               | HA057                                                            | HA057 | HA057 | HA057 | HA057 | HA057 | HA057 | HA057 | HA057                       | HA057 | HA057 | HA057 | HA057 | HA057 | HA057 | HA057              | HA057 | HA057                         | HA057                       | HA057                    | HA057                       |  |
| HA058                        | HA058                                                                               | HA058                                                            | HA058 | HA058 | HA058 | HA058 | HA058 | HA058 | HA058 | HA058                       | HA058 | HA058 | HA058 | HA058 | HA058 | HA058 | HA058              | HA058 | HA058                         | HA058                       | HA058                    |                             |  |



| Risikoanalyse - Risk Analysis             |                        |                                      |             |                                                                               |                    | Maßnahmen zur Risikosteuerung - Risk Control                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                |                                    |                               |                               |                               |                               |                               |                               |                               |                               |                               |                               |                               |
|-------------------------------------------|------------------------|--------------------------------------|-------------|-------------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|------------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| HA                                        | Definition des Risikos | Beschreibung des Schadens            | Schweregrad | Ursache des Risikos                                                           | Häufigkeit         | Maßnahmen zur Risikosteuerung                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Maßnahmen zur Risikosteuerung                  | Maßnahmen zur Risikosteuerung      | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung | Maßnahmen zur Risikosteuerung |
|                                           |                        |                                      |             |                                                                               |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                |                                    |                               |                               |                               |                               |                               |                               |                               |                               |                               |                               |                               |
| HA240                                     | Line voltage hazards   | Injury as a result of electric shock | disastrous  | Wrong design of the device                                                    | occasional         | There is a liquid storage chamber at the MedStar. The liquid is in a closed loop. Filling of water and overflow outside of the device. Overflow test according to IEC 60601-1, clause 11.5.2.<br>Type of liquid: BC4<br>Volumen: 150ml (15% of 1000ml)<br>Duration of spill: 1min<br>device: Shad through an angle of 15° in the least favourable direction starting from the position of NORMAL USE<br><br>After these procedures, the device is to pass the appropriate dielectric strength and leakage current tests | IEC 60601-1:2005 11.5.2 [TRF]                  | IEC 60601-1:2005 / EN 60601-1:2006 | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           |
| HA250                                     | Line voltage hazards   | Injury as a result of electric shock | disastrous  | Wrong design of the device                                                    | often              | Spillage on ME EQUIPMENT:<br>Closed housing system<br>Handling only with Ultrasound Gel (UG: Gel) in normal use<br>Spillage test according to IEC 60601-1, clause 11.5.3.<br><br>Type of liquid: BC4<br>Volumen: 200ml<br>Duration of spill: 1min<br>- silicon 5-ay (top of device)<br><br>Type of liquid: UG gel<br>Volumen: 10ml<br>Duration of spill: 1min<br>- tests with gel on hand piece<br><br>After these procedures, the device is to pass the appropriate dielectric strength and leakage current tests      | IEC 60601-1:2005 11.5.3 [TRF]<br>MDO 53-42 EEC | IEC 60601-1:2005 / EN 60601-1:2006 | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           |
| HA260                                     | Line voltage hazards   | Injury as a result of electric shock | disastrous  | Wrong design of the device                                                    | occasional         | Entry of liquid system<br>Drip test of all hose connections for simulating single fault condition (leaky seal)                                                                                                                                                                                                                                                                                                                                                                                                          | IEC 60601-1:2005 13.2.6 [TRF]<br>MDO 53-42 EEC | IEC 60601-1:2005 / EN 60601-1:2006 | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           |
| HA270                                     | Line voltage hazards   | Injury as a result of electric shock | disastrous  | Wrong device handling                                                         | hardly conceivable | Identify hazard due to incorrect connection of accessible connectors.<br>Following interfaces are identified:<br>- USB Interface<br>- Service Interface (PS2, Sub D)<br>- Mains Input<br>- Disinfectant<br>- Foot switch Interface<br>- protective earthing<br>- Handpiece Interface<br><br>Shape coding of the connectors. No risk of interchanging of the plugs by users, patients and third parties.<br><br>power sources have female connectors<br>unpowered applied parts have male connectors                     | IEC 60601-1:2005 15.4.1 [TRF]                  | IEC 60601-1:2005 / EN 60601-1:2006 | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           |
| HA280                                     | Line voltage hazards   | Injury as a result of electric shock | disastrous  | Entry of liquid(s) into the device. Entry of solid materials into the device. | hardly conceivable | Determination of the IP grade:<br>- IPX0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | IEC 60601-1:2005 11.6.5 [TRF]<br>MDO 53-42 EEC | IEC 60601-1:2005 / EN 60601-1:2006 | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           | Yes                           |
| 2.1.3 Short Circuit of insulation barrier |                        |                                      |             |                                                                               |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                |                                    |                               |                               |                               |                               |                               |                               |                               |                               |                               |                               |                               |



| Hazard Category: Fall Hazards |                                                                                          |                                                                           |          |                                                |            | Risk Assessment: Risk Control                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                           |    |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |      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| No.                           | Description of Hazard                                                                    | Med. Action: Accounting (Mechanical, Electrical, etc.)                    | S        | Consequence: Potential Severity of the Hazard  | A          | Exposure: Frequency of the Hazard                                                                                                                                                                                                                                                                                | Measures: Counter Measures                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | GM Manual                 | PA | PA 731 | PA 732 | PA 733 | PA 734 | PA 735 | PA 736 | PA 737 | PA 738 | PA 739 | PA 740 | PA 741 | PA 742 | PA 743 | PA 744 | PA 745 | PA 746 | PA 747 | PA 748 | PA 749 | PA 750 | PA 751 | PA 752 | PA 753 | PA 754 | PA 755 | PA 756 | PA 757 | PA 758 | PA 759 | PA 760 | PA 761 | PA 762 | PA 763 | PA 764 | PA 765 | PA 766 | PA 767 | PA 768 | PA 769 | PA 770 | PA 771 | PA 772 | PA 773 | PA 774 | PA 775 | PA 776 | PA 777 | PA 778 | PA 779 | PA 780 | PA 781 | PA 782 | PA 783 | PA 784 | PA 785 | PA 786 | PA 787 | PA 788 | PA 789 | PA 790 | PA 791 | PA 792 | PA 793 | PA 794 | PA 795 | PA 796 | PA 797 | PA 798 | PA 799 | PA 800 | PA 801 | PA 802 | PA 803 | PA 804 | PA 805 | PA 806 | PA 807 | PA 808 | PA 809 | PA 810 | PA 811 | PA 812 | PA 813 | PA 814 | PA 815 | PA 816 | PA 817 | PA 818 | PA 819 | PA 820 | PA 821 | PA 822 | PA 823 | PA 824 | PA 825 | PA 826 | PA 827 | PA 828 | PA 829 | PA 830 | PA 831 | PA 832 | PA 833 | PA 834 | PA 835 | PA 836 | PA 837 | PA 838 | PA 839 | PA 840 | PA 841 | PA 842 | PA 843 | PA 844 | PA 845 | PA 846 | PA 847 | PA 848 | PA 849 | PA 850 | PA 851 | PA 852 | PA 853 | PA 854 | PA 855 | PA 856 | PA 857 | PA 858 | PA 859 | PA 860 | PA 861 | PA 862 | PA 863 | PA 864 | PA 865 | PA 866 | PA 867 | PA 868 | PA 869 | PA 870 | PA 871 | PA 872 | PA 873 | PA 874 | PA 875 | PA 876 | PA 877 | PA 878 | PA 879 | PA 880 | PA 881 | PA 882 | PA 883 | PA 884 | PA 885 | PA 886 | PA 887 | PA 888 | PA 889 | PA 890 | PA 891 | PA 892 | PA 893 | PA 894 | PA 895 | PA 896 | PA 897 | PA 898 | PA 899 | PA 900 | PA 901 | PA 902 | PA 903 | PA 904 | PA 905 | PA 906 | PA 907 | PA 908 | PA 909 | PA 910 | PA 911 | PA 912 | PA 913 | PA 914 | PA 915 | PA 916 | PA 917 | PA 918 | PA 919 | PA 920 | PA 921 | PA 922 | PA 923 | PA 924 | PA 925 | PA 926 | PA 927 | PA 928 | PA 929 | PA 930 | PA 931 | PA 932 | PA 933 | PA 934 | PA 935 | PA 936 | PA 937 | PA 938 | PA 939 | PA 940 | PA 941 | PA 942 | PA 943 | PA 944 | PA 945 | PA 946 | PA 947 | PA 948 | PA 949 | PA 950 | PA 951 | PA 952 | PA 953 | PA 954 | PA 955 | PA 956 | PA 957 | PA 958 | PA 959 | PA 960 | PA 961 | PA 962 | PA 963 | PA 964 | PA 965 | PA 966 | PA 967 | PA 968 | PA 969 | PA 970 | PA 971 | PA 972 | PA 973 | PA 974 | PA 975 | PA 976 | PA 977 | PA 978 | PA 979 | PA 980 | PA 981 | PA 982 | PA 983 | PA 984 | PA 985 | PA 986 | PA 987 | PA 988 | PA 989 | PA 990 | PA 991 | PA 992 | PA 993 | PA 994 | PA 995 | PA 996 | PA 997 | PA 998 | PA 999 | PA 1000 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    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| HA213                         | Hazards due to insufficient function: injury of patient, operator or thirds persons fire | Insufficient function: injury of patient, operator or thirds persons fire | critical | Inadequate or faulty manufacturing and testing | occasional | Manufacturing and testing specifications under design development and change processes of ALT and standard's compliant verified and released. Effectiveness and appropriateness constantly monitored by continuously market observation and feedback by service, sales, supplier and other acc. to ALT OA system | GM Manual PA 731 PA 732 PA 733 PA 734 PA 735 PA 736 PA 737 PA 738 PA 739 PA 740 PA 741 PA 742 PA 743 PA 744 PA 745 PA 746 PA 747 PA 748 PA 749 PA 750 PA 751 PA 752 PA 753 PA 754 PA 755 PA 756 PA 757 PA 758 PA 759 PA 760 PA 761 PA 762 PA 763 PA 764 PA 765 PA 766 PA 767 PA 768 PA 769 PA 770 PA 771 PA 772 PA 773 PA 774 PA 775 PA 776 PA 777 PA 778 PA 779 PA 780 PA 781 PA 782 PA 783 PA 784 PA 785 PA 786 PA 787 PA 788 PA 789 PA 790 PA 791 PA 792 PA 793 PA 794 PA 795 PA 796 PA 797 PA 798 PA 799 PA 800 PA 801 PA 802 PA 803 PA 804 PA 805 PA 806 PA 807 PA 808 PA 809 PA 810 PA 811 PA 812 PA 813 PA 814 PA 815 PA 816 PA 817 PA 818 PA 819 PA 820 PA 821 PA 822 PA 823 PA 824 PA 825 PA 826 PA 827 PA 828 PA 829 PA 830 PA 831 PA 832 PA 833 PA 834 PA 835 PA 836 PA 837 PA 838 PA 839 PA 840 PA 841 PA 842 PA 843 PA 844 PA 845 PA 846 PA 847 PA 848 PA 849 PA 850 PA 851 PA 852 PA 853 PA 854 PA 855 PA 856 PA 857 PA 858 PA 859 PA 860 PA 861 PA 862 PA 863 PA 864 PA 865 PA 866 PA 867 PA 868 PA 869 PA 870 PA 871 PA 872 PA 873 PA 874 PA 875 PA 876 PA 877 PA 878 PA 879 PA 880 PA 881 PA 882 PA 883 PA 884 PA 885 PA 886 PA 887 PA 888 PA 889 PA 890 PA 891 PA 892 PA 893 PA 894 PA 895 |                           |    |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |         |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |      |
| HA214                         | Hazards due to insufficient function: injury of patient, operator or thirds persons fire | Insufficient function: injury of patient, operator or thirds persons fire | critical | Inadequate or faulty manufacturing and testing | occasional | Exclusive use of professionals (engineers, technicians)                                                                                                                                                                                                                                                          | Extensively trained personnel in a certified company with years of experience in manufacturing and testing of such technology.                                                                                                                                                                                                                                                                                                      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|                   |                                                      |                                              |                                                                                                                                                             |
|-------------------|------------------------------------------------------|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Form 7302         | Risk analysis and control acc. to EN ISO 14971: 2009 |                                              | <br><small>Asclepion</small><br><small>© 2009 The Asclepion Group</small> |
| Revision index: F | Identification number:                               | <b>RH/14/11/10-01</b>                        | FB 7302 RAaC MSPRO V03 RH141110-01                                                                                                                          |
|                   |                                                      | Member code/Year/month/day-sequential number |                                                                                                                                                             |

|                              |                   |   |                         |                          |                      |                                           |
|------------------------------|-------------------|---|-------------------------|--------------------------|----------------------|-------------------------------------------|
| Medical Product:             | <b>MeDioStar</b>  | X | MDD 93/42/EEC           | X                        | IEC 60 601-2-22:2007 | <input type="checkbox"/> before R&D       |
| Item number:                 | <b>1591/1592</b>  | X | IEC/ EN 60601-1:2006    | X                        | EN 60 825-1:2007     | <input type="checkbox"/> during R&D       |
| Assessed construction level: | <b>pre-series</b> | X | IEC/ EN 60 601-1-2:2007 | <input type="checkbox"/> | .....                | X after R&D                               |
| Revision user's Manual:      | 159099001-V06     | X | IEC/ EN 62304:2006      | <input type="checkbox"/> | .....                | X before serial production                |
|                              | 159099002-V06     | X | IEC/ EN 62366:2008      | <input type="checkbox"/> | .....                | <input type="checkbox"/> after production |

**Note:** The risk management of the device was carried out according to EN ISO 14971:2009. At present, an analysis of the implementation of EN ISO 14971:2012 is performed. For this purpose, a GAP analysis was performed to the previous made risk management.

Related documents:

Drawn up:

| Vs. | Description of change                                                                                          | Date          | Name     | Sign        |
|-----|----------------------------------------------------------------------------------------------------------------|---------------|----------|-------------|
| 01  | First edition: Initial version with risk analysis, first risk evaluation and proposal of risk control measures | Feb. 04, 2014 | M.Möller | sgd. Möller |
| 02  | update risk control / Counter Measures Implementation / Residual Risk Evaluation                               | Aug. 20, 2014 | M.Möller | sgd. Möller |
| 03  | updated Risk from inadequate controlled processes in design, manufacture and maintenance (chap.1)              | Nov. 10, 2014 | Herbst   | G. Cret     |

| Checked and released: | Division | Date          | Name      | Sign   |
|-----------------------|----------|---------------|-----------|--------|
| Participant 1         | Pen      | Nov. 11, 2014 | I. Streif | Streif |
| Participant 2         |          |               |           |        |
| Participant 3         |          |               |           |        |
| Released by           | Pen      | 11.11.14      | Thieme    | Thieme |

Grund für die letzte Änderung des FB: Neue Dokumentenstruktur mit Spreadsheet

Case of last modification form: new dokument structure with spread sheet

Formular erstellt durch FuE:

Form drawn by R&D:

Formular geprüft und genehmigt durch QM:

Form checked and released by QM:

|            |           |                         |            |           |                         |
|------------|-----------|-------------------------|------------|-----------|-------------------------|
| 06.06.2013 | I. Streit | gez. Streit             | 10.06.2013 | R. Thieme | gez. Thieme             |
| Datum/Date | Name      | Unterschrift/ Signature | Datum/Date | Name      | Unterschrift/ Signature |

File name: FB 7302 RAaC MSPRO V03 RH141110-01.xlsm

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wahlweise  
4070 XLHP  
4071 XLS  
4072 XLL

4073 CXS  
4074 CXL

wahlweise  
4020 HSST  
4021 HSVAS  
4022 HSHP  
4024 ALX 14x10

4023 COS  
4028 ALX 14x10

(153099024  
Aufkleber  
Laser Aperture Handstück)

(159099029  
Aufkleber Serien-Nr.)

660604120  
TiltWatch Plus

660604097  
Aufkleber Laser Not-Aus  
transparent

Kennzeichnung  
EIN / AUS auf  
Schlüsselschalter

Gerätefront

159199023  
Aufkleber MSPRO ETA 3120-F

C-C

159199024  
Schriftzug-Haube  
MSNeXT PRO (Standard HS)

Labelingzeichnung für MeDioStar NeXT<sup>PRO</sup> 1591, 1592, 1595

|                                                 |   |                                                                                       |       |                                                                                      |           |    |                                                                                       |               |              |    |
|-------------------------------------------------|---|---------------------------------------------------------------------------------------|-------|--------------------------------------------------------------------------------------|-----------|----|---------------------------------------------------------------------------------------|---------------|--------------|----|
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| -                                               | - | 01                                                                                    | 15124 | gednd. 660604115 in 660604116 (1,2E)                                                 |           |    |                                                                                       |               | 19.01.15     | MU |
| -                                               | - | INDEX                                                                                 |       | ANDER.                                                                               |           |    |                                                                                       |               | AM           | VO |
| -                                               | - | RoHS-konform                                                                          |       |                                                                                      |           |    |                                                                                       |               | Pro/ENGINEER |    |
| PASSMASSTOL.                                    |   |  |       | Maße werden bei Abnahme besonders geprüft                                            |           |    |                                                                                       | Werkst.: -    |              |    |
| FREI MASSTOL:                                   |   | WERKSTÜCKKANTEN<br>NACH DIN 6784                                                      |       | BEARB.                                                                               | 28-Oct-14 | KI |  | Seite 2 von 2 |              |    |
| ISO 2768<br>m K                                 |   | GEPR.                                                                                 |       | -                                                                                    | -         | -  |                                                                                       |               |              |    |
| OBERFLÄCHEN-<br>BESCHAFFENHEIT<br>NACH ISO 1302 |   | NORM                                                                                  |       | -                                                                                    | -         | -  |                                                                                       |               |              |    |
| MASSTAB:                                        |   | 3:10                                                                                  |       |                                                                                      | 159199020 |    | LABELING MSPRO                                                                        |               |              |    |



Anschluss für  
Master  
USB  
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EIN/AUS  
auf Schaltwippe

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Fußschalter  
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Zeichnung 159001003)

wahlweise  
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Laser-K14 MSPRO/EN  
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Schild Manufactured

wahlweise  
660604116 CE-Zeichen 0197  
für 1591/1592  
oder für MSPRO cos.  
660604108 CE-Zeichen  
für 1595

159199021  
Typschild MeDioStar (NeXTPRO)

159099036  
Aufkleber Seriennummer

660604036  
Aufkleber Potentialausgleich

## Geräterückseite

170199031  
Hinweisschild Anwendungsteil B  
nur für 1591/1592

159099038  
Aufkleber BC4 Rückw.

159099032  
Aufkleber Caution

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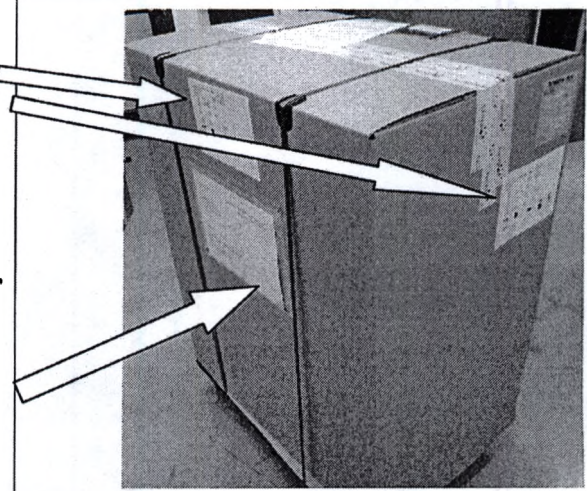
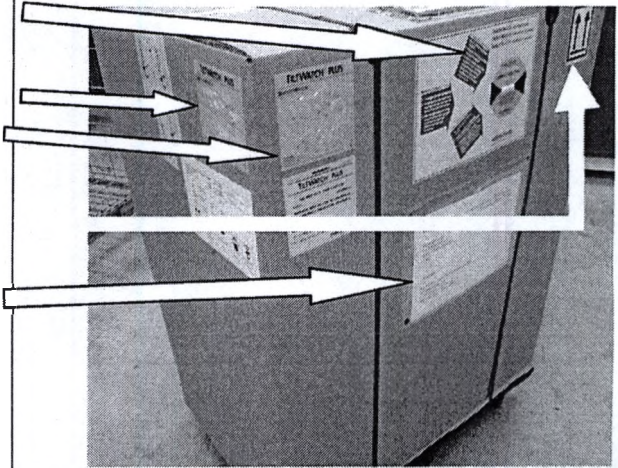
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Stecker POAG-S6/25

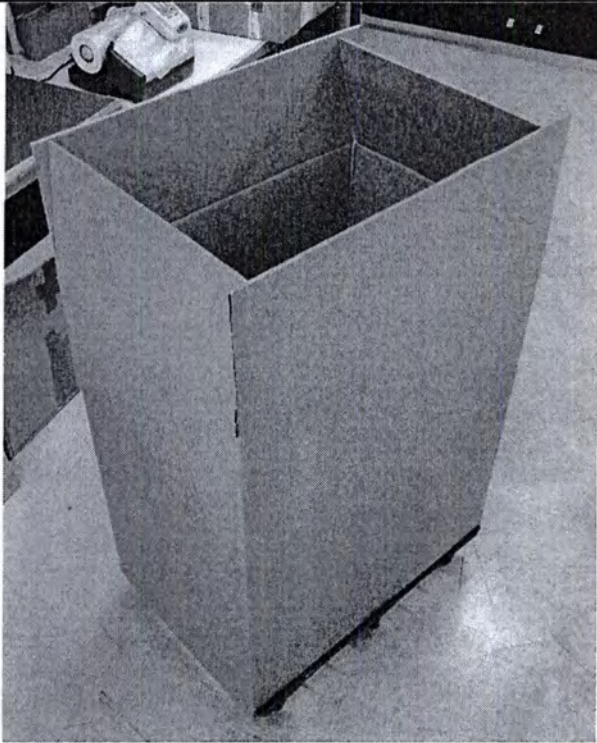
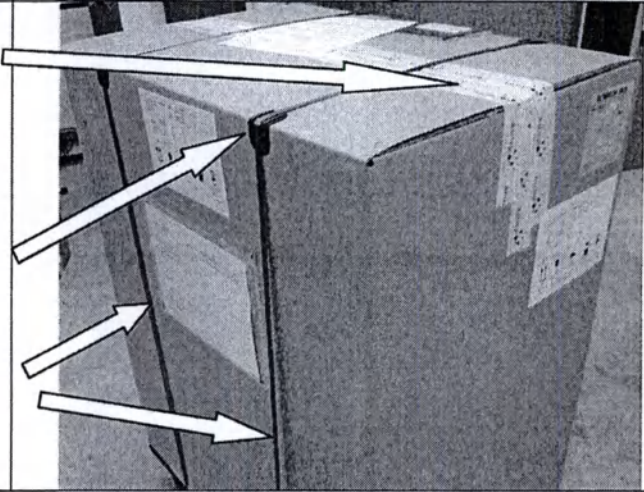
Labelingzeichnung für MeDioStar **NeXT<sup>PRO</sup>** 1591, 1592, 1595

|                                                 |   |                                                                                       |       |                                                                                      |           |                |                                                                                       |               |
|-------------------------------------------------|---|---------------------------------------------------------------------------------------|-------|--------------------------------------------------------------------------------------|-----------|----------------|---------------------------------------------------------------------------------------|---------------|
| -                                               | - | 02                                                                                    | 15136 | geänd. B12 159099028 in 159199023 (7,8A) nachg. (153099024) (1,2F), 660604120 (3,4C) |           |                | 02.04.15                                                                              | MJ            |
| -                                               | - | 01                                                                                    | 15124 | geänd. 660604115 in 660604116 (1,2E)                                                 |           |                | 19.01.15                                                                              | MJ            |
|                                                 |   | INDEX                                                                                 |       |                                                                                      | ÄNDER.    |                | AM                                                                                    | VON           |
| -                                               | - | RoHS-konform                                                                          |       |                                                                                      |           | Pro/ENGINEER   |                                                                                       |               |
| PASSMASSTOL.                                    |   |  |       | Maße werden bei Abnahme besonders geprüft                                            |           |                | Werkstf.:                                                                             | -             |
| FREIMASSTOL:                                    |   | WERKSTÜCKKANTEN<br>NACH DIN 6784                                                      |       | BEARB.                                                                               | 28-Oct-14 | KI             |  | Seite 1 von 2 |
| ISO 2768<br>m K                                 |   |                                                                                       |       | GEPR.                                                                                | -         | -              |                                                                                       |               |
|                                                 |   |                                                                                       |       | NORM                                                                                 | -         | -              |                                                                                       |               |
| OBERFLÄCHEN-<br>BESCHAFFENHEIT<br>NACH ISO 1302 |   | MASSTAB:<br>3:10                                                                      |       | 159199020                                                                            |           | LABELING MSPRO |                                                                                       |               |

|                            |                                                               |                    |                                                                                    |
|----------------------------|---------------------------------------------------------------|--------------------|------------------------------------------------------------------------------------|
| TP 7338/Änderungs-Index: C | <b>Verpackungsvorschrift</b><br><b>MeDioStar Familie 159x</b> |                    |  |
|                            | Dokumentennummer: <b>1590 08 004</b>                          | Version: <b>06</b> | Seite 9 von 9<br>159008004 PackInstruct MS 159x V06                                |

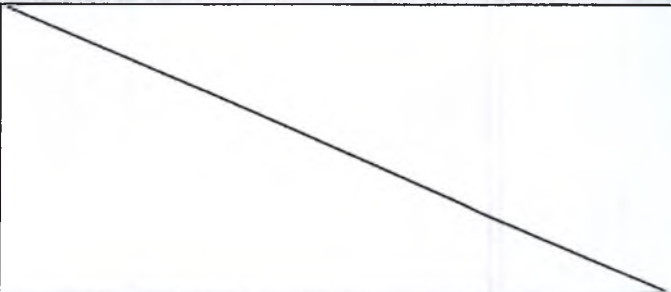
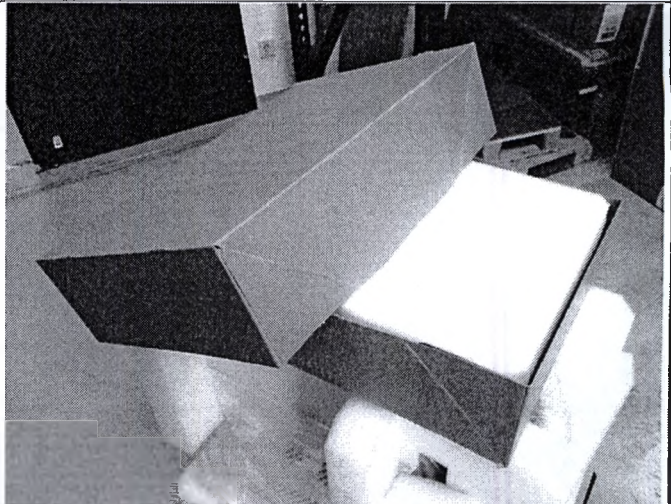
| MP       | Montagevorgang                                                                                                                                                                                                                                                                                                                                                                                                               | Bemerkung                                                                           |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>8</b> | <b>Abschließende Arbeiten / Aufkleber anbringen</b>                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     |
| 8.1      | <ul style="list-style-type: none"> <li>• 2x Aufkleber „Transportverpackung“ (817-3099-004) anbringen und Artikel- und Seriennummer des Gerätes mit wasserfestem Stift eintragen</li> </ul> <p style="text-align: center;"><b>Achtung!</b><br/>Für MOTUS LD Aufkleber „Transportverpackung MOTUS“ (815-9199-038) verwenden!</p> <ul style="list-style-type: none"> <li>• 1. Versandtasche (866-0805-260) anbringen</li> </ul> |   |
| 8.2      | <ul style="list-style-type: none"> <li>• Schocksensor (866-0604-029) anbringen</li> <li>• 2x Kippindikatoren (866-0604-031) über Eck anbringen und antackern</li> <li>• Aufkleber „Nicht Stürzen, Oben“ (866-0604-127) anbringen</li> <li>• 2. Versandtasche (866-0805-260) anbringen</li> </ul>                                                                                                                             |  |
| 8.3      | <ul style="list-style-type: none"> <li>• Bei Transport in Länder außerhalb Deutschlands sind gegebenenfalls länderspezifische Label nach AA 7756 zu beachten!</li> </ul>                                                                                                                                                                                                                                                     |                                                                                     |



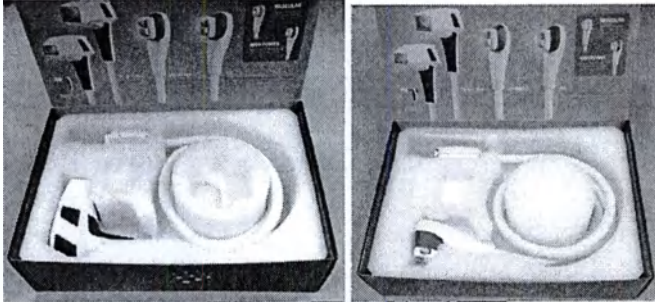
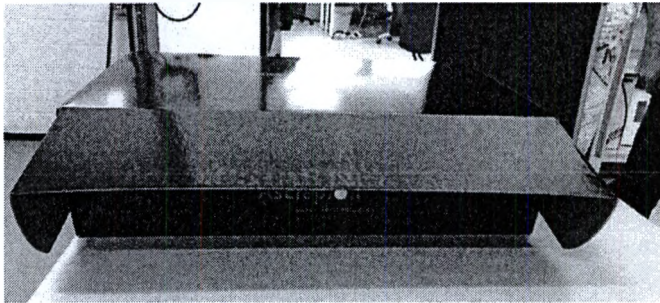
| MP | Montagevorgang                                                                                                                                                                                                                                                                                                                                                                           | Bemerkung                                                                                                                                                                   |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6  | <ul style="list-style-type: none"><li>- Umkarton (866-0805-247) überstülpen</li></ul>                                                                                                                                                                                                                                                                                                    | <br> |
| 7  | <p><b>Überkarton verschließen</b></p> <ul style="list-style-type: none"><li>- Überkarton mit Klebeband verschließen</li></ul> <p><b>Achtung!</b><br/>Für MOTUS LD nur neutrales oder „DEKA“-Klebeband verwenden!</p> <ul style="list-style-type: none"><li>- Kantenschutz mit Dornen anbringen</li><li>- Wände des Überkartons mittels WZ 1 mit 2 x Umreifungsband umschließen</li></ul> |                                                                                         |



|                            |                                                         |                    |                                                                                    |
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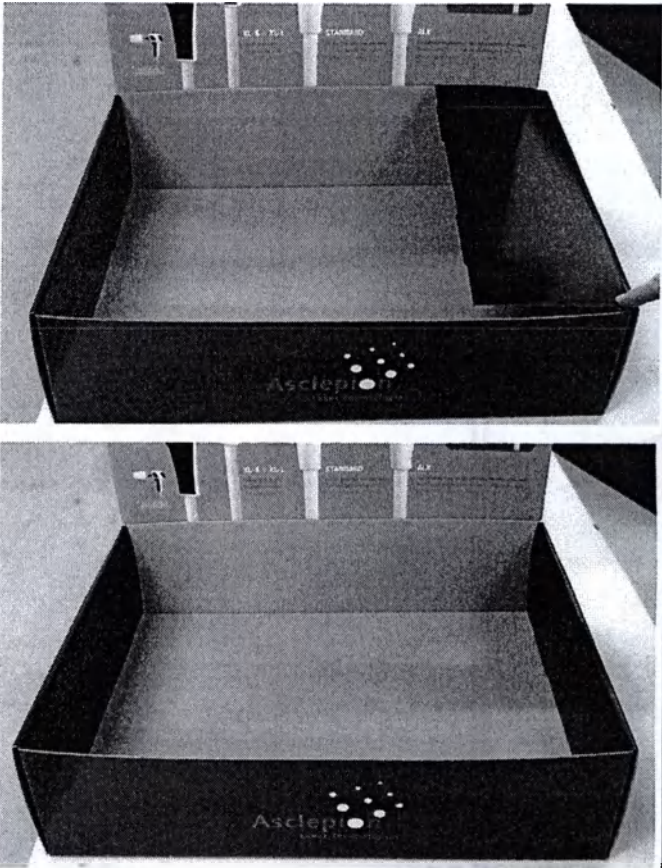
| MP      | Montagevorgang                                                                                                                                                                                                                                                                                                   | Bemerkung                                                                            |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 5.1.2.5 | - Umverpackung auf Gerät auflegen                                                                                                                                                                                                                                                                                |    |
| 5.2     | <b>Verpackung der Derivat-Handstücke 4060-4068 und 40709 (XL) für die Geräte:<br/>The Epi Lab/Pronto/Smoothpulse PRO</b>                                                                                                                                                                                         |                                                                                      |
| 5.2.1   | <ul style="list-style-type: none"> <li>- Faltkarton (866-0805-259) mit PE-Schaumeinsatz analog zu den Punkten: 5.1.2.1 – 5.2.2.5 falten und auf das Gerät legen</li> </ul> <p><b>Achtung:</b> XL Handstück für die Derivate (40709) ebenfalls im Handstück-Falbkarton der Derivate (866-0805-259) verpacken!</p> |  |
| 5.3     | <b>Handstück 4079 für die Geräte: MeDioStar PROmo und MOTUS LD</b>                                                                                                                                                                                                                                               |                                                                                      |
| 5.3.1   | <ul style="list-style-type: none"> <li>- neutralen Umkarton (ratioform: SA60) falten und Handstück 10x10 (4079) im PE-Einsatz (866-0805-218) einlegen</li> </ul>                                                                                                                                                 |  |

|                            |                                                               |                    |                                                                                    |
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|                            | Dokumentennummer: <b>1590 08 004</b>                          | Version: <b>06</b> | Seite 6 von 9<br>159008004 PackInstruct MS 159x V06                                |

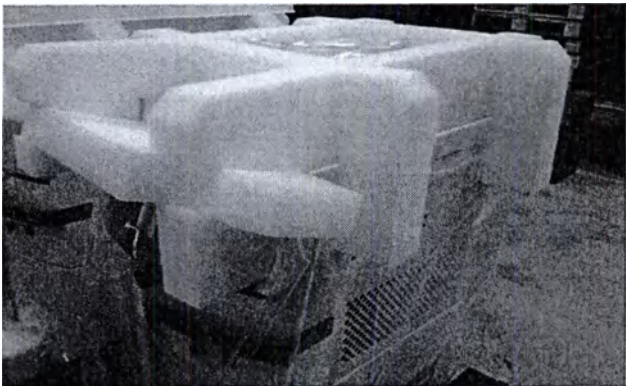
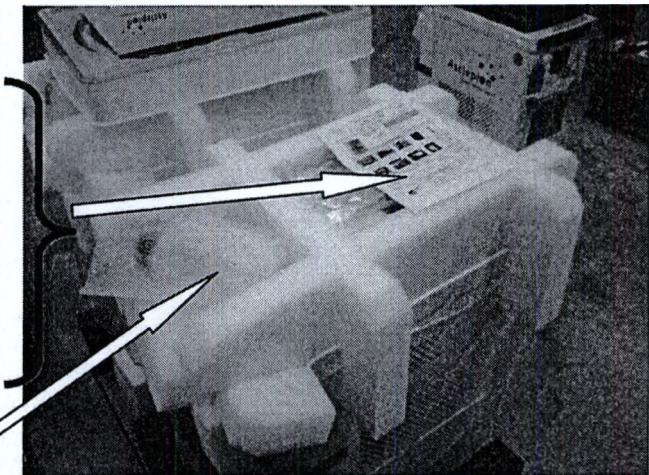
| MP      | Montagevorgang                                                                                                                                                                                                                                                                                                                                  | Bemerkung                                                                                                                                                                 |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.1.2.3 | <ul style="list-style-type: none"> <li>- PE-Schaumeinsatz inkl. Handstück in Umverpackung einlegen;</li> <li>- PE-Deckel auflegen</li> </ul> <p><b>Hinweis:</b></p> <ul style="list-style-type: none"> <li>- PE-Schaumeinsatz für 4070 XL-Handstück: 866-0805-218</li> <li>- PE-Schaumeinsatz für 4020-4028 Handstücke: 866-0805-258</li> </ul> |      |
| 5.1.2.4 | <ul style="list-style-type: none"> <li>- Deckel des Umkartons schließen und seitliche Führungspappen einführen</li> </ul>                                                                                                                                                                                                                       |   |



|                            |                                                               |                    |                                                                                                                              |
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| TP 7338/Änderungs-Index: C | <b>Verpackungsvorschrift</b><br><b>MeDioStar Familie 159x</b> |                    | <br><b>Asclepion</b><br>Laser Technologies |
|                            | Dokumentennummer: <b>1590 08 004</b>                          | Version: <b>06</b> | Seite 5 von 9<br>159008004 Packinstruct MS 159x V06                                                                          |

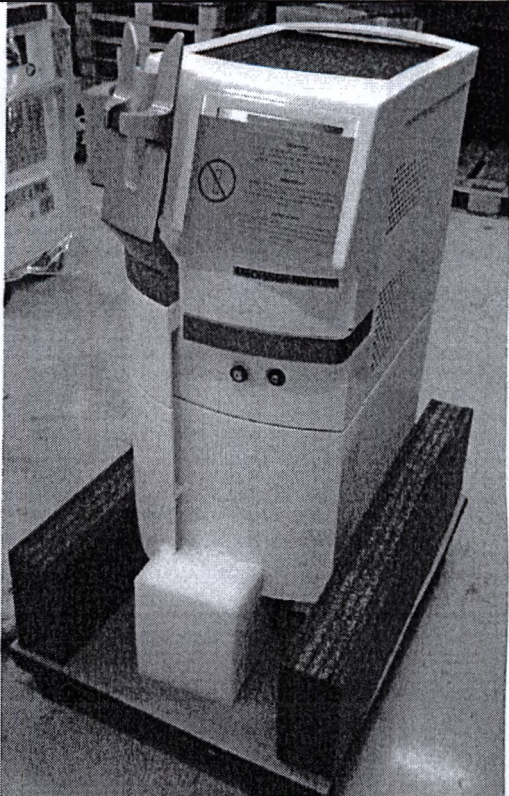
| MP      | Montagevorgang                                                                                                                                                                              | Bemerkung                                                                           |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 5.1.2   | <b>Schaumstoffverpackung mit Umkarton</b> (falls vorhanden)                                                                                                                                 |                                                                                     |
| 5.1.2.1 | <ul style="list-style-type: none"> <li>- vordere Seitenwand und hintere Seitenwand mit Deckel von Karton der Umverpackung (866-0805-221) hochklappen und Seitenflanken einfallen</li> </ul> |   |
| 5.1.2.2 | <ul style="list-style-type: none"> <li>- Seitenwände umklappen und in Bodenfläche einrasten</li> </ul>                                                                                      |  |



| MP      | Montagevorgang                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Bemerkung                                                                            |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 3       | <ul style="list-style-type: none"><li>- Oberes Schaumteil (866-0805-246) gemäß Abbildung lagerichtig aufsetzen</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                  |    |
| 4       | <p>Zubehör gemäß zugehöriger Pack- und Übergabeliste <u>und</u> Kundenauftrag verpacken. Diese enthalten zum Beispiel:</p> <ul style="list-style-type: none"><li>- Klappfußschalter</li><li>- ggf. Laserschutzbrille(n), Patientenaugenschutz</li><li>- Netzkabel, Schlüssel, Door-Interlock und Touchstick in Luftpolsterfolie verpacken</li><li>- Kühlflüssigkeit und PE-Schlauch</li><li>- Kopie Pack- und Übergabeliste hinzufügen</li><li>- Starting Kit</li><li>- Befüllset in Luftposter-Folie verpacken</li></ul> |   |
| 5       | <b>Verpackung der Handstücke</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                      |
| 5.1     | <b>Verpackung der Handstücke 4020-4028 (z.B. ST, VAS, HP) und 4070 (XL) in Blister- oder Schaumstoffverpackung</b>                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                      |
| 5.1.1   | <b>Blisterverpackung</b> (falls vorhanden)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                      |
| 5.1.1.1 | <ul style="list-style-type: none"><li>- Handstück in Blister (866-0805-181; 866-0805-192) auf Gerät auflegen</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                    |  |



|                            |                                                               |                    |                                                                                                                                             |
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|                            | Dokumentennummer: <b>1590 08 004</b>                          | Version: <b>06</b> | Seite 3 von 9<br><small>159008004 PackInstruct MS 159x V06</small>                                                                          |

| MP | Montagevorgang                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Bemerkung                                                                            |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 1  | <ul style="list-style-type: none"> <li>- Verpackung MeDioStar (826-0900-000) bereitstellen (besteht aus Palette, Pappzuschnitt, Seitenfaltbeutel, Überkarton, Schaumteilsatz und Label)</li> <li>- Unteres Schaumteil (866-0805-245) auf Pappzuschnitt legen</li> <li>- Gerät auf Schaumteil stellen - dabei <u>nicht über 20° neigen!</u></li> <li>- sofern noch nicht vorhanden Hinweisschild (1590-99-046) „12h warten vor Einschalten NeXT“ auf Display kleben</li> </ul> |   |
| 2  | <ul style="list-style-type: none"> <li>- Seitenfaltbeutel (866-0805-226) über Gerät ziehen</li> </ul>                                                                                                                                                                                                                                                                                                                                                                         |  |

|                            |                                                         |                                                                                    |
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| TP 7338/Änderungs-Index: C | <b>Verpackungsvorschrift<br/>MeDioStar Familie 159x</b> |  |
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| Montagevoraussetzungen        |                                  |
|-------------------------------|----------------------------------|
| Werkzeuge und Hilfsmittel:    |                                  |
| Lfd.-Nr.                      | Benennung                        |
| Werkzeug                      |                                  |
| 1                             | WZ 1 Spannbandschweißvorrichtung |
| Hilfsmittel                   |                                  |
|                               | keine                            |
| Verwendete Abkürzungen:       |                                  |
|                               | Siehe QM-Handbuch                |
| Spezielle Montagebedingungen: |                                  |
|                               | Keine speziellen Anforderungen   |



|                            |                                                         |                    |                                                                                     |
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| <b>Verpackungsvorschrift für die Geräte der MeDioStar-Familie einschließlich Komponenten und Zubehör für LKW- und Luft-Transport</b>                                                                                                                          |                        |                           |          |                    |        |                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---------------------------|----------|--------------------|--------|-----------------|
| Gerätebezeichnung<br>gem. Typschild                                                                                                                                                                                                                           | MeDioStar              |                           | MOTUS LD | The Epi Lab        | Pronto | SmoothPulse PRO |
|                                                                                                                                                                                                                                                               | (NeXT <sup>PRO</sup> ) | (NeXT <sup>PROneo</sup> ) |          |                    |        |                 |
| Artikelnummer                                                                                                                                                                                                                                                 | 1591<br>1592<br>1595   | 15912                     | 15913    | 15911<br><br>15951 | 15921  | 15922           |
| <u>Verteiler:</u> Fertigung<br>Vertrieb<br>Service<br>Entwicklung<br><br><u>Montageort:</u> Fertigung Warenausgang / Logistik<br>Servicebereich<br>Kundenräume<br><br><u>Mitgeltende</u><br><u>Unterlagen:</u> DMR-Index 1591 08 010<br>DMR-Index 1595 08 010 |                        |                           |          |                    |        |                 |

erstellt:

| Vs. | Kurzbeschreibung der Änderung                                                                                                                                                  | Datum      | Name     | Unterschrift                                                                          |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|----------|---------------------------------------------------------------------------------------|
| 06  | Aktualisierung Abbildungen und Verpackungsablauf, Umverpackung für MS Derivate hinzu, Label Begrenzte Menge und Ausrichtungspfeile hinzu, gültige Gerätevarianten aktualisiert | 23.05.2016 | T. Kloss |  |

Prüfung und Freigabe:

|                   | Bereich | Datum      | Name         | Unterschrift                                                                          |
|-------------------|---------|------------|--------------|---------------------------------------------------------------------------------------|
| Geprüft durch     | FuE     | 23.05.2016 | A. Winter    |  |
| Freigegeben durch | F       | 24.05.2016 | R. Schließer |  |

### A.3 Recommended protection distances

Recommended separation distances between portable and mobile RF communications equipment and the MeDioStar according to IEC 60 601-1-2.

The MeDioStar is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MeDioStar can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MeDioStar as recommended below, according to the maximum output power of the communications equipment

| Transmitter frequency                  | 150 kHz to 80 MHz                           | 80 MHz to 800 MHz                           | 800 MHz to 2.5 GHz                        |
|----------------------------------------|---------------------------------------------|---------------------------------------------|-------------------------------------------|
| Equation                               | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$ | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$ | $d = \left[ \frac{7}{3} \right] \sqrt{P}$ |
| Rated output of the transmitter (Watt) | Protection distance (meter)                 | Protection distance (meter)                 | Protection distance (meter)               |
| 0.01                                   | 0.12                                        | 0.12                                        | 0.23                                      |
| 0.1                                    | 0.37                                        | 0.37                                        | 0.74                                      |
| 1                                      | 1.17                                        | 1.17                                        | 2.33                                      |
| 10                                     | 3.70                                        | 3.70                                        | 7.37                                      |
| 100                                    | 11.70                                       | 11.70                                       | 23.30                                     |

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The MeDioStar is intended for use in the electromagnetic environment specified below. The customer and/or the user of the MeDioStar should assure that it is used in an electromagnetic environment as described below.

| Immunity test                                          | Test level acc.<br>IEC 60601-1-2        | Compliance<br>level | Electromagnetic environment guidelines                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--------------------------------------------------------|-----------------------------------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Conducted<br>HF interferences acc.<br>to IEC 61000-4-6 | 3 V <sub>eff</sub><br>150 kHz to 80 MHz | 3V                  | Portable and mobile RF communications equipment should be used no closer to any part of the MeDioStar, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance:<br>$d = \left[ \frac{3,5}{3V} \right] \sqrt{P}$                                                                                                                                                                                                                                                                                                                                                                                                    |
| Radiated<br>HF interferences acc.<br>to IEC 61000-4-3  | 3 V/m<br>80 MHz to 2.5 GHz              | 3 V/m               | $d = \left[ \frac{3,5}{3} \right] \sqrt{P} \quad \text{for 80 MHz to 800 MHz}$<br>$d = \left[ \frac{7}{3} \right] \sqrt{P} \quad \text{for 800 MHz to 2,5 GHz}$<br>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br> |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MeDioStar is used exceeds the applicable RF compliance level above, the MeDioStar should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MeDioStar.

<sup>b</sup> Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.



## A.2 Electromagnetic interference immunity

The MeDioStar is intended for use in the electromagnetic environment specified below. The customer and/or the user of the MeDioStar should assure that it is used in an electromagnetic environment as described below.

| Immunity test                                                                                            | Test level acc. IEC 60601-1-2                                                                                                                                                                   | Compliance level             | Electromagnetic environment guidelines                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD) acc. to IEC 61000-4-2                                                      | +/- 6 kV contact charge<br>+/- 8 kV air discharge                                                                                                                                               | +/- 6kV<br>+/- 8kV           | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.                                                                                                                                  |
| Electrical fast transient / bursts acc. to IEC 61000-4-4                                                 | +/- 2 kV for power supply lines<br>+/- 1 kV for input/output lines                                                                                                                              | +/- 2kV<br>+/- 1kV           | Mains power quality should be that of a typical commercial and/or hospital environment.                                                                                                                                                                                          |
| Surges acc. to IEC 61000-4-5                                                                             | +/- 1 kV line(s) to line(s)<br>+/- 2 kV line(s) to earth                                                                                                                                        | +/- 1kV<br>+/- 2kV           | Mains power quality should be that of a typical commercial and/or hospital environment.                                                                                                                                                                                          |
| Voltage dips, short interruptions and voltage variations on power supply input lines acc. IEC 61000-4-11 | < 5 % $U_T$ for 0.5 cycle (> 95 % dip in $U_T$ )<br>40 % $U_T$ for 5 cycles (60 % dip in $U_T$ )<br>70 % $U_T$ for 25 cycles (30 % dip in $U_T$ )<br>< 5 % $U_T$ for 5 s (> 95 % dip in $U_T$ ) | < 5 %<br>40%<br>70%<br>< 5 % | Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60Hz) magnetic field acc. to IEC 61000-4-8                                           | 3 A/m                                                                                                                                                                                           | 3 A/m                        | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.                                                                                                                                    |
| Note: $U_T$ is the a.c. mains voltage prior to application of the test level                             |                                                                                                                                                                                                 |                              |                                                                                                                                                                                                                                                                                  |



#### Important information

For the MeDioStar the following essential performance features of EMC are determined:

- independent leaving of the preset operating mode
- independent change of the preselected output energy
- independent (unintentional) release of output power

### A.1 Electromagnetic interference emissions

The MeDioStar is intended for use in the electromagnetic environment specified below. The customer and/or the user of the MeDioStar should assure that it is used in an electromagnetic environment as described below.

| Emissions measurement                                                   | Compliance   | Electromagnetic environment guidelines                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF emissions<br>to CISPR 11                                             | Group 1      | The MeDioStar uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.                                                                                                                                                                                     |
| RF emissions<br>according to CISPR 11                                   | Class B      | The MeDioStar is suitable for use in all establishments, including domestic establishments and those directly connected to the public power supply network that supplies buildings used for domestic purposes.                                                                                                                                                         |
| Harmonics emissions<br>according to IEC 61000-3-2                       | Class A      | For harmonics:<br><br>The MeDioStar is intended for use in all establishments, including domestic establishments and those directly connected to the public power supply network that also supplies buildings used for domestic purposes                                                                                                                               |
| Voltage fluctuations / flickers emissions<br>according to IEC 61000-3-3 | Complies 1*) | For flickers:<br><br>During operation an influence of the supply network cannot be absolutely excluded. If necessary, it is to be ensured – after consultation with the energy supplier- that the max. admissible grid impedance<br><br>$Z_{max} = 0,1753 \text{ Ohm}$ (for MeDioStar 1590)<br>$Z_{max} = 0,3911 \text{ Ohm}$ (for MeDioStar 1591)<br>is not exceeded. |

1\*) acc. to IEC 61000-3-11:2000 with max. allowed impedance of the power grid of:

$Z_{max} = 0.1753 \text{ Ohm}$  (MeDioStar 1590).

$Z_{max} = 0.3911 \text{ Ohm}$  (MeDioStar 1591).



## A Appendix: EMC declaration



### Important information

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the device as replacement parts for internal components, may result in increased emissions or decreased immunity of the device.

| Device model                                                | Description                                                                 |
|-------------------------------------------------------------|-----------------------------------------------------------------------------|
| MeDioStar, item no. 1590<br>(brand name: MeDioStar NeXT)    | High power diode laser (main unit)<br>Note: for handpieces ST, HP, VAS only |
| MeDioStar, item no. 1591<br>(brand name: MeDioStar NeXTPRO) | High power diode laser (main unit)<br>Note: for all handpieces suited       |

| Accessory / designation                   | Item no.              | Length / dimensions |
|-------------------------------------------|-----------------------|---------------------|
| Foot switch with cable                    | 6608 06 008           | < 3.0 m             |
| Cold device supply line                   | 5507 04 013           | < 3.0 m             |
| Door-Interlock-Plug                       | 1601 01 078           | -                   |
| Handpiece ST                              | 4020 00 000           | < 3.0 m             |
| Handpiece VAS                             | 4021 00 000           | < 3.0 m             |
| Handpiece HP                              | 4022 00 000           | < 3.0 m             |
| Handpiece with laser tip XLS <sup>1</sup> | 4070 with 4071 00 000 | < 3.0 m             |
| Handpiece with laser tip XLL <sup>1</sup> | 4070 with 4072 00 000 | < 3.0 m             |

Note: The MeDioStar 1590 may be used with all accessory specified above, except the accessories marked with (1).  
The MeDioStar 1591 may be used with all accessory specified above



### Important information

This device is subject to special terms of network connections. The maximally allowed impedance of the power grid is:

$Z_{\max} = 0,1753 \text{ Ohm}$  for MeDioStar 1590 and

$Z_{\max} = 0.3911 \text{ Ohm}$  for MeDioStar 1591 at the power supply point.

If necessary, the local energy supplier is to be contacted to ensure that the device will be plugged in a supply which has an impedance lower or equal  $Z_{\max}$ .



### Important information

The use of the accessory, transducer or cable with other medical electrical equipment than the MeDioStar specified may result in increased emissions or decreased immunity of the equipment/ system.



### Important information

The equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.



**Asclepion**  
Laser Technologies

## EG-Konformitätserklärung

### EC Declaration of Conformity

**Asclepion Laser Technologies GmbH**  
Brüsseler Straße 10  
07747 Jena  
Germany

Wir erklären hiermit die Übereinstimmung des Mediosstar Produktes  
mit der EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II

(Benannte Stelle: TÜV Rheinland LGA Products GmbH, Tüftstraße 2, 90431 Nürnberg, Nr. 0197;  
Registrierenummer HD 60105768 0001.)

Durch nicht von der Asclepion Laser Technologies GmbH autorisierte Änderungen an diesem Produkt  
verliert diese Erklärung ihre Gültigkeit.

with the requirements of the European Council Directive 93/42/EEC Annex II  
(notified body: TÜV Rheinland LGA Products GmbH, Tüftstr. 2, 90431 Nürnberg, no. 0197;  
registration no. HD 60105768 0001)

Any modification to the product, not authorized by Asclepion Laser Technologies GmbH, will invalidate  
this declaration.

Zugrundeliegende Konformitätsakte/ underlying technical file: ALT 02/10

Harmonisierte Normen/ Harmonized Standards:  
Grundlegende Anforderungen nach RL 93/42/EWG Anhang I mit allen zutreffenden harmonisierten  
Normen.

Essential requirements of Directive 93/42/EEC, Annex I with all relevant harmonized standards.

Jena, December 31st 2015  
Asclepion Laser Technologies GmbH

  
**Peter Amann**  
Technical Director

Diese Erklärung ist gültig bis: 2020-12-02  
This declaration is valid until:

**Mediosstar**

ALT-Artikel-Nr./ALT-commodity no.: 1590

Klassifizierung/Classification:  
Klasse II gemäß 93/42/EWG Anhang IX  
Class II according to 93/42/EEC Annex IX

## 14 EC declaration of conformity – copy

The declarations of conformity are issued for a limited time. Please consult our Technical Customer Service if you need the actual version.



**EG-Konformitätserklärung**  
**EC Declaration of Conformity**

**Asclepion Laser Technologies GmbH**  
Brüsseler Straße 10  
07747 Jena  
Germany

Wir erklären hiermit die Übereinstimmung des Medizinproduktes  
*We declare the compliance of the medical device*

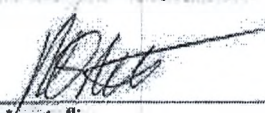
**MeDioStar**

|                                    |                                                                                     |
|------------------------------------|-------------------------------------------------------------------------------------|
| ALT-Artikel-Nr./ALT-commodity no.: | 1591; 1592                                                                          |
| Klassifizierung/classification:    | Klasse II b gemäß 93/42/EWG Anhang IX<br>Class II b according to 93/42/EEC Annex IX |

mit der EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II  
(Benannte Stelle: „TÜV Rheinland LGA Products GmbH“, Tillystraße 2, 90431 Nürnberg, Nr. 0197;  
Registriernummer HD 60105768 0001 ).  
Durch nicht von der Asclepion Laser Technologies GmbH autorisierte Änderungen an diesem Produkt  
verliert diese Erklärung ihre Gültigkeit.

*with the requirements of the Medical Devices 93/42/EEC Annex II  
(notified body: „TÜV Rheinland LGA Products GmbH“, Tillystr. 2, 90431 Nürnberg, no. 0197;  
registration no. HD 60105768 0001).*  
*Any modification to the product, not authorized by Asclepion Laser Technologies GmbH, will invalidate  
this declaration.*

Zugrundeliegende Konformitätsakte/ underlying technical file: ALT M 03/14  
Harmonisierte Normen/ Harmonized Standards:  
Grundlegende Anforderungen nach RL 93/42/EWG Anhang I mit allen zutreffenden harmonisierten  
Normen.  
*Essential requirements of Directive 93/42/EEC, Annex I with all relevant harmonized standards.*

Jena, December 3<sup>rd</sup> 2015  
Asclepion Laser Technologies GmbH  
i.V.,  
  
Pietro Amatulli  
Technical Director

Diese Erklärung ist gültig bis:  
*This declaration is valid until:* 2020-12-02

## 13 Disposal

The device must be disposed of in accordance with the directive 2012/19/EU of the European Council for Waste Electrical and Electronic Equipment [WEEE].



### WARNING

During treatment the handpieces are in contact to the uninjured skin of the patient. There is the danger of microorganisms being transferred.

Before disposal according to the acts stated above, the handpieces must be cleaned and disinfected!

Please consult our Technical Customer Service if you have any questions regarding disposal.



The tests should be run in the specified order:

- Visual inspection of laser device and accessories
- Measurement of protective earth resistance
- Measurement of leakage currents
- Measurement of insulation resistance
- Functional test

Additionally to be performed:

- Measurement of the actual output power of the laser modules at the handpiece or other application parts; adjustment of laser power, if necessary



**Tip**

Contact your dealer or Asclepion Laser Technologies GmbH directly for detailed specifications on the scope and implementation of the visual inspection.

**Additional information**

On request, the manufacturer can provide circuit diagrams, bills of material, descriptions, calibration instructions or other information not contained in the user manual to support appropriately skilled technical personnel with repairing parts of the device that have been deemed reparable by the manufacturer. "Appropriately skilled technical personnel" in this context is defined as personnel that have completed service training at the manufacturer's facilities and have been authorized to repair this device.



#### WARNING

Liquid and vapor of BC4 are flammable and cause severe eye irritation.

BC 4 must be kept away from heat, hot surfaces, sparks, open flames and other ignition sources. It cannot be allowed to smoke and the box containing BC 4 shall be kept closed as long as possible. **In particular, after transfilling and filling the device with BC 4, the vapor must be removed thoroughly by ventilation before the laser is activated!**

During transfilling and filling of BC 4 an eye protection / face protection must be used.

In case the eyes were in contact with the liquid or vapor of BC 4 besides the precautions, the eyes must be rinsed cautiously for several minutes. If present and easy to do, contact lenses must be removed. Continue with rinsing. In case the eye irritation persists, an eye specialist must be consulted.

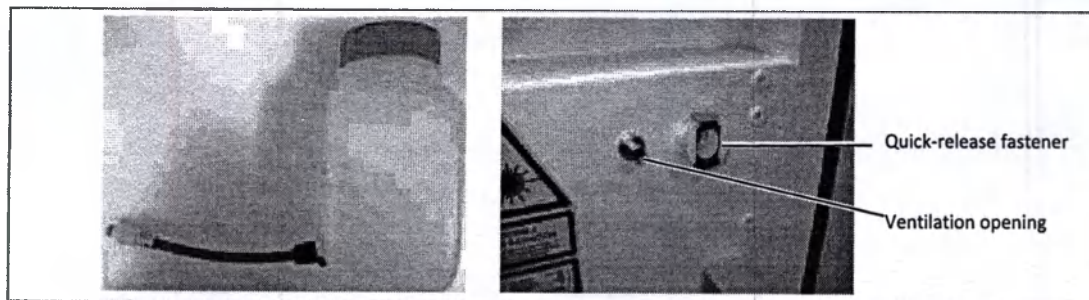


Figure 53: Filling set (left), quick-release fastener (right)

The coolant has to be re-filled as described below if a corresponding message appears on the display or at the latest after 1-2 months.

- Switch off the device
- Fill the bottle of the Filling Set up to about two-thirds with coolant
- Remove the protective cap from the ventilation opening (Luer Lock, on the backside of the device)
- Connect the transparent hose to the Luer Lock and put the other end into a glass with water that can hold some of the coolant. The tube must be in the water.
- Connect the quick-release fastener of the blue hose to the counterpart by pushing it until it snaps in
- The top of the bottle must be open
- The coolant must be carefully filled until no more air bubbles come back out of the ventilation opening, but coolant only (to see in the water of the glass)
- Disconnect the blue hose from the device by unlocking (pressing) both contact of the quick release
- Switch on the device to check whether the message to fill the coolant is still displayed
- If it is no longer displayed, the process is complete
- If this message continues to be displayed (not enough coolant was filled due to air bubbles), repeat the procedure. It can be helpful to lift a bit the left side of the front of the device (seen from the front) by underlaying an object, which is about 1-2cm thick (e.g. the top of the bottle).
- Close the ventilation opening again using the protective cap

## 12.2 Regular safety checks

### SCOPE OF THE ANNUAL SAFETY CHECKS

At least the checks listed below have to be performed according to the legal requirements in their currently valid version as well as to the international standard for Medical Electrical Equipment – recurrent test and test after repair of medical electrical equipment (IEC 62353).



#### Important information

Asclepion Laser Technologies grants a one-year warranty for the device. The warranty can be extended if you fill out a short-term registration on our website.

The carefully performed cleaning and repair as described in the chapter *Cleaning and disinfection* and in this chapter, ensures a long lifespan of your device.

The maximum number of pulses can be limited depending on the handpiece version.

Improper handling during operation, maintenance, safety checks or calibration may void the warranty. For any questions not answered in this manual, contact your customer service representative (see chapter *Customer service*).

Annual inspection of the device is required for granting the extended warranty.

Wear parts are not covered by the warranty. A current list of wear parts can be requested from the customer service department.

## 12.1 Routine maintenance

The routine maintenance described below must be carried out by hospital or clinic personnel:

#### Inspection of the outside of the device

Make sure that all cable connections are undamaged and plugged in securely.

Frequency: Weekly

Inspection by: Hospital or clinic personnel

#### Inspection of the cooling system

Make sure that all of the cooling system's ventilation grilles are free.

Frequency: Weekly

Inspection by: Hospital or clinic personnel

#### Inspection of the handpiece

Check whether the handpiece is in proper condition.

Frequency: Before each use

Inspection by: User of the device



#### Important information

Several reminders will appear on the display before the end of the connected handpiece's lifetime is reached (based on the handpiece). This allows this point to be scheduled.

#### Filling the coolant

A filling set with coolant (BC 4) is included with the device.



#### Important information

**Caution - Only use this coolant for filling!**

BC 4 is a ready to use liquid and must NOT be mixed with other fluids. BC 4 must NOT be used together with ion exchangers.



## 12 Regular maintenance, safety checks and calibration

The device does not contain any internal parts that can be maintained by the operator.



### WARNING

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure and there is a risk of electric shock. Any deviation from the specified methods and, of course, any opening of devices or handpieces (except replacing the laser tip for the XL handpiece as described) are prohibited.

Before maintenance, disconnect the device from the line voltage by unplugging the power cable from the power socket.

Service work may not be performed by anyone other than our service technicians or other technicians trained and authorized by us. This also applies for the mandatory annual safety checks including calibration. That applies to the mandatory annual safety checks including calibration, too.

In addition, the persons carrying out must have the necessary work equipment (e.g. laser measuring devices suitable for this laser). The service work has to be carried out correctly and comprehensible with regard to nature and extent and to be documented.

The work for maintenance and repair, which requires switching on of the device have to be carried out in the laser area. All precaution measures described in chapter *Safety/ Laser* must be observed.

Malfunctioning or damaged parts have to be exchanged immediately. Only spare parts supplied by Asclepion Laser Technologies may be used. The safety cannot be guaranteed for the use of other parts, even if they have a certificate.

Any modification of the device is strictly prohibited.



### CAUTION

If the output power of the laser is too high, this can cause increased side effects!

The power emitted from the therapy laser must be checked at least every year by an Asclepion Laser Technologies GmbH customer service technician or a trained customer service technician of the dealer as part of safety checks. A calibration is carried out if necessary. The results of the checks are to be documented in the medical device book.

If a calibration was done, the following (test) treatments must be carried out especially carefully. It is possible, that the real fluence is a bit higher than before (to the factory setting), even for the same setting. The service technician should inform whether there was a deviation after adjustment. The same applies after refurbishing of handpieces.



### Important information

To guarantee high reliability and long lifetime, the coolant specially developed by Asclepion for the device must be used (corrosion protection, antibacterial, antifreeze, effective cooling)!

This coolant must not be mixed with distilled water. Please note the corresponding labels on the device (see chapter *Installation / Labels on the device*).

## 11 Customer service



### WARNING

The device is operated using line voltage and emits infrared radiation. There is a risk of electric shock and injury to the eyes!

You must never open the device and/ or attempt to carry out repair work yourself.

The device does not contain any parts inside the device or handpiece that can be maintained by the operator.

Service work may not be performed by anyone other than our service technicians or other technicians trained and authorized by us. This also applies for the mandatory annual safety checks.



### WARNING

During treatment, the handpieces are in contact with the uninjured skin of the patient. There is the danger of microorganisms being transferred.

If it is necessary to survey or to repair handpieces or the basic device in the medical centre or at the manufacturer, of course they have to be cleaned and disinfected before!

If you need help from customer service, use the address or telephone number below: When you contact your Asclepion Laser Technologies GmbH customer service representative, always have the model and serial number ready. The numbers are located on the type plate on the back side of the laser device.

Asclepion Laser Technologies GmbH

Brüsseler Str. 10

D - 07747 JENA

Germany

[www.asclepion.com](http://www.asclepion.com)

### Customer service:

Phone: +49 (0) 3641 / 7700 - 401

Fax: +49 3641 / 7700 - 402

E-mail: [service@asclepion.com](mailto:service@asclepion.com)

Note that manufacturers, installers or importers are only responsible for the effects on the safety, reliability and performance of the device if:

- Assembly, expansions, readjustments, changes or repairs are carried out by personnel authorized by them.
- The electric installation of the room in question corresponds to the requirements of the standard IEC 64 that is currently in force.
- The device is used in compliance with the user manual.



#### Possible malfunctions

| Error                                                                     | Explanation/solution                                                                                                                                                                                                                                                          |
|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>No power supply</b>                                                    | <p>Check whether the power cable is connected to a socket.</p> <p>Is the switch set to "On" or "I"?</p> <p>Check whether the "Laser emergency STOP" switch is deactivated.</p> <p>Check the power fuses of the in-house installation.</p>                                     |
| <b>Display function buttons are not responding (or only sporadically)</b> | <p>Faulty calibration of the touchscreen</p> <p>The calibration must be carried out by an authorized customer service employee. Therefore, please inform your dealer or Asclepion Laser Technologies GmbH customer service directly (see chapter <i>Customer service</i>)</p> |
| <b>No laser emission with the foot switch pressed</b>                     | <p>Check whether the connecting cable of the foot switch is properly connected.</p> <p>The device is in the STANDBY state. Switch to READY by pressing the READY button</p>                                                                                                   |



For safety-relevant errors, the device shuts off within milliseconds. A note on the display is not possible in such cases. If this is the case or an error occurs that is not described in this user manual, disconnect the device by unplugging the power plug from the power supply at the power outlet.

This chapter includes information for the possible causes of an error in the case of a function error in the MeDioStar system. Troubleshooting actions can be carried out by personnel. An exception is made for errors featuring a special note that the errors may only be eliminated by Asclepion Laser Technologies GmbH or authorized personnel.

## 10.2 Error messages and error elimination

The MeDioStar is equipped with alarm systems. If these are triggered, the system switches to the safe state and laser emission is stopped. Please first attempt to eliminate the error as described in the table below. If the error persists, contact Asclepion Laser Technologies GmbH or personnel that have been expressly authorized by Asclepion Laser Technologies GmbH.

Before contacting the Asclepion Laser Technologies GmbH technical customer service department, **please write down the name of the error and the error code.**

| Error message                                     | Explanation/solution                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Coolant</b><br>(Error 513)                     | BC4 coolant must be filled using the filling set (supplied with the device) using the connections on the rearside of the device (see the <i>Routine maintenance</i> section).                                                                                                                                                   |
| <b>Communication error</b><br>(all 50 XXX errors) | Communication has been interrupted.<br>Restart the device. Operation can be continued. Contact Technical Service if the error occurs again.                                                                                                                                                                                     |
| <b>Temperature error</b><br>(all 150 XXX errors)  | The operating temperature is too low or too high.<br>Check sufficient air supply to the housing. Restart the device.<br>Operation can be continued. Contact the service department if the error occurs again.                                                                                                                   |
| <b>Foot switch</b><br>(400 XXX errors)            | Please release the foot switch.<br>(Do not press foot switch too early, wait until the display shows READY with a yellow warning sign)                                                                                                                                                                                          |
| <b>Door interlock</b><br>(600 601 errors)         | The door contact plug is not (correctly) connected.<br>If the door has been connected to the door contact, the door is open.<br>Properly connect the door contact plug.<br>If the door has been connected to the door contact: close the door.<br>Restart the device. Contact the service department if the error occurs again. |
| <b>Handpiece error</b><br>(all 61XX errors)       | Check the handpiece connection.<br>Restart the device. Contact the service department if the error occurs again.                                                                                                                                                                                                                |

## 10 Error messages and troubleshooting



### WARNING

The device is operated using line voltage and emits laser radiation. There is a risk of electric shock and injury to the eyes!

The troubleshooting procedures specified below must be followed at all times. Any deviation from the specified methods and, of course, any opening of devices or handpieces are prohibited (except replacing the laser tip for the XL handpiece).



### Important information

Improper use or maintenance of the laser system can invalidate the Asclepion Laser Technologies GmbH warranty.

For any questions not answered in this manual, contact your customer service representative (see chapter *Customer service*).

### 10.1 General information

If the device does not respond after turning the key switch, check that:

1. The device is connected to the power supply
2. The main power switch on the rear side of the device is switched on
3. The *Laser Emergency STOP* button is disengaged. If it is engaged, disengage it by turning the red button to the left until the lock is released and the button pops out.

As previously mentioned, the user interface on the display will help you with error analysis.



Figure 52: Error message screen (example)

For general errors, the display shows an error message with an operating instruction in plain text. Some errors can be remedied by the user. To do so, follow the instructions on the display.

### 9.3 Special instructions for cleaning and disinfecting the handpieces

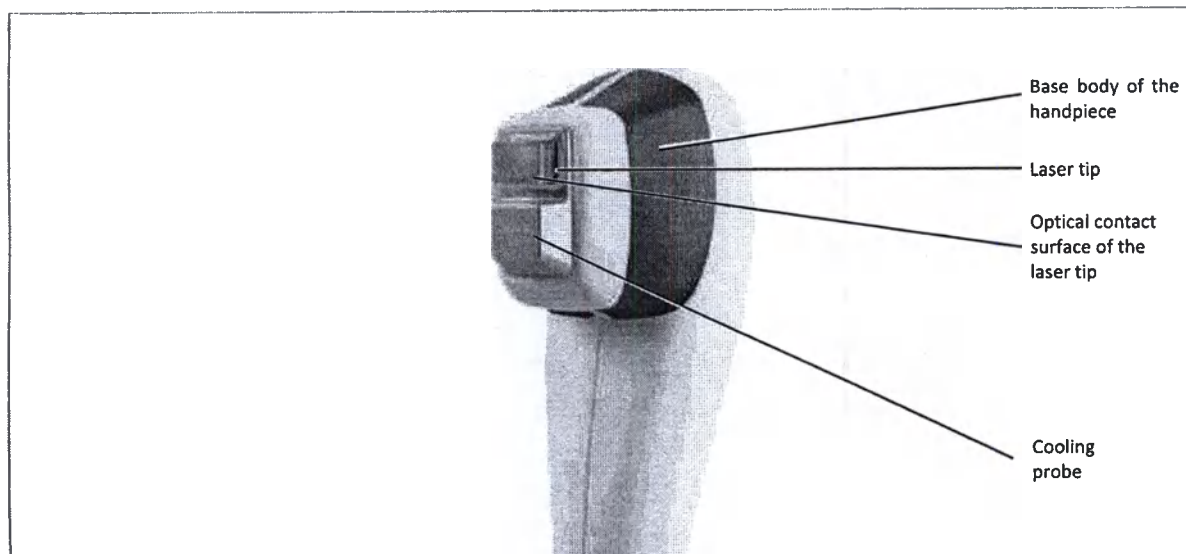


Figure 50: ST handpiece

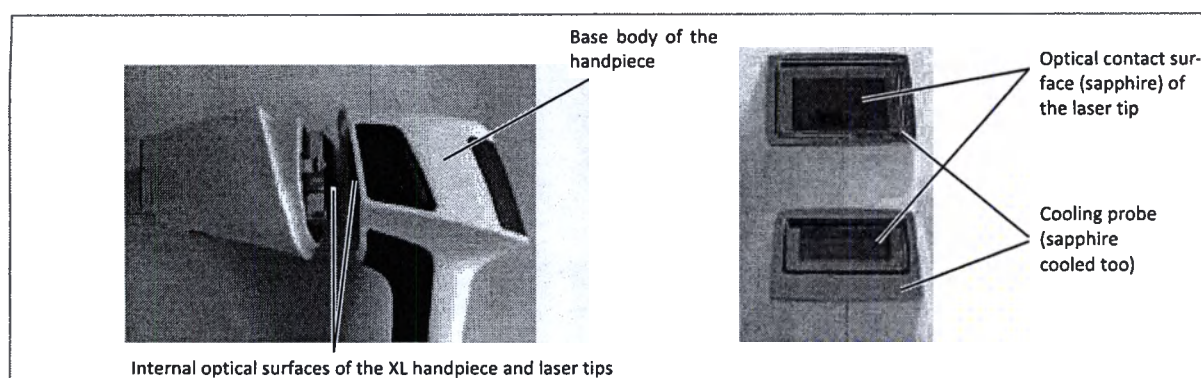


Figure 51: Handpiece (left) with XLL laser tip (top) and XLS (bottom)

#### During treatment:

The optical contact surfaces of the laser tip are largely protected against contamination by the recommended treatment technology and the material (sapphire). Despite this, they must be kept clean during treatment (particularly when treating thick, dark hair)!

To do so, check the optical contact surfaces regularly and clean them as described above. For example, each time that a line has been treated with the laser, briefly wipe off the surface before treating the next line with the laser. This prevents any contamination that may be present from burning onto the surface by additional laser treating and causing more severe side effects.

Please observe that the internal optical surfaces must be kept clean when exchanging the laser tips of the XL handpiece.



| INSTRUCTIONS                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cleaning:<br>Manual                     | <p>2. <b>Process for the optical contact surfaces of the laser tips and for the optical surfaces of the XL handpiece, which are accessible after disconnecting the laser tip:</b><br/>The accessible optical surfaces must be clean.<br/>First, breathe on the optical surface and then clean with a microfiber cloth. In the event of stubborn dirt, first use disinfecting wipes followed by microfiber cloths. Do not scratch the optical surface.</p> |
| Cleaning and disinfecting:<br>Automatic | Not possible and prohibited.                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Disinfection                            | <p>After cleaning, disinfect the accessible outer surfaces using a disinfecting <u>wipe</u> (e.g. Kodan® or Bacillol® wipes).<br/>Do not scratch the optical surface. Visually inspect it without any tools (look at the optical surface horizontally).</p>                                                                                                                                                                                               |
| Sterilization                           | Not possible, not required and prohibited.                                                                                                                                                                                                                                                                                                                                                                                                                |
| Storage and transport:                  | <p>The parts must be stored and transported in a clean container that is protected from contamination and damage. The parameters must be observed according to the permissible ambient conditions in the <i>Technical data</i> section.</p>                                                                                                                                                                                                               |

Once reprocessing of the handpiece is complete, continue to hold it while you clean and disinfect the handpiece holder on the device as described for the handpiece base body. Only then can the completed handpiece be stored safely in the holder on the device.

The manufacturer has validated that the instructions listed above for reprocessing are **SUITABLE** for reusing the application parts.



#### WARNING

The contact surface of the handpiece comes into contact with the patient when treating the skin. There is the risk of transmitting microorganisms.  
The person performing the reprocessing work is responsible for ensuring that the reprocessing process actually carried out with the equipment, materials and personnel used in the reprocessing facility achieve the desired results.

This usually requires normal validations and routine monitoring of the process. The person performing the reprocessing work should also carefully evaluate each deviation from the provided instructions for effectiveness and adverse consequences.

The reprocessing may only be carried out by trained and authorized staff.

The manufacturer does not accept any liability for any direct or consequential damages if the reprocessing was improperly.

## 9.2 General procedure for cleaning and disinfecting the handpieces



### Important information

Cleaning the handpieces with wet cloths or under running water, or spraying with products, such as disinfectants, is prohibited. Cleaning in this way can damage the internal optics and electronics. Only damp cloths may be used, such as Kodan<sup>®</sup> or Bacillol<sup>®</sup> wipes. (Parts are damaged by strongly acidic or basic solutions!)

The handpieces cannot be sterilized.

Frequent cleaning has little effect on the handpieces. Colors can become faded or changed, but this does not affect the use.

The end of the product's service life is normally determined by wear and damage.

The handpieces must be protected from contamination if they are not used for prolonged periods.

### INSTRUCTIONS

#### Workstation

The workstation must be clean and disinfected and all required tools must be within reach.

Equipment: Non-woven cloths; microfiber cloths supplied by Asclepion or eyeglasses cleaning wipes of the same type; disinfecting wipes (e.g. Kodan<sup>®</sup> or Bacillol<sup>®</sup> -wipes); Disposable gloves.

#### Preparation for cleaning

The device must be switched off.

The handpieces must be reprocessed as soon as possible after use (within 30 minutes).

Opening or disassembling the handpieces is prohibited.

Only exception:

for the XL handpiece, disconnection of the laser tip from the base body to change the spot size (see chapter *Operating the device/ Changing the handpiece and changing the spot size on the XL handpiece*).).

It is neither necessary nor recommended to disconnect the handpiece from the device for cleaning and disinfecting.

The laser device should be positioned so that it is directly next to the workstation. If necessary, unplug the power plug to do so. Then, refurbishing can occur since the hose is long enough.

Put on gloves.

The handpiece is not removed from the holder until reprocessing begins. It is held firmly in one hand (wearing gloves) by the end of the handle throughout the entire process while the other hand is used to clean and disinfect. This prevents the handpiece from falling.

#### Cleaning: Manual

##### 1. Method for the base body of the handpiece:

The accessible outer surface of the handpiece base body and cooling probe are first cleaned coarsely from gel using a non-woven cloth. Then they are cleaned with a new, slightly damp cloth or disinfecting wipe. The cloth or wipe must never be wet or dripping wet.

Disinfecting wipes have to be used in the event of stubborn dirt.



## 9 Cleaning and disinfection

### 9.1 General rules

#### Device



##### WARNING

The device is operated using line voltage. There is risk of electric shock!

Before cleaning and disinfecting, disconnect the device from the line voltage by unplugging the power cable from the power socket.

The user may only clean the outside surfaces of the device. Only slightly moistened, soft wipes, such as Kodan® - or Bacillol® wipes, may be used for cleaning and disinfecting. Cleaning or disinfecting using wet cloths or spraying products such as disinfectants is prohibited.

The device must be cleaned and disinfected at least daily after the last use of the device. The device should be covered with a clean cloth when it is not being used every day.

#### Procedure:

- Switch off the device by the key switch and power switch. Disconnect the device from the line voltage by unplugging the power cable from the power socket.
- Put on single use gloves.
- All accessible outside surfaces are cleaned using a slightly moistened, soft wipe. Doing this, the connections at the rear side of the device are left out.
- Use Kodan® or Bacillol® wipes to remove stubborn dirt. Abrasive agents must not be used!
- After, all accessible outside surfaces are carefully disinfected using Kodan® or Bacillol® wipes. Observe the instructions for disinfection given by the manufacturers. Doing this, the connections at the rear side of the device are left out. Aggressive disinfectants must not be used!

#### Handpieces



##### WARNING

The contact surface of the handpiece comes into contact with the patient when treating the skin. There is the risk of transmitting microorganisms.

The handpiece used must be thoroughly cleaned and disinfected by hand immediately after each use and directly before use on the patient. Automatic cleaning or disinfection is prohibited, as is sterilization.

If cleaning is required during a treatment, the device must be switched to the STANDBY state before cleaning starts! In this case, do not use any flammable substances, such as alcohol or isopropyl alcohol, near the treatment area, since there is a risk of fire if the laser is activated afterwards, even if the risk is low!



##### CAUTION

Dirt deposits on the optical surfaces can burn in due to the laser radiation and cause side effects such as redness, potential formation of blisters or scabs, and scars in rare cases!

Make sure that accessible optical surfaces are not damaged and remain clean after cleaning and during treatment.

The notes for the procedure in the following sections must be observed.



## 8 Accessories



### WARNING

The use of accessories not tested and approved by Asclepion Laser Technologies GmbH for use with this laser device can cause severe damage to the eye or electrical shocks.

Accessories and application parts other than those specified in this user manual may not be used with this device.

All removable accessories and cables are approved for this device only and may be used only together with this device.

We strongly advise against the use of accessories or other parts made by other manufacturers. Even if an official testing authority has certified that a specific accessory unit is technically safe, Asclepion Laser Technologies GmbH cannot assume any liability for these products.

A current list can be procured at any time at Asclepion Laser Technologies GmbH.

Many different lasers have been used with a high degree of efficacy and low incidence of adverse effects including Q-switched Nd:YAG, ruby and alexandrite, frequency-doubled long-pulsed Nd:YAG, Erbium YAG, ultra-short pulsed CO<sub>2</sub> and others. This study evaluated treatment of lentigines with a long-pulsed 808 nm diode laser which is in common clinical use for the purpose of hair reduction.

#### **Material and method**

Twelve healthy consenting female adults, age range 44 to 74 years, exhibiting numerous (at least 10) lentigines on the dorsum of the hands and/or the arms participated in this trial. A long pulsed 808 nm diode laser (MeDioStar, Carl Zeiss Meditec, Jena, Germany) was used only in the 'Pro 2' mode – single pulse without interval. Three patients were initially treated with a 12 mm spot. The remaining 9 patients were treated with a 6 mm spot which allowed higher fluence with a shorter pulse width. Treatment was carried out with a silicone spacer to hold the circular flat lens 1 mm from the skin surface (in contrast to the recommended method of treatment for hair reduction which is skin contact with clear gel coupling). All patients were treated with energies commencing at 25 J/cm<sup>2</sup> and increasing in 5 J/cm<sup>2</sup> increments until darkening of the lentigines within 5 minutes of treatment was observed. The remainder of the lesions were treated at this fluence.

One lentigo per patient located on the posterior arm was treated at a pre-selected fluence and was biopsied immediately after the treatment. A total of 12 biopsies were studied with 2 at each fluence between 25 and 50 J/cm<sup>2</sup>. At follow-up 4 weeks later, the estimated percentage disappearance of lentigines was recorded as 0-25%, 51-75% and 76-100%. Any side effects were noted.

#### **Results**

All patients showed 50% or greater reduction in lentigines at one month except one patient treated with a 12 mm spot and 30 J who showed only 25-50%. There was poor correlation between clearance and fluence but strong correlation between clearance and color of the original lesions with darker lesions showing greater clearance.

There was no scarring at one month but some lesions showed residual erythema at this short post-treatment interval. Histology consistently showed streaking of the nuclear chromatin of the pigmented basal keratinocytes, clefting of a thin upper rim of the papillary dermal collagen. The effects were more pronounced with the 6 mm than the 12 mm spot.

#### **Summary**

A diode laser emitting 25 to 50 J/cm<sup>2</sup> at 808 nm is capable of inducing limited and focal necrosis of solar lentigines in the forearm skin of Caucasian females with satisfactory clinical results. Treatment is rapid and well tolerated. Results are more dependent on the color of the lentigo than the fluence of the laser. Operator judgment and experience is therefore important in obtaining good results.

### Clinical outcome of Acne inversa treatments:

| Study                                                                                                                                                                                                                                                                                        | Methods                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Results                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Bechara et al.:<br/>Prospective study comparing laser epilation treatment versus no treatment of mild and moderate Hidradenitis suppurativa/ Acne inversa (HS/ AI)<br/>Lecture at 44th annual conference of DGPRAC<br/>September 2013, Münster, Germany<br/>(translation from German)</p> | <p>Prospective randomized comparison study<br/><b>Objective:</b><br/>The therapy of choice in advanced stage of HS/AI is the surgical removal of all affected areas. A possible causal approach could be the destruction of hair follicles in early stages.<br/><b>Patients:</b><br/>68 patients with HS/AI included<br/>58 treatments finished at present<br/>40 with follow up of 12 month evaluated<br/><b>Parameter and method:</b><br/>Side by side comparison: treatment with MeDioStar vs. untreated control<br/>Spot size 12mm,<br/>Fluence and pulse duration dependent on skin type (as for hair removal)<br/>6 laser treatments with interval of 4 weeks<br/><b>Evaluation:</b><br/>Evaluation by HS Score before and after 12 months</p> | <p>Destruction of hair follicles by laser hair removal seems to be an effective therapy option for mild and moderate HS/AI.<br/><br/><b>Details:</b><br/>After treatment:<br/>average reduction of HS score: 47,62%.<br/><br/>Average reduction of HS score after 12 months: 77,33%.</p> |

## 7.7 Treatment of actinic elastosis

Treatment of actinic elastosis is an improvement of skin damage caused mainly by light, it means a regeneration of the skin structure (skin tightening, reduction in pore size), brightening of pigmentation and reduction in small wrinkles (also simplistically referred to as "skin rejuvenation").

The treatment—including contraindications, side effects and treatment method—are identical to epilation (see above).

However, unlike epilation treatment, 3 passes using the *Professional* mode are carried out immediately one after the other. Then it is best to cool the skin with a cooling mask for a prolonged period. The process requires 3 treatments one month apart.

If, however, treatment is intended specifically for brightening liver spots (**diagnosis must be verified** to rule out cancerous and precancerous conditions!), treatment is carried out with a small spot size at a distance of approximately 1 mm from the skin. After the treatments, the lentigines initially become darker! The patients must be made aware of this accordingly.

Presentation by Sue McCoy, M.D. for the 'Joint Laser Conference' in Edinburgh, 2004

**Treatment of lentigines with a diode laser at 808 nm**  
S. McCoy; Laser, Skin & Vein Clinic, North Adelaide, South Australia

### Background

Lentigines are common benign epidermal skin lesions which occur predominantly on sun-exposed areas of individuals with fair (Fitzpatrick Types I-III) skin, increasing incidence with advancing age. Histologically, solar lentigines exhibit elongation of the epidermal rete ridges and an increase in the number of melanocytes and the amount of epidermal pigment.



Lumpy, isolated inflammatory foci arise at the affected locations. These recur over time and coalesce to form carbuncle-like formations. It often results in widespread, centimeter-thick scar plates with cutaneous/subcutaneous fistulas that can only be removed via surgery. The patient is not only strained by the inflammatory pain and limitations to movement due to scar formation, but also by the recurring, fetid infections.

Causes include possible genetic disposition, development in conjunction with other illnesses (M. Dowling-Degos), follicular hyperkeratosis, seborrhea, existing bacterial colonization by propionibacteria and Staph. aureus, smoking and obesity.

For some patients, the possible cause of the development of the illness can be traced back anamnestically to the time of a strong hormone imbalance (temporary secondary amenorrhea due to a considerable loss in weight). However, the illness does not subside after the potential causes are no longer present.

Previous therapy includes repeated antibiotic and antiseptic treatment, abscess splitting as well as scar excision and wound coverage using split-thickness skin grafts. Disadvantages of this procedure include recurring relapses, repeated small or large-scale surgical procedures, pain, required bandage changes, loss of work time due to calling in sick and mental stress with possible subsequent limitations of social contact.

Laser treatment using a diode laser such as the MeDioStar offers an alternative therapy option. The laser has been developed primarily for epilation. It penetrates deep into the skin and works by having light energy absorbed mostly through pigment or similar light-sensitive substances. This first causes hair follicle involution due to the thermal damage that results after multiple treatments.

Porpyrhin-forming bacteria and fungi considered local causes of acne inversa are also destroyed in this procedure. During normal epilation treatment, this manifests itself as reduced underarm odor after treatment.

Treatment occurs in the affected areas at 810 nm with 30-40 J/cm<sup>2</sup>. Initially, this is a single treatment of the affected regions (note: single treatment includes a series of sessions as for hair removal). In the best-case scenario, the treatment should be carried out in the primary pustule or abscess stage without scar formation.

Within the last three years, 20 patients were treated. Their illnesses showed very different development stages starting from recessive abscess formation in the inguinal region to extensive diagnostic findings, sometimes with considerable complications (repeated operations, condition after sepsis with vertebral abscess formation).

All patients showed a positive reaction to the therapy. In the most favorable cases, new abscesses healed within a few days without requiring additional antibiotic therapy. In cases of inflammation reactions that had already existed for a prolonged period (longer than 6 months), inflammation showed signs of healing within 6 weeks. In cases of extensive scar abscess cavities, treatment achieved an antiseptic effect but the cavity was not healed; a relapse in symptoms is to be expected here.

Adequate relapse prevention was able to be achieved on patients without excessive scarring and on all patients in non-scarred areas. In the longest monitoring period up to 3 years, a complete absence of symptoms of relapse was observed after an abscess separation was performed under general anesthetic once a month. Odor development was reduced as a secondary result.

Compared to earlier tests, an alternative therapy option for treating acne inversa can be definitively verified. This option can be used at the beginning of the illness and, if there is a positive prognosis, surgery can be avoided completely.

A clear improvement in prognosis and the general state of the illness can be achieved in more advanced cases of the disease. This provides the advantage of foregoing the need for primary radical surgery and subsequent wound covering. Instead, it limits treatment to the necessary minimally invasive surgeries that make the symptoms easier for the patients to tolerate.

| Study                                                                                                                                                                                                                               | Methods                                                                                                                                                                                                                                                                                                   | Results                                                                                                                                                                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V. Tsepkenko, S. Khaustov, A. Burov<br>"Our experience in vessels' laser coagulation"<br>Clinic of plastic and aesthetic surgery "VIRTUS"<br>Odessa, Ukraine<br>(translation from Russian)                                          | <b>Objective:</b><br>efficacy of selective laser coagulation in patients with blue veins (up to 3mm)<br><b>Parameter:</b><br>MeDioStar (Asclepion, Germany), wavelength 810 nm, spot size 6 mm, fluence 80-160 J/cm <sup>2</sup><br><b>Patients:</b><br>105 patients with blue vessels up to 3mm diameter | complete healing – 75% (79 patients),<br>significant improvement – 20% (21 patients),<br>moderate improvement – 4 % (4 patients),<br>inconsiderable improvement – 1% (1 patient).                       |
| Wollina U, Konrad H, Schmidt WD, Haroske G, Astafeva LG, Fassler D.<br>Response of spider leg veins to pulsed diode laser (810 nm): a clinical, histological and remission spectroscopy study.<br>J Cosmet Laser Ther 2003;5:154-62 | 35 patients with spider leg veins, 2 treatments 2 weeks apart, 810 nm diode laser<br>12 mm spot size, 60 ms pulse length, 80-100 J/cm <sup>2</sup> fluence<br>Skin biopsies<br>Remittance spectroscopy                                                                                                    | Complete clearance after 1 <sup>st</sup> treatment with 15 of 35 patients, 20 of 35 remarkable improvement; stable situation after 6 month,<br>2 patients had mild scarring, otherwise no side effects. |

## 7.6 Treatment of acne

**Acne vulgaris** is one of the most frequently treated illnesses in dermatology practices. The treatment is usually lengthy and sometimes associated with substantial side effects. The young people affected usually suffer severely from this.

Acne is primarily an illness of the sebaceous gland follicles, which are located predominantly on the face, back and chest. At first, they create non-inflammatory blackheads, but later a series of inflammatory efflorescences such as papules, pustules and lumps can also develop. Acne vulgaris or "common acne" is caused by increased androgen levels during puberty and subsides at the beginning of the thirties at the latest.

Similar to hair removal, the infrared radiation of the MeDioStar penetrates deep enough into the skin to reach the sebaceous gland follicles.

The treatment—including contraindications, side effects and treatment method—are identical to epilation (see above).

However, unlike epilation treatment, 3 - 4 passes are carried out immediately one after the other. Then it is best to cool the skin with a cooling mask for a prolonged period. The treatment is painful due to inflammation.

The process requires 3 to 5 treatments one week apart.

**Acne Inversa<sup>(1)</sup>** is an illness of skin appendages. It starts from the sebaceous glands and has a secondary effect on the apocrine perspiratory glands. Men and women are equally susceptible. The illness often begins as early as puberty, but can appear at any other time in life later on.

Areas particularly susceptible include axillae and the groin-pubic region up to and including the gluteal region. It affects the back and stomach less frequently and very rarely affects otherwise typical acne regions, such as the face.

(1) Courtesy of Dr. med. C. Passos Pereira, Hürth-Hermühlheim, published in DERMAforum, Sept. 2003 (translated from German)

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to**  
**Registration No.:** SX 60105769 0001  
**Report No.:** 21232818 001

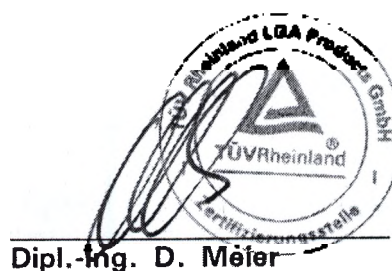
**Organization:** Asclepion Laser Technologies GmbH  
Brüsseler Str. 10  
07747 Jena  
Deutschland

**Scope:** Design and development, production, installation and servicing of surgical and dermatological lasers, electrotherapeutical medical devices, local skin cooling systems, sterile and re-sterilisable laser fibers, percutaneous sheaths for the area of ENT, GYN, urology, dermatology, plastic and endovascular surgery, laser supply systems, and light fibers

**Certification Body**



**Date:** 2015-12-01





# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**Asclepion Laser Technologies GmbH**  
**Brüsseler Str. 10**  
**07747 Jena**  
**Deutschland**

has established and applies a quality management system for medical devices  
for the following scope:

**see attachment**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012**  
**EN ISO 13485:2012/AC:2012**

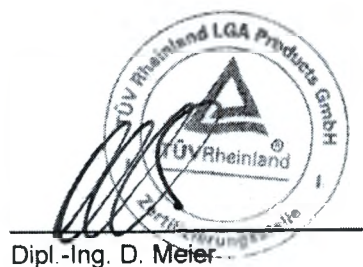
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2015-12-03  
Certificate Registration No.: SX 60105769 0001  
An audit was performed. Report No.: 21232818 001  
This Certificate is valid until: 2018-12-02

Certification Body



Date 2015-12-01



Dipl.-Ing. D. Meier

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HD 60105768 0001  
**Report No.:** 21232818 001

**Manufacturer:** Asclepion Laser Technologies GmbH  
Brüsseler Str. 10  
07747 Jena  
Deutschland

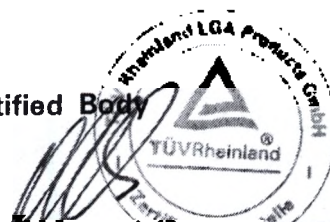
**Products included:**

- surgical and dermatological lasers
- electrotherapeutical medical devices
- sterile and re-sterilisable laser fibers
- Laser supply systems, light fibers

**Date:** 2015-12-01

**Notified Body**

**Dipl.-Ing. D. Meier**



**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60105768 0001

**Report No.:** 21232818 001

**Manufacturer:** Asclepion Laser Technologies GmbH  
Brüsseler Str. 10  
07747 Jena  
Deutschland

**Products:** see attachment for products included  
Replaces Approval, Registration No.: HD 60097279 0001

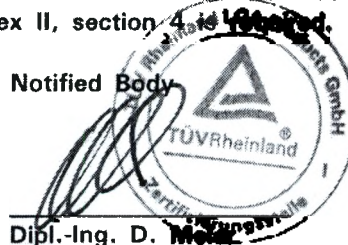
**Expiry Date:** 2020-12-02

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is ~~not required~~.

**Effective Date:** 2015-12-03

**Date:** 2015-12-01

Notified Body



Dipl.-Ing. D. Moll

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



|                             |                                                                                                          |                                                                                    |
|-----------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| FB <b>7351e</b>             | <b>Verification / Validation Report</b>                                                                  |  |
| Revision Index:<br><b>B</b> | <b>Identification number: ZI/14/03/27-01</b><br><small>Member Code/year/month/day-sequential no.</small> | Page 14 of 14<br>FB7351e ClinEval MSPRO<br>V01_ZI140327-01.doc                     |

- Stasis dermatitis
- Pododema
- Neuropathy of the legs
- Intake of corticosteroids in the last three months
- Thrombophlebitis

#### 4.3 Conclusions

- (1) This new MS version in question is completely identical to the intended use (including indications and contraindications) of the current MS version. For the user the only difference is a new, larger handpiece allowing faster treatments. The positive result of the CEval 2011 and CEval 2014 keeps valid.
- (2) The high number of MS devices sold in the last years demonstrates clearly the clinical efficacy and safety (as well as usability and reliability) of the MS device. Otherwise this success would not have been possible.
- (3) In the updated review (2013) as well as in former reviews of recommendations and recalls of medical lasers comparable to MS, listed by BfArM and FDA, nothing could be found, that could be a reason to modify the MS device.
- (4) In this evaluation studies and experience reports about treatments with the MS were assessed with respect to efficacy. Altogether 906 patients were included.  
For all indications of the intended use the effectiveness was demonstrated including histological proof.
- (5) Also, in this evaluation studies and experience reports about treatments with the MS were assessed with respect to side effects. Altogether at least 3285 treatment sessions\* were evaluated. A total of 1% of the treatment sessions caused side effects only, most of them transient. As little as 3 small scars (less than 0.1%) are permanent. But one must take into account, that these scars are limited in size to the vessel size. That means they are small and light from color. So, the area looks not perfect, but the light spot or light line doesn't catch the eye as much as the red or purple line of the vessel before.  
The very low incidence of side effects is in particular impressive whilst taking into account, that all skin types, including Asian, were treated. Dark skin and Asian skin have more tendency to side effects due to higher melanin absorption.

\*The total number of sessions was estimated, because not exactly stated in a few studies

#### 4.4 Summery:

It was demonstrated in this evaluation, that treatments with the MS are effective and safe. The incidence of side effects is very low and mainly transient. This allows the assessment, that the advantage for the patient overbalances the risks. The new MS version was shown to be equivalent to the current device with respect to the application.

22. Okt. 2014 *G. Zimmerman*

|                             |                                                                                                          |                                                                                     |
|-----------------------------|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| FB <b>7351e</b>             | <b>Verification / Validation Report</b>                                                                  |  |
| Revision Index:<br><b>B</b> | <b>Identification number: ZI/14/03/27-01</b><br><small>Member Code/year/month/day-sequential no.</small> | Page 13 of 14<br>FB7351e ClinEval MSPRO<br>V01_ZI140327-01.doc                      |

### 3.4 Evaluation of reports of the BfArM\* and FDA

During all the time the MS is sold there were never recommendation or recalls of the BfArM related to the MS or to similar devices.

The last research of the recommendations of the BfArM as well as the recalls of medical devices stated by BfArM and FDA was done at the 2th of September 2014 and gave once more no results relevant for the MS. For details see App.B.

\* German Federal Department for Drugs and Medical Devices

## 4. Final assessment

### 4.1 Indications of the device

Identical to the forerunner device. the MS is used for

- removing unwanted hair
- treating acne
- vascular treatments
- skin rejuvenation (treatment of actinic elastosis)

For all these treatments, the laser is applied on uninjured skin.  
These indications are stated in chapter 2.1 of the UM.

### 4.2 Contraindications

In CEval 2011 all studies and standard books cited were evaluated for stated contraindications/ exclusion criteria in detail (chapter 3.4). The CEval 2014 relates to the handpiece ALX, which was new to that time. As a result of this evaluation (chapters 3.1. d, 3.2 B, 4-2), patients with skin type VI are added in the list of contraindications and therefore excluded from treatments with handpiece ALX (see list below).

Identical to the forerunner device. the following contraindications have to be observed and are stated in chapter 2.2 of the UM:

- Light sensitivity
- Intake of preparations that increase sensitivity to light
- Cellulite therapies in the treatment area (wait a few weeks)
- Cancerous and pre-cancerous lesions in the treatment area
- Haired nevi in the treatment area
- Herpes simplex in the treatment area
- Tendency towards excessive scarring
- When using the ALX handpiece: Patients with skin type VI
- The laser must not be applied to the area near the eyes
- Treatment of children or women who are pregnant or nursing
- Tanned skin in the area to be treated, particularly when using the ALX handpiece
- Tattoos in the area to be treated

#### Contraindications specifically for the treatment of spider veins on legs:

- Surface varicose veins with a diameter larger than 3 mm
- Branch and secondary varicose veins
- Ulcer
- Diabetes
- Vasculitis

|                             |                                                                                                          |                                                                                    |
|-----------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| FB <b>7351e</b>             | <b>Verification / Validation Report</b>                                                                  |  |
| Revision Index:<br><b>B</b> | <b>Identification number: ZI/14/03/27-01</b><br><small>Member Code/year/month/day-sequential no.</small> | Page 12 of 14<br><small>FB7351e ClinEval MSPRO<br/>V01_ZI140327-01.doc</small>     |

| No. | No. of patients | Side effects stated                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Notes of the author                                                                                                                                      |
|-----|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 17  | 31              | Investigation of skin changes after hair removal treatment by objective measurements vs. untreated control:<br>-erythema response can continue up to the second week<br>-no difference in melanin index, although pigment changes are common side effects of laser treatments<br>- no changes in biophys. properties of skin, incl. trans-epidermal water loss, capacity of stratum corneum hydration, sebum and PH level                                                                                                                                                                                                                | This is a very interesting study focusing especially to skin changes and demonstrating therefore the safety of the treatments by objective measurements. |
| 18  | 27              | After treatments for hair removal one salient aspect was:<br>- the virtual painlessness, particularly of the "Multipass"<br>- virtually insignificant side effects (i.e. cursory erythema and short-term perifollicular edema) with the Multipass<br><br>17 out of these patients already had prior treatments with other devices for hair reduction before.<br>These patients assessed the treatment with MS NeXT as:<br>- having less side effects: 71%<br>- more efficient and less side effects: 65%<br>- only 1 patient had edema lasting for 3 days (but after treatment with another device before, the edema lasted even 7 days) | Very valuable result for MS NeXT demonstrating the safe and virtually painlessness of treatments with the MS NeXT, especially with SmoothPulse mode.     |
| 19  | (2)             | See below                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Case report of no.20                                                                                                                                     |
| 20  | 68              | After treatment of AI it was stated:<br>- side effects as for epilation besides pain<br>- pain is clearly increased due to the inflammation caused by AI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Very valuable study. Demonstration of a very safe treatment option for a disease, which is difficult to treat so far.                                    |
| 21  | 29              | Side effects stated after treatments for hair reduction of MS NeXT vs. MS miXT (forerunner):<br>- Side effects were low and never exceeded a level of short time erythema.                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Study very valuable, demonstrating the safety of MS NeXT and forerunner MS miXT                                                                          |
| 22  | 30              | Side effects stated after rejuvenation treatments of skin laxity:<br>- no serious adverse effects<br>- only temporary pain and erythema, which was well tolerated in the followed treatments.<br>- patients were skin type III to IV (Asian),<br>- however, majority of the patients reported no hyperpigmentation<br>- few cases reported only transient and mild hyperpigmentation, which do not need any treatment                                                                                                                                                                                                                    | Very valuable study, because patients with Asian skin are treated, which are prone to have side effects, especially hyperpigmentation.                   |



|                             |                                                                                                          |                                                                                    |
|-----------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| FB <b>7351e</b>             | <b>Verification / Validation Report</b>                                                                  |  |
| Revision Index:<br><b>B</b> | <b>Identification number: ZI/14/03/27-01</b><br><small>Member Code/year/month/day-sequential no.</small> | Page 11 of 14<br><small>FB7351e ClinEval MSPRO<br/>V01_ZI140327-01.doc</small>     |

| No. | No. of patients | Side effects stated                                                                                                                                                                                                                                                                                                                                                        | Notes of the author                                                                                                  |
|-----|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 7   | 29              | Comparison MS vs. market leader "LightSheer" for hair removal<br>No scarring or pigment change after any treatment.<br>Degree of erythema and incidence of burned hair are less with MS.<br>Edema and pain not statistically different.                                                                                                                                    | Evidence, that MS causes no more side effects than leading product; transient erythema and burned hair is even less. |
| 8   | 24              | Epilation treatments did not result in any serious side effect.<br><br>Histology after treatment:<br>dermal vessels, eccrine ducts, elastic fibers and adipose tissue did not show any alteration after treatment.                                                                                                                                                         | Very good result.<br>Important proof!                                                                                |
| 9   | (106)           | Not mentioned.                                                                                                                                                                                                                                                                                                                                                             | Experience report                                                                                                    |
| 10  | 200 !!!         | 978 treatments for hair reduction!!!<br>- no permanent sequelae or scarring<br>- 0.5% transient hyperpigmentations only                                                                                                                                                                                                                                                    | Very good result, especially because a huge number of patients were evaluated and all skin types were included!!     |
| 11  | 17              | After treatment for hair reduction:<br>- no pigmentary changes<br>- burning sensation related to Fluence used and area<br>- slight burnings in 2 patients healed without pigment change                                                                                                                                                                                    | Small number of patients.                                                                                            |
| 12  | 143             | After hair removal treatment:<br>- 4 patients had blisters<br>- 7 transient hyperpigmentations lasted 2 months                                                                                                                                                                                                                                                             | Very valuable study due to high patient number. Very good proof of safety for Asian patients.                        |
| 13  | 25              | Hair reduction comparison of 810nm versus 940nm:<br>- 1 patient (skin type IV) had crusting at 810nm side only<br>- 1 patient (skin type III) had prolonged erythema and hyperpigmentation at the 810nm side only<br>- no side effects at the 940nm side                                                                                                                   | Advantage for 940nm (940nm is applied with MS miXT)                                                                  |
| 14  | 12              | 1 months after treatment of lentigines (more than 120 lesions treated):<br>- no scarring<br>- some lesions showed residual erythema after this short time                                                                                                                                                                                                                  | Very good result, because it is ordinary, that the erythema stays sometimes longer than 1 months                     |
| 15  | 12              | After rejuvenation treatment no side effects were seen, such as persistent erythema, edema, blister, hyperpigmentation or scarring.                                                                                                                                                                                                                                        | Due to low absorption in rejuvenation treatments the risk of side effects is lower.                                  |
| 16  | 5               | Areas treated for hair reduction with either laser MS XT (forerunner) and MS miXT had no differences:<br>-no cases of pigment changes, scabbing or scarring<br>-slight perifollicular erythema and edema is normal and seen as clinical endpoint<br>-none of the patients felt more than light warming in the treatment areas; one of the patients was very pain sensitive | Low number of patients, but direct side by side comparison demonstrated same safety for both MS.                     |

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These treatments caused:

- 0.21% transient hypopigmentations
- 0.67% transient hyperpigmentations ("few" patients of study no.22 are estimated to be 5 of 30)
- 0.03% prolonged erythema
- 0.09% small scars (all after vessel treatments)
- no permanent hypopigmentation
- no permanent hyperpigmentation
- no other serious side effects

All these side effects listed are stated in the manual.

All side effects together are 1% of the treatments only. This percentage is especially very low with respect to the fact, that patients with all skin types were treated including Asians. Dark and Asian skin has more melanin and therefore the risk of side effects is higher compared to light skin.

The only permanent side effects were the small scars, which all developed after treatment of leg veins. One has to know, that these small scars are as small as the vessel diameter only and light from color. So, the patients accept this risk almost always, because the small, light scar looks better than the (darker) vessel before.

Details of the studies related to side effects are listed in the table below.

**Table 2: Details of side effects:**

| No. | No. of patients | Side effects stated                                                                                                                                                                                                                        | Notes of the author                                                                                                                          |
|-----|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | 20              | Perifollicular erythema and edema after hair removal in 16 of 20 patients<br>Pain during treatments: 0.8 of max. 10 point scale<br>No permanent pigment or textural changes, no scarring<br>Transient hypopigmentation in 6 of 20 patients | Normal clinical endpoint<br><br>Low pain                                                                                                     |
| 2   | 33              | 30% of patients had crusting after treatment of leg veins, 4 patients had hyperpigmentation, 1 had hypopigmentation, 1 scar (at ankle)                                                                                                     | All side effects are normally transient, besides scar.<br>(vascular treatments cause from tendency more side effects due to more absorption) |
| 3   | 20              | There was no pigment change, persistent erythema or scarring after hair removal treatment.<br>Pain during treatment was greater in patients with darker, denser hair.                                                                      | That's clear due to more absorption                                                                                                          |
| 4   | (20)            | Not mentioned                                                                                                                                                                                                                              | Lecture at ASLMS; only abstract available.                                                                                                   |
| 5   | 20              | Verbal information:<br>No more side effects for treatment of AI than stated for hair removal, besides pain.                                                                                                                                | Pain is increased, because of inflammation caused by AI.                                                                                     |
| 6   | 35              | No side effects after treatment of leg veins, besides 2 patients with mild scarring.                                                                                                                                                       | Vascular treatments cause from tendency more side effects due to more absorption.                                                            |

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### 3.3. Evaluation of the studies with respect to side effects

Altogether 780 patients were treated with the MS and evaluated for side effects. Side effects were not mentioned in the abstract of the ASLMS lecture of study no.4 and in experience report no.9. For nearly all treatments multiple treatment sessions are necessary, usually 2-3 for vascular and rejuvenation treatments, 5 - 12 for hair removal. So, the number of treatments, which could cause side effects potentially, is much higher – in study no.10 the number of treatments was 978 (!) for 200 patients.

For the assessment of the side effects one has to know, that the laser treatment works by absorption of laser light by the skin.

Absorption means, that the light is converted into heat. The more absorption the more heat comes up. Heat is wanted for the thermal damage to the target (e.g. hair, blood), but not in the surrounding. It is not possible in each case to avoid too much heating, because absorption is dependent not on the laser parameters only, but also on the individual patient: e.g. skin type (unwanted pigment absorption), hair color and thickness, vessel size.

Therefore it is demanded in the manual, that test spot has to be done before treatment to find the appropriate parameters. But even if a test has been done, e.g. the hair color and thickness is different, vessel size and depth is different and so on.

The side effects are stated in the manual and were not changed to the forerunner device. In chapter 6.4.5 they are specified for hair removal. The treatment of acne is based on hair removal, therefore the side effects are the same besides discomfort during treatment. More pain in AI treatments is caused by the inflammation connected with AI. Rejuvenation treatment causes even less side effects, because there is normally no hair and so lower absorption.

As stated in the manual all side effects are less significant for light skin and light hair and become more intensive for darker, thicker and denser hair and for darker skin.

Treatment of vessels causes from tendency more side effects than epilation treatments, because the diameter of vessels (blood volume) is larger than the diameter of the hair shaft. As stated in the manual in chapter 6.5.3, all side effects are less for patients with light skin and thinner vessels and become stronger the thicker the vessel and the darker the skin.

#### Note:

Erythema and edema (sometimes followed by small blisters) in the treatment area as well as discomfort during treatment are seen as clinical endpoint and therefore not seen as real side effects by the authors of studies. These "side effects" are not mentioned in most studies and that's why not discussed below, despite they are stated in the manual and listed in the detailed table below (there it is listed for completeness).

No side effects were seen in studies no.3 (20 patients), no.7 (29 patients), no.8 (24 patients), 15 (12 patients), no.16 (5 patients), no.17 (31 patients), no.18 (27 patients), no.21 (29 patients) and no.22 (30 patients).

Transient hypopigmentation was seen in studies no.1 (6 of 20 patients) and no.2 (1 of 33 patients) only. Transient hyperpigmentation was reported in studies no. 2 (4 of 33 patients), no.10 (5 of 978 treatments), no.12 (7 of 143 patients), no.13 (1 patient of 25, side treated with 810nm only) and no.22 (mild hyperpigmentation of few patients out of 30). One case of prolonged erythema was seen in study no.13 (of 25 patients). Small scars were seen after treatments of leg veins in study no.2 (1 of 33 patients) and no.6 (2 patients with mild scarring of 35).

The total number of treatment sessions is estimated, because it is in some studies not exactly mentioned. Altogether at least 3285 sessions are evaluated for side effects.



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| Study No. | No. of patients | Most significant results                                                                                                                                                                                                                                                                     | Notes of the author                                                                                                                 |
|-----------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 16        | 5               | Areas treated for hair reduction with either laser MS XT (forerunner) and MS miXT had no significant differences                                                                                                                                                                             | Low number of patients, but direct side by side comparison demonstrated same efficacy for both MS                                   |
| 17        | 31              | After 1 hair treatment (objective was to evaluate the change of skin properties, not an effective treatment):<br>- hair density and thickness decreased statistically significant after treatment and remained in follow up<br>- 51.85% hair reduction 6 weeks after treatment               | 1 treatment is not enough, but the objective of this study was to evaluate skin changes – please see side effects.                  |
| 18        | 27              | 17 out of these patients already had prior treatments with other devices for hair reduction before. These patients assessed the treatment with MS NeXT as:<br>- more efficient: 82%<br>- more efficient and less side effects: 65%<br>average of 5.8 treatments per patient (157 treatments) | Very valuable result for MS NeXT                                                                                                    |
| 19        | (2)             | See below                                                                                                                                                                                                                                                                                    | Case report of no.20                                                                                                                |
| 20        | 68              | Improvement of AI after 6 treatments (based on epilation):<br>reduction of HS* score after treatments: 47.62%<br>reduction of score after 12 months follow up: 77.33%<br>*HS=Hidradenitis suppurativa=Acne inversa=AI)                                                                       | Very valuable study (see also notes of no.5). Demonstration of very good success. So far follow up of 40 patients possible.         |
| 21        | 29              | Hair reduction of MS NeXT vs. MS miXT (forerunner) after 3 treatments:<br>- 64.3% vs. 50.1% for skin type I-II<br>- 65.1% vs. 61.6% for skin type III<br>- SmoothPulse of NeXT: 67.1%                                                                                                        | Study very valuable, demonstrating even better efficacy of MS NeXT vs. forerunner MS miXT                                           |
| 22        | 30              | Mild improvement of skin laxity after 4 treatments for: 53.3% of patients, 1 and 3 months after treatments, 66.7% of patients, 6 months after treatments                                                                                                                                     | Very valuable study due to objective measurement of skin laxity. It is shown, that for these treatments the improvement needs time! |

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| Study No. | No. of patients | Most significant results                                                                                                                                                                                                                                                                                                                                                                           | Notes of the author                                                                                                                                            |
|-----------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6         | 35              | Improvement of leg veins after 1 treatment was assessed to:<br>- 15 patients had complete clearance<br>- 20 had remarkable improvement (>80%)<br>- stable situation after 6 months                                                                                                                                                                                                                 | Very good result.<br>Up to 3 treatments are necessary. 70% is good for leg veins.                                                                              |
| 7         | 29              | 6 months after 3 treatments hair reduction: reduction 49% with MS, 48% with "LightSheer"                                                                                                                                                                                                                                                                                                           | Evidence, that MS is as efficient as the leading product.                                                                                                      |
| 8         | 24              | 6 months after 3 treatments hair reduction: reduction 70%<br><br>Histology: reduction in anagen phase : other phase treated area at least 1:1 versus normal 8:2                                                                                                                                                                                                                                    | Very good result.<br><br>Important proof!                                                                                                                      |
| 9         | 106             | After three treatments of leg veins up to 3mm:<br>- complete healing: 75% of patients<br>- significant improvement: 20%<br>- moderate improvement 4%<br>- inconsiderable improvement: 1%                                                                                                                                                                                                           | Experience report only, but valuable due to high number of patients                                                                                            |
| 10        | 200 !!!         | Hair reduction after 3. Treatment: 64%<br><br>978 treatments!!!<br>(average about 5 treatments per patient necessary)                                                                                                                                                                                                                                                                              | Good result, especially because a huge number of patients evaluated!!                                                                                          |
| 11        | 17              | After treatments for hair removal it was assessed:<br>- best results for pubic and beard area:<br>> 80% hair reduction after 5 treatments<br>- arms and legs: > 50% after 10-12 treatments<br>- hair follicle nevus:<br>complete removal after 1 treatment<br>- effect lasted between 6-12 months                                                                                                  | Only abstract available. Therefore it is not very detailed.<br><br>Small number of patients.                                                                   |
| 12        | 143             | Best result for hair removal for axilla – upper lip, limbs and chest ranks behind<br><br>Skin type III exhibiting the best effect, type V poorest                                                                                                                                                                                                                                                  | Very valuable study due to high patient number and patients with Asian skin                                                                                    |
| 13        | 25              | Hair reduction comparison - no significant difference in efficacy: 58.11% for 810nm versus 60.35% for 940nm after an average of 3.52 treatments                                                                                                                                                                                                                                                    | Advantage for 940nm see side effects (940nm is applied in MS miXT)                                                                                             |
| 14        | 12              | All patients had more than 50% reduction in lentigines (except 1 treated with 12mm spot in the beginning)<br>Histology (1 biopsy per patient) demonstrated streaking of nuclear chromatin, clefting of the epidermal-dermal junction and variable homogenization of a thin upper rim of the papillary dermal collagen.<br>The effects were more pronounced with the 6mm compared to the 12mm spot. | Very valuable study due to included histology.<br>12 patients only, but at least 10 lentigines per patient (> 120).<br>(Spot size used for lentigines is 6mm.) |
| 15        | 12              | After 3 treatments for rejuvenation improvement was:<br>for spots (lentigines): 20%; for pore size: 30%<br>for wrinkles: 40%; for texture: 40%                                                                                                                                                                                                                                                     | Very valuable study due to objective measurement of skin.                                                                                                      |

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The study no.9 is an experience report about treatments of leg veins up to 3mm. The large number of 106 patients was evaluated. Also here is confirmed, that after 3 treatments 75% had complete healing, 20% significant improvement, 4% moderate and 1% only inconsiderable improvement.

The efficiency of rejuvenation treatments is evaluated in the studies no.14 (2005), no.15 (2006) and no.22 (2014).

The so called "rejuvenation" means the healing of skin from damages caused by the UV part of sun light mainly. It includes pigmented lesions such as benign lentigines, skin texture, wrinkles, laxity etc. In study no.14 (2005) more than 120 lentigines of 12 patients were treated, a biopsy taken from each patient and the outcome was assessed. All patients had more than 50% reduction in lentigines (besides one) and the effect was demonstrated in histological findings also. The one patient with unsatisfying result was one of the first patients and treated with 12mm spot size instead of 6mm.

Study no.15 (2006) is very important even though only 12 patients were treated. But in this study a special camera was used, delivering really objective data of skin properties. In this way it could be shown, that with this treatment, the improvement for lentigines was 20%, for pore size 30%, for wrinkles 40% and for skin texture 40%. Of course one cannot expect a strong effect, because this treatment method is very mild and less aggressive compared to e.g. the treatment procedure used in no.14 for lentigines or compared to laxity treatment by surgery.

Study no.22 (2013) is focused to skin laxity. Also for this study an objective instrument was used for evaluation of improvement. 53% of the patients had mild improvement 1 and 3 months after treatment and even 67% had mild improvement 6 months after – demonstrating the known effect, that the formation of new collagen needs time.

**Table 1: Details of treatment results of the studies:**

| Study No. | No. of patients | Most significant results                                                                                                                                                                                                                                                | Notes of the author                                                                                                                                              |
|-----------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1         | 20              | Reduction of hair 3 months after 3 treatments:<br>Spot 8mm: 33%, spot 12mm: 46%, spot 14mm: 45%<br>Hair thickness reduced to 85%.<br>Reduction correlated to hair color after 1 month/ 8mm:<br>black hair 89%, brown 74%, fair 69%                                      | Result is good for 3 treatments.<br><br>Better result for dark hair, because higher melanin absorption causes more heat.                                         |
| 2         | 33              | After three treatments of leg veins<br>- 1-2mm diameter: 70% completely healed<br>- 2-3mm diameter: 50% completely healed<br>- 4mm diameter: 30%, but with more than 3 treatments                                                                                       | Vessels with 3mm and more are excluded in the manual                                                                                                             |
| 3         | 20              | After 3 treatments for hair removal was assessed:<br>- the MS laser is effective in treating brown or black hair in skin type I-IV<br>- MS achieved long lasting hair reduction in most patients after 3 treatments<br>- hair of thicker caliber responded most readily | Results of the study were presented at ASLMS, only the abstract is available. Therefore it is not very detailed.                                                 |
| 4         | 20              | 6 months after 3 treatments for hair reduction: efficiency 75%<br>Hair destruction proven by histology (5 patients).                                                                                                                                                    | Very good result.<br><br>Important proof!                                                                                                                        |
| 5         | 20              | Improvement of Acne inversa (AI) based on hair removal:<br>- fresh inflammations: regression within a few days<br>- scarred inflammations for more than 6 months: healing of inflammations in 6 weeks<br>- scarred abscess cavities: antiseptic effect                  | Experience report only, but very valuable due to the fact, that therapy of AI is very difficult in general.<br>(as expected healing of cavities is not possible) |



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### 3.2. Evaluation of the studies with regard to efficacy

Altogether 906 patients were treated with the MS in the studies and the results were evaluated for efficacy.

The result of the laser treatments for the intended use in question is in general dependent on individual patient (e.g. skin type, area treated, for hair removal: hair color/ thickness, for vascular treatments: vessel diameter), on parameters used, number of treatment sessions and time of follow up. So, it is normal, that the efficacy stated in the studies varies.

Details of the studies related to efficacy are listed in the table 1 below.

The efficacy stated for hair removal is between 50 and 75% after 3 treatments. This is a very good result, because the average number of necessary treatments is higher. In study no.10 with 200 patients the average number of treatment sessions was about 5. The more treatments the more hair reduction can be achieved (up to about 12).

A total hair removal of 100% is not possible, because – dependent on genetics and hormones – during life time the nearly invisible vellus hair develops into the "normal" terminal hair.

In the standard book of Bodendorf et al.: "Dermatologische Lasertherapie/ Laserepilation" (of year 2013), at page 80, it is stated, that hair reduction is possible between 40 and 80% after multiple treatments. This statement is based on the evaluation of actual, comprehensive literature.

In study no.7 of the year 2003 it was already shown, that the treatments with the MS are at least as effective as the "LightSheer" (market leader worldwide and also high power diode as MS) by a very scientific side by side comparison.

Additionally it could be shown in study no.21 (2013), that the last MS version (MS NeXT) is even better than the forerunner device (MS miXT). In study no.18 (2012) it was demonstrated that 82% of patients, who were treated for hair removal with other devices before, had a better efficacy with MS treatment (2013, MS NeXT).

Also important is the histological proof in studies no. 1 (published 2002), 4 (2002) and 8 (2003), that the hair follicles are effectively damaged by the laser light applied with the MS.

The efficacy for treatments of acne could be shown in studies no. 5 (2003) and in a very scientific way in study no. 20 (no.19 was a preliminary case report of 2 patients out of study 20). In 2013 results of this study are published, despite the study is not finished yet. The follow up after 12 months is ready for 40 out of 68 patients. But the outcome of these treatments is so positive, that it was already published before.

One has to know, that acne inversa\* is a very difficult to treat indication. AI is in the first stage an inflammation of the sebaceous gland and outer root sheath of the terminal hair. Later abscesses develop and fistulas and abscess cavities connected with scarring, even though medication is applied. AI is very painful and smells unpleasantly. At the end very often the abscesses have to be split again and again.

It is shown in study no.20, that the HS\* score of 68 patients could be reduced by about 48% after treatment (for hair removal) and even by 77% after one year. That means, the healing process goes on at least for one year and improves the quality of life for these patients. Of course it is not possible to heal abscess cavities (therefore recurrence in these cases possible, but retreatment is no problem). The intention must be to treat in an early stage of AI to prevent later stages.

The efficacy of vascular treatments is demonstrated in studies no.2 (2002), 6 (2003) and 9 (2003). In study no.2 is shown, that the outcome of vessel treatments is dependent on vessel diameter. The vessels were 3 times treated. 70% of leg veins with 1-2mm diameter healed completely. 70% of leg veins with 2-3mm diameter healed completely and 30% only of 4mm vessels healed completely even with more than 3 treatments.

In the user manual leg veins of 3mm and more are excluded, because the efficacy is low.

In study no.6 15 patients (out of 35) had complete clearance and 20 patients had 80% improvement after 1 treatment. That's a very good result, because in general it is not possible to remove all leg veins of all patients. In the standard book of Bodendorf et al.: "Dermatologische Lasertherapie/ Gefäßlaser" (of year 2012), at page 15, it is stated, that a complete removal of leg veins is not always possible.

\*acne inversa = AI = acne at back, breast, axilla or pubic area

= hidradenitis suppurativa = HS (outdated and misleading, because the sweat glands don't cause AI)

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Therefore, it is the clear demand in the RS for this device in question, that the changes to the current device have to be as minor as possible:

- **The intended use is identical to the current MS version**  
Please see also RS chapter 1 (specification of application in detail) and chapters 4.1 (indications) as well as 4.2 (contraindications) of this document.
- The POFs including safety measures are identical to the current version of MS as required in the RS (please see RS, chapter 3.1).
- The basic unit is not changed for the customer. All handpieces, which are available today, keep unchanged.
- For the customer the only difference is the (optional) new, larger handpiece for faster treatments.

Therefore this clinical evaluation can be based on studies and experience with the forerunner device versions of the MS. The CEval 2011 and 2014 of the current MS remains valid.

### 3. Evaluation of literature

#### 3.1. Design of studies realized with MeDioStar

For this evaluation, all clinical studies with MS, published and unpublished, are listed in App.A.

There are 22 studies after approval of the first MS 1999 until now.

Due to the fact, that all studies are realized with the MS, it is not necessary to make a comparison to other devices used in the studies.

In the compilation of studies of App.A, the author of the study, title and source is stated as well as the study design incl. objective, patients treated, parameters used, evaluation, results and safety.

The studies are listed according to the time issued, with the last studies with highest number.

- (A) Out of the 22 studies listed, there are 18 prospective studies and 4 case/ experience reports.  
All literature is hereinafter referred to as "study".

The case/ experience reports are included in this evaluation for a complete overview about published and unpublished literature of treatments realized with the MS so far.

Out of the 18 prospective studies there are 6 comparative studies:

- Comparing spot sizes of 8/ 12/ 14mm for hair removal at legs (no.1)
- Comparing the MS versus the "LightSheer" (no.7), which was and is the most sold high power diode laser worldwide and is equivalent to the MS
- Comparing the MS versions XT (forerunner) and miXT (advanced to that time)
- Comparing MS treatment side versus untreated control (randomized) for hair removal and change of skin properties (no.17)
- Comparing MS treatment side (for acne inversa) versus untreated control (randomized)
- Comparing the MS versions miXT (forerunner) versus NeXT and placebo control (randomized) for hair removal (no.21)

- (B) All treatments in these studies are based on the manual of the MS, including intended use.  
Only in no.2 (see App.A) leg veins are treated, which are larger in diameter than stated in the manual. Vessels larger than 3 mm are stated as contraindication due to the insufficient treatment result, which was the outcome in this case report also.
- (C) Altogether 906 patients were treated in these studies and the results were evaluated for efficacy.  
The quality of the studies is different. Details are listed and discussed in chapter 3.2.
- (D) Altogether 780 patients were treated and evaluated for side effects. Side effects were not mentioned in the abstract of the ASLMS lecture of study no.4 and in experience report no.9.  
The quality of the studies is different. Details are listed and discussed in chapter 3.3.

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## 1. Qualification of the author and the reviewer

The intended use of this new MS version in question has an identical intended use as the approved fore-runner device (CE 1275; see next chapter also). Therefore it is possible, that this evaluation is assessed and review by product managers of Asclepion with long experience in laser application.

The author of this evaluation, Mrs. G. Zimmermann is the Senior Product Manager and the person in duty for medical validation and application by Asclepion Laser Technologies with a lot of experience to carry out clinical evaluations.

Mrs. G. Zimmermann has a diploma in physics and has experience in application of medical lasers for more than 25 years, especially for surgical lasers, lasers for dermatology and aesthetics including MS.

After graduation she developed laser devices as a scientific engineer for more than 10 years. Since 1988 she was responsible for medical application of different lasers including MS and worked together with physicians in various specialties. She also performed laser safety courses including medical application for physicians for 20 years now and educated the sales staff and doctors in using the devices. She was in charge to supervising own application studies and evaluating scientific literature.

Working as Product Manager for more than 20 years she was also responsible for fixing of application parameters of new lasers as well as supporting the development in respect to ergonomically questions, writing the application part of user manuals, evaluating new devices in respect to medical use and ergonomics.

The reviewer of this evaluation, Mrs. Dipl.-Phys. Antje Katzer is an academically certified physicist. She has many years of experience in the application of medical equipment, especially dermatological and laser devices.

In 1986, she completed her study of physics, majoring in laser physics, with a degree in physics.

She then worked in the field of scientific engineering, collecting practical experience in the development and design of laser instruments.

Since 1996, Mrs. Katzer has held the position of Product Manager for Medical Laser Devices, especially equipment for dermatology.

Her job responsibilities include close cooperation with doctors (application of products), which has enabled her to accumulate the medical and application experience that is required for this type of work.

Her special work focus has been, and continues to be, on clinical application studies and participation in the preparation of publications and the evaluation of scientific literature.

## 2. Argument for literature route

The intention for the development of this advanced version of the MS was to reduce the treatment time (especially of extended body areas, e.g. men's back) for the customers and patients.

This is possible with larger spot sizes in a way that with one laser pulse a larger area of skin is simultaneously treated. For realization of these large spot sizes with parameters suitable for the intended treatments, higher power out of the diode laser is necessary. Nowadays more laser power for a reasonable price is available.

Technical changes are necessary, e.g. more diodes in the new handpiece and a more powerful power supply internally in the basic unit. All these technical changes are not relevant for the clinical evaluation.

At the same time complete functionality and intended use of the current MS version (including all handpieces) shall be maintained unchanged.

Nearly 1000 devices were sold of the actual MS versions since 2011 and more than 2500 devices of all versions of the MS family since 1999.

Such a success for our company was only possible because the treatments with MS are very effective on one side, had very low side effects for all skin types on the other side and is uncomplicated, convenient and safe to use for the therapist. There were no reportable complaints and no more side effects than usual for the intended use in question (and stated in the manual) since 15 years, despite the high number of lasers sold.

Last but not least the device is very reliable. Some users from Italy and Turkey reached even 10 million pulses last year with one handpiece, one customer reached already 15 million. With diode lasers for hair removal of other manufacturers on the market, the customers have to replace the handpiece after 1 or 2 million pulses.



|                             |                                                                                                          |                                                                                    |
|-----------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| FB <b>7351e</b>             | <b>Verification / Validation Report</b>                                                                  |  |
| Revision Index:<br><b>B</b> | <b>Identification number: ZI/14/03/27-01</b><br><small>Member Code/year/month/day-sequential no.</small> | Page 2 of 14<br>FB7351e ClinEval MSPRO<br>V01_ZI140327-01.doc                      |

#### History:

| Rev | Brief description of change | Date     | Name       | Signature                                                                           |
|-----|-----------------------------|----------|------------|-------------------------------------------------------------------------------------|
| 01  | First edition               | 22.10.14 | Zimmermann |  |
|     |                             |          |            |                                                                                     |
|     |                             |          |            |                                                                                     |
|     |                             |          |            |                                                                                     |

#### Linked documents:

| document                                                                           | abbreviation | file name                                                                    |
|------------------------------------------------------------------------------------|--------------|------------------------------------------------------------------------------|
| Requirement Specification of the new MS* version                                   | RS           | FB 7321 LH MSPRO V01 ZI140127-01                                             |
| Protocol of search report BfArM + FDA (in KA 7.6: App.3 of usability validation)   | App.3        | TP 7342 Usab-App3-BfArM+FDA Vs1-ZI130827-1                                   |
| Clinical Evaluation MeDioStar SE (brand names: MeDioStar NeXT, The EpiLab, Pronto) | CEval 2011   | FB 7351e ClinEval MS-SE ZI-2011-10-05-01**                                   |
| Clinical Evaluation of the handpiece ALX (supplement to the CEval 2011)            | CEval 2014   | FB 7351e ClinEval ALX HP V01_ZI140113-01**                                   |
| Draft of the user manual of the new MS* version                                    | UM           | 159099001-V06-2.Sept2014-GA-MSPRO-DE<br>159099002-V06-2.Sept2014-GA-MSPRO-EN |

\*MS = MeDioStar

\*\*the CEval 2011 and 2014 are attached at the end of the pdf version of this document (attachments resided in KA MSPRO ALT-M003\_14/ 7.7/ Anhänge ClinEval 2011+2014)

#### CLINICAL EVALUATION MEDIOSTAR

##### CONTENTS:

- 1 Qualification of the author and the reviewer
- 2 Argument for literature route
- 3 Evaluation of literature
  - 3.1 Design of studies realized with MeDioStar
  - 3.2 Evaluation of the studies with regard to efficacy
  - 3.3 Evaluation of the studies with respect to side effects
  - 3.4 Evaluation of reports of the BfArM and FDA
- 4 Final assessment of results
  - 4.1 Indications of the device
  - 4.2 Contraindications
  - 4.3 Conclusions
  - 4.4 Summery

Attached in pdf file of this document:

App.A: TP7342 LiteratureMS V01\_ZI140328-01.pdf

App.B: TP 7342 EvalReports BfArM+FDA 2014

CEval 2011 and CEval 2014

Literature of App.A: resided in KA MSPRO ALT-M003\_14/ 7.7/ AnhangClinEval ZI140327-01

|                             |                                                                                                          |                                                                                    |
|-----------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| FB <b>7351e</b>             | <b>Verification / Validation Report</b>                                                                  |  |
| Revision Index:<br><b>B</b> | <b>Identification number: ZI/14/03/27-01</b><br><small>Member Code/year/month/day-sequential no.</small> | Page 1 of 14<br><small>FB7351e ClinEval MSPRO<br/>V01_ZI140327-01.doc</small>      |

|                           |                                                                                                                                                  |                                                                                                       |                                                      |
|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| <b>VERIFICATION</b>       | <input type="checkbox"/>                                                                                                                         | <b>VALIDATION</b>                                                                                     | <input checked="" type="checkbox"/> <b>CLINICAL</b>  |
| <b>Product / part:</b>    | MeDioStar                                                                                                                                        | <b>Material number:</b>                                                                               | 1591, 1592                                           |
| <b>Cause:</b>             | <input type="checkbox"/> Product development                                                                                                     | <input checked="" type="checkbox"/> Product change                                                    | <input type="checkbox"/>                             |
| <b>Original document:</b> | <input checked="" type="checkbox"/> Requirement specification: FB<br>7321 LH MSPRO V01 ZI140127-01<br><input type="checkbox"/> Risk analysis of: | <input type="checkbox"/> Design specification of:<br><input type="checkbox"/> Change-application no.: | <input type="checkbox"/><br><input type="checkbox"/> |
| <b>Serial number:</b>     | n/a                                                                                                                                              |                                                                                                       |                                                      |

#### BRIEF DESCRIPTION: LITERATURE ROUTE

This clinical evaluation of the advanced, new MeDioStar version in question is based on the current, approved medical device MeDioStar (no. 1590) for the identical intended use. The difference and advantage for the user is simply the new handpiece with larger spots to reduce the treatment time. This new handpiece will be added optionally to the handpieces currently available.

The intended use in all aspects, including treatment procedure is not changed and therefore identical to the current device.

Treatments with devices of the MeDioStar family, which is now sold since 15 years, never caused problems more than the side effects stated in the manual and the treatments with the device are very effective.

#### SELECTED MEASURING AND TEST EQUIPMENT N/A

#### DOCUMENTS OF THE ENCLOSURE: (TEST REPORTS ETC.)

App.A: TP7342 LiteratureMS V01\_ZI140328-01.pdf

App.B: TP 7342 EvalReports BfArM+FDA 2014

#### FINAL ASSESSMENT OF RESULTS: (BRIEF ASSESSMENT, SUMMARY MEASURES)

It was demonstrated in this evaluation, that treatments with the MS are effective and safe. The incidence of side effects is very low and mainly transient. This allows the assessment, that the advantage for the patient overbalances the risks. The new MS version was shown to be equivalent to the current device with respect to the application.

☐ **VERIFICATION / VALIDATION NEGATIVE**  
 If negative, derived measures:

☒ **VERIFICATION / VALIDATION POSITIVE**

Plan Ident-No.: n/a

Verification/Validation performed:

\_\_\_\_\_

Date Name Signature

Oct. 22, 2014 G.Zimmermann 

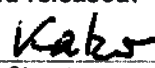
Date Name Signature

Plan checked and released: n/a

Verification/Validation checked and released:

\_\_\_\_\_

Date Name Signature

Oct. 28, 2014 A.Katzer 

Date Name Signature

|                                         |           |             |                                |           |             |
|-----------------------------------------|-----------|-------------|--------------------------------|-----------|-------------|
| Cause of latest modification FB: review |           |             | FB checked and released by QA: |           |             |
| FB drawn by process owner R&D:          |           |             | FB checked and released by QA: |           |             |
| 05.07.2012                              | I. Streit | sdg. Streit | 06.07.2012                     | R. Thieme | sdg. Thieme |
| Date                                    | Name      | Signature   | Date                           | Name      | Signature   |

|                              |                                                                                            |                                                                                     |
|------------------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>CL 7321</b>               | <b>Liste heranzuziehender Richtlinien und harmonisierter und begleitender Normen (MED)</b> |  |
| Änderungs-Index:<br><b>K</b> | Identifikationsnummer: <b>MMo/14/08/21-01</b><br>Kürzel / Jahr / Monat / Tag-lfd.-Nr       | Seite 10 von 10<br>CL 7321 RNmed MSPRO V02 MMo140821-01.doc                         |

#### Anlage 1 Anwendung nicht harmonisierter Normen

| Nr. | Angewandte nicht harmonisierte Normen                                                             | Begründung                                                                                                                                                                                                        |
|-----|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16  | IEC 60 601-2-22: 2007                                                                             | Diese Norm wurde angewendet in Verbindung mit der IEC 60601-1: 2005. Laut Vorwort zur EN 60601-1 ist der Text identisch mit der IEC 60601-1.                                                                      |
| 17  | EN 60 825-1: 2007+ Corr.1: 2008 + Corr.2: 2009                                                    | Die EN 60 601-1 verweist auf diese Norm und wird daher angewendet.                                                                                                                                                |
| 22  | EN ISO 15223-1: 2012                                                                              | Die EN 60 601-1 verweist auf diese Norm und wird daher angewendet.                                                                                                                                                |
| 33  | DIN EN 60 529: 1991/A1:2000                                                                       | Die EN 60 601-1 verweist auf diese Norm und wird daher angewendet.                                                                                                                                                |
| 36  | DIN EN 60721-3-2 : 1998 – 03                                                                      | Diese Norm wurde als Hilfestellung zur Definition von Transportbedingungen herangezogen, da keine vergleichbare harmonisierte Norm vorhanden ist.                                                                 |
| 39  | 21 CFR 1040 (04-1-02 edition) / Notice 50 FDA<br>Code of federal regulations - Food and Drugs 21. | Für Zulassungen in die USA                                                                                                                                                                                        |
| 42  | EN 207:2009 + AC:2011                                                                             | Die Norm wurde herangezogen um die Schutzstufe von Laserbrillen zu bestimmen. Sie wurde verwendet, da keine vergleichbare harmonisierte Norm vorhanden ist.                                                       |
| 44  | DIN EN 50 419: 2006-06                                                                            | Die Norm wurde herangezogen für eine korrekte Kennzeichnung von Elektro- und Elektronikgeräte. da keine vergleichbare harmonisierte Norm vorhanden ist.                                                           |
| 46  | EN ISO 14971: 2009-10                                                                             | Die aktuell harmonisierte EN ISO14971:2012 entspricht normativ der EN ISO 14971: 2009 und wird daher noch angewendet. Änderungen gegenüber der EN ISO14971:2012 (Anhang ZA) wurden in einer GAP Analyse bewertet. |



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| Nr. | zutreffend                          | Richtlinie/ Norm/ Regeln                                                                                                                                                             | Zugehörige CL | Vorhanden |
|-----|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------|
| 46. | <input checked="" type="checkbox"/> | <b>EN ISO 14971: 2009-10</b><br>Medizinprodukte: Anwendung des Risikomanagements auf Medizinprodukte.<br><i>Medical devices - Application of risk management to medical devices.</i> |               |           |

Legende: ☒ zutreffend ☐ nicht zutreffend

|                              |                                                                                            |                                                               |                                                                                     |
|------------------------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>CL 7321</b>               | <b>Liste heranzuziehender Richtlinien und harmonisierter und begleitender Normen (MED)</b> |                                                               |  |
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| Nr.              | zutreffend                          | Richtlinie/ Norm/ Regeln                                                                                                                                                                                      | Zugehörige CL | Vorhanden                           |
|------------------|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------------------------|
| 38.              | <input type="checkbox"/>            | <b>UL 60601-1</b> (U.S. national deviations)<br>Medical Electrical Equipment, Part 1<br><i>General Requirements for Safety</i>                                                                                |               |                                     |
| 39.              | <input checked="" type="checkbox"/> | <b>21 CFR 1040</b> (04-1-02 edition) / Notice 50 FDA<br><i>Code of federal regulations - Food and Drugs 21.</i>                                                                                               |               |                                     |
| 40.              | <input type="checkbox"/>            | <b>CAN/CSA-ISO 13485:2003</b><br>Quality management systems- Requirements for regulatory purpose CMDCAS<br><i>Canadian Medical Devices Conformity Assessment System</i>                                       |               |                                     |
| 41.              | <input type="checkbox"/>            | <b>ISO 14971: 2007</b><br>Medical devices - Application of risk management to medical devices<br><i>Medical devices - Application of risk management to medical devices.</i>                                  |               |                                     |
| 42.              | <input type="checkbox"/>            | <b>EN 207:2009 + AC:2011</b><br>Personal eye-protection equipment - Filters and eye-protectors against laser radiation<br><i>Persönlicher Augenschutz - Filter und Augenschutzgeräte gegen Laserstrahlung</i> |               |                                     |
| 43.              | <input type="checkbox"/>            | <b>DIN 58298:2010</b><br>Medizinische Instrumente - Werkstoffe, Ausführung und Prüfung<br><i>Medical instruments - Materials, finish and testing</i>                                                          |               |                                     |
| 44.              | <input checked="" type="checkbox"/> | <b>DIN EN 50 419: 2006-06</b><br>Kennzeichnung von Elektro- und Elektronikgeräten.<br><i>Marking of electrical and electronic equipment.</i>                                                                  |               |                                     |
| 45. <sup>H</sup> | <input checked="" type="checkbox"/> | <b>EN 980: 2008</b><br>Symbole zur Kennzeichnung von Medizinprodukten<br><i>Symbols for use in the labeling of medical devices</i>                                                                            | CL 7363       | <input checked="" type="checkbox"/> |

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|------------------------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| <b>CL 7321</b>               | <b>Liste heranzuziehender Richtlinien und harmonisierter und begleitender Normen (MED)</b> |  |
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| Nr.  | zutreffend                          | Richtlinie/ Norm/ Regeln                                                                                                                                                                                                                                                                                                                                           | Zugehörige CL | Vorhanden                           |
|------|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------------------------|
| 31.H | <input type="checkbox"/>            | <b>EN ISO 14971: 2012</b><br>Medizinprodukte: Anwendung des Risikomanagements auf Medizinprodukte.<br><i>Medical devices - Application of risk management to medical devices.</i>                                                                                                                                                                                  |               |                                     |
| 32.  | <input checked="" type="checkbox"/> | <b>EN 50581:2012</b><br>Technisch Dokumentation zur Beurteilung von Elektro- und Elektronikgeräten hinsichtlich der Beschränkung gefährlicher Stoffe<br><i>Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances</i>                                                            | CL 7375       | <input checked="" type="checkbox"/> |
| 33.  | <input checked="" type="checkbox"/> | <b>DIN EN 60 529: 1991/A1:2000</b><br>Schutzarten durch Gehäuse (IP- Code).<br><i>Degrees of protection provided by enclosures (IP code).</i>                                                                                                                                                                                                                      |               |                                     |
| 34.  | <input type="checkbox"/>            | <b>DIN EN ISO 14644-1:1999 – 07</b><br>Reinräume und zugehörige Reinraumbereiche Teil1: Klassifizierung der Luftreinheit<br><i>Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness</i>                                                                                                                                   |               |                                     |
| 35.  | <input type="checkbox"/>            | <b>DIN EN ISO 14644-2: 2001 – 02</b><br>Reinräume und zugehörige Reinraumbereiche Teil2: Festlegung zur Prüfung und Überwachung zum Nachweis der laufenden Übereinstimmung mit ISO 14644-1<br><i>Cleanrooms and associated controlled environments – Part 2: Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1</i> |               |                                     |
| 36.  | <input checked="" type="checkbox"/> | <b>DIN EN 60721-3-2 : 1998 – 03</b><br>Klassifizierung von Umweltbedingungen Teil 3 Klassen von Umwelteinflußgrößen und deren Grenzwerte<br>Hauptabschnitt 2: Transport<br><i>Classification of environmental conditions - Part 3: Classification of groups of environmental parameters and their severities - Section 2: Transportation</i>                       |               |                                     |
| 37.  | <input type="checkbox"/>            | <b>CAN/CSA C22.2 No. 601.1 (Canadian national deviations)</b><br>Medical Electrical Equipment, Part 1<br><i>General Requirements for Safety</i>                                                                                                                                                                                                                    |               |                                     |

Legende: ☒ zutreffend ☐ nicht zutreffend



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|------------------------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>CL 7321</b>               | <b>Liste heranzuziehender Richtlinien und harmonisierter und begleitender Normen (MED)</b> |                                                               |  |
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| Nr.   | zutreffend                          | Richtlinie/ Norm/ Regeln                                                                                                                                                                                                                                                                                                                                                                                                         | Zugehörige CL | Vorhanden                |
|-------|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--------------------------|
| 26. H | <input type="checkbox"/>            | <b>EN 556-1: 2001 +AC:2006</b><br>Sterilisation von Medizinprodukten: Anforderungen an Medizinprodukte, die als „STERIL“ gekennzeichnet werden;<br>Teil 1: Anforderungen an Medizinprodukte, die in der Endpackung sterilisiert wurden.<br><i>Sterilization of medical devices – Requirements for medical devices to be designated "STERIL" – Part 1: Requirements for terminally sterilized medical devices.</i>                |               |                          |
| 27. H | <input type="checkbox"/>            | <b>EN ISO 11135-1:2007</b><br>Sterilisation von Produkten für die Gesundheitsfürsorge - Ethylenoxid<br>Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte<br><i>Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices</i> | CL 7522       | <input type="checkbox"/> |
| 28.H  | <input type="checkbox"/>            | <b>EN ISO 17665-1: 2006</b><br>Sterilisation von Produkten für die Gesundheitsfürsorge – Feucht Hitze - Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte<br><i>Sterilization of health care products – Moist heat</i>                                                                                                                                  | CL 7377       | <input type="checkbox"/> |
| 29.H  | <input type="checkbox"/>            | <b>EN ISO 11607-1 : 2009</b><br>Verpackung für in der Endverpackung zu sterilisierende Medizinprodukte<br>Teil 1: Anforderungen an Materialien, Sterilbarriersysteme und Verpackungssysteme<br><i>Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems</i>                                                                                    | CL 7521       | <input type="checkbox"/> |
|       |                                     | <b>EN ISO 11607-2 : 2006</b><br>Verpackung für in der Endverpackung zu sterilisierende Medizinprodukte<br>Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens<br><i>Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes</i>                                                                           |               |                          |
| 30.H  | <input checked="" type="checkbox"/> | <b>EN ISO 13485: 2012 + AC2012</b><br>Qualitätssicherungssysteme - Medizinprodukte – Anforderungen für regulatorische Zwecke<br><i>Quality systems - Medical devices - Requirements for regulatory purposes.</i>                                                                                                                                                                                                                 |               |                          |

|                       |                                                                                      |                                                                                    |
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| CL 7321               | Liste heranzuziehender Richtlinien und harmonisierter und begleitender Normen (MED)  |  |
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| Nr.   | zutreffend                          | Richtlinie/ Norm/ Regeln                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Zugehörige CL | Vorhanden                               |
|-------|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------------|
| 19.   | <input checked="" type="checkbox"/> | <b>MEDDEV 271 2.7.1 Rev.3 Clinical Evaluation</b><br>Guidelines on Medical Devices- Evaluation of clinical Data (A guide for Manufactures and Notified Body)                                                                                                                                                                                                                                                                                                                           | CL 73641      | <input checked="" type="checkbox"/>     |
| 20. H | <input type="checkbox"/>            | <b>EN ISO 14155: 2011 + AC:2011</b><br>Klinische Prüfung von Medizinprodukten an Menschen-Teil 1: Allgemeine Anforderungen<br><i>Clinical Investigation of medical devices for human subjects.</i>                                                                                                                                                                                                                                                                                     |               |                                         |
| 21. H | <input checked="" type="checkbox"/> | <b>EN 1041: 2008</b><br>Bereitstellung von Informationen durch den Hersteller von Medizinprodukten<br><i>Information supplied by the manufacturer of medical devices</i>                                                                                                                                                                                                                                                                                                               | CL 7364       | <input checked="" type="checkbox"/>     |
| 22.   | <input checked="" type="checkbox"/> | <b>EN ISO 15223-1: 2012</b><br>Medizinprodukte - Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen - Teil 1: Allgemeine Anforderungen<br><i>Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements</i>                                                                                                                                    | CL 7363       | <input checked="" type="checkbox"/>     |
| 23. H | <input checked="" type="checkbox"/> | <b>EN ISO 10993-1:2009 / AC:2010</b><br>Biologische Beurteilung von Medizinprodukten; Teil 1: Beurteilung und Prüfungen.<br><i>Biological evaluation of medical devices -- Part 1: Evaluation and testing.</i>                                                                                                                                                                                                                                                                         | CL 7372       | <input checked="" type="checkbox"/> * ^ |
| 24. H | <input type="checkbox"/>            | <b>EN ISO 14937: 2009</b><br>Sterilisation von Medizinprodukten - Allgemeine Anforderungen an die Charakterisierung eines Sterilisierungsmittels und an die Entwicklung, Validierung und Routineüberwachung eines Sterilisierungsverfahrens für Medizinprodukte.<br><i>Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices</i> |               |                                         |
| 25. H | <input type="checkbox"/>            | <b>EN ISO 17664: 2004</b><br>Sterilisation von Medizinprodukten – vom Hersteller bereitzustellende Informationen für die Wiederaufbereitung von resterilisierbaren Geräten.<br><i>Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.</i>                                                                                                                                                          | CL 7376       | <input type="checkbox"/>                |

\* Verifizierung vorhanden

Legende: ☒ zutreffend ☐ nicht zutreffend

|                              |                                                                                            |                                                                                     |
|------------------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>CL 7321</b>               | <b>Liste heranzuziehender Richtlinien und harmonisierter und begleitender Normen (MED)</b> |  |
| Änderungs-Index:<br><b>K</b> | Identifikationsnummer: <b>MMo/14/08/21-01</b><br>Kürzel / Jahr / Monat / Tag-lfd.-Nr       | Seite 4 von 10<br>CL 7321 <del>MMo</del> MSPRO V02 MMo140821-01.doc                 |

| Nr.   | zutreffend                          | Richtlinie/ Norm/ Regeln                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Zugehörige CL                                     | Vorhanden                           |
|-------|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------------------------------|
| 13. H | <input checked="" type="checkbox"/> | <b>EN 60601-1-6: 2010</b><br>Medizinische elektrische Geräte - Teil 1-6: Allgemeine Festlegungen für die Sicherheit – Ergänzungsnorm: Gebrauchstauglichkeit.<br><i>Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability.</i><br>(Anwendung in Verbindung mit EN 60601-1: 2006)                                                                                                                                                                                                                         | CL 73523                                          | <input checked="" type="checkbox"/> |
| 14. H | <input checked="" type="checkbox"/> | <b>EN 62 366: 2008</b><br>Medizinprodukte - Anwendung der Gebrauchstauglichkeit auf Medizinprodukte.<br><i>Medical devices - Application of usability engineering to medical devices.</i>                                                                                                                                                                                                                                                                                                                                                                   | CL 73523                                          | <input checked="" type="checkbox"/> |
| 15. H | <input type="checkbox"/>            | <b>EN 60 601-2-22: 1996- mit Berichtigung 1:1997 + Beiblatt 1</b><br>Medizinische elektrische Geräte - Teil 2: Besondere Festlegungen für die Sicherheit von diagnostischen und therapeutischen Lasergeräten.<br><i>Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.</i>                                                                                                                                                                                                        | CL 7354                                           | <input type="checkbox"/>            |
| 16.   | <input checked="" type="checkbox"/> | <b>IEC 60 601-2-22: 2007</b><br>Medizinische elektrische Geräte - Teil 2-22: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für chirurgische, therapeutische und diagnostische Lasergeräte<br><i>Medical Electrical Equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, therapeutic and diagnostic laser equipment</i><br>(Anzuwenden nur in Verbindung mit IEC 60601-1: 2005)                                                                                | CL 7354<br>oder Prüfbericht<br>externe Prüfstelle | <input checked="" type="checkbox"/> |
| 17.   | <input checked="" type="checkbox"/> | <b>EN 60 825-1: 2007+ Corr.1: 2008 + Corr.2: 2009</b><br>Sicherheit von Lasereinrichtungen; Teil 1: Klassifizierung von Anlagen und Anforderungen.<br><i>Safety of laser products; Part 1: Equipment classification and requirements.</i>                                                                                                                                                                                                                                                                                                                   | CL 7355                                           | <input checked="" type="checkbox"/> |
| 18.   | <input type="checkbox"/>            | <b>EN 60601-2-57:2011</b><br>Medizinische elektrische Geräte - Teil 2-57: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten mit Nicht-Laser-Lichtquellen für die Anwendung in der Therapie, Diagnose, Überwachung und für kosmetische/ästhetische Zwecke.<br><i>Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.</i> |                                                   |                                     |



|                       |                                                                                      |                                                                                                                         |
|-----------------------|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| CL 7321               | Liste heranzuziehender Richtlinien und harmonisierter und begleitender Normen (MED)  | <br>Asclepion<br>Labor Technik, Sales |
| Änderungs-Index:<br>K | Identifikationsnummer: <b>MMo/14/08/21-01</b><br>Kürzel / Jahr / Monat / Tag-lfd.-Nr | Seite 3 von 10<br>CL 7321 RNmed MSPRO V02 MMo140821-01.doc                                                              |

| Nr.   | zutreffend                          | Richtlinie/ Norm/ Regeln                                                                                                                                                                                                                                                                                                                                                                                                                              | Zugehörige CL                                                                                     | Vorhanden                                                                      |
|-------|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| 7.    | <input type="checkbox"/>            | <b>EN 60601-1: 1990 + A1:1993 + A2:1995</b><br>Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit.<br><i>Medical electrical equipment - Part 1: General requirements for safety.</i><br>(Nicht für Neuentwicklung, nur für Änderung/ Ergänzung)                                                                                                                                                                     | CL 7352                                                                                           | <input type="checkbox"/>                                                       |
| 8. H  | <input checked="" type="checkbox"/> | <b>EN 60601-1: 2006</b><br>Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit.<br><i>Medical electrical equipment - Part 1: General requirements for safety.</i>                                                                                                                                                                                                                                                    | CL 73525<br>oder TRF externe Prüfstelle<br><br>CL 73524<br>oder<br>Prüfbericht externe Prüfstelle | <input checked="" type="checkbox"/><br><br><input checked="" type="checkbox"/> |
| 9. H  | <input checked="" type="checkbox"/> | <b>EN 60 601-1-2: 2007</b><br>Medizinische elektrische Geräte – Teil 1-2: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Elektromagnetische Verträglichkeit - Anforderungen und Prüfungen.<br><i>Medical electrical equipment - Part 1-2: General requirements for safety and essential performance- Collateral standard: Electromagnetic compatibility - Requirements and tests.</i> | CL 73532                                                                                          | <input checked="" type="checkbox"/>                                            |
| 10.   | <input type="checkbox"/>            | <b>EN 60601-1-4: 1996 + A1: 1999</b><br>Medizinische elektrische Geräte - Teil 1-4: Allgemeine Festlegungen für die Sicherheit - Ergänzungsnorm: Programmierbare elektrische medizinische Systeme.<br><i>Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems.</i><br>(Anwendung in Verbindung mit EN 60601-1: 1990 + A1:1993 + A2:1995)                           | CL 7361                                                                                           | <input type="checkbox"/>                                                       |
| 11. H | <input checked="" type="checkbox"/> | <b>EN 62304: 2006 / AC:2008</b><br>Medizinische Software - Software-Lebenszyklus-Prozesse<br><i>Medical device software - Software life-cycle processes</i>                                                                                                                                                                                                                                                                                           | CL 7365                                                                                           | <input checked="" type="checkbox"/>                                            |
| 12.   | <input type="checkbox"/>            | <b>EN 60601-1-6: 2007</b><br>Medizinische elektrische Geräte - Teil 1-6: Allgemeine Festlegungen für die Sicherheit – Ergänzungsnorm: Gebrauchstauglichkeit.<br><i>Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability.</i><br>(Anwendung in Verbindung mit EN 60601-1: 1990 + A1:1993 + A2:1995)                                                                                               |                                                                                                   |                                                                                |

Legende: ☒ zutreffend ☐ nicht zutreffend

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|------------------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>CL 7321</b>               | <b>Liste heranzuziehender Richtlinien und harmonisierter und begleitender Normen (MED)</b> |  |
| Änderungs-Index:<br><b>K</b> | Identifikationsnummer: <b>MMo/14/08/21-01</b><br>Kürzel / Jahr / Monat / Tag-lfd.-Nr       | Seite 2 von 10<br>CL 7321 RNmed MSPRO V02 MMo140821-01.doc                          |

| Nr.  | zutreffend                          | Richtlinie/ Norm/ Regeln                                                                                                                                                                                                                                                                                                      | Zugehörige CL | Vorhanden                           |
|------|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------------------------|
| 1. H | <input checked="" type="checkbox"/> | <b>93/42/EWG</b><br>Richtlinie 93/42/EWG des Rates über Medizinprodukte (Stand 21.03.2010)<br><i>Council directive 93/42/EEC of 14 June 1993 concerning medical devices</i><br><i>Official Journal of the European Communities</i>                                                                                            | CL 7351       | <input checked="" type="checkbox"/> |
| 2.   | <input checked="" type="checkbox"/> | <b>2011/65/EU (RoHS)</b><br>Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (Stand 08.06.2011)<br><i>Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment</i>      | CL 7373       | <input checked="" type="checkbox"/> |
| 3.   | <input checked="" type="checkbox"/> | <b>2012/19/EU (WEEE)</b><br>Richtlinie 2012/19/EU über Elektro- und Elektronik-Altgeräte (Stand 4. Juli 2012)<br><i>Directive 2012/19/EU of 4 July 2012 on waste electrical and electronic equipment</i>                                                                                                                      |               |                                     |
| 4.   | <input type="checkbox"/>            | <b>89/686/EWG +M1 + M2 + M3 + M4</b><br>Richtlinie des Rates zur Angleichung der Rechtsvorschriften der Mitgliedstaaten für persönliche Schutzausrüstungen (Stand 31.10.2003)<br><i>Council directive of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment</i> |               |                                     |
| 5.   | <input type="checkbox"/>            | <b>2006/42/EG</b><br>Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates (Stand 17. Mai 2006) über Maschinen und zur Änderung der Richtlinie 95/16/EG<br><i>Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery , and amending Directive 95/16/EC</i>                  |               |                                     |
| 6.   | <input checked="" type="checkbox"/> | <b>Medical Devices Regulations (SOR/98-282)</b><br><i>(FOOD AND DRUGS ACT) Canada</i><br><b>Code of Federal Regulation; Quality System Regulation 21 CFR Part 820</b><br><i>(FOOD AND DRUGS) USA</i>                                                                                                                          | CL 7350       | <input checked="" type="checkbox"/> |

|                              |                                                                                            |                                                                                    |
|------------------------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| <b>CL 7321</b>               | <b>Liste heranzuziehender Richtlinien und harmonisierter und begleitender Normen (MED)</b> |  |
| Änderungs-Index:<br><b>K</b> | Identifikationsnummer: <b>MMo/14/08/21-01</b><br>Kürzel / Jahr / Monat / Tag-lfd.-Nr       | Seite 1 von 10<br>CL 7321 RNmed MSPRO V02 MMo140821-01.doc                         |

| Für:                            |                               | Erstellt: |                                        |          |          |                                                                                     |
|---------------------------------|-------------------------------|-----------|----------------------------------------|----------|----------|-------------------------------------------------------------------------------------|
| Entwicklungsprojekt:            | MeDioStar WE                  | Vs.       | Kurzbeschreibung der Änderung          | Datum    | Name     | Unterschrift                                                                        |
| Projektnummer:                  | 4800 93A 73400                | 01        | Erstausgabe                            | 07.02.14 | I.Streit | Sgd. Möller                                                                         |
| Produktname (falls vergeben):   | MeDioStar NeXT <sup>Pro</sup> | 02        | Kontrolle der herangezogenen RL/Normen | 21.08.14 | M.Möller |  |
| Artikelnummer (falls vergeben): | 1591, 1592                    |           |                                        |          |          |                                                                                     |

Hinweis: Diese Liste enthält grundlegende Normen und ist bei Bedarf um entsprechende gerätespezifische Normen zu erweitern.

Mit „H“ gekennzeichnete Normen sind harmonisiert nach RL 93/42/EWG

Mit „V“ gekennzeichnet bedeutet – verbindliche Guideline der Europäischen Kommission

| Prüfung und Freigabe: | Bereich | Datum      | Name      | Unterschrift                                                                          |
|-----------------------|---------|------------|-----------|---------------------------------------------------------------------------------------|
| Geprüft durch         | QS FuE  | 13.11.2014 | C. Kötter |   |
| Freigegeben durch     | QM      | 13.11.2014 | Thieme    |  |

|                                                                                                                                                           |                   |                             |                                      |                   |                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------|--------------------------------|
| Grund für letzte Änderung der CL: Ergänzung Nr.2, 3, 4, 16,32, 42, 43; Aktualisierung Ausgabe Nr. 13H, 19, 22; Checkliste für 22, 25H und 28H hinzugefügt |                   |                             |                                      |                   |                                |
| CL erstellt durch Prozesseigner FuE:                                                                                                                      |                   |                             | CL geprüft und freigegeben durch QM: |                   |                                |
| 27.01.2014<br>Datum                                                                                                                                       | C. Möller<br>Name | Gez. Möller<br>Unterschrift | 29.01.14<br>Datum                    | R. Thieme<br>Name | Gez. R. Thieme<br>Unterschrift |

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|------------------------|-----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| TP <b>7342</b>         | <b>Supporting documents</b><br>Appendix to „CL7351 93-42-EEC MSPRO V01 CaM141112-01“          | <br><b>Asclepion</b><br>www.aclepion.ru |
| Änderungs-<br>Index: A | <b>Idendification number: CaM/14/11/12-02</b><br>Member code/year/month/day-sequential number | Seite 1 von 1<br>TP 7342 Appendix 93-42-EEC<br>MSPRO V01 CaM141112-02.doc                                                 |

### Supporting documents

| Identification                           | Name of document                                                                                                                                    | Filing<br>(KA ALT M 003/14) |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| User manual                              | 159099002-V06-2.Sept.2014-GA-MSPRO-EN                                                                                                               | 2.2                         |
| Type plate                               | Typenschild MeDioStar (NeXTPRO)                                                                                                                     | 2.3                         |
| Risk analysis and control                | FB 7302 RAaC MSPRO V03 RH141110-01                                                                                                                  | 7.2.2                       |
| Risk Management Report                   | FB 7301 RMR MSPRO V02 RH141110-02                                                                                                                   | 7.2.1                       |
| GAP Analysis to EN ISO 14971:2012        | FB 7303 14971 Anhang ZA MSPRO V01_MMo140826-03                                                                                                      | 7.2.1                       |
| Product Characterization Form            | IEC 60601-1 PCF MSPRO                                                                                                                               | 7.2.2                       |
| Test Report EN 60601-1                   | 21215627_001_ IEC60601-1 Test report                                                                                                                | 7.3                         |
| Test Report EN 60601-1-2                 | 1430-13-EE-14-PB001                                                                                                                                 | 7.4                         |
| Conformity Evaluation EMV                | CL 73532 Bewertung EMV MSPRO V01_MMo140825-01                                                                                                       | 7.4                         |
| Conformity Evaluation IEC 60601-1-22     | 21215627_001_attm#3_ IEC60601-2-22                                                                                                                  | 7.3                         |
| Conformity Evaluation EN 60825-1         | CL 7355 EN 60 825-1 MSPRO VS01 IS140212-02                                                                                                          | 7.8                         |
| Conformity Evaluation EN 62304           | CL 7365 62304 MSPRO V01 RH140701-01                                                                                                                 | 7.5                         |
| Conformity Evaluation Usability          | FB 73513 UsabilityFile MSPRO Vs01 ZI 140429-01                                                                                                      | 7.6                         |
|                                          | CL 73523 Usab MSPRO Vs01_ZI140703-01                                                                                                                | 7.6                         |
| Conformity Evaluation EN 1041            | CL 7364 EN 1041 MSPRO 159x V01_MMo140704-01                                                                                                         | 7.9                         |
| Conformity Evaluation EN 980 / EN15223-1 | CL 7363 EN 980 EN 15223-1 MSPRO V01_MMo140819-04                                                                                                    | 7.9                         |
| Clinical Evaluation                      | CL73641 ClinEval MSPRO-Vs01_ZI140429-01                                                                                                             | 7.7                         |
|                                          | FB7351e ClinEval MSPRO V01_ZI140327-01                                                                                                              | 7.7                         |
| Evaluation material compatibility        | FB7351e Veri Biocom MS NeXT HP V02 IH140617-01<br>FB7351e Veri Biocom MS PRO HP V01 IH140710-01<br>FB 7336 Bewertung MatVer Gerät V01 AWi 141010-01 | 7.13                        |
| Conformity Evaluation EN ISO 10993-1     | CL7372 EN ISO 10993 MSPRO HP IH141111-04                                                                                                            | 7.13                        |
| Checklist user manual                    | CL7356 GA MSPRO V02_ZI141027-01                                                                                                                     | 7.9                         |
| Checklist device labels                  | CL7357 Geräteschilder MSPRO V04_AWi141110-02                                                                                                        | 7.9                         |
| Device Classification                    | FB 7320 Klassifizierung MPG_MDR MSPRO V01 MMo140207-01                                                                                              | 3.2.1                       |
| Device Verification                      | FB 7351 Veri Gesamtgerät MSPRO V02 AWi141110-01                                                                                                     | 7.9                         |
| Handpiece Verification                   | FB7351e Veri MSPRO HP V01 IH141111-03                                                                                                               | 7.12                        |

Drawn up:

| Vs. | Description of change | Date     | Name        | Sign |
|-----|-----------------------|----------|-------------|------|
| 01  | First edition         | 12.11.14 | C. Kahlberg | UKL  |

|                   |                                                                                                                                                                       |                                                                                                                      |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| CL 7351           | <b>Grundlegende Anforderungen zur Bewertung der Konformität nach<br/>RL 93/42/EWG *</b><br><b>Conformity Evaluation Essential Requirements acc. to CD 93/42/EEC *</b> | <br>Asclepion<br>Laser Technology |
| Revision index: C | <b>Identification number: CaM/14/11/12-01</b><br>Identification code/year/month/day-number                                                                            | page 30 of 30<br>CL7351 93-42-EEC MSPRO V.01<br>CaM141112-01.doc                                                     |

| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Übereinstimmung<br>compliance       |                                     |                                     | harmonized<br>standard                              | remarks, deviations<br>and/or risks |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-----------------------------------------------------|-------------------------------------|
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ja<br>yes                           | nein<br>no                          | N/A                                 |                                                     |                                     |
|            | Der Nachweis der Übereinstimmung mit den grundlegenden Anforderungen auf der Grundlage klinischer Daten ist notwendig:<br>Evidence of compliance with the essential requirements is me on the basis of clinical data is necessary:<br><br>wenn „Nein“, If „NO“<br><br>diese Ausnahme ist angemessen begründet<br>this exception is properly justified<br><br>Die Begründung beruht auf dem Ergebnis des Risikomanagements und berücksichtigt die Besonderheiten der Wechselwirkung zwischen Körper und Produkt, die bezweckte klinische Leistung und die Angaben des Herstellers.<br>The reasoning is based on the outcome of the risk management and takes into account the specificities of inter-actions between body and product, the clinical performance and the manufacturer's claims.<br><br>Der Nachweis der Übereinstimmung mit den grundlegenden Anforderungen erfolgt „NICHT“ allein durch Leistungsbewertung, Produktprüfung und präklinische Bewertung.<br>Evidence of compliance with the essential requirements to be done "NOT" solely by performance, pro-duktpfung and preclinical evaluation.<br><br>Wenn „NEIN“: If „NO“<br><br>die Eignung dieses Nachweises ist ordnungsgemäß begründet.<br>the adequacy of that evidence is properly grounded. | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | EN ISO 13485:2003<br>+ AC 2009<br>MEDDEV 2.7.1:2009 | Clinical Evaluation                 |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |                                                     |                                     |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |                                                     |                                     |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |                                                     |                                     |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |                                                     |                                     |
| N          | <b>Anhang IX Klassifizierungskriterien</b><br><b>Annex IX classification criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                     |                                     |                                     |                                                     |                                     |
|            | Eine Klassifizierung des Gerätes entsprechend der Regeln des Anhanges IX ist erfolgt.<br>Das Vorgehen wurde dokumentiert<br>A classification of the device according to the rules of Annex IX is erfolgt.Das approach has been documented                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | EN ISO 13485:2003<br>+ AC 2009                      | Class IIb<br>Device Classification  |





|                   |                                                                                                                                                                       |                                                                                     |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| CL 7351           | <b>Grundlegende Anforderungen zur Bewertung der Konformität nach<br/>RL 93/42/EWG *</b><br><b>Conformity Evaluation Essential Requirements acc. to CD 93/42/EEC *</b> |  |
| Revision index: C | <b>Identification number: CaM/14/11/12-01</b><br><small>Identification code/year/month/day-number</small>                                                             | page 28 of 30<br><small>CL7351 93-42-EEC MSPRO V01<br/>CaM141112-01.doc</small>     |

| para-<br>graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                            | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard                                 | remarks, deviations<br>and/or risks                                                                              |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | ja<br>yes                           | nein<br>no               | N/A                                 |                                                        |                                                                                                                  |
| 1.1.2          | Oder einer kritischen Bewertung der Ergebnisse sämtlicher durchgeführten klinischen Prüfungen<br>Or a critical evaluation of the results of all clinical examinations                                                                                                                                                                                                                                                                                                                                         | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                        | n.a.                                                                                                             |
| 1.1.3          | Oder einer kritischen Bewertung der kombinierten klinischen Daten gemäß 1.1.1 und 1.1.2<br>Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2                                                                                                                                                                                                                                                                                                                                 | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                        | n.a.                                                                                                             |
| 1.1a           | Implantierbares Produkt oder Produkt der Klasse III<br>Implantable device or product of class III<br>Wenn ja, If yes<br><br><ul style="list-style-type: none"> <li>Klinische Prüfung ist durchgeführt<br/>Clinical examination is carried out oder / or</li> <li>Klinische Prüfung ist nicht durchgeführt, die Verwendung bereits bestehender klinischer Daten ist ausreichend gerechtfertigt<br/>Clinical examination is not performed, the use of existing clinical data is sufficient justified</li> </ul> | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                        | n.a.                                                                                                             |
| 1..b           | Die klinische Bewertung und ihre Ergebnis ist dokumentiert.<br>Die Dokumentation und/ oder ein ausführlicher Verweis darauf sind in der technischen Dokumentation über das Produkt aufgenommen.<br>The clinical evaluation and its result is documented. The documentation and / or fully referenced in the technical documentation included on the product.                                                                                                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | MEDDEV 2.7.1:2009<br>EN 60601-1-6:2010<br>EN 1041:2008 | Clinical Evaluation<br>Conformity Evaluation Usability Conformity<br>Evaluation EN 1041<br>Checklist user manual |

|                   |                                                                                                                                                                       |                                                                                    |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| CL <b>7351</b>    | <b>Grundlegende Anforderungen zur Bewertung der Konformität nach<br/>RL 93/42/EWG *</b><br><b>Conformity Evaluation Essential Requirements acc. to CD 93/42/EEC *</b> |  |
| Revision index: C | <b>Identification number: CaM/14/11/12-01</b><br><small>Identification code/year/month/day-number</small>                                                             | page 27 of 30<br><small>CL7351 93-42-EEC MSPRO V01<br/>CaM141112-01 doc</small>    |

| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Übereinstimmung<br>compliance       |                          |                          | harmonized<br>standard | remarks, deviations<br>and/or risks                                                                            |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|------------------------|----------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | ja<br>yes                           | nein<br>no               | N/A                      |                        |                                                                                                                |
| N          | q) Datum der Ausgabe oder der letzten Überarbeitung der Gebrauchsanweisung.<br>Date or edition or the last modification of the user manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 1041:2008           | Conformity Evaluation EN 1041<br>Checklist user manual                                                         |
| N          | <b>Anhang X</b><br>Annex X<br><b>Klinische Bewertung</b><br>Clinical evaluation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                     |                          |                          |                        |                                                                                                                |
| 1.<br>1.1  | <b>Allgemeine Bestimmungen</b><br><b>General requirements</b><br>Der Nachweis, dass die Anforderungen den Abschnitten 1, 3 und 6 nach Anhang I erfüllt werden, erfolgt auf der Grundlage klinischer Daten.<br>The verification, that the requirements of sections 1,3 and 6 acc. Annex I will be fulfilled, is based on clinical data.<br>Die Bewertung dieser Daten (klinische Bewertung) erfolgt gemäß einem definierten und methodisch einwandfreien Verfahren auf der Grundlage:<br>The evaluation of these data (clinical evaluation) must follow a defined and methodologically sound procedure based on Ver:                                                                                                                                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | MEDDEV 2.7.1:2009      | Same applications and similar parameters as the forerunner device<br>MedioStar NeXT<br><br>Clinical Evaluation |
| 1.1.1      | Einer kritischen Bewertung der einschlägigen, derzeit verfügbaren wissenschaftlichen Literatur über Sicherheit, Leistung, Auslegungsmerkmale und Zweckbestimmung des Produkts Dabei<br>A critical evaluation of the relevant scientific literature currently available cash-on security, performance, design characteristics and intended use of the Product database<br>- wird die Gleichartigkeit des Produkts mit dem Produkt nachgewiesen, auf dass sich die Daten beziehen<br>Is the similarity of the product to the device, refer to that data<br>Und /and<br>- belegen die Daten in angemessener Weise die Übereinstimmung mit den einschlägigen grundlegenden Anforderungen<br>The data as appropriate, the Convention with the consent relevant basic requirements | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | MEDDEV 2.7.1:2009      | Clinical Evaluation                                                                                            |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                        |                                                                                                                |

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| para-<br>graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard                                   | remarks, deviations<br>and/or risks                                                                       |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ja<br>yes                           | nein<br>no               | N/A                                 |                                                          |                                                                                                           |
| k)             | <p>Gegebenenfalls Angaben die es dem medizinischen Personal erlauben, den Patienten auf Gegenanzeigen und zu treffende Vorsichtsmaßnahmen hinzuweisen. Dabei handelt es sich insbesondere um folgende Punkte:<br/>Vorsichtsmaßnahmen, die im Falle von Änderungen in der Leistung des Produkts zu treffen sind;<br/>The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:<br/>precautions to be taken in the event of changes in the performance of the device;</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1-6:2010<br>IEC 60601-2-22:2007<br>EN 1041:2008 | <p>Checklist user manual<br/>Conformity Evaluation IEC 60601-1-22<br/>Conformity Evaluation Usability</p> |
| l)             | <p>Vorsichtsmaßnahmen für den Fall, dass es unter vernünftigerweise vorhersehbaren Umgebungsbedingungen zu einer Exposition gegenüber Magnetfeldern, elektrischen Fremdeinflüssen, elektrostatischen Entladungen, Druck oder Druckschwankungen, Beschleunigung, Wärmequellen mit der Gefahr einer Selbstentzündung usw. kommt<br/>precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;</p>                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 60601-1-2:2007                     | <p>Test Report EN 60601-1<br/>Test Report EN 60601-1-2<br/>Checklist user manual</p>                      |
| m)             | <p>ausreichende Angaben zu Arzneimitteln, für deren Verabreichung das betreffende Produkt bestimmt ist; hierzu zählen auch Angaben zu Beschränkungen in der Wahl der zu verabreichenden Stoffe<br/>adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;</p>                                                                                                                                                                                                                | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                          | Delivery of substances is not intended                                                                    |
| n)             | <p>Vorsichtsmaßnahmen für den Fall, dass ein Produkt im Hinblick auf seine Entsorgung eine besondere oder ungewöhnliche Gefahr darstellt;<br/>precautions to be taken against any special, unusual risks related to the disposal of the device;</p>                                                                                                                                                                                                                                                                                                                                                                   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                          | No unusual risks related to the disposal of the device                                                    |
| o)             | <p>Stoffe oder Derivate aus menschlichem Blut, die gemäß Abschnitt 7.4 einen festen Bestandteil des Produkts bilden;<br/>medicinal substances incorporated into the device as an integral part in accordance with Section 7.4;</p>                                                                                                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                          | No medical substances in accordance with Section 7.4                                                      |
| p)             | <p>bei Produkten mit Messfunktion der vom Hersteller vorgegebene Genauigkeitsgrad;<br/>degree of accuracy claimed for devices with a measuring function.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                          | No measuring function implemented                                                                         |



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| para-<br>graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard                                 | remarks, deviations<br>and/or risks                                              |
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|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ja<br>yes                           | nein<br>no               | N/A                                 |                                                        |                                                                                  |
| N              | h) bei wiederzuverwendenden Produkten Angaben über geeignete Aufbereitungsverfahren, z. B. Reinigung, Desinfektion, Verpackung und gegebenenfalls Sterilisationsverfahren, wenn eine erneute Sterilisation erforderlich ist, sowie Angaben zu einer eventuellen zahlenmäßigen Beschränkung der Wiederverwendungen;<br>if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfections, packaging and, where appropriate, the method of sterilization of the device to be desterilised, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I; | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 1041:2008                        | Test Report EN 60601-1<br>Conformity Evaluation EN 1041<br>Checklist user manual |
|                | Sofern das Produkt einen Hinweis trägt, dass es für den einmaligen Gebrauch bestimmt ist.<br>Nach 13.1 keine Gebrauchsanweisung erforderlich ist, jedoch Informationen über bekannte Merkmale und technische Faktoren, von denen der Hersteller weiß, dass sie eine Gefahr darstellen könnten vorliegen, werden die Informationen dem Benutzer auf Anfrage zugänglich gemacht.                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                        |                                                                                  |
|                | i) Hinweise auf eine möglicherweise vor der Anwendung eines Produkts erforderliche besondere Behandlung oder zusätzliche Aufbereitung (z.B. Sterilisation, Montage usw.);<br>details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 1041:2008                        | Test Report EN 60601-1<br>Conformity Evaluation EN 1041<br>Checklist user manual |
|                | j) bei Produkten, die Strahlungen zu medizinischen Zwecken aussenden, Angaben zu Beschaffenheit, Art, Intensität und Verteilung dieser Strahlungen.<br>in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>IEC 60601-2-22:2007<br>EN 1041:2008 | Checklist user manual<br>Conformity Evaluation IEC 60601-1-22                    |

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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard                                                                                        | remarks, deviations<br>and/or risks                                                                                                                                                              |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | ja<br>yes                           | nein<br>no               | N/A                                 |                                                                                                               |                                                                                                                                                                                                  |
| b)         | die Leistungsdaten gemäß Abschnitt 3 sowie etwaige unerwünschte Nebenwirkungen;<br>the performances referred to in Section 3 and any undesirable side-effects;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>IEC 60601-2-22:2007                                                                        | Test Report EN 60601-1<br>Conformity Evaluation IEC 60601-1-22<br>Checklist user manual                                                                                                          |
| c)         | bei Produkten, die zur Erfüllung ihrer Zweckbestimmung mit anderen medizinischen Einrichtungen oder Ausrüstungen kombiniert oder an diese angeschlossen werden müssen: alle Merkmale, soweit sie zur Wahl der für eine sichere Kombination erforderlichen Einrichtungen oder Ausrüstungen erforderlich sind;<br>if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;                                              | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                                                                               | No combination intended                                                                                                                                                                          |
| d)         | alle Angaben, mit denen überprüft werden kann, ob ein Produkt ordnungsgemäß installiert worden ist und sich in sicherem und betriebsbereitem Zustand befindet, sowie Angaben zu Art und Häufigkeit der Instandhaltungsmaßnahmen und der Kalibrierungen, die erforderlich sind, um den sicheren und ordnungsgemäßen Betrieb der Produkte fortwährend zu gewährleisten<br>all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 60601-1-2:2007<br>IEC 60601-2-22:2007<br>EN 15223-1:2012<br>EN 980:2008<br>EN 1041:2008 | Test Report EN 60601-1<br>Test Report EN 60601-1-2<br>Conformity Evaluation IEC 60601-1-22<br>Conformity Evaluation EN 980 / EN15223-1<br>Conformity Evaluation EN 1041<br>Checklist user manual |
| e)         | gegebenenfalls zweckdienliche Angaben, die zur Vermeidung bestimmter Risiken im Zusammenhang mit der Implantation des Produkts zu beachten sind;<br>where appropriate, information to avoid certain risks in connection with implantation of the device;                                                                                                                                                                                                                                                                                                                                                                                            | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                                                                               |                                                                                                                                                                                                  |
| f)         | Angaben zu den Risiken wechselseitiger Störung, die sich im Zusammenhang mit dem Produkt bei speziellen Untersuchungen oder Behandlungen ergibt;<br>information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;                                                                                                                                                                                                                                                                                                                                                     | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                                                                               |                                                                                                                                                                                                  |
| g)         | Anweisungen für den Fall, dass die Steril-Verpackung beschädigt wird; dazu gegebenenfalls die Angabe geeigneter Verfahren zur erneuten Sterilisation;<br>the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                                                                               |                                                                                                                                                                                                  |

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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard                                                                                        | remarks, deviations<br>and/or risks                                                                                                                                                                                   |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | ja<br>yes                           | nein<br>no               | N/A                                 |                                                                                                               |                                                                                                                                                                                                                       |
| i)         | gegebenenfalls besondere Hinweise zu Lagerung und/oder Handhabung;<br>any special storage and/or handling conditions;                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 1041:2008                                                                               | User manual<br>Test Report EN 60601-1<br>Conformity Evaluation EN 1041<br>Checklist user manual                                                                                                                       |
| j)         | gegebenenfalls besondere Anwendungshinweise;<br>any special operating instructions;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1-6:2010<br>EN 62366:2008<br>EN 1041:2008                                                            | Conformity Evaluation Usability<br>Conformity Evaluation EN 1041                                                                                                                                                      |
| k)         | gegebenenfalls Warnungen und/oder Hinweise auf zu treffende Vorsichtsmaßnahmen;<br>any warnings and/or precautions to take;                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | see 13.1 a                                                                                                    | Checklist user manual                                                                                                                                                                                                 |
| l)         | bei aktiven Produkten mit Ausnahme der Produkte gemäß Buchstabe e) Angabe des Herstellungsjahres; diese Angabe kann in der Los bzw. Seriennummer erscheinen;<br>year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;                                                                                                                                                                                                                                                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | see 13.1 a                                                                                                    | Type plate                                                                                                                                                                                                            |
| m)         | gegebenenfalls das Sterilisationsverfahren;<br>where applicable, method of sterilization.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                                                                               | No sterile or sterilizable product                                                                                                                                                                                    |
| 13.4       | Ist die Zweckbestimmung eines Produkts für den Anwender nicht offensichtlich, ist diese deutlich auf der Kennzeichnung und in der Gebrauchsanweisung angeben.<br>If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.                                                                                                                                                                                                                                                    | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | see 13.1 a                                                                                                    | Checklist user manual<br>User manual                                                                                                                                                                                  |
| 13.5       | Die Produkte und ihre abnehmbaren Bauteile sind — gegebenenfalls auf der Ebene der Produktlose und soweit vernünftigerweise praktikabel — identifizierbar, damit jede geeignete Maßnahme getroffen werden kann, um mögliche Risiken im Zusammenhang mit den Produkten und ihren abnehmbaren Bauteilen festzustellen.<br>Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN ISO 14971:2009<br>EN 60601-1:2006<br>IEC 60601-2-22:2007<br>EN 980:2008<br>EN 15223-1:2012<br>EN 1041:2008 | Removable hand piece, signed with manufacturer, item and serial number<br>Test Report EN 60601-1<br>Conformity Evaluation IEC 60601-1-22<br>Conformity Evaluation EN 980 / EN15223-1<br>Conformity Evaluation EN 1041 |
| 13.6       | Die Gebrauchsanweisung enthält nach Maßgabe des konkreten Falles folgende Angaben:<br>Where appropriate, the instructions for use must contain the following particulars:                                                                                                                                                                                                                                                                                                                                                                                                  |                                     |                          |                                     |                                                                                                               | Test Report EN 60601-1                                                                                                                                                                                                |
| a)         | Angaben gemäß Abschnitt 13.3 mit Ausnahme der Angaben in Buchstaben d) und e);<br>the details referred to in Section 13.3, with the exception of (d) and (e);                                                                                                                                                                                                                                                                                                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 1041:2008                                                                               | Checklist user manual<br>Conformity Evaluation EN 1041                                                                                                                                                                |



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| para-<br>graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard          | remarks, deviations<br>and/or risks                                            |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|---------------------------------|--------------------------------------------------------------------------------|
|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ja<br>yes                           | nein<br>no               | N/A                                 |                                 |                                                                                |
| N              | a) Name oder Firma und Anschrift des Herstellers; bei Produkten, die in die Gemeinschaft eingeführt werden, um dort vermarktet zu werden, muss die Kennzeichnung oder die äußere Verpackung oder die Gebrauchsanweisung ferner den Namen und die Anschrift des Bevollmächtigten enthalten, wenn der Hersteller keinen Firmensitz in der Gemeinschaft hat; the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14 (2) or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006                 | Test Report EN 60601-1<br>Checklist device labels<br>Type plate<br>User manual |
|                | b) alle unbedingt erforderlichen Angaben, aus denen, insbesondere für die Anwender, ersichtlich ist, worum es sich bei dem Produkt und dem Packungsinhalt handelt; the details strictly necessary for the user to identify the device and the contents of the packaging;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 1041:2008<br>see also 13.1 a | User manual<br>Conformity Evaluation EN 1041<br>Checklist user manual          |
|                | c) gegebenenfalls den Hinweis „STERIL“; where appropriate, the word 'STERILE';                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> | EN 980:2008                     | No sterile or sterilizable product                                             |
|                | d) gegebenenfalls den Loscode — nach dem Wort „LOS“ — oder die Seriennummer; where appropriate, the batch code, preceded by the word 'LOT', or the serial number;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 15223-1:2012                 | Type plate<br>Conformity Evaluation EN 980 / EN15223-1                         |
|                | e) gegebenenfalls das Datum, angegeben nach Jahr und Monat, bis zu dem eine gefahrlose Anwendung des Produkts möglich ist; where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> | EN 60601-1:2006                 | Test Report EN 60601-1                                                         |
|                | f) gegebenenfalls den Hinweis, dass das Produkt für den einmaligen Gebrauch bestimmt ist. (Der Hinweis des Herstellers auf den einmaligen Gebrauch muss in der gesamten Gemeinschaft einheitlich sein; where appropriate, an indication that the device is for single use;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> | /                               | /                                                                              |
|                | g) bei Sonderanfertigungen den Hinweis „Sonderanfertigung“; if the device is custom-made, the words 'custom-made device';                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                 |                                                                                |
|                | h) bei für klinische Prüfungen bestimmten Produkten den Hinweis „nur für klinische Prüfungen“; if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                 |                                                                                |

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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Übereinstimmung<br>compliance       |                          |                          | harmonized<br>standard                                                                     | remarks, deviations<br>and/or risks                                                                                                                                                             |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | ja<br>yes                           | nein<br>no               | N/A                      |                                                                                            |                                                                                                                                                                                                 |
| b)         | Die für die sichere Anwendung erforderlichen Informationen sind, soweit dies praktikabel und angemessen ist, auf dem Produkt selbst und/oder auf der Stückpackung oder gegebenenfalls auf der Handelspackung angegeben. Falls eine Einzelverpackung nicht möglich ist, sind die Angaben auf einer Begleitinformation für ein oder mehrere Produkte.<br><i>As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.</i> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | IEC 60601-2-22:2007<br>EN 980:2008<br>EN 15223-1:2012<br>EN 1041:2008<br>EN 60601-1-6:2010 | Conformity Evaluation IEC 60601-1-22<br>Conformity Evaluation Usability                                                                                                                         |
| c)         | Jedem Produkt ist in seiner Verpackung eine Gebrauchsanweisung beigegeben. (Eine Gebrauchsanweisung ist für Produkte der Klasse I und der Klasse IIa dann entbehrlich, wenn die vollständig sichere Anwendung des Produkts ohne Gebrauchsanweisung gewährleistet ist.)<br><i>Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.</i>                                                                                                                                                                                                            | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 1041:2008<br>EN 60601-1-6:2010<br>EN 62366:2008                                         | User manual<br>Conformity Evaluation EN 1041<br>Conformity Evaluation Usability<br>Checklist user manual                                                                                        |
| 13.2       | Die Angaben werden in Form von Symbolen gemacht. Werden Symbole und gegebenenfalls Identifizierungsfarben verwendet, entsprechen diese den harmonisierten Normen. Falls solche Normen für den betreffenden Bereich nicht existieren, werden die Symbole und Identifizierungsfarben in der beigegebenen Produktdokumentation erläutert.<br><i>Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.</i>                                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | IEC 60601-2-22:2007<br>EN 980:2008<br>EN 15223-1:2012<br>EN 1041:2008<br>EN 60601-1:2006   | Conformity Evaluation IEC 60601-1-22<br>Conformity Evaluation EN 980 / EN15223-1<br>Conformity Evaluation EN 1041<br>Test Report EN 60601-1<br>Checklist device labels<br>Checklist user manual |
| 13.3       | Die Kennzeichnung enthält folgende Angaben:<br><i>The label must bear the following particulars:</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                     |                          |                          |                                                                                            |                                                                                                                                                                                                 |

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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Übereinstimmung<br>compliance       |                          |                          | harmonized<br>standard                                                                 | remarks, deviations<br>and/or risks                                                                                                                                                                                         |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | ja<br>yes                           | nein<br>no               | N/A                      |                                                                                        |                                                                                                                                                                                                                             |
| 12.8.2     | <p>Die Produkte sind mit Einrichtungen ausgestattet, die jegliche Störung der Mengenregelung, die eine Gefahr darstellen kann, verhindern und/oder signalisieren.<br/>Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.</p> <p>Die Produkte sind mit geeigneten Vorrichtungen ausgestattet, welche die unbeabsichtigte gefährlich überhöhte Abgabe von Energie durch die Energiequelle bzw. von Stoffen verhindern.<br/>Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.</p>            | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>IEC 60601-2-22:2007<br>EN 62304:2006                              | <i>Risk Management Report</i><br><i>Risk analysis and control</i><br><i>Conformity Evaluation IEC 60601-1-22</i><br><i>Test Report EN 60601-1</i><br><i>Conformity Evaluation EN 62304</i>                                  |
| 12.9       | <p>Die Funktion von Bedienungs- und Anzeigeeinrichtungen ist auf den Produkten deutlich angegeben sein.<br/>The function of the controls and indicators must be clearly specified on the devices.</p> <p>Sind die Anweisungen für die Anwendung des Produkts auf diesem selbst angebracht oder werden die Betriebs- oder Regelungsparameter visuell angezeigt, so sind diese Angaben für den Anwender und gegebenenfalls den Patienten verständlich.<br/>Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | IEC 60601-2-22:2007<br>EN 980:2008<br>EN 15223-1:2012                                  | <i>Conformity Evaluation IEC 60601-1-22</i><br><i>Conformity Evaluation EN 980 / EN15223-1</i>                                                                                                                              |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1-6:2010<br>EN 62366:2008                                                     | <i>Conformity Evaluation Usability</i>                                                                                                                                                                                      |
| 13.        | <b>Bereitstellung von Informationen durch den Hersteller</b><br><b>Information supplied by the manufacturer</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                     |                          |                          |                                                                                        |                                                                                                                                                                                                                             |
| 13.1 a)    | <p>Jedem Produkt sind Informationen beigelegt, die — unter Berücksichtigung des Ausbildungs- und Kenntnisstandes des vorgesehenen Anwenderkreises — die sichere und ordnungsgemäße Anwendung des Produkts und die Ermittlung des Herstellers möglich machen. Diese Informationen bestehen aus Angaben auf der Kennzeichnung und solchen in der Gebrauchsanweisung.<br/>Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use.</p>                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006<br>EN 15223-1:2012<br>EN 980:2008<br>EN 1041:2008 | <i>Risk Management Report</i><br><i>Test Report EN 60601-1</i><br><i>Conformity Evaluation EN 980 / EN15223-1</i><br><i>Conformity Evaluation EN 1041</i><br><i>Checklist user manual</i><br><i>Checklist device labels</i> |



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| para-graph     | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Übereinstimmung<br>compliance       |                          |                          | harmonized<br>standard                                                                 | remarks, deviations<br>and/or risks                                                                                                                                |
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|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ja<br>yes                           | nein<br>no               | N/A                      |                                                                                        |                                                                                                                                                                    |
| 12.7.3         | <p>Die Produkte sind so ausgelegt und hergestellt, dass die Risiken, die durch von den Produkten erzeugten Lärm bedingt sind, unter Berücksichtigung des technischen Fortschritts soweit wie möglich verringert werden, soweit die akustischen Signale nicht im Rahmen der vorgesehenen Anwendung beabsichtigt sind; dabei wurden die vorhandenen Möglichkeiten zur Minderung des Lärms, insbesondere an dessen Ursprung, genutzt.</p> <p>Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006                                                   | <i>Risk Management Report<br/>Product Characterization Form<br/>Test Report EN 60601-1<br/>Device Verification</i>                                                 |
| 12.7.4         | <p>Vom Anwender zu bedienende Endeinrichtungen und Anschlüsse an Energiequellen für den Betrieb mit elektrischer, hydraulischer oder pneumatischer Energie oder mit Gas, sind so ausgelegt und hergestellt, dass alle möglichen Risiken soweit wie möglich verringert werden.</p> <p>Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.</p>                                                                                                                                                                                                                                                               | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006<br>EN 980:2008<br>EN 15223-1:2012<br>EN 1041:2008 | <i>Risk Management Report<br/>Test Report EN 60601-1<br/>Conformity Evaluation EN 980 / EN15223-1<br/>Conformity Evaluation EN 1041</i>                            |
| 12.7.5         | <p>Zugängliche Teile von Produkten — mit Ausnahme von Teilen oder Bereichen, die Wärme abgeben oder bestimmte Temperaturen erreichen sollen — sowie deren Umgebung erreichen keine Temperaturen, die bei normaler Anwendung eine Gefährdung darstellen können.</p> <p>Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.</p>                                                                                                                                                                                                                                                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006                                                   | <i>Risk Management Report<br/>Product Characterization Form<br/>Test Report EN 60601-1</i>                                                                         |
| 12.8<br>12.8.1 | <p>Schutz vor Risiken infolge der Abgabe von Energie oder Stoffen an den Patienten</p> <p>Protection against the risks posed to the patient by energy supplies or substances</p> <p>Produkte, die zur Abgabe von Energie oder Stoffen an den Patienten bestimmt sind, sind so ausgelegt und hergestellt, dass die abgegebene Menge zur Gewährleistung der Sicherheit von Patient und Anwender mit ausreichender Genauigkeit eingestellt und diese Einstellung beibehalten werden kann.</p> <p>Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.</p>                               | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>IEC 60601-2-22:2007<br>EN 60601-1:2006<br>EN 62304:2006           | <i>Risk Management Report<br/>Risk analysis and control<br/>Conformity Evaluation IEC 60601-1-22<br/>Test Report EN 60601-1<br/>Conformity Evaluation EN 62304</i> |

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| para-<br>graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Übereinstimmung<br>compliance       |                          |                          | harmonized<br>standard                 | remarks, deviations<br>and/or risks                                                                      |
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|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | ja<br>yes                           | nein<br>no               | N/A                      |                                        |                                                                                                          |
| 12.5           | Die Produkte sind so ausgelegt und hergestellt, dass die Risiken im Zusammenhang mit der Erzeugung elektromagnetischer Felder, die in ihrer üblichen Umgebung befindliche weitere Einrichtungen oder Ausrüstungen in deren Funktion beeinträchtigen können, soweit wie möglich verringert werden.<br>Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.                                                                                                                                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1-2:2007 | Risk Management Report<br>Risk analysis and control<br>Test Report EN 60601-1-2                          |
| 12.6           | Schutz vor Risiken durch elektrischen Strom<br>Protection against electrical risks<br>Die Produkte sind so ausgelegt und hergestellt, dass das Risiko von unbeabsichtigten Stromschlägen bei sachgemäßer Installation und normaler Anwendung sowie beim Erstauftreten eines Defekts soweit wie möglich ausgeschaltet wird.<br>Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.                                                                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006   | Risk Management Report<br>Risk analysis and control<br>Test Report EN 60601-1                            |
| 12.7<br>12.7.1 | Schutz vor mechanischen und thermischen Risiken<br>Protection against mechanical and thermal risks<br>Die Produkte sind so ausgelegt und hergestellt, dass Patient und Anwender vor mechanischen Risiken, beispielsweise im Zusammenhang mit mangelnder Festigkeit oder Stabilität oder infolge des Vorhandenseins von beweglichen Teilen, geschützt sind.<br>Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.                                                                                                                        | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006   | Risk Management Report<br>Product Characterization Form<br>Test Report EN 60601-1                        |
| 12.7.2         | Die Produkte sind so ausgelegt und hergestellt, dass die Risiken, die durch von den Produkten erzeugte mechanische Schwingungen bedingt sind, unter Berücksichtigung des technischen Fortschritts soweit wie möglich verringert werden, soweit diese Schwingungen nicht im Rahmen der vorgesehenen Anwendung beabsichtigt sind.<br>Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006   | Risk Management Report<br>Product Characterization Form<br>Test Report EN 60601-1<br>Device Verification |

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| para-graph      | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard           | remarks, deviations<br>and/or risks                                                                      |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|----------------------------------|----------------------------------------------------------------------------------------------------------|
|                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | ja<br>yes                           | nein<br>no               | N/A                                 |                                  |                                                                                                          |
|                 | Für den Fall des Erstauftretens eines Defekts im System sind geeignete Vorkehrungen getroffen, um sich daraus ergebende Risiken auszuschließen oder soweit wie möglich zu verringern.<br>In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.                                                                                                                                                                                                            | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006                  | Test Report EN 60601-1                                                                                   |
| 12.1a)<br><br>N | Bei Produkten, die Software enthalten oder bei denen es sich um medizinische Software an sich handelt, ist die Software entsprechend dem Stand der Technik validiert, wobei die Grundsätze des Software-Lebenszyklus, des Risikomanagements, der Validierung und Verifizierung berücksichtigt sind.<br>Devices which include software or the software is medical software, the software is validated according to the state of the technology. The principles of the software life-circle, risk management, validation and verification were respected.      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 62304:2006 | Test Report EN 60601-1<br>Conformity Evaluation EN 62304<br>Software verification and validation reports |
| 12.2            | Produkte mit interner Energiequelle, von der die Sicherheit des Patienten abhängt, sind mit einer Einrichtung versehen, die eine Überprüfung des Ladezustands der Energiequelle gestattet.<br>Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.                                                                                                                                                                                                       | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                  | n.a.                                                                                                     |
| 12.3            | Produkte mit externer Energiequelle, von der die Sicherheit des Patienten abhängt, sind mit einem Alarmsystem ausgestattet sein, das jeden Ausfall der Energiequelle signalisiert.<br>Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.                                                                                                                                                                                                                                 | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                  | n.a.                                                                                                     |
| 12.4            | Produkte, die zur Überwachung eines oder mehrerer klinischer Parameter eines Patienten dienen, sind mit geeigneten Alarmsystemen ausgestattet, durch die der Anwender vor Situationen gewarnt wird, die den Tod oder eine erhebliche Verschlechterung des Gesundheitszustands des Patienten bewirken können.<br>Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                  | n.a.                                                                                                     |



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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard                                            | remarks, deviations<br>and/or risks                                                                                                                            |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ja<br>yes                           | nein<br>no               | N/A                                 |                                                                   |                                                                                                                                                                |
| 11.5.2     | Produkte, die ionisierende Strahlungen aussenden und für die radiologische Diagnostik bestimmt sind, sind so ausgelegt und hergestellt, dass sie im Hinblick auf den vorgesehenen Anwendungszweck eine angemessene Bild- und/oder Ausgabequalität bei möglichst geringer Strahlenexposition von Patient und Anwender gewährleisten.<br><small>Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.</small> | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                                   | no emission of ionizing radiation                                                                                                                              |
| 11.5.3     | Produkte, die ionisierende Strahlungen aussenden und für die radiologische Therapie bestimmt sind, sind so ausgelegt und hergestellt, dass sie eine zuverlässige Überwachung und Kontrolle der abgegebenen Strahlungs-dosis, des Strahlentyps und der Strahlenenergie sowie gegebenenfalls der Qualität der Strahlung ermöglichen.<br><small>Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.</small>        | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                                   | no emission of ionizing radiation                                                                                                                              |
| 12.        | <b>Anforderungen an Produkte mit externer oder interner Energiequelle</b><br><b>Requirements for medical devices connected to or equipped with an energy source</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                     |                          |                                     |                                                                   |                                                                                                                                                                |
| 12.1       | Produkte, die programmierbare Elektroniksysteme umfassen, sind so ausgelegt, dass<br><small>Devices incorporating electronic programmable systems must be designed to ensure</small><br><br>die Wiederholbarkeit,<br><small>the repeatability</small><br><br>die Zuverlässigkeit und<br><small>reliability and</small><br><br>die Leistung dieser Systeme entsprechend der Zweckbestimmung gewährleistet wird.<br><small>performance of these systems according to the intended use.</small>                                                                                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN ISO 14971:2009<br>EN 62304:2006<br><br><br>IEC 60601-2-22:2007 | <i>Risk Management Report</i><br><i>Test Report EN 60601-1</i><br><i>Conformity Evaluation EN 62304</i><br><br><br><i>Conformity Evaluation IEC 60601-1-22</i> |

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| para-<br>graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard                                                | remarks, deviations<br>and/or risks                                                                                 |
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|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ja<br>yes                           | nein<br>no               | N/A                                 |                                                                       |                                                                                                                     |
| 11.3<br>11.3.1 | <b>Unbeabsichtigte Strahlung</b><br>Unintended radiation<br>Die Produkte sind so ausgelegt und hergestellt, dass die Exposition von Patienten, Anwendern und sonstigen Personen gegenüber unbeabsichtigter Strahlung bzw. Streustrahlung so weit wie möglich verringert wird.<br>Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.                                                                                                                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | IEC 60601-2-22:2007<br>EN 60825-1: 2007+<br>Corr.1:2008 + Corr.2:2009 | Contact tip<br>protective laser goggles<br>Conformity Evaluation IEC 60601-1-22<br>Conformity Evaluation EN 60825-1 |
| 11.4<br>11.4.1 | <b>Gebrauchsanweisung</b><br>Instructions<br>Die Gebrauchsanweisung von Produkten, die Strahlungen aussenden, beinhaltet genaue Angaben<br>The operating instructions for devices emitting radiation must give detailed information as to<br><br>zur Art der Strahlenemissionen,<br>the nature of the emitted radiation<br><br>zu den Möglichkeiten des Strahlenschutzes für Patienten und Anwender und<br>means of protecting the patient and the user and<br><br>zur Vermeidung von Mißbrauch und installationsbedingten Risiken.<br>on ways of avoiding misuse and of eliminating the risks inherent in installation.          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | IEC 60601-2-22:2007<br>EN 60825-1: 2007+<br>Corr.1:2008 + Corr.2:2009 | Conformity Evaluation IEC 60601-1-22<br>Conformity Evaluation EN 60825-1                                            |
| 11.5<br>11.5.1 | <b>Ionisierende Strahlungen</b><br>Ionizing radiation<br>Produkte, die zum Aussenden ionisierender Strahlungen bestimmt sind, sind so ausgelegt und hergestellt, dass - soweit durchführbar - die Quantität, die Geometrie und die Qualität der ausgesandten Strahlung unter Berücksichtigung des beabsichtigten Zwecks verändert und kontrolliert werden können.<br>Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use. | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                                       | no emission of ionizing radiation                                                                                   |

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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Übereinstimmung<br>compliance       |                          |                          | harmonized<br>standard                                               | remarks, deviations<br>and/or risks                                                                                       |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ja<br>yes                           | nein<br>no               | N/A                      |                                                                      |                                                                                                                           |
| 11.        | <b>Schutz vor Strahlungen</b><br>Protection against radiation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                     |                          |                          |                                                                      |                                                                                                                           |
| 11.1       | Allgemeine Bestimmungen<br>General                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                     |                          |                          |                                                                      |                                                                                                                           |
| 11.1.1     | Die Produkte sind so ausgelegt und hergestellt, dass die Strahlenexposition von Patienten, Anwendern und sonstigen Personen so weit verringert wird, wie dies mit der Zweckbestimmung der jeweiligen für therapeutische oder diagnostische Zwecke angezeigten Dosiswerte nicht beschränkt wird.<br>Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.                                                                                                                                                                                                                                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1-2:2007<br><br>IEC 60601-2-22:2007                         | Test Report EN 60601-1-2<br><br>Conformity Evaluation IEC 60601-1-22                                                      |
| 11.2       | Beabsichtigte Strahlung<br>Intended radiation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                     |                          |                          |                                                                      |                                                                                                                           |
| 11.2.1     | Bei Produkten, die zum Aussenden von Strahlung in einer gefährlichen Dosierung ausgelegt sind, die zur Erreichung eines speziellen medizinischen Zwecks erforderlich ist, dessen Nutzen als vorrangig gegenüber den von der Emission ausgelösten Risiken angesehen werden kann, ist es dem Anwender möglich, die Emission zu kontrollieren. Diese Produkte sind so ausgelegt und hergestellt, dass die Reproduzierbarkeit und Toleranz relevanter variabler Parameter gewährleistet ist.<br>Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions.<br>Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1:2006<br>IEC 60601-2-22:2007<br><br>EN ISO 14971:2009      | Test Report EN 60601-1<br>Conformity Evaluation IEC 60601-1-22<br><br>Risk Management Report<br>Risk analysis and control |
| 11.2.2     | Produkte, die zum Aussenden von potentiell gefährlichen sichtbaren und/oder unsichtbaren Strahlungen bestimmt sind, sind, soweit durchführbar, mit visuellen und/oder akustischen Einrichtungen zur Anzeige dieser Strahlungen ausgestattet.<br>Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.                                                                                                                                                                                                                                                                                                                                                                                                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | IEC 60601-2-22:2007<br>EN 980:2008<br>EN15223-1:2012<br>EN 1041:2008 | Conformity Evaluation IEC 60601-1-22<br>Conformity Evaluation EN 980 / EN15223-1<br>Conformity Evaluation EN 1041         |



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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard | remarks, deviations<br>and/or risks                             |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|------------------------|-----------------------------------------------------------------|
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | ja<br>yes                           | nein<br>no               | N/A                                 |                        |                                                                 |
| 9.3        | <p>Die Produkte sind so ausgelegt und hergestellt, dass bei normaler Anwendung und beim Erstauftreten eines Defektes das Brand- oder Explosionsrisiko soweit wie möglich verringert wird. Dies gilt insbesondere für solche Produkte, die bestimmungsgemäß entflammbaren oder brandfördernden Stoffen ausgesetzt werden.</p> <p>Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.</p>  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006        | <p>Test Report EN 60601-1</p> <p>single fault safety design</p> |
| 10.        | <p><b>Produkte mit Meßfunktion</b><br/>Devices with a measuring function</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                     |                          |                                     |                        |                                                                 |
| 10.1       | <p>Produkte mit Meßfunktion sind so ausgelegt und hergestellt sein, dass unter Berücksichtigung angemessener Genauigkeitsgrenzen entsprechend der Zweckbestimmung des Produkts eine ausreichende Konstanz und Genauigkeit der Meßwerte gewährleistet wird.</p> <p>Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device.</p> <p>Die vom Hersteller gewählten Genauigkeitsgrenzen sind angegeben.</p> <p>The limits of accuracy must be indicated by the manufacturer.</p> | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | No measuring function                                           |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                                                 |
| 10.2       | <p>Meßskalen, Bedienungs- und Anzeigeeinrichtungen sind so ausgelegt, dass sie unter Berücksichtigung der Zweckbestimmung des Produkts ergonomischen Grundsätzen entsprechen.</p> <p>The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.</p>                                                                                                                                                                                                                                                                                                     | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | No measuring function                                           |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                     |                          |                                     |                        |                                                                 |
| 10.3       | <p>Bei Produkten mit Meßfunktionen werden die gesetzlichen Einheiten im Meßwesen gemäß den Vorschriften der Richtlinie 80/181/EWG des Rates(1) verwendet.</p> <p>The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).</p>                                                                                                                                                                                                                                                                                                                   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | No measuring function                                           |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                     |                          |                                     |                        |                                                                 |



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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Übereinstimmung<br>compliance |                          |                                     | harmonized<br>standard | remarks, deviations<br>and/or risks          |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------------|-------------------------------------|------------------------|----------------------------------------------|
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | ja<br>yes                     | nein<br>no               | N/A                                 |                        |                                              |
| 8.6        | <p>Verpackungssysteme für nicht sterile Produkte sind so beschaffen, dass die vorgesehene Reinheit des Produkts unbeschadet erhalten bleibt und,<br/>Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and,</p> <p>wenn das Produkt vor einer Anwendung sterilisiert werden soll, das Risiko einer mikrobiellen Kontamination soweit wie möglich verringert wird;<br/>if the devices are to be sterilized prior to use, minimize the risk of microbial contamination;</p> <p>das Verpackungssystem eignet sich für das vom Hersteller angegebene Sterilisationsverfahren<br/>the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.</p> | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | No sterile product<br>No sterile accessories |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                              |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                              |
| 8.7        | <p>Verpackung und/oder Kennzeichnung des Produkts erlauben eine Unterscheidung von gleichen oder ähnlichen Produkten, die sowohl in steriler als auch in nicht steriler Form in Verkehr gebracht werden.<br/>The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.</p>                                                                                                                                                                                                                                                                                                                                                                                                               | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Only non sterile accessories                 |
| 9.         | <b>Eigenschaften im Hinblick auf die Konstruktion und die Umgebungsbedingungen</b><br>Construction and environmental properties                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                               |                          |                                     |                        |                                              |
| 9.1        | <p>Wenn das Produkt zur Verwendung in Kombination mit anderen Produkten oder Ausrüstungen bestimmt ist:<br/>If the device is intended for use in combination with other devices or equipment,</p> <p>-die Kombination einschließlich der Anschlüsse ist sicher,<br/>the whole combination, including the connection system must be safe</p> <p>- beeinträchtigt die vorgesehene Leistung der Produkte nicht.<br/>must not impair the specified performances of the devices.</p> <p>Jede Einschränkung der Anwendung ist auf der Kennzeichnung oder in der Gebrauchsanweisung angegeben.<br/>Any restrictions on use must be indicated on the label or in the instructions for use.</p>                                                                                         | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Not intend to us with other ME-products      |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                              |
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                              |



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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Übereinstimmung<br>compliance |                          |                                     | harmonized<br>standard | remarks, deviations<br>and/or risks          |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Ja<br>yes                     | nein<br>no               | N/A                                 |                        |                                              |
| 8.2        | <p>Gewebe tierischen Ursprungs stammen von Tieren, die tierärztlichen Kontroll- und Überwachungsmaßnahmen unterzogen wurden, die der bestimmungsgemäßen Verwendung der Gewebe angemessen sind. Die benannten Stellen bewahren Angaben über den Herkunftsort der Tiere auf. Die Verarbeitung, Konservierung, Prüfung und Behandlung von Geweben, Zellen und Stoffen tierischen Ursprungs erfolgt so, dass optimale Sicherheit gewährleistet ist. Insbesondere ist durch anerkannte Verfahren zur Ausmerzung oder Inaktivierung von Viren im Verlauf des Herstellungsprozesses für den Schutz vor Viren und anderen übertragbaren Erregern zu sorgen.</p> <p>Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.</p> | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | No use of tissues of animal origin           |
| 8.3        | <p>In sterilem Zustand gelieferte Produkte sind so ausgelegt, hergestellt und in einer nicht wiederverwendbaren Verpackung und/oder unter Verwendung geeigneter Verfahren so verpackt, dass ihre Sterilität beim Inverkehrbringen unter den vom Hersteller vorgesehenen Lager- und Transportbedingungen erhalten bleibt, bis die Steril-Verpackung beschädigt oder geöffnet wird.</p> <p>Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | No sterile product<br>No sterile accessories |
| 8.4        | <p>In sterilem Zustand gelieferte Produkte sind nach einem geeigneten, validierten Verfahren hergestellt und sterilisiert worden.</p> <p>Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | No sterile product<br>No sterile accessories |
| 8.5        | <p>Produkte, die sterilisiert werden sollen, sind unter angemessenen überwachten Bedingungen (z. B. Umgebungsbedingungen) hergestellt.</p> <p>Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <input type="checkbox"/>      | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | No sterile product<br>No sterile accessories |

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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard                  | remarks, deviations<br>and/or risks                                                                                                                            |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | ja<br>yes                           | nein<br>no               | N/A                                 |                                         |                                                                                                                                                                |
| 7.4        | Gehört zu den festen Bestandteilen eines Produkts ein Stoff, der bei gesonderter Anwendung als Arzneimittel im Sinne des Artikels 1 der Richtlinie 2001/83/EG gelten kann und der in Ergänzung zu dem Produkt eine Wirkung auf den menschlichen Körper entfalten kann, ist die Qualität, die Sicherheit und der Nutzen dieses Stoffes analog zu den in der Richtlinie 2001/83/EG Anhang I genannten Verfahren überprüft.<br>Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC. | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                         | device does not incorporates a substance which may be considered to be a medicinal product                                                                     |
| 7.5        | Die Produkte sind so ausgelegt und hergestellt, dass die Risiken durch Stoffe, die dem Produkt entweichen, soweit wie möglich verringert sind.<br>The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                         |                                                                                                                                                                |
| 7.6        | Die Produkte sind so ausgelegt und hergestellt, dass die Risiken durch unbeabsichtigtes Eindringen von Stoffen in das Produkt unter Berücksichtigung des Produkts und der Art der Umgebung, in der es eingesetzt werden soll, soweit wie möglich verringert sind.<br>Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.                                                                                                                                                                                                                                                                                                                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 1041:2008         | Test Report EN 60601-1<br>Conformity Evaluation EN 1041                                                                                                        |
| 8.         | Infektion und mikrobielle Kontamination<br>Infection and microbial contamination                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                     |                          |                                     |                                         |                                                                                                                                                                |
| 8.1 a)     | Die Produkte und ihre Herstellungsverfahren sind so ausgelegt, dass das Infektionsrisiko für Patienten, Anwender und Dritte ausgeschlossen ist oder soweit wie möglich verringert wird.<br>The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN ISO 10993-1: 2009 | Test Report EN 60601-1<br>Evaluation material compatibility<br>Conformity Evaluation EN ISO 10993-1                                                            |
| b)         | Die Auslegung erlaubt ein leichte Handhabung und die Kontamination des Produkts durch den Patienten oder umgekehrt während der Anwendung ist so gering wie möglich gehalten.<br>The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN ISO 10993-1: 2009                    | Non invasive procedure:Only the hand-piece tip is in contact with the patient<br><br>Evaluation material compatibility<br>Conformity Evaluation EN ISO 10993-1 |

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| para-<br>graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Übereinstimmung<br>compliance       |                          |                                     | harmonized<br>standard | remarks, deviations<br>and/or risks                                       |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|------------------------|---------------------------------------------------------------------------|
|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ja<br>yes                           | nein<br>no               | N/A                                 |                        |                                                                           |
| 7.2            | <p>Die Produkte sind so ausgelegt, hergestellt und verpackt, dass die Risiken für das Transport-, Lager- und Bedienpersonal sowie die Patienten durch Schadstoffe und Rückstände bei bestimmungsgemäßer Anwendung soweit wie möglich verringert wird. Dabei ist den exponierten Geweben sowie der Dauer und Häufigkeit der Exposition besondere Aufmerksamkeit gewidmet.</p> <p>The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.</p> | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | no contaminants and residues                                              |
| 7.3 a)         | <p>Die Produkte sind so ausgelegt und hergestellt, dass eine sichere Anwendung in Verbindung mit</p> <p>The devices must be designed and manufactured in such a way that they can be used safely with</p> <p>Materialien,<br/>the materials,<br/>Stoffen und<br/>substances and<br/>Gasen,<br/>gases</p> <p>mit denen sie bei normaler Anwendung oder bei Routineverfahren in Kontakt kommen, gewährleistet ist;<br/>with which they enter into contact during their normal use or during routine procedures.</p>                                                                                                                                                                                                                                                               | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN ISO 10993-1:2009    | Evaluation material compatibility<br>Conformity Evaluation EN ISO 10993-1 |
| b)             | <p>Sind die Produkte zur Verabreichung von Arzneimitteln bestimmt, sind sie so ausgelegt und hergestellt, dass sie entsprechend den für diese Arzneimittel geltenden Bestimmungen und Beschränkungen mit den Arzneimitteln verträglich sind und dass ihre Leistung entsprechend ihrer Zweckbestimmung aufrechterhalten bleibt.</p> <p>If the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.</p>                                                                                                       | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | not intended to administer medicinal products                             |





|                   |                                                                                                                                                                       |                                                                                     |
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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Übereinstimmung<br>compliance       |                          |                          | harmonized<br>standard                                                                       | remarks, deviations<br>and/or risks                                                                                                                                                                                                                                                                                                                           |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ja<br>yes                           | nein<br>no               | N/A                      |                                                                                              |                                                                                                                                                                                                                                                                                                                                                               |
| 3.         | Die Produkte erbringen die vorgegebenen Leistungen, d.h. sie sind so ausgelegt, hergestellt und verpackt, dass sie geeignet sind, eine oder mehrere der in Art. 1 Abs.2 a) genannten Funktionen entsprechende den Angaben des Herstellers zu erfüllen.<br>The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.                                                                                                                                                                                                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1:2006<br>IEC 60601-2-22:2007<br>EN 980:2008<br><br>EN 1041:2008                    | Essential performance features are:<br>- Laser energy and pulse Duration<br>- Protection against electrical hazards<br><i>Risk Management Report</i><br><i>Test Report EN 60601-1</i><br><i>Conformity Evaluation IEC 60601-1-22</i><br><i>Conformity Evaluation EN 980 / EN15223-1</i><br><i>Conformity Evaluation EN 1041</i><br><i>Device Verification</i> |
| 4.         | Die Merkmale und Leistungen gemäß den Abschnitten 1, 2 und 3 ändern sich nicht derart, dass der klinische Zustand und die Sicherheit der Patienten und gegebenenfalls Dritter während der Lebensdauer der Produkte nach Maßgabe der gemachten Angaben gefährdet werden, wenn diese Produkte Belastungen ausgesetzt sind, die unter normalen Einsatzbedingungen auftreten können.<br>The characteristics and performances described in Sections 1, 2 and 3 must not be adversely affected compromising both the clinical status and safety of the patients and, where applicable, of other persons during the device lifetime as indicated by the manufacturer, taking into account that the devices undergo the stresses which can occur during normal use conditions. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1:2006<br>IEC 60601-2-22:2007                                                       | <i>Test Report EN 60601-1</i><br><i>Conformity Evaluation IEC 60601-1-22</i><br><i>Device Verification</i><br><i>Handpiece Verification</i>                                                                                                                                                                                                                   |
| 5.         | Die Produkte sind so ausgelegt, hergestellt und verpackt, dass sich ihre Einsatzmerkmale und -leistungen während Lagerung und Transports unter Berücksichtigung der Anweisungen und Informationen des Herstellers nicht ändern.<br>The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.                                                                                                                                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1:2006<br>EN 980:2008<br><br>EN 1041:2008                                           | <i>Test Report EN 60601-1</i><br><i>Conformity Evaluation EN 980 / EN15223-1</i><br><i>Conformity Evaluation EN 1041</i><br><i>Device Verification</i><br><i>Handpiece Verification</i>                                                                                                                                                                       |
| 6.         | Unerwünschte Nebenwirkungen stellen unter Berücksichtigung der vorgegebenen Leistungen keine unvermeidbaren Risiken dar.<br>Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>RL 93/42/EEC<br>MEDDEV 2.7.1:2009<br>EN 60601-1-6:2010<br>EN 62366:2008 | <i>Clinical Evaluation</i><br><i>Conformity Evaluation Usability</i>                                                                                                                                                                                                                                                                                          |

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| para-<br>graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Übereinstimmung<br>compliance       |                          |                          | harmonized<br>standard                                                                                                                                                                                                                                              | remarks, deviations<br>and/or risks                                                                                                                                                                                                                                                                                                                                                                                                                               |
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|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ja<br>yes                           | nein<br>no               | N/A                      |                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2.             | <p>Die vom Hersteller bei der Auslegung und der Konstruktion der Produkte gewählten Lösungen richten sich nach den Grundsätzen der integrierten Sicherheit, und zwar unter Berücksichtigung des allgemein anerkannten Standes der Technik.</p> <p>The solutions selected by the manufacturer for the device design and construction must conform to safety principles, considering the generally acknowledged state of the art.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Major Standards:<br>EN ISO 14971:2009<br><br>EN 60601-1:2006<br>EN 60601-1-2:2007<br>IEC 60601-2-22:2007<br>EN 60825-1: 2007+<br>Corr.1:2008 + Corr.2:2009<br>EN 62304:2006<br>EN 60601-1-6:2010<br>EN 62366:2008<br>EN 15223-1:2012<br>EN 980:2008<br>EN 1041:2008 | <i>Risk analysis and control</i><br><i>Risk Management Report</i><br><i>GAP Analysis to EN ISO 14971:2012</i><br><i>Test Report EN 60601-1</i><br><i>Test Report EN 60601-1-2</i><br><i>Conformity Evaluation IEC 60601-1-22</i><br><i>Conformity Evaluation EN 60825-1</i><br><br><i>Conformity Evaluation EN 62304</i><br><i>Conformity Evaluation Usability</i><br><br><i>Conformity Evaluation EN 980 / EN15223-1</i><br><i>Conformity Evaluation EN 1041</i> |
| 2.1            | <p>Bei der Wahl der angemessensten Lösung hat der Hersteller folgende Grundsätze angewandt, in folgender Reihenfolge:<br/>In order to select the most appropriate solutions, the manufacturer must apply the following principles in the following order:</p> <ul style="list-style-type: none"> <li>- Beseitigung oder Minimierung der Risiken (Integration des Sicherheitskonzepts in der Entwicklung und den Bau des Produkt)<br/>eliminate or reduce risks as soon as possible (safety integration in device design and construction),</li> <li>- Ergreifen angemessener Schutzmaßnahmen, einschl. Alarmvorrichtungen gegen nicht zu beseitigende Risiken<br/>if necessary take adequate protection measures against those risks that cannot be eliminated, at any rate by alarm signals.</li> <li>- Unterrichtung der Benutzer über Restrisiken für die keine angemessenen Schutzmaßnahmen getroffen werden können<br/>Inform users about the residual risks due to any deficiency of the protection measures adopted</li> </ul> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009                                                                                                                                                                                                                                                   | <i>Risk analysis and control</i><br><i>Product Characterization Form</i><br><i>Risk Management Report</i><br><i>GAP Analysis to EN ISO 14971:2012</i><br><br><i>Checklist user manual</i>                                                                                                                                                                                                                                                                         |



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| para-graph | Anforderungen der Richtlinie<br>requirements of the directive<br>Beschreibung<br>short description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Übereinstimmung<br>compliance       |                          |                          | harmonized<br>standard                                                                                                                | remarks, deviations<br>and/or risks                                                                                                                                                                                                                                      |
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|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | ja<br>yes                           | nein<br>no               | N/A                      |                                                                                                                                       |                                                                                                                                                                                                                                                                          |
|            | <b>Anhang I / Annex I</b><br><b>Grundlegende Anforderungen / Basic requirements</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                     |                          |                          |                                                                                                                                       |                                                                                                                                                                                                                                                                          |
| I.         | <b>Allgemeine Anforderungen</b><br>General requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                     |                          |                          |                                                                                                                                       |                                                                                                                                                                                                                                                                          |
| 1.         | <p>Die Geräte sind so ausgelegt und hergestellt, dass ihre Anwendung unter den vorgesehenen Bedingungen und zu den vorgesehenen Zwecken weder klinischen Zustand und die Sicherheit der Patienten noch die Sicherheit und die Gesundheit der Anwendung oder gegebenenfalls Dritter gefährdet, wobei etwaige Risiken im Zusammenhang mit der vorgesehenen Anwendung gemessen am Nutzen für den Patienten vertretbar und mit einem hohen Maß an Gesundheitsschutz und Sicherheit vereinbar sind.</p> <p>The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.</p> <p>Dazu gehört: this includes</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | MDD 93/42/EEC<br>EN ISO 14971:2009<br><br>EN 60601-1:2006<br>EN 60601-1-2:2007<br>EN 60601-1-6:2010<br>EN 62366:2008<br>EN 62304:2006 | <i>Risk analysis and control</i><br><i>Risk Management Report</i><br><i>GAP Analysis to EN ISO 14971:2012</i><br><i>Test Report EN 60601-1</i><br><i>Test Report EN 60601-1-2</i><br><i>Conformity Evaluation Usability</i><br><br><i>Conformity Evaluation EN 62304</i> |
| N          | <p>- eine weitestgehende Verringerung der durch Anwendungsfehler bedingten Risiken aufgrund ergonomischer Merkmale und Umgebungsbedingungen<br/>(Produktauslegung in Hinblick auf Sicherheit des Patienten)<br/>-as far as possible reduce the risks caused by application errors due to ergonomic and environmental characteristics (design in terms of patient safety)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 62366:2008<br>EN 60601-1-6:2010                                                                                                    | <i>Conformity Evaluation Usability</i>                                                                                                                                                                                                                                   |
| N          | <p>- Berücksichtigung der Kenntnisse, Erfahrungen und Bildung und gegebenenfalls der medizinisch physischen Voraussetzungen der vorgesehenen Anwender<br/>(Produktauslegung für Laien, Fachleute, Behinderte oder sonstige Anwender)<br/>-Into account the knowledge, experience and education and any medical physical condition of intended users (design for lay, professional, disabled or other users)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 62366:2008<br>EN 60601-1-6:2010                                                                                                    | <i>Conformity Evaluation Usability</i><br>Use only by physicians or under responsibility of a physician. In any cases only by well trained persons which are introduces in the device and applications certified quality management system                               |



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#### Identification

##### **Details of examiner:**

Identification of the person responsible for examining the product under inspection:

Name: CAROLIN KÜHLING  
print full name (block letters)

Position: QUALITY ASSURANCE R&D  
print full title

If the above named person is not an employee of the manufacturer of the product to be examined, state the details of the examiner's employer or organization:

Organisation: \_\_\_\_\_

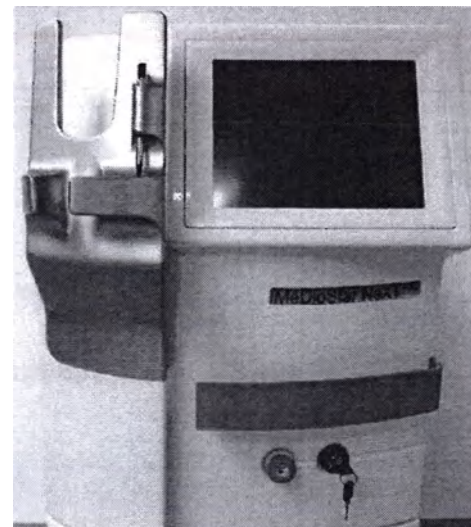
Address: \_\_\_\_\_

##### **Medizinprodukt/Medical device**

Details of product to be inspected:

See *User manual*

#### Picture of the device



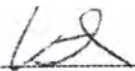
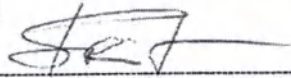


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| CL <b>7351</b>    | <b>Grundlegende Anforderungen zur Bewertung der Konformität nach<br/>RL 93/42/EWG *</b><br><b>Conformity Evaluation Essential Requirements acc. to CD 93/42/EEC *</b> |  |
| Revision index: C | <b>Identification number: CaM/14/11/12-01</b><br><small>Identification code/year/month/day-number</small>                                                             | page 1 of 30<br><small>CL7351 93-42-EEC MSPRO V01<br/>CaM141112-01.doc</small>     |

**Tested device:** *pre-series device*  
**Name and/or model:** *MeDioStar 1591/1592*  
**Seriennummer:**  
**Serial number:** *n./a.*  
**Herstellungsdatum (wenn bekannt):**  
**Date of manufacturing (if known):** *n./a.*  
**Hersteller**  
**Manufacturer:** *Asclepion Laser Technologies GmbH*  
**Anschrift**  
**Address:** *Brüsseler Straße 10, 07747 Jena, Deutschland*  
**Applied standard:** Richtlinie 93/42/EWG vom 14.06.1993 über Medizinprodukte \*  
 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices \*  
**Attachments:** TP7342 Appendix 93-42-EEC MSPRO V01 CaM141112-02

\* RL 93/42/EWG - Stand zum 21.03.2010  
 einschließlich der Änderungen  
 -RL 98/79/EG  
 -RL 2000/70/EG  
 -RL 2001/104/EG  
 -Verordnung (EG) 1882/2003  
 -RL 2007/47/EG

**Examined by:** C. Kühling  
 Name Date 12.11.2014  
**Checked by:** I. Streit  
 Name Date 12.11.2014

Sign   
 Sign 

|                                                                                      |           |              |                                          |           |              |
|--------------------------------------------------------------------------------------|-----------|--------------|------------------------------------------|-----------|--------------|
| Grund für letzte Änderung des Formulars: Einarbeitung Änderungen durch RL 2007/47/EG |           |              |                                          |           |              |
| Formular erstellt durch FuE:                                                         |           |              | Formular geprüft und genehmigt durch QM: |           |              |
| 25.09.09                                                                             | I. Streit | Gez. Streit  | 25.09.09                                 | R. Thieme | Gez. Thieme  |
| Datum                                                                                | Name      | Unterschrift | Datum                                    | Name      | Unterschrift |

|                             |                                                                                                          |                                                                                             |
|-----------------------------|----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| FB <b>7351e</b>             | <b>Verification / Validation Report</b>                                                                  |          |
| Revision Index:<br><b>B</b> | <b>Identification number: ZI/14/04/22-01</b><br><small>Member Code/year/month/day-sequential no.</small> | <b>Page 8 of 8</b><br><small>FB 7351e UsabilityValid MSPRO<br/>Vs01 ZI140422-01.doc</small> |

### 3. ASSESSMENT OF USABILITY

The goal of this advancement of the MeDioStar was, to reduce the treatment time for large areas by keeping the whole functionality, intended use and safety of the current device. This evaluation is based on the proof of safety and efficacy of the current device, positive validation of the requirement specification (beside the 2 small deviations, which will be fixed) and first test treatments.

Summarizing, it can be assessed that the usability for the advanced new MeDioStar version is even better than that of the current device, because the treatment time is shorter by keeping safety and effectiveness of the current device.

## 4 Технические данные

### 4.1 Модели устройств

| Обозначение*                                                      | Описание                                                                                                      |
|-------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| MeDioStar, модельный № 1590, модель MeDioStar NeXT                | Диодный лазер высокой мощности (основной блок)<br>Примечание: Возможно использование аппликаторов ST, HP, VAS |
| MeDioStar, модельный № 1591, модель MeDioStar NeXT <sup>PRO</sup> | Диодный лазер высокой мощности (основной блок)<br>Примечание: Возможно использование всех аппликаторов        |
| Аппликатор MeDioStar ST (модельный № 4020)                        | Стандартный аппликатор                                                                                        |
| Аппликатор MeDioStar HP (модельный № 4022)                        | Аппликатор высокой мощности (например, для удаления волос)                                                    |
| Аппликатор MeDioStar VAS (модельный № 4021)                       | Аппликатор для обработки сосудов                                                                              |
| Аппликатор MeDioStar с наконечником XLS (модельный № 4070+4071)   | Аппликатор с большим размером пятна для анатомически сложных областей (например, верхняя губа)                |
| Аппликатор MeDioStar с наконечником XLL (модельный № 4070+4072)   | Аппликатор с очень большим размером пятна для обработки больших областей                                      |

- Модельный номер устройства указан на табличке. Модельный номер аппликатора указан на шланге аппликатора. Модельный номер наконечника аппликатора XL выгравирован внутри наконечника. Стандартная поставка включает основной блок с одним аппликатором.

### 4.2 Спецификации

| Спецификация                                      | MeDioStar                                                                                                                                                                                       |
|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Дисплей                                           | Жидкокристаллический дисплей 8,4"                                                                                                                                                               |
| Управление оператора                              | Сенсорный экран                                                                                                                                                                                 |
| Охлаждение                                        | Внутренний цикл охлаждения                                                                                                                                                                      |
| Разъем дверного замка                             | 12В / макс. 20 мА                                                                                                                                                                               |
| Предупреждающая лампа лазера                      | Беспотенциальный релейный контакт<br>макс. 24В / 1А (нормально разомкнутый контакт)                                                                                                             |
| Допустимые окружающие условия                     | Температура: от 15°C до 30°C<br>относительная влажность воздуха: макс. 85% (без конденсации)<br>высота: макс. 2000 м над уровнем моря<br>Запрещено использовать устройство внутри операционной. |
| Допустимые условия при транспортировке и хранении | Вертикальное положение (не класть!)<br>Температура: от 5°C до + 50°C<br>Относительная влажность воздуха: от 10% до 90% (без конденсации)<br>Давление воздуха: 700 – 1070 гПа                    |
| Размеры                                           | 365 × 560 × 920 мм (Ширина × Глубина × Высота)<br>без ручек и держателя аппликатора                                                                                                             |



### 3.5.2 Опасность возгорания, обусловленная действием лазера



#### ПРЕДУПРЕЖДЕНИЕ

Из-за лазерного излучения устройств существует риск возгорания или взрыва, если лазер используется в присутствии горючих материалов, растворов или газов, или в среде, обогащенной кислородом.

Запрещается применять во взрывоопасных местах устройства, относящиеся к категории AP и APG согласно стандарту EN 60 601-1).

Для этого Пользователи должны принимать следующие меры предосторожности:

- Некоторые материалы, которые насыщены кислородом (например, вата), могут воспламениться при высоких температурах, которые создаются при предусмотренном использовании лазера.  
Держите одежду как можно дальше от зоны проведения процедуры.
- Растворители и горючие растворы\*, используемые для очистки и дезинфекции должны быть испарены перед применением лазера.
- Внимание также должно быть обращено на опасность воспламенения эндогенных газов. \*
- Не используйте легковоспламеняющиеся вещества для охлаждения кожи (например, горючий спрей для охлаждения, например, CoolPacks) непосредственно до или во время лечения
- Используйте негорючие вещества для анестезии, если она осуществляется.
- Не допускайте использования окисляющих газов, например, оксида азота (N<sub>2</sub>O) и кислорода. Будьте особенно осторожны при использовании кислорода. Кислород повышает как интенсивность, так и продолжительность горения.
- Храните в процедурном помещении только минимальное количество горючих материалов. Если для процедуры необходимо использовать горючие материалы, увлажните их.
- Для лазерной эмиссии должны быть открыты только предусмотренные участки тела.
- В процедурном помещении всегда держите наготове небольшой огнетушитель и воду.

\* не применяется для процедур на MeDioStar



Рисунок 1: Знак, предупреждающий о работающем лазере

**3. Индивидуальная защита глаз**

Во время идущего лазерного сеанса все лица, присутствующие в помещении, где работает лазер, должны надеть очки для защиты глаз, а пациенты – очки для пациентов!

Очки для защиты глаз от лазерного излучения и очки для пациентов должны соответствовать спецификациям, указанным в разделе Технические данные!

**4. Дополнительные меры предосторожности**

- Закройте окна и входы в помещение для проведения процедуры, чтобы предотвратить нежелательную эмиссию лазерного излучения.
- Ограничьте круг лиц, которым предоставлен доступ в процедурную, теми, кто обучен обращению с этим лазерным устройством и будет проводить процедуру или ассистировать (за исключением пациентов, которые будут проходить процедуру).
- Убедитесь в том, что обученный персонал, помогающий при проведении сеанса терапии, знает, как выключить лазер в случае возникновения аварийной ситуации.
- Удалите все объекты, такие как часы, кольца, браслеты или подобные предметы, из рабочей зоны и, по возможности, воздержитесь от использования отражающих приборов или прочих подобных материалов.  
(Отражающие объекты могут прервать лазерный луч и направить его на другой участок, вместо предусмотренного. Многие поверхности, даже те, которые кажутся матовыми, могут сильно отражать длину волны лазерного излучения.)
- Направляйте излучение лазера только на участок, на котором предусмотрено проведение процедуры.
- Воздержитесь от того, чтобы смотреть непосредственно на выходное отверстие аппликатора или оптического волокна, даже если вы носите очки для защиты от лазерного излучения.
- Для фаз нерабочего времени, следует переключиться на режим *STANDBY* (в режиме *STANDBY* предотвращено случайное включение лазера).
- Всегда вынимайте ключ из держателя ключа после отключения питания, и держите ключ в безопасном месте.

**5. Ответственность**

Пользователь, включающий лазерное излучение, несет ответственность за лазерную безопасность. Он/она должны обеспечить, чтобы **перед** активацией лазера были приняты все меры предосторожности. Особенно важно, чтобы все лица, присутствующие в помещении, где работает лазер, в том числе, пациенты, носили соответствующие очки для защиты от лазерного излучения, или козырьки для защиты глаз.



**ПРЕДУПРЕЖДЕНИЕ**

- Устройство не должно быть состыковано с другими устройствами / установлено вблизи других устройств или в сочетании с другими устройствами. Если устройство работает рядом с другими устройствами или вместе с ними, необходимо проверить, работает ли устройство правильно в такой компоновке.

- Использование аксессуаров, наконечников, кабелей с другими медицинскими электрическими устройствами, которые не разрешены изготовителем, может привести к увеличению передачи или к увеличению интерференции устройства с указанными выше эффектами.

Используйте только аксессуары, наконечники и кабели, которые предназначены для использования с данным устройством компанией «Асклепион Лейзер Текнолоджис» (Asclepion Laser Technologies).

- Устройство излучает небольшое количество электромагнитного излучения, которое может потенциально повлиять на устройства, которые не отвечают стандартам, перечисленным выше. Это может привести к непредвиденным изменениям настроек этих устройств.

### 3.5 Лазер

#### 3.5.1 Оптические опасности, обусловленные лазерной эмиссией

Лазеры классифицируют, в соответствии с их потенциалом опасности. Наибольшей опасности соответствует класс 4 (наименее опасным является класс 1). Mediostar относится к классу 4.

С основными правилами обращения с лазерными устройствами вы можете ознакомиться в международном стандарте EN 60825 «Безопасность лазерных устройств», включая раздел 8 «Руководство по безопасному воздействию лазерного излучения на человека». Они дополнены национальными правилами, предусматривающими общую защиту от опасного лазерного излучения. Они направлены на защиту работающего персонала и пациентов во время медицинских применений.

Также необходимо следовать специальным национальным правилам, которые могут действовать для вашего региона.



**ПРЕДУПРЕЖДЕНИЕ**

Внимание - использование оборудования, проведение процедур, технического обслуживания, осмотра или калибровки, кроме тех, которые указаны в этом руководстве, может привести к опасному лазерному облучению.

Меры защиты, описанные далее, необходимо строго соблюдать.

Особенно важно, чтобы все лица, присутствующие в помещении, где работает лазер, пользовались соответствующими средствами защиты глаз во время активной работы лазера.

Приведенные далее меры безопасности представляют собой ряд важных требований, которые в конкретных обстоятельствах должны быть дополнительно обеспечены со стороны старшего должностного лица по защите от лазерного излучения.

1. Старшее должностное лицо по защите от лазерного излучения должно быть назначено в письменной форме и несет следующие ответственности:

- оказание поддержки пользователю по вопросам безопасной эксплуатации и необходимым защитным мерам
- мониторинг работы лазера
- сотрудничество с опытным персоналом по обеспечению производственной безопасности при выполнении соответствующих задач, включая информацию по важным вопросам защиты от лазерного излучения.

2. Лазерная зона

Во время работы, зона, где может быть превышен максимальный допустимый уровень излучения, т.е. так называемая лазерная зона, должна быть ограничена и маркирована знаком, предупреждающим о работающем лазере. Лазерная зона представляет собой помещение, в котором используется лазер. Во всех местах доступа должны быть обеспечены предупреждающие световые сигналы и желтые знаки, предупреждающие о работающем лазере, треугольной формы.



### 3.2 Электрические опасности



#### ПРЕДУПРЕЖДЕНИЕ

Лазер работает с линейным напряжением.

Для предотвращения поражения электрическим током необходимо соблюдать следующие требования:

- Устройство должно эксплуатироваться только с надежным заземлением.
- Не открывайте устройство, если у вас нет соответствующих навыков, или если вы не авторизованы на выполнение таких действий.
- Не размещайте устройство так, чтобы его отключение от сети было затруднительно.
- Устройство обеспечивает указанные предельные значения токов утечки. Тем не менее, убедитесь, что контакт с пациентом и устройством происходит не одновременно, когда устройство включено.
- Конструкцией устройства предусмотрено предотвращение попадания жидкостей при нормальной эксплуатации. При попадании жидкости во внутреннее пространство системы или аппликатора, в исключительных случаях, вы должны отключить питание и вынуть кабель питания из сетевой розетки. Свяжитесь с нашей Технической службой.

### 3.3 Биологические опасности

Лазер разработан и произведен таким образом, что безопасное использование обеспечивается также и за счет совместимости материалов. Контактное взаимодействие с материалами, из которых изготовлен лазер, или с его компонентами (жидкости, газы и т.д.) не опасны.



#### ПРЕДУПРЕЖДЕНИЕ

Контактная поверхность аппликатора контактирует с кожей пациента во время процедуры. Существует риск переноса микроорганизмов.

Выбранный аппликатор должен быть полностью очищен и продезинфицирован после каждого применения; стерилизация невозможна.

### 3.4 Радиопомехи

Устройство соответствует требованиям стандарта EN 60601-1-2. На систему не оказывают влияние электромагнитные помехи, создаваемые другими устройствами, которые соответствуют тому же самому стандарту. Более того, система не вырабатывает электромагнитное излучение сверх предельных значений, указанных в EN 60601-1-2. Декларация изготовителя относительно электромагнитной совместимости, в соответствии с 60601-1-2, включена в это руководство.



#### ПРЕДУПРЕЖДЕНИЕ

Медицинские устройства подчинены особым мерам предосторожности, касающимся электромагнитной совместимости (ЕМС):

- Соблюдайте примечания в декларации ЕМС изготовителя в Приложении при установке и эксплуатации устройства.
- На устройство могут оказывать влияние устройства, не соответствующие указанному выше стандарту. Результатом могут стать непредусмотренные настройки. В связи с этим, отключите сотовые телефоны и подобное оборудование, прежде чем приступить к эксплуатации лазерного устройства.
- Использование вспомогательного оборудования и кабелей, не санкционированных изготовителем, может привести к повышенной эмиссии помех или к уменьшенной помехоустойчивости устройства с вышеупомянутыми последствиями. Используйте только вспомогательное оборудование и кабели, санкционированные компанией «Асклепион Лейзер Текнолоджис» (Asclepion Laser Technologies).

### 3 Техника безопасности

#### 3.1 Общая информация о технике безопасности

Устройство MeDioStar соответствует требованиям Директивы ЕС по медицинским устройствам (93/42/ЕЕС) и немецкого закона о медицинской продукции (MPG).

MeDioStar представляет собой медицинское устройство класса IIb, в соответствии с директивой в Приложении IX (т.е. хирургическое инвазивное изделие, предназначенное для осуществления биологического воздействия – это не следует путать с лазерным классом!).

Как любое устройство, MeDioStar при своей работе может быть источником потенциальных рисков. Пользователь должен знать о них, прежде чем запускать систему. Среди этих рисков – оптические, электрические и биологические опасности, а также – опасности возгорания.

Соблюдайте национальные правила, применимые для эксплуатации медицинского изделия.

Применимое законодательство при использовании устройств класса IIb операторами и пользователями может требовать соблюдение определенных мер безопасности в строгом порядке. Эксплуатация таких устройств допускается только в соответствии с общепризнанными правилами техники безопасности и охраны труда.

Вдобавок, законодательство может потребовать от Вас ведение паспорта медицинского устройства (см. соответствующую копию, приведенную в Руководстве пользователя).



#### ПРЕДУПРЕЖДЕНИЕ

Внимание - Использование элементов управления или настроек, или выполнение действий, отличных от указанных в данном документе, может привести к опасному воздействию излучения. Кроме того, есть также риск электрических и биологических опасностей, а также опасностей, связанных с радиопомехами.

Безоговорочно соблюдайте инструкции, включенные в это Руководство пользователя:

- Никакая модернизация этого оборудования недопустима.
- Безоговорочно соблюдайте инструкции, включенные в это Руководство пользователя, в отношении оборудования, и порядок выполнения действий при эксплуатации, техническом обслуживании, проверке или калибровке.
- Обратите внимание, что это изделие должно проходить регулярные испытания на техническую безопасность, которые должны проводиться через год, чтобы обеспечить безопасность персонала и пациентов. Если не проводить регулярные испытания, могут возникнуть серьезные проблемы со здоровьем.

Результаты таких испытаний на безопасность должны быть занесены в регистрационный журнал медицинского устройства.

- Обратите внимание, что работы по обслуживанию, ремонту или модификации не могут выполняться никем, кроме персонала компании «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) или других органов, должным образом авторизованных на проведение таких работ, чтобы обеспечить безопасность персонала и пациентов.

Если неавторизованные лица выполняют работы по обслуживанию, ремонту или модификациям устройства, могут возникнуть серьезные проблемы со здоровьем.



#### ПРЕДУПРЕЖДЕНИЕ

В США и Канаде это устройство должно быть установлено и эксплуатироваться в соответствии со стандартом США ANSI Z136.3 или канадского стандарта CAN / CSA-Z386: «Безопасное использование лазеров в здравоохранении» в его текущей версии.

### 2.3 Возможные побочные эффекты

См. раздел *Применение/ Эпиляция/ Возможные побочные эффекты и Применение/ Лечение сосудов/ Возможные побочные эффекты*

### 2.4 Требования к пользователю



#### ПРЕДУПРЕЖДЕНИЕ

Лазерное излучение от устройства может вызвать термальные изменения структуры тканей. Лечение следует проводить только практикующим врачам или под ответственность практикующих врачей (здесь и далее – пользователь для упрощения).

Активные медицинские продукты могут применяться только пользователями, имеющими соответствующую квалификацию и достаточный уровень подготовки, профессиональные знания и опыт.

Также отдельно отмечается, что к пользованию устройством допускаются только лица, прошедшие инструктаж по работе с устройством, и подтвердившие прохождение инструктажа соответствующей подписью в регистрационном журнале медицинского устройства.

Среди прочих видов инструктажа, «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH), также предлагает курсы медицинского применения лазера.

### 2.5 Классификация медицинского аппарата

Аппарат MeDioStar удовлетворяет требованиям Директивы по Медицинскому оборудованию стран ЕС 93/42/ЕЕС.

Категория аппарата согласно Директиве 93/42/ЕЕС: II b



UMDNS-No.:  
лазер

16-948, терапевтический



## 2. Целевое использование

### 2.1 Рекомендации по применению

MeDioStar – это импульсный диодный лазер (класс лазерной опасности - 4), который используется для удаления нежелательных волос, терапии акне, лазерной деструкции сосудов и омоложения кожи. Меланин и кровь соответственно достаточно сильно поглощают излучение волн той длины, которые испускаются этим лазером, в то время, как окружающая кожа поглощает очень мало. Таким образом, излучение разрушает мишень, но кожа остается защищенной.

Для получения подробной информации о применении прибора см. гл. Применение.

### 2.2 Противопоказания



#### ОСТОРОЖНО

Интенсивный лазер в инфракрасном диапазоне может вызвать термальное повреждение структуры кожи. Нижеуказанные противопоказания основаны на клиническом опыте, полученном при эксплуатации лазерных устройств по вышеуказанному назначению в течение около 15 лет. Список этих противопоказаний не является исчерпывающим и не подразумевает бессрочную актуальность.

- Высокая чувствительность к свету
- Применение препаратов, повышающих чувствительность к свету
- Антицеллюлитные программы (необходимо выждать несколько недель)
- Злокачественные и предзлокачественные поражения обрабатываемой области
- Волосяные родимые пятна
- Симплекс герпеса
- Риск образования келоидных рубцов
- Лазер не должен применяться к области около глаз! (Были отдельные сообщения об офтальмитах и ухудшении зрения, несмотря на применение защиты глаз интраокулярными экранами!)
- Лечение детей и беременных или кормящих грудью женщин (Отсутствуют клинические исследования для этих пациентов)
- Загорелая кожа в обрабатываемой области. (Отложите лечение, используйте защитный крем от солнца!)
- Татуировки в обрабатываемой области (обходить во время лечения)

#### Противопоказания, в частности, для лечения паукообразных вен на ногах

- Поверхностное варикозное расширение вен с диаметром более 3 мм
- Ветвистые и боковые ветвистые варикозные вены
- Язвы
- Диабет
- Васкулит
- Застойный дерматит
- Отек стопы
- Невропатия ног
- Лечение кортикостероидами в течение последних трех месяцев
- Тромбофлебит

### 1.3. Изменения и авторское право

Спецификации могут быть изменены в ходе дальнейшего технического развития. Для получения новейшей информации свяжитесь с отделом технического обслуживания «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) или с вашим дистрибьютором «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH).

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Все права защищены на случай предоставления патентов или регистрации полезной модели.

## 1. Введение

Все модели в данном Руководстве лазера называются MeDioStar или устройство.

### 1.1. Общая информация

- Настоящее Руководство пользователя содержит информацию, необходимую для целевого использования устройства.
- Оно является неотъемлемой частью полного набора самого прибора, в соответствии с применимыми национальными, европейскими и международными директивами и законами о надежности продукции.
- Важнейшей задачей является защита лиц от опасных ситуаций и прибора от повреждений в результате неправильного обращения.

Для эксплуатации устройства необходимо знание настоящего Руководства пользователя. Поэтому, ознакомьтесь с содержанием настоящего Руководства и обратите особое внимание на информацию, касающуюся безопасной эксплуатации устройства.

#### ПРЕДУПРЕЖДЕНИЕ

Неправильное применение устройства может повлечь за собой серьезную угрозу здоровью.



Несоблюдение настоящего Руководства считается неправильным применением, обслуживанием и модификацией устройства!

### 1.2. Символы, используемые в настоящем Руководстве пользователя

В настоящем руководстве будут использованы следующие символы для привлечения вашего внимания к опасностям, или для того, чтобы дать вам инструкции по применению устройства:



#### ПРЕДУПРЕЖДЕНИЕ

Этот символ указывает на возможную угрозу жизни и здоровью людей. Несоблюдение данной инструкции может повлечь за собой **серьезную** опасность для здоровья, вплоть до тяжелых увечий.



#### ОСТОРОЖНО

Этот символ указывает на возможную опасность. Несоблюдение данной инструкции может повлечь за собой травмы.

Следующие символы будут использованы для того, чтобы дать вам инструкции по управлению устройством:



#### ВАЖНАЯ ИНФОРМАЦИЯ

Этот символ указывает на важную информацию о правильной эксплуатации устройства. Несоблюдение данной инструкции может повлечь за собой повреждение имущества или неисправность устройства, или повреждение окружающих предметов.



#### СОВЕТ

Этот символ указывает на наличие практической рекомендации и полезной информации, которая позволяет пользователю оптимально использовать все возможности устройства.



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«Асклепион Лейзер Текнолоджис» (Asclepion Laser Technologies)

Руководство пользователя

## MeDioStar

Модели:

**MeDioStar NeXT**

**MeDioStar NeXT<sup>PRO</sup>**





Перевод с английского и немецкого языков

Нотариально заверенная копия

Нотариальный акт

Экхарт Маас

Йена

Настоящим подтверждаю, что вышеуказанный документ является верной копией оригинала, который был подготовлен для меня.

Йена, 13.04.2016

/Подпись/

Маас  
Нотариус

*Печать нотариуса*

|                               |                                                                                    |                                                                  |
|-------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------|
| FB 7331                       | Список защитных материалов и компонентов                                           | «Асклепион<br>Лейзер Текнолоджис» (Asclepion Laser Technologies) |
| Редакция:<br><b>ПРИМЕНИМО</b> | Идентификационный №: AWi/15/02/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 6 из 6<br>FB 7331 LoCC MSPRO V04_AWi150212-01.docx      |

| №     | Тип и номер детали                                                                         | Производитель                             | Рабочие параметры                                                                                            | Номинальные параметры                                                                                        | Стандарт №, редакция                       | Знаки и сертификаты соответствия |
|-------|--------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------|
|       | VAS                                                                                        |                                           |                                                                                                              |                                                                                                              |                                            |                                  |
| 7.3.4 | <u>альтернатива для раздела 7.2.1:</u><br>Лазерный диод JOLD-150-QA-3A для аппликатора VAS | «Хеноптик ГмбХ» (Jenoptik GmbH)           | $U \leq 16 \text{ В}$<br>$I_p \leq 90 \text{ А}$<br>$P_p \leq 250 \text{ Вт}$<br>$P_m \leq 44 \text{ Вт}$    | $U \leq 6 \text{ В}$<br>$I_p \leq 100 \text{ А}$<br>$P_p \leq 250 \text{ Вт}$<br>$P_m \leq 44 \text{ Вт}$    | Испытано и проверено компанией «АЛТ» (ALT) | -                                |
| 7.3.5 | <u>Часть поз.7:</u><br>Лазерный диод DILAS_C3N-IS62 (2xVO99)-808+940 нм для аппликатора XL | «Дилас ГмбХ» (Dilas GmbH)                 | $U \leq 45 \text{ В}$<br>$I_p \leq 110 \text{ А}$<br>$P_p \leq 2400 \text{ Вт}$<br>$P_m \leq 260 \text{ Вт}$ | $U \leq 48 \text{ В}$<br>$I_p \leq 130 \text{ А}$<br>$P_p \leq 2640 \text{ Вт}$<br>$P_m \leq 400 \text{ Вт}$ | Испытано и проверено компанией «АЛТ» (ALT) | -                                |
| 7.3.6 | <u>Часть поз.7:</u><br>Лазерный диод C3N-760-940-VO68.3-E5.1.15 для аппликатора ALX        | «Дилас ГмбХ» (Dilas GmbH)                 | $U \leq 16 \text{ В}$<br>$I_p \leq 80 \text{ А}$<br>$P_p \leq 560 \text{ Вт}$<br>$P_m \leq 100 \text{ Вт}$   | $U \leq 16 \text{ В}$<br>$I_p \leq 80 \text{ А}$<br>$P_p \leq 560 \text{ Вт}$<br>$P_m \leq 100 \text{ Вт}$   | Испытано и проверено компанией «АЛТ» (ALT) | -                                |
| 7.4   | <u>Часть поз.7:</u><br>ESD Relais CP1A-12V 550103054                                       | «Наис» (Nais)/<br>«Панасоник» (Panasonic) | 12 В<br>< 1 А<br>500 В                                                                                       | 14 В<br>10 А<br>500 В                                                                                        | Испытано и проверено компанией «АЛТ» (ALT) | -                                |
|       | <u>Часть поз.7:</u><br>Датчик температуры LM35 (TO-92) 661203009                           | «Нэшнл Семик» (National Semic)            | 5 В<br>0,05 А                                                                                                | 5 В<br>0,05 А                                                                                                | Испытано и проверено компанией «АЛТ» (ALT) | -                                |
|       | Альтернатива:<br>Датчик температуры LTS LM45 760106097                                     | «АЛТ» (ALT)/<br>«ЭйСиДи» (ACD)            | 5 В<br>0,05 А                                                                                                | 5 В<br>0,05 А                                                                                                | Испытано и проверено компанией «АЛТ» (ALT) | -                                |

|                               |                                                                                    |                                                                  |
|-------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------|
| FB 7331                       | Список защитных материалов и компонентов                                           | «Асклепион<br>Лейзер Текнолоджис» (Asclepion Laser Technologies) |
| Редакция:<br><b>ПРИМЕНИМО</b> | Идентификационный №: AWi/15/02/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 5 из 6<br>FB 7331 LoCC MSPRO V04_AWi150212-01.docx      |

| №     | Тип и номер детали                                                                                               | Производитель                   | Рабочие параметры                                                                                           | Номинальные параметры                                                                                       | Стандарт №, редакция                       | Знаки и сертификаты соответствия |
|-------|------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------|
|       | 550806040                                                                                                        |                                 |                                                                                                             |                                                                                                             | CSA 198                                    | -                                |
| 6.    | <b>Корпус устройства</b>                                                                                         |                                 |                                                                                                             |                                                                                                             |                                            |                                  |
| 6.1   | Пластиковая крышка устройства 159006023 или альтернативная 159506027 Стирол/бутадиен (с защитой от огня – SB V0) | «Керн ГмбХ» (Kern GmbH)         | Внутри устройства < 50 °C                                                                                   | 75°C                                                                                                        | UL 94<br>RoHS<br><br>Проверено «АЛТ» (ALT) | E83071<br>.<br>.                 |
| 7.    | <b>Аппликатор</b>                                                                                                |                                 |                                                                                                             |                                                                                                             |                                            |                                  |
| 7.1   | Пластиковая крышка аппликатора 400106035 / 400106103 Bayblend T65 Allruna W55 E203                               | «Байер Эллод» (Bayer Allod)     | Внутри устройства < 50 °C                                                                                   | 70°C                                                                                                        | RoHS, REACH<br><br>Проверено «АЛТ» (ALT)   | -<br>.                           |
| 7.2   | <u>альтернатива для раздела 7.1:</u><br>Пластиковая крышка аппликатора 400106035 Bayblend T65 Allruna W55 E203   | «Байер Эллод» (Bayer Allod)     | Внутри устройства < 50 °C                                                                                   | 70°C                                                                                                        | RoHS, REACH<br><br>Проверено «АЛТ» (ALT)   | -<br>.                           |
| 7.3   | <b>Лазерный модуль</b>                                                                                           |                                 |                                                                                                             |                                                                                                             |                                            |                                  |
| 7.3.1 | <u>Часть поз.7:</u><br>Модуль лазерного диода DILAS_C3N-VO68 808 + 940 нм для аппликатора ST и HP                | «Дилас ГмбХ» (Dilas GmbH)       | $U \leq 16 \text{ В}$<br>$I_p \leq 100 \text{ А}$<br>$P_p \leq 700 \text{ Вт}$<br>$P_m \leq 126 \text{ Вт}$ | $U \leq 16 \text{ В}$<br>$I_p \leq 120 \text{ А}$<br>$P_p \leq 840 \text{ Вт}$<br>$P_m \leq 126 \text{ Вт}$ | Испытано и проверено компанией «АЛТ» (ALT) | -                                |
| 7.3.2 | <u>альтернатива для раздела 7.2.1:</u><br>Модуль лазерного диода JOLD-580-QA-8A для аппликатора ST и HP          | «Хеноптик ГмбХ» (Jenoptik GmbH) | $U \leq 16 \text{ В}$<br>$I_p \leq 100 \text{ А}$<br>$P_p \leq 700 \text{ Вт}$<br>$P_m \leq 126 \text{ Вт}$ | $U \leq 16 \text{ В}$<br>$I_p \leq 130 \text{ А}$<br>$P_p \leq 840 \text{ Вт}$<br>$P_m \leq 126 \text{ Вт}$ | Испытано и проверено компанией «АЛТ» (ALT) | -                                |
| 7.3.3 | <u>Часть поз.7:</u><br>Лазерный диод DILAS_C3N-VO68.5-940 нм для аппликатора                                     | «Дилас ГмбХ» (Dilas GmbH)       | $U \leq 6 \text{ В}$<br>$I_p \leq 90 \text{ А}$<br>$P_p \leq 250 \text{ Вт}$<br>$P_m \leq 44 \text{ Вт}$    | $U \leq 6 \text{ В}$<br>$I_p \leq 100 \text{ А}$<br>$P_p \leq 250 \text{ Вт}$<br>$P_m \leq 44 \text{ Вт}$   | Испытано и проверено компанией «АЛТ» (ALT) | -                                |



|                               |                                                                                    |                                                                  |
|-------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------|
| FB 7331                       | Список защитных материалов и компонентов                                           | «Асклепион<br>Лейзер Текнолоджис» (Asclepion Laser Technologies) |
| Редакция:<br><b>ПРИМЕНИМО</b> | Идентификационный №: AWI/15/02/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 4 из 6<br>FB 7331 LoCC MSPRO V04_AWi150212-01.docx      |

| №   | Тип и номер детали                                                                     | Производитель                            | Рабочие параметры       | Номинальные параметры  | Стандарт №, редакция                                                                | Знаки и сертификаты соответствия |
|-----|----------------------------------------------------------------------------------------|------------------------------------------|-------------------------|------------------------|-------------------------------------------------------------------------------------|----------------------------------|
| 4.3 | Часть поз. 4:<br>Насос системы охлаждения лазера PDH-E054 IT9                          | «СансоЭлектроник» (SanzoElectronic)      | 24 В<br>2,3 А           | 24 В<br>2,3 А          | испытано и проверено компанией «АЛТ» (ALT)                                          | -                                |
| 4.4 | Часть поз. 4:<br>1х вентилятор конденсатора SanAce 9GV1224P1H03                        | «Санио Денки» (Sanyo Denki)              | <24 В<br><0,8 А         | 20,4 - 27,6 В<br>0,8 А | TÜV<br>UL<br>CSA                                                                    | R 50145867<br>GPWV2.E46810       |
|     | Альтернативный вариант:<br>2х вентилятор конденсатора SanAce 9G0924A202                | «Санио Денки» (Sanyo Denki)              | <24 В<br><0,3 А         | 20,4 - 27,6 В<br>0,3 А | UL<br>CSA                                                                           | GPWV2.E46810                     |
| 4.5 | Часть поз. 4:<br>Датчик температуры LM35 (TO-92) 661203011 LM35 (TO-220) 661203010     | «Нэшнл Семик» (National Semic)           | 5 В<br>0,05 А           | 5 В<br>0,05 А          | испытано и проверено компанией «АЛТ» (ALT)                                          | -                                |
| 4.6 | Датчик расхода FS-380P Series 661201017                                                | «Джемс Сенсорс Инк.» (Gems Sensors Inc.) | 15 В<br>< 0,1 А<br>3 КВ | 30 В<br>0,3 А<br>4 КВ* | испытано и проверено компанией «АЛТ» (ALT)                                          | -                                |
| 5.  | <b>Жгут проводов</b>                                                                   |                                          |                         |                        |                                                                                     |                                  |
| 5.1 | Проволочная оплетка H07V-K 550701117 550701118 550701121 550701122 550701144 550701145 | «У.И. Лэпп» (U.I.Lapp)                   | 240 В                   | 700 В                  | HAR: H07V-K IEC60332-1-2<br>HD 21/VDE 0281<br>VDE 0298 Teil4<br>HD 516/VDE 0298-300 | -<br>-<br>-<br>-<br>-            |
| 5.2 | Проволочная оплетка H05V-K 550701116 550701120 550701147                               | «У.И. Лэпп» (U.I.Lapp)                   | 240 В                   | 500 В                  | HAR: H05V-K IEC60332-1-2<br>HD 21/VDE 0281<br>VDE 0298 Teil4<br>HD 516/VDE 0298-300 | -<br>-<br>-<br>-                 |
| 5.3 | Защитная трубка, ПВХ                                                                   | «Алфа Вайр» (Alpha Wire)                 | не применимо            | не применимо           | UL 224                                                                              | E38155                           |

|                        |                                                                                    |                                                                  |
|------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------|
| FB 7331                | Список защитных материалов и компонентов                                           | «Асклепион<br>Лейзер Текнолоджис» (Asclepion Laser Technologies) |
| Редакция:<br>ПРИМЕНИМО | Идентификационный №: AWi/15/02/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 3 из 6<br>FB 7331 LoCC MSPRO V04_AWi150212-01.docx      |

| №     | Тип и номер детали                                                                                                                    | Производитель                                 | Рабочие параметры            | Номинальные параметры             | Стандарт №, редакция                                                                                                                                            | Знаки и сертификаты соответствия                                       |
|-------|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|------------------------------|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| 2.2   | Ножной переключатель<br>KF1SD1S MED<br>SK1 2<br>660806008                                                                             | «Штойте»<br>(Steute)                          | 10 В~<br>4..20 мА            | макс. 25 В~<br>макс. 1 А          | IEC 60601-1<br>IEC 60601-2-2<br>IEC 60601-2-22<br>IEC 60529 (IPX8)<br>UL 60601-1<br>UL 94<br>CSA 22.2                                                           | E9812309E01<br>-<br>110405-<br>E178188A<br>E41871<br>E80168<br>1312657 |
| 3.    | Система управления                                                                                                                    |                                               |                              |                                   |                                                                                                                                                                 |                                                                        |
| 3.1   | ECD4PCB<br>760106027                                                                                                                  | «АЛТ» (ALT)/<br>«ЭйСиДи» (ACD)                | +15 В<br><2 А                | +8-40 В<br>4 А                    | UL<br><br>Проверено<br>«АЛТ» (ALT)                                                                                                                              | E156885<br>-                                                           |
| 3.1.1 | Часть поз. 3.1:<br><br>Реле «АЛД»<br>(ALD) 105<br>Реле «АЛД»<br>(ALD) 112                                                             | «Панасоник»<br>(Panasonic)                    | +5 В<br>< 40 мА<br>1,5 кВ    | 277 В~ / 3А<br>30 В- / 3А<br>4 кВ | IEC 61810-1<br>UL 508<br>CSA 22.2 № 14-10                                                                                                                       | 40014384<br><br>E43028                                                 |
| 3.1.2 | Часть поз. 3.1:<br>Преобразователь<br>пост.т./пост.т.<br>NMV0512                                                                      | «Мурата» (Murata)                             | 1,5 кВ                       | 3 кВ                              | RoHS<br>испытано и<br>проверено<br>компанией<br>«АЛТ» (ALT)                                                                                                     | -<br>-                                                                 |
| 4.    | Система охлаждения                                                                                                                    |                                               |                              |                                   |                                                                                                                                                                 |                                                                        |
| 4.1   | Часть поз. 4:<br>Миниатюрный датчик давления<br>580067<br>Альтернативный вариант:<br>18575:<br>HR30211B3 HP<br>19732:<br>HR10611B3 HP | «Уилспек»<br>(Wilspec)                        | 12-15 бар<br><br>24 В / <1 А | 17,7 бар<br><br>28В / 3А          | UL 873<br>CSA 22.2 № 24-93<br><br>EN 12263                                                                                                                      | E196928<br><br>D 23 2005 T1                                            |
| 4.2   | Часть поз. 4:<br>Компрессор<br>Aspen 19-24                                                                                            | «Аспен<br>Компрессорс»<br>(Aspen Compressors) | 24 В<br>9,5 А                | 24 В<br>10 А                      | Директива<br>2006/42/ЕС<br>(1S012100-1/-2,60204-1)<br>2004/108/ЕС<br>(Электромагнитная<br>совместимость)<br>испытано и<br>проверено<br>компанией<br>«АЛТ» (ALT) | 960107902<br>-                                                         |

|                               |                                                                                    |                                                                  |
|-------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------|
| FB 7331                       | Список защитных материалов и компонентов                                           | «Асклепион<br>Лейзер Текнолоджис» (Asclepion Laser Technologies) |
| Редакция:<br><b>ПРИМЕНИМО</b> | Идентификационный №: AWi/15/02/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 2 из 6<br>FB 7331 LoCC MSPRO V04_AWi150212-01.docx      |

| №   | Тип и номер детали                                                                                                            | Производитель                                               | Рабочие параметры                                                                                                                        | Номинальные параметры                                                                                                                    | Стандарт №, редакция                                                                  | Знаки и сертификаты соответствия                                                |
|-----|-------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| 1.  | <b>Электропитание</b>                                                                                                         |                                                             |                                                                                                                                          |                                                                                                                                          |                                                                                       |                                                                                 |
| 1.1 | Сетевой шнур<br>550704013                                                                                                     | «Феллер Бурклин, ОТО» (Feller Bürklin OHG)                  | 240 В<br>< 15 А                                                                                                                          | 250 В<br>16 А                                                                                                                            | IEC60884<br>VDE 0250<br>UL 817<br><br>CSA<br>GB17465.1<br>EN 60320/C19<br><br>ENEC 11 | •<br>107641<br>E42003<br>(ELBZ.E42003)<br>•<br>•<br>•<br>15-003<br>(28.02.2006) |
| 1.2 | «Холодная» приборная вилка<br>550206080                                                                                       | «Шуртер» (Schurter) / «О. Хейл» (O. Heil)                   | 240 В<br>< 15 А                                                                                                                          | 250 В<br>16 А                                                                                                                            | IEC 60320-1<br>VDE<br>CSA 22.2 № 42<br>UL 498<br>UL                                   | 40026179<br>121440<br>27324<br>E45115<br>E96454                                 |
| 1.3 | Автоматический выключатель<br>550901094                                                                                       | «Э-Т-П Электротехн. Приборы» (E-T-A Elektrotechn. Apparate) | 240 В~<br>< 15 А                                                                                                                         | 240 В~<br>16 А                                                                                                                           | IEC 60934<br>CSA C22.2 № 14<br>UL 1077<br>GB 17701                                    | 40011839<br>QVNU8.E67320<br>QVNU2.E67320                                        |
| 1.4 | Линейный фильтр<br>FN2060B-16-06<br>550301122                                                                                 | «Шаффнер Груп» (Schaffner Group)                            | 240 В~<br>макс. 12 А                                                                                                                     | 250 В~<br>30 А                                                                                                                           | IEC 60939<br>UL 1283<br>CSA 22.2 № 8<br>ENEC 14                                       | •<br>FOKY2.E64388<br>1059975<br>SE/0037-28C                                     |
| 1.5 | Источник питания НРС825<br>A2-825-00<br>550399113                                                                             | «ПиЭмБи Электроник» (PMB Elektronik), Штарнберг             | Вход<br>115 В~<br>50/60 Гц<br>1400 ВА<br><br>220- 240 В~<br>50/60 Гц<br>1500 ВА<br><br>Выход<br>24 В-<br>400 Вт<br><br>6-45 В<br>0-130 А | Вход<br>115 В~<br>50/60 Гц<br>1400 ВА<br><br>220- 240 В~<br>50/60 Гц<br>1500 ВА<br><br>Выход<br>24 В-<br>400 Вт<br><br>6-45 В<br>0-130 А | IEC 60601-1                                                                           | Испытано «ЛГА» (LGA)                                                            |
| 2.  | <b>Цепь включения</b>                                                                                                         |                                                             |                                                                                                                                          |                                                                                                                                          |                                                                                       |                                                                                 |
| 2.1 | Выключатель с ключом / аварийный выключатель лазера, переключающий элемент Oktron BZOI 482550101039 BZOO/1.000.7706 550101040 | «Шлегель» (Schlegel)                                        | 12 В-<br>1 А                                                                                                                             | 250 В~<br>6 А                                                                                                                            | EN 61058<br>IEC60947-5-1/-5<br>UL 508<br>CSA 22.2 № 0-M91 / № 14-95                   | •<br>71363393<br>NKCR2.E72889<br>1107935                                        |



|                        |                                                                                    |                                                                        |
|------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| FB 7331                | Список защитных материалов и компонентов                                           | «Асклепион<br>Лейзер Текнолоджис»<br>(Asclepion Laser<br>Technologies) |
| Редакция:<br>ПРИМЕНИМО | Идентификационный №: AWi/15/02/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 1 из 6<br>FB 7331 LoCC MSPRO<br>V04 AWi150212-01.docx         |

Для:

|                                |                                                                |
|--------------------------------|----------------------------------------------------------------|
| Опытно-конструкторский проект: | Модернизация MedioStar                                         |
| Номер проекта:                 | 4800 93A 73 400                                                |
| Наименование продукта:         | MedioStar, торговое наименование: MedioStarNeXT <sup>PRO</sup> |
| Арт. номер <sup>*)</sup> :     | 1591, 1592                                                     |

Исполнено:

| №  | Краткое описание изменений                                                                              | Дата               | Имя, фамилия | Подпись        |
|----|---------------------------------------------------------------------------------------------------------|--------------------|--------------|----------------|
| 04 | Обновление: № 7.4 : альтернативный датчик температуры                                                   | 12 февраля 2015 г. | А. Винтер    | /Подпись/      |
| 03 | Обновление: № 4.4 альтернативный вентилятор; № 7.2.5 обновленная спецификация XL модуля лазерного диода | 02 февраля 2015 г. | А. Винтер    | Подпись Винтер |
| 02 | Обновление № 1.5 (рабочие параметры НРС825)                                                             | 19 мая 2014 г.     | М. Мёллер    | Подпись Мёллер |
| 01 | Первая редакция                                                                                         | 18 февраля 2014 г. | М. Мёллер    | Подпись Мёллер |

| Проверка и выпуск: | Отдел                                                         | Дата               | Имя, фамилия | Подпись   |
|--------------------|---------------------------------------------------------------|--------------------|--------------|-----------|
| Проверил           | Отдел научно-исследовательских работ                          | 12 февраля 2015 г. | Штрайт       | /Подпись/ |
| Выпустил           | Отдел контроля качества, Отдел научно-исследовательских работ | 13 февраля 2015 г. | С. Кутли     | /Подпись/ |

|                                                                     |           |                 |                                                                 |         |               |
|---------------------------------------------------------------------|-----------|-----------------|-----------------------------------------------------------------|---------|---------------|
| Основание для последнего изменения FB: Первоначальная версия        |           |                 |                                                                 |         |               |
| Технический отчет (FB) создан собственником процесса (отдел НИОКР): |           |                 | Технический отчет (FB) проверен и выдан Менеджером по качеству: |         |               |
| 17.07.05                                                            | И. Штрайт | Подписал Штрайт | 10.09.05                                                        | Р. Тиме | Подписал Тиме |
| Дата                                                                | ФИО       | Подпись         | Дата                                                            | ФИО     | Подпись       |

«Асклепион Лейзер Текнолоджис» (Asclepion Laser Technologies)

**Декларация ЕС о соответствии**

**«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)**

Брюсселер штрассе, 10

07747 Йена

Германия

*Мы заявляем о соответствии медицинского прибора*

MeDioStar

ALT-товар №:

1591; 1592

Классификация:

Класс II b в соответствии с 93/42/ЕЕС Приложение IX

*Со стандартами Медицинского оборудования 93/42/ЕЕС Приложение II*

*(орган технической экспертизы: «ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH), адрес: Тиллиштр., 2, 90431 Нюрнберг, № 0197, регистрационный номер: HD 60105768 0001).*

*Любая модификация изделия, не разрешенная «Асклепион Лейзер Текнолоджис ГмбХ», сделает эту декларацию недействительной.*

*На основании технического документа: ALT M 03/14*

*Согласованные стандарты:*

*Основные требования Директивы 93/42/ЕЕС, Приложение I, со всеми соответствующими согласованными стандартами.*

Йена, 3 декабря 2015 г.

«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)

От лица

/Подпись/

Пиетро Аматулли

Технический директор

Настоящая декларация действительна до:  
02.12.2020

Приложение:

| №  | Глава                                                                  | Документ                                                                                           |
|----|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| 1  | 1,2 Декларация о соответствии                                          | CE MeDioStar 1591, 1592                                                                            |
| 2  | 3 Краткое изложение материалов по безопасности                         | FB 7331 LoCC MSPRO V03_AWi/15/02/03-01                                                             |
| 3  | 6.1 Очистка и стерилизация<br>Описание процесса очистки и стерилизации | 1590 99 002_V06 – 2 Сент 2014 – GA-MSPRO – EN                                                      |
| 4  | 7,1 Описание и оценка процесса упаковки                                | 1590 08 004 Verpackungsvorschrift MDS 159x Vs.01 KI/11/09/05-01                                    |
| 5  | 7.2 Описание и оценка процесса маркировки                              | 159099020 Labeling MSPRO                                                                           |
| 6  | 8 Управление рисками                                                   | FB 7302 RAaC MSPRO V03 RH/14/11/10-01                                                              |
| 7  | 9 Эксплуатационная пригодность                                         | CL 73523 EN 62366 / 60601-1-6 MeDioStar 1591, 1592 ZI/15/04/10-03                                  |
| 8  | 9 Эксплуатационная пригодность                                         | FB 7351e MeDioStar 1591, 1592 ZI/14/04/22-01-01                                                    |
| 9  | 10.1 Основные требования<br>Контрольный список основных требований     | CL 7351 Conformity MDD 93_42_EEC MeDioStar 1591/1592 CaM/14/11/12-01                               |
| 10 | 10.2 Основные требования<br>Перечень применимых стандартов             | CL 7321 Relevante Sicherheitsnormen MeDioStar NeXT <sup>PRO</sup> SE Vs. 02 MMo/14/08/21-01        |
| 11 | 11 Клинические данные                                                  | FB 7351e ClinEval MSPRO V01 ZI/14/03/27-01                                                         |
| 12 | 12 Сертификаты качества                                                | Сертификат ЕС, Директива 93/42/ЕЕС (Регистрационный номер: HD 60105768 0001)                       |
| 13 | 12 Сертификаты качества                                                | Сертификат EN ISO 13485:2012 / EN ISO 13485:2012/AC:2012 (Регистрационный номер: SX 60105769 0001) |



## 12 Сертификаты качества

Учреждения и организации, участвующие в разработке и производстве этого устройства, получили следующие сертификаты ISO:

«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH), Брюсселерштрассе 10, 07747 Йена, Германия,

- Сертификат ЕС, Директива 93/42/ЕЕС (регистрационный номер: HD 60105768 0001)
- Сертификат EN ISO 13485:2012 / EN ISO 13485:2012/AC:2012 (Регистрационный номер: SX 60105769 0001)

Печать:

Соответствие настоящей копии оригиналу удостоверяется

г. Йена, 11 августа 2016 года

Нотариус

/Подпись/

Тиснёная печать нотариуса

## 8 Управление рисками

Анализ рисков, управление рисками и послепродажный контроль для данного устройства приведены в файле Risk Management (Управление рисками):

*FB 7302 RAaC MSPRO V03 RH/14/11/10-01*

## 9 Эксплуатационная пригодность

Файл с данными проектирования эксплуатационной пригодности и документальное подтверждение эксплуатационной пригодности см. в следующем документе:

*CL 73523 EN 62366 / 60601-1-6 MeDioStar 1591, 1592 ZI/15/0410-01*

*FB 7351e MeDioStar 1591, 1592 ZI/14/04/22-01-01*

## 10 Основные требования

### 10.1 Контрольный список основных требований

Доказательства соответствия Основным требованиям для этого устройства описаны в следующем документе:

*CL 7351 Conformity MDD 93\_42\_EEC MeDioStar 1591/1592 CaM/14/11/12-01*

### 10.2 Перечень применимых стандартов

Полный список всех стандартов, которые были применены на этапах проектирования / испытаний / оценки устройства см. в следующем документе:

*CL 7321 Relevante Sicherheitsnormen MeDioStar NeXTPRO SE Vs. 02 MMo/14/08/21-01*

## 11 Клинические данные

Клинические данные устройства указаны в следующем отчете:

*FB 7351e ClinEval MSPRO V01 ZI/14/03/27-01*

## 5 Изготовление

Устройство произведено на предприятии по адресу:

«Асклепион Лейзер Технолоджис ГмбХ » (Asclepion Laser Technologies GmbH), Брюсселерштрассе 10,  
07747 Йена, Германия

## 6 Очистка и стерилизация

### 6.1 Описание процесса очистки и стерилизации

Очистка, дезинфекция и стерилизация устройства должна проводиться согласно инструкциям в Руководстве пользователя:

*1590 99 047\_V1 – 24 Марта 2016 – UM-MSPRO RUS (en)*

### 6.2 Валидация процесса очистки и стерилизации

Стерилизация невозможна и не требуется.

## 7 Упаковка и маркировка

### 7.1 Описание и оценка процесса упаковки

Упаковка устройства показана на следующих иллюстрациях:

*159008004 Verpackungsvorschrift MS 159x V03.pdf*

### 7.2 Описание и оценка процесса маркировки

Этикетки устройства перечислены на следующих чертежах:

*159099020 Labeling MSPRO*

Этикетки были проверены по протоколу заключительных испытаний.



### 3 Конструкция

История проектирования находится в файле истории проекта DHF под номером:

ALT-M 003/14 MeDioStar NeXT<sup>PRO</sup> 1591/1592

Краткое изложение материалов по безопасности см. в следующем документе:

FB 7331 LoCC MSPRO V03\_AWi/15/02/03-01

### 4 Тестирование

Полный список испытаний и протоколов испытаний по оценке и проверке безопасности / эффективности устройства указан в следующей таблице:

| Испытания и тестовые протоколы                                                                          | Документ                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Протокол испытаний IEC60601-1                                                                           | 21215627_001_IEC60601-1 Test report.pdf                                                                                                                                                                                |
| Протокол испытаний на электромагнитную совместимость (ЭМС)                                              | MSPRO EMC CB Test Report SLG - 1430-13-EE-14-PB002                                                                                                                                                                     |
| Оценка ЭМС                                                                                              | CL 73532 Bewertung EMV MSPRO V01- MMo/14/08/25-01                                                                                                                                                                      |
| Оценка разработки программного обеспечения                                                              | CL 7365 IEC 62304 MSPRO - RH/14/07/01-01                                                                                                                                                                               |
| Оценка безопасности лазерного устройства                                                                | 21215627_001_atm#3_IEC60601-2-22.pdf<br>CL 7355 IEC EN 60 825-1 MSPRO- IS/14/02/12-02                                                                                                                                  |
| Проверка и валидизация устройства                                                                       | FB 7351 Verifizierung MSPRO Vs.02 – AWi/14/11/10-01                                                                                                                                                                    |
| Проверка упаковки                                                                                       | FB 7351 Validierung Verpackung MSPRO Vs.02 – KL/14/11/06-01                                                                                                                                                            |
| Проверка маркировки                                                                                     | CL 7356 CL GA MeDioStar Vs.02 ZI/14/10/27-01<br>CL 7357 GeräteSchilder MeDioStar Vs.05 AWi/15/01/20-01<br>CL 7363 EN 980 MeDioStar Vs.01 MMo/14/08/19-04<br>CL 7364 EN 1041 MSPRO MMo/14/07/04-01                      |
| Программное обеспечение для проверки и подтверждения (перечислено в документе «Анализ отслеживаемости») | FB 7314 Traceability Analysis MSPRO Vs.04 – RH/15/02/03-04                                                                                                                                                             |
| Проверка лазера                                                                                         | FB 7351e Verification Report MSPRO Energy Adjustment rev 01- MMo/14/08/19-01<br>FB 7351e Verification Stability of Laser putput MSPRO V01_MMo/14/08/19-02<br>FB 7351e Veri Energy Adjustment HS XL V01 MMo/14/08/19-01 |
| Проверка аппликатора                                                                                    | FB7351e Veri MSPRO HP V01 IH141111-03.pdf<br>FB 7355 Laborbericht MSPRO Spotgröße Homogenität JE141204-01.pdf                                                                                                          |
| Проверка на биосовместимость                                                                            | FB 7351e Verification Biocompatibility Vs02 - IH/14/06/17-01<br>FB 7351e FB 7351e Verification Biocompatibility Vs02 - IH/14/12/01-02                                                                                  |
| Проверка электронных компонентов                                                                        | FB 7351_ Verifizierung ACB3 Vs.01 – CB/14/07/01-01                                                                                                                                                                     |

## 2.5 Список устройств

| Обозначение                                                                | Описание                                                                                           |
|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| MeDioStar (NeXTPRO)<br>(деталь №1591)                                      | Полупроводниковый лазер высокой мощности (основной блок)                                           |
| MeDioStar, аппликатор SDT<br>(деталь №4020)                                | Стандартный аппликатор для эпиляции                                                                |
| MeDioStar, аппликатор HP (деталь<br>№4022)                                 | Аппликатор высокой мощности для эпиляции                                                           |
| MeDioStar, аппликатор VAS<br>(деталь №4021)                                | Аппликатор для обработки сосудов                                                                   |
| MeDioStar, аппликатор с лазерной<br>насадкой XLS (деталь № 4070 и<br>4071) | Аппликатор с большим лазерным пятном для анатомически<br>сложных областей (например, верхняя губа) |
| MeDioStar, аппликатор с лазерной<br>насадкой XLL (деталь № 4070 и<br>4072) | Аппликатор с очень большим лазерным пятном для больших зон<br>обработки                            |

## 2.6 Материалы

Это устройство изготовлено из стандартных материалов, используемых при производстве электронного оборудования. К ним относятся печатные платы, жидкокристаллический дисплей (ЖК дисплей), электронные переключатели и проводка, а также металлическая рама основания.

## 2.7 Дополнительные принадлежности

См. Список устройств 2.5

## 2.8 Классификация

Классификация: 93/42/ЕЕС класс IIb, правило 9

UMDNS № 16-948 Лазер терапевтический

Классификация лазера согласно стандарту EN 60825-1:2007: MeDioStar классифицируется как лазер 4 класса.

Классификация программного обеспечения по безопасности согласно EN 62304:2006: Класс В

## 2.4 **Функциональное описание**

### **Техническое описание**

#### **Лазер**

Лазер MeDioStar - это импульсный высокой мощности полупроводниковый лазер (класс лазера 4).

Излучаемые волны находятся в ближней ИК-области спектра от 755 нм до 950 нм.

Излучение лазерного пучка активируется нажатием педали на устройстве.

#### **Блок питания**

Встроенный блок питания преобразует сетевой ток в выпрямленный ток низкого напряжения для подачи на лазер.

#### **Управление устройством**

Система микроконтроллеров отвечает за контроль и управление выходными параметрами и защитными системами устройства.

#### **Режимы работы**

Устройство работает и в моноимпульсном режиме и в режиме непрерывной работы.

Устройство рассчитано на непрерывную работу в определенных условиях окружающей среды.

При высокой комнатной температуре и высокой средней мощности, возможно, что после длительной обработки, устройство на короткое время переходит в режим охлаждения, чтобы гарантировать эффективность охлаждения кожи.

#### **Работа**

Устройство управляется через сенсорный экран. Данные выводятся на ЖК дисплей с рекомендациями пользователю в виде простого текста. В зависимости от режима работы можно задать различные параметры, такие как плотность энергии, длительность импульса, частота повторения импульсов и др., как описано в главе «Работа».

В дополнение к выбранным параметрам, на дисплее отображаются другие данные, такие как режим лазера (ожидание или готовность), применяемый аппликатор и, при необходимости, текстовые сообщения об ошибках.

#### **Охлаждение**

Внутренняя система охлаждения необходима для предотвращения перегрева групп компонентов. Неиспользованное тепло рассеивается в окружающей среде через водно-воздушный теплообменник. Насос циркулирует охлаждающую жидкость через группы компонентов и теплообменник. Кроме того, интегрированные температурные датчики и датчики расхода обеспечивают безопасную эксплуатацию.

Устройство охлаждается при помощи воздуха в помещении. Вода для внешнего охлаждения не требуется.

Для поддержания эффекта охлаждения устройство должно эксплуатироваться только в указанных условиях окружающей среды. Воздух в помещении должен быть чистым, без пыли. Необходимо следить, чтобы между воздухозаборными отверстиями модуля охлаждения и воздухо непроницаемыми объектами (например, стены помещения) всегда оставался минимальный необходимый зазор. (См. главу «Установка»).

#### **Охлаждение кожи**

Рядом с лазерной насадкой на аппликаторе расположен металлический датчик, который охлаждается с помощью встроенного элемента Пельтье. Вместе с процедурой, описанной в главе «Применение», он гарантирует, что перед воздействием лазерных импульсов эпидермис будет холодным. Температура датчика контролируется.

#### **Предохранительные устройства**

Установка имеет ряд защитных устройств, функция которых - не допустить неправильную работу установки, а также ее случайное включение:

Аварийный выключатель лазерной установки, клавишный переключатель, выключатель питания, ножной переключатель, режим ожидания (STANDBY), автоматическое отключение, контакт удаленной блокировки двери, звуковой сигнал



2 Описание устройства

2.1 Описание устройства

MeDioStar NeXT PRO - это импульсный полупроводниковый лазер (4 класс лазерной продукции), который используется для удаления нежелательных волос, обработки угрей, обработки сосудов и омоложения кожи. Меланин и кровь относительно сильно поглощают излучение в диапазоне волн лазера, в то время как окружающие кожа поглощает только небольшую часть излучения. Таким образом, излучение термически разрушает указанную структуру, не повреждая кожу вокруг.

Данное медицинское устройство имеет компактный дизайн, не требует технического обслуживания и отличается длительным сроком службы. Компания «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) использует свой многолетний опыт в области производства медицинского лазерного оборудования, предлагает новое и эффективное медицинское устройство.

2.2 Назначение устройства

- Эпиляция
- Акне
- Обработка сосудов
- Омоложение кожи

2.3 Противопоказания

- Чувствительность к свету
- Использование препаратов, которые усиливают чувствительность к свету
- Терапия целлюлита в зоне обработки (подождите несколько недель)
- Раковые и предраковые патологические изменения в зоне обработки
- Покрытые волосами родимые пятна в зоне обработки
- Простой герпес в зоне обработки
- Склонность к чрезмерному образованию рубцов
- Когда применяется аппликатор ALX: Пациенты с типом кожи VI
- Лазер нельзя применять на участках, находящихся близко к глазам!
- Применение для детей и беременных и кормящих женщин
- Загорелая кожа на участках для обработки, особенно при использовании аппликатора ALX.
- Татуировки на участках для обработки

Противопоказания, особенно для обработки сосудистой сеточки на ногах

- Поверхностное варикозное расширение вен диаметром больше 3 мм
- Ветви и боковые ветви варикозно расширенных вен
- Язва
- Диабет
- Васкулит
- Гемостатический дерматит
- Отек стоп и лодыжек
- Невропатия ног
- Лечение кортикостероидами за последние три месяца
- Тромбофлебит

## 1 Декларация о соответствии

### 1.1 Процедура оценки соответствия

Данное устройство было проверено на предмет соответствия требованиям в соответствии со следующей процедурой:

Директива ЕС 93/42/EWG по медицинскому оборудованию, Приложение VI, Декларация изготовителя

### 1.2 Декларация о соответствии

Декларация о соответствии для этого устройства прилагается к данному документу.

CE MeDioStar 1591; 1592

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Технический файл

# MeDioStar NeXT<sup>PRO</sup>

(Версия 1591)



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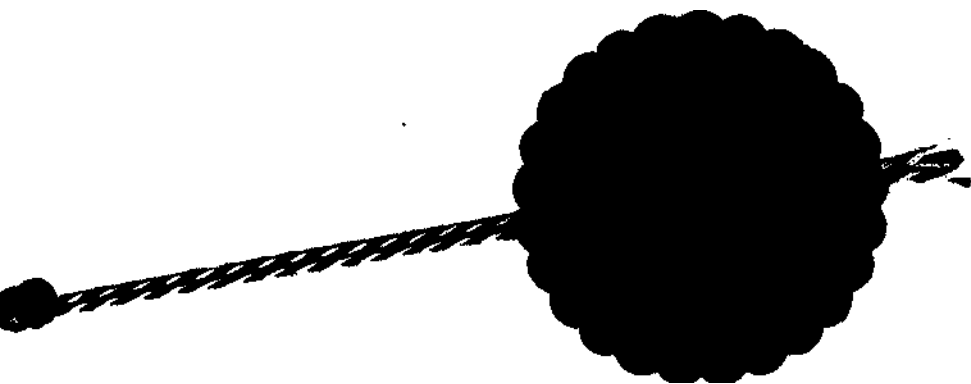
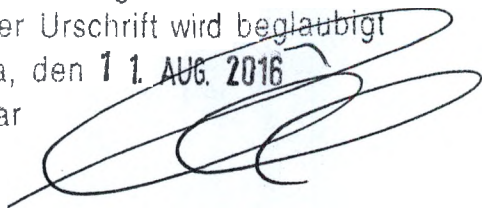
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Die Ubereinstimmung vorstehender Abschrift mit der Urschrift wird beglaubigt

Jena, den 1. AUG. 2016

Der Notar



| Спецификация                                | MeDioStar                                                          |
|---------------------------------------------|--------------------------------------------------------------------|
| Вес                                         | примерно 45 кг                                                     |
| Энергетические требования                   | 115 В, 50/60 Гц, 1400 ВА<br>220-240 В, 50/60 Гц, 1500 ВА           |
| Основной плавкий предохранитель             | срабатывание при 16А, средний медленно перегорающий предохранитель |
| Категория перенапряжения                    | II (IEC 60664-1)                                                   |
| Максимальный пик сетевого напряжения        | V MT пиковое = 2500 В пиковое                                      |
| Максимальное номинальное сетевое напряжение | V MN эффективное = 300 В эффективное                               |
| Класс защиты                                | I                                                                  |
| Классификация, согласно директиве 93/42/ЕЕС | IIb                                                                |
| Класс защиты используемого устройства       | B                                                                  |
| Принадлежности                              | смотри главу Принадлежности.                                       |
| Режим работы                                | Устройство спроектировано для непрерывной работы*                  |

- При высокой температуре в кабине и высокой средней мощности при проведении больших процедур устройство может переключаться в режим охлаждения на короткие промежутки времени для обеспечения охлаждения кожи.

| Спецификация                                                              | Лазер                                                                                                                                                                                                                                              |
|---------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Лазерная модель                                                           | Система диодных лазеров высокой мощности                                                                                                                                                                                                           |
| Длина волны                                                               | 810 – 950 нм (в зависимости от модели устройства)                                                                                                                                                                                                  |
| Класс лазера                                                              | 4                                                                                                                                                                                                                                                  |
| Необходимые очки для защиты от лазерного излучения (согласно EN 207:2009) | 810 – 950 нм D LB5                                                                                                                                                                                                                                 |
| Длительность импульса                                                     | максимально 400 мс (в зависимости от режима и аппликатора)                                                                                                                                                                                         |
| Энергия импульса                                                          | максимально 200 Дж (в зависимости от режима и аппликатора)                                                                                                                                                                                         |
| Частота повторения импульсов                                              | максимально 12 Гц (в зависимости от режима и аппликатора)                                                                                                                                                                                          |
| Размеры пятна (аппликаторы)                                               | аппликаторы ST: 14 × 10 мм <sup>2</sup><br>аппликатор HP: 8 × 6 мм <sup>2</sup><br>аппликатор VAS: 4 × 3 мм <sup>2</sup><br>аппликатор XL с наконечником XLL: 38 × 24 мм <sup>2</sup><br>аппликатор XL с наконечником XLS: 30 × 10 мм <sup>2</sup> |
| Допуск для выходной энергии                                               | +/- 20%                                                                                                                                                                                                                                            |
| Модовый состав излучения                                                  | многомодовый                                                                                                                                                                                                                                       |
| Диаметр лазерного луча на выходе аппликатора                              | смотри размеры пятна                                                                                                                                                                                                                               |



| Спецификация                                                             | Лазер                                                                                                                                                                                                                                                                                                                              |
|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Плотность энергии                                                        | максимально 47 Дж/см <sup>2</sup> для аппликатора ST<br>максимально 90 Дж/см <sup>2</sup> для аппликатора HP<br>максимально 210 Дж/см <sup>2</sup> для аппликатора VAS<br>максимально 20 Дж/см <sup>2</sup> для аппликатора XL с<br>наконечником XLL<br>максимально 60 Дж/см <sup>2</sup> для аппликатора XL с<br>наконечником XLS |
| Расходимость луча на выходе аппликатора (полный угол, 1/ε <sup>2</sup> ) | стандартно 0,12 x 0,97 рад для аппликаторов ST<br>стандартно 0,19 x 1,66 рад для аппликатора HP<br>стандартно 0,12 x 1,62 рад для аппликатора VAS<br>стандартно 0,11 x 0,68 рад для аппликатора XL с<br>наконечником XLS<br>стандартно 0,06 x 0,51 рад для аппликатора XL с<br>наконечником XLL                                    |
| Допустимое минимально безопасное расстояние для глаз (с аппликатором)    | 35 м                                                                                                                                                                                                                                                                                                                               |

\*доступно в режиме «Профессионал»

## 4.3 Техническое описание

### 4.3.1 Аппликаторы (с интегрированным источником и системой охлаждения кожи)

**Примечание:**

Обычно в комплект поставки входит один аппликатор с пятном определенного размера. Дополнительные аппликаторы могут быть поставлены дополнительно (другие размеры пятна / длин волн) (см. Модели устройства в главе Технические данные).

Размер лазерного пятна (см. главу Технические данные / Спецификации) может варьироваться в зависимости от аппликатора или в случае аппликатора XL в зависимости от установленного наконечника. Устройство автоматически обнаружит новый аппликатор или новый наконечник и отобразит это на дисплее.

#### Конструкция аппликатора

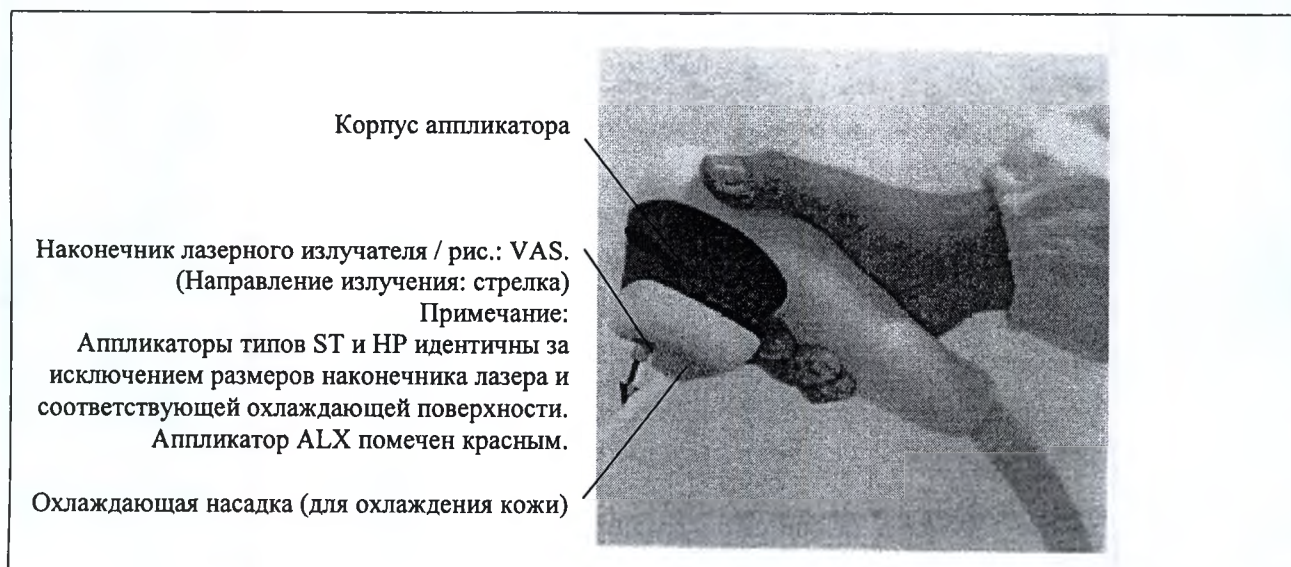


Рисунок 2: Аппликатор (например, аппликатор VAS)

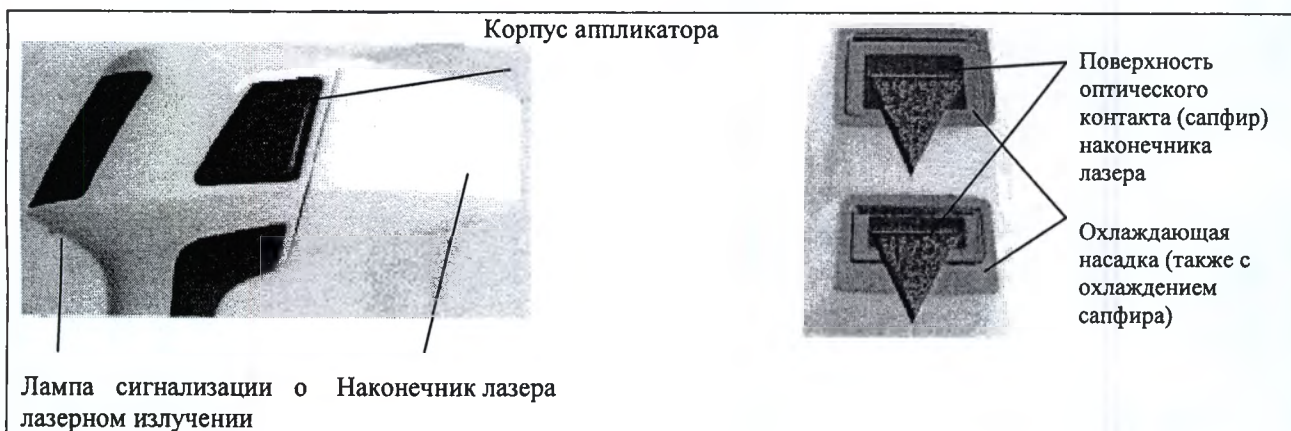


Рисунок 3: Аппликатор (слева) с наконечником XLL (справа сверху) или XLS (справа внизу)

#### Лазер

Лазер MeDioStar представляет собой импульсный диодный лазер высокой мощности (класс лазера 4). Линейка лазерных диодов расположена в корпусе аппликатора. Излучаемая длина волны находится в ближней области спектра инфракрасного излучения (NIR) и определяется аппликатором (см. Раздел Технические данные / Спецификации).

Эмиссия лазерного луча активируется при нажатии на ножную педаль.

### Прохождение излучения

Излучение от системы диодных лазеров высокой мощности формируется оптической системой, расположенной в аппликаторе. Таким образом, формируется профиль луча с «Плоской вершиной»; это означает, что плотность энергии равномерно распределена по области лечения. В результате этого отсутствуют «горячие» точки, способные приводить к побочным эффектам.

### Охлаждение кожи

Рядом с лазерным наконечником на аппликаторе находится металлическая насадка, которая охлаждается встроенным элементом Пельтье. Дополнительно охлаждается сапфировое окно аппликатора XL. Это гарантирует (вместе с процедурой, описанной в главе *Применение*), что эпидермис находится в холодном состоянии перед воздействием лазерного импульса. Осуществляется мониторинг температуры насадки. При высокой средней мощности при проведении больших процедур устройство может переключаться в режим охлаждения на короткие промежутки времени для обеспечения охлаждения кожи.

## 4.3.2 Основной блок

### Блок питания

Встроенный блок питания преобразует линейное напряжение в выпрямленное низкое напряжение для подвода электроэнергии к устройству.

### Управление

Мониторинг и управление выходными параметрами и защитными системами устройства осуществляется микропроцессором.

### Режимы работы

Устройство работает как в режиме одиночного импульса, так и в непрерывном режиме.

Устройство спроектировано для непрерывной работы в указанных окружающих условиях.

### Важная информация



Максимальное время использования аппликатор типа HP (арт. 4022) в непрерывном импульсном режиме ограничено 10 минутами. После этого необходим перерыв в 5 минут.

При высокой средней мощности при проведении больших процедур устройство может переключаться в режим охлаждения на короткие промежутки времени для обеспечения охлаждения кожи.

### Работа

Управление устройством осуществляется через сенсорный экран. Данные выводятся на жидкокристаллический дисплей с открытым текстом для руководства пользователя. В зависимости от режима работы, можно настроить различные параметры, такие как плотность энергии лазерного излучения, продолжительность импульса, скорость импульса и прочие, в соответствии с тем, как описано в главе Работа.

В дополнение к выбранным параметрам, отображаются прочие данные, такие как режим, в котором находится лазер (*STANDBY* или *READY*), используемый аппликатор и, если необходимо, сообщения об ошибках, в виде открытого текста.

Устройство содержит базу данных, в которой пользователь может сохранять отчеты о процедурах с параметрами, которые стандартно используются для различных типов процедур.

### Охлаждение

Система внутреннего охлаждения необходима для предотвращения перегрева групп компонентов. Потеря тепла рассеивается в окружающую среду через теплообменник вода-воздух. Насос обеспечивает циркуляцию охладителя через группы компонентов и теплообменник. В дополнение к этому, безопасная работа обеспечивается встроенными датчиками температуры и потока.

Охлаждение устройства обеспечивается воздухом в помещении. Вода для охлаждения извне не требуется.

Для поддержания эффекта охлаждения, устройство всего лишь должно работать в указанных окружающих условиях. Окружающий воздух не должен содержать пыли. В зоне расположения отверстий, предусмотренных для охлаждения устройства, должно быть обеспечено минимальное расстояние до воздухонепроницаемых предметов (например, до стены помещения). (Смотри главу *Установка*).



#### 4.4 Защитное оборудование

Устройство оснащено рядом защитных блоков, которые предусмотрены для предотвращения неправильного функционирования и непреднамеренной активации системы. Все лица, работающие с лазером или ассистирующие во время проведения процедуры, должны сами ознакомиться с этими блоками.

##### Аварийный выключатель лазера STOP

Красный аварийный выключатель лазера STOP на передней стороне устройства (смотри рисунок ниже) предназначен для немедленного отключения системы в аварийной ситуации. Его следует активировать только в аварийных ситуациях, т.е. если необходимо немедленно прервать эмиссию.

Чтобы немедленно выключить систему, нажмите на эту кнопку. Чтобы разблокировать кнопку после устранения аварийной ситуации, поверните ее влево, пока она снова не «выскочит» в прежнее положение.

##### Примечание



Аварийный лазерный выключатель STOP не следует использовать для включения и выключения системы в нормальных условиях ее работы.

##### Выключатель с ключом

Выключатель с ключом используется для активации системы. Только авторизованные лица, имеющие доступ к этому выключателю, могут произвести запуск системы. Систему можно запустить через выключатель с ключом, только если не нажат аварийный лазерный выключатель STOP.



##### ПРЕДУПРЕЖДЕНИЕ

Лазерное устройство испускает мощное излучение в инфракрасном диапазоне. Это излучение может вызвать серьезные травмы глаз при несоответствующей эксплуатации устройства.

Включение устройства или управление им не должны производиться не авторизованным персоналом.

Всегда вынимайте ключ после выключения системы и обеспечьте его хранение только авторизованными лицами.



Рисунок 4: Защитные блоки на передней панели устройства (приведен пример лазера MeDioStar NeXT<sup>PRO</sup>, для лазера MeDioStar NeXT то же самое)

### Силовой выключатель

Силовой выключатель разъединяет устройство и источник линейного напряжения. Если устройство не используется, выключатель должен находиться в положении OFF (ВЫКЛ.) (O).



Рисунок 5: Силовой выключатель на задней панели устройства (приведен пример лазера MeDioStar NeXT<sup>PRO</sup>, для лазера MeDioStar NeXT то же самое)

### Ножная педаль

В ножную педаль встроены два резервных элемента переключения. Это не влияет на характер использования устройства. Вдобавок, предохранительная крышка исключает случайное нажатие на переключатель. Чтобы откинуть крышку (когда она закрыта), нужно нажать на нее ногой.

Ножная педаль – электрическая кнопка, которая при нажатии запускает лазерное излучение, когда устройство находится в режиме *ГОТОВ (READY)*.

Всегда устанавливайте ножную педаль рядом с зоной проведения процедуры.

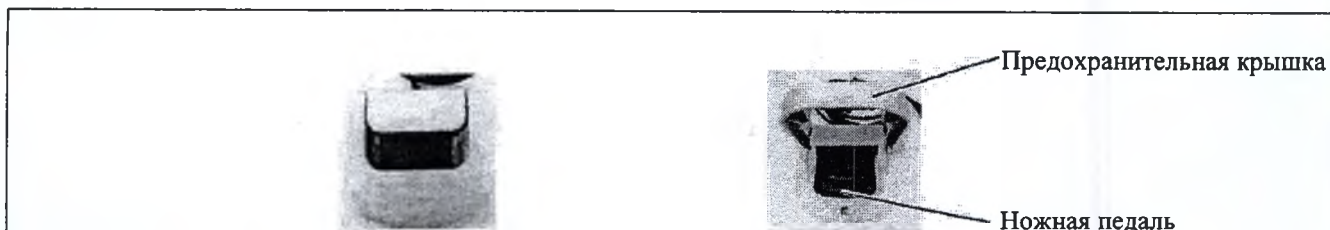


Рисунок 6: Ножная педаль (слева с закрытым защитным щитком, справа – с открытым)



### Режим *STANDBY* (ОЖИДАНИЕ)

Режим *STANDBY* предотвращает непреднамеренное или случайное включение лазера. Если устройство находится в режиме *STANDBY*, лазерная эмиссия не может быть активирована. Пользователь может запустить эмиссию только тогда, когда нажата кнопка *READY* (ГОТОВ),

Система переключается на *STANDBY* в следующих ситуациях:

- после первого запуска устройства,
- если пользователь нажимает на одну из кнопок для выбора параметров лазера,
- если система долгое время находится в режиме *READY*, но пуск лазерного луча не производится,
- если пользователь нажимает на кнопку *STANDBY*, когда система находится в режиме *READY*

### Автоматическое отключение

Устройство оснащено системой автоматического отключения. Если возникает особая проблема, система автоматически перейдет в следующий безопасный режим:

Створка лазерного луча закрывается, выход лазера прерывается, и ножная педаль деактивируется. На экране появляется сообщение о неисправности, идентифицирующее конкретную ошибку (смотри Раздел *Сообщения об ошибках и устранение неисправностей*).

### Контакт дистанционной блокировки дверного замка

Система оснащена контактом дистанционной блокировки дверного замка, который может быть соединен с входами в помещение, где находится лазер. Если контакт дистанционной блокировки замка открыт (например, если открыта дверь), происходит автоматическое прерывание лазерной эмиссии, и устройство переходит в режим *STANDBY*.

### Уравнивание потенциалов

Дополнительное уравнивание потенциалов образует основную защитную меру в соответствии с IEC/EN 60601-1 в помещениях группы 1, используемых в медицинских целях (например, офисы врача) и группы 2 (например, операционные залы; в помещениях группы 2 используют дополнительные соединения для дополнительного уравнивания потенциалов).

Это обеспечивает уравнивание разности потенциалов между различными устройствами в окружении пациента, чтобы предотвратить нарушение заземления устройств класса защиты I (однократная защита) и обеспечить соблюдение требуемого контактного напряжения относительно корпуса устройства класса защиты I.

Цепь уравнивания потенциалов может быть подключена к выходу на задней панели устройства, к соответствующим разъемам других устройств и к стационарной системе (комнаты). Уравнивание потенциала не исключает необходимость заземления устройства.

### Примечание



Соблюдайте требования Инструкции IEC/EN 60601-1 в отношении электрических систем медицинского назначения.

### Акустический сигнал

На лазерную эмиссию указывает акустический сигнал в момент эмиссии.

### Предупреждающие бирки

На устройстве имеется ряд предупреждающих бирок (смотри главу *Включение – Установка – Бирки*). Эти бирки всегда должны быть легко читаемыми, их необходимо немедленно заменять в случае повреждения.

В таких случаях, немедленно свяжитесь с Технической службой.



**Изготовитель гарантирует безопасность, надежность и эксплуатационные характеристики устройства только, если:**

1. устройство эксплуатируется в соответствии с инструкциями, приведенными в этом руководстве (по мерам обеспечения безопасности и по эксплуатации системы),
2. установка, сборка, модернизация, замены, ремонт и техническое обслуживание выполняются лицами, авторизованными для выполнения этих работ и обладающими соответствующей квалификацией, и
3. электрическая система на месте установки соответствует требованиям, предъявляемым IEC/EN 60601-1 и местными правилами.

## 5 Включение

### 5.1 Комплект поставки



#### Примечание

Проверьте вместе с перевозчиком, присутствуют ли все компоненты, перечисленные ниже и необходимые для безопасной работы устройства, и не повреждены ли они. О некомплектности и/или повреждениях при перевозке необходимо немедленно заявить поставщику.

Компания «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) не принимает на себя никакую ответственность, если только однозначно не заключен еще один договор.

Сохраняйте упаковку для будущей безопасной отправки устройства.



#### ОСТОРОЖНО

Воздержитесь от работы с лазером, если обнаружены механические повреждения устройства или его вспомогательного оборудования. Если пренебречь этой рекомендацией, вы рискуете получить физические травмы. В таких случаях, свяжитесь с Технической службой компании «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH).

Основное оборудование содержит следующие детали устройства:

- основной блок
- силовой кабель
- ножная педаль
- аппликатор
- предупреждающая лампочка/разъем дверного замка
- ключи (два, для выключателя с ключом)
- очки для защиты от лазерного излучения, средства для защиты глаз пациента
- руководство пользователя
- предупреждающий знак о работающем лазере

## 5.2 Установка



### ПРЕДУПРЕЖДЕНИЕ

Лазерное устройство находится под сетевым напряжением и испускает излучение в инфракрасном диапазоне. Существует риск поражения электрическим током и риск поражения глаз!

Включение устройства и обязательная функциональная проверка должны производиться только авторизованным персоналом.

### 5.2.1 Конструкция устройства

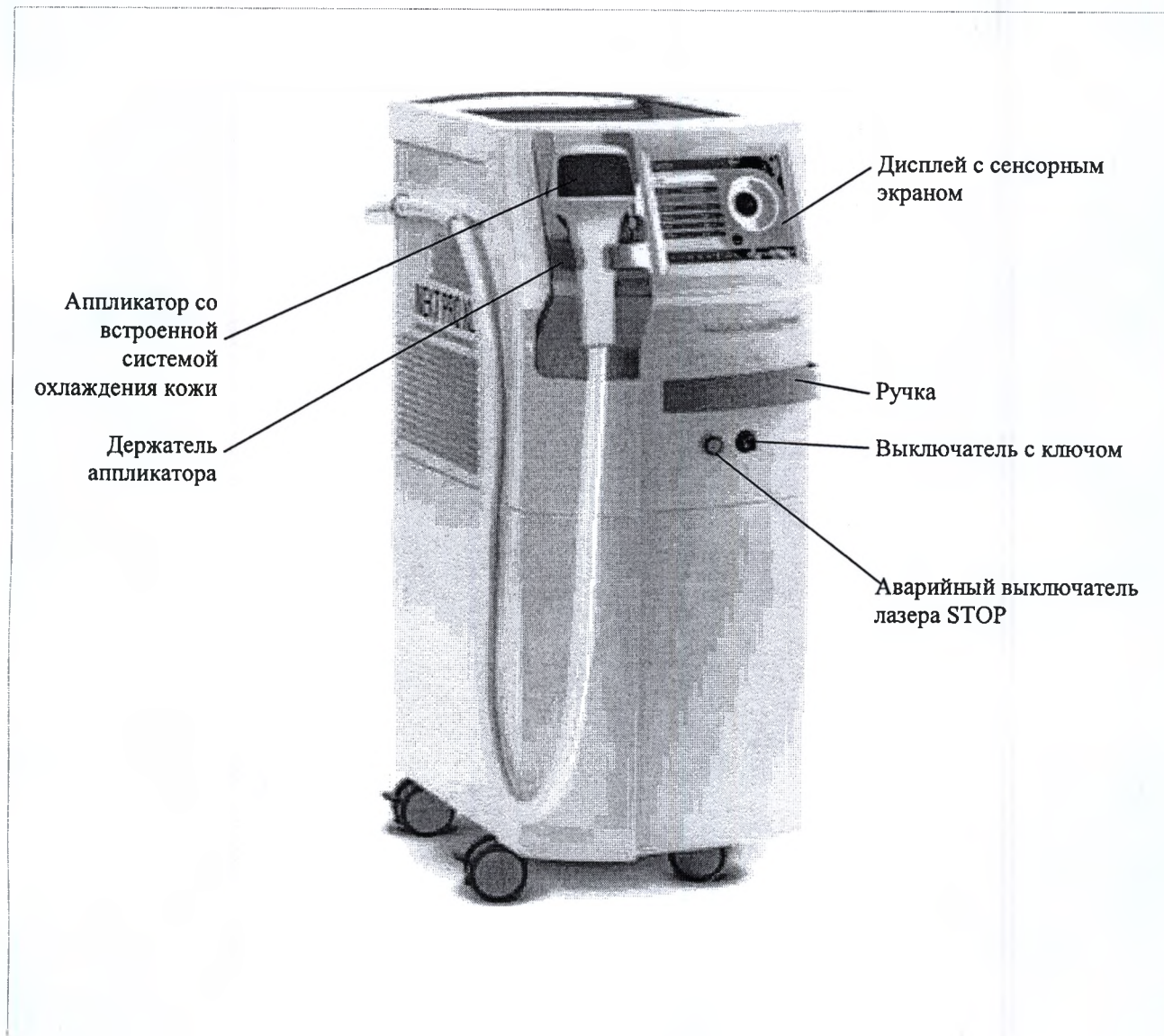


Рисунок 7: Передняя панель устройства (приведен пример лазера MeDioStar NeXT<sup>PRO</sup>, для лазера MeDioStar NeXT то же самое)





### 5.2.2 Значки на устройстве



#### ПРЕДУПРЕЖДЕНИЕ

Лазерное устройство испускает мощное излучение в инфракрасном диапазоне. Это излучение может вызвать серьезные травмы глаз при несоответствующей эксплуатации устройства.

В соответствии с этим, на соответствующих местах устройства прикреплены предупреждающие и информационные значки.

Весь персонал должен знать об этих значках и об их значении, чтобы гарантировать соответствующую эксплуатацию устройства.

Все значки должны находиться на своих местах и быть в хорошем состоянии.

Немедленно заменяйте дефектные значки, чтобы гарантировать соответствующую эксплуатацию устройства.



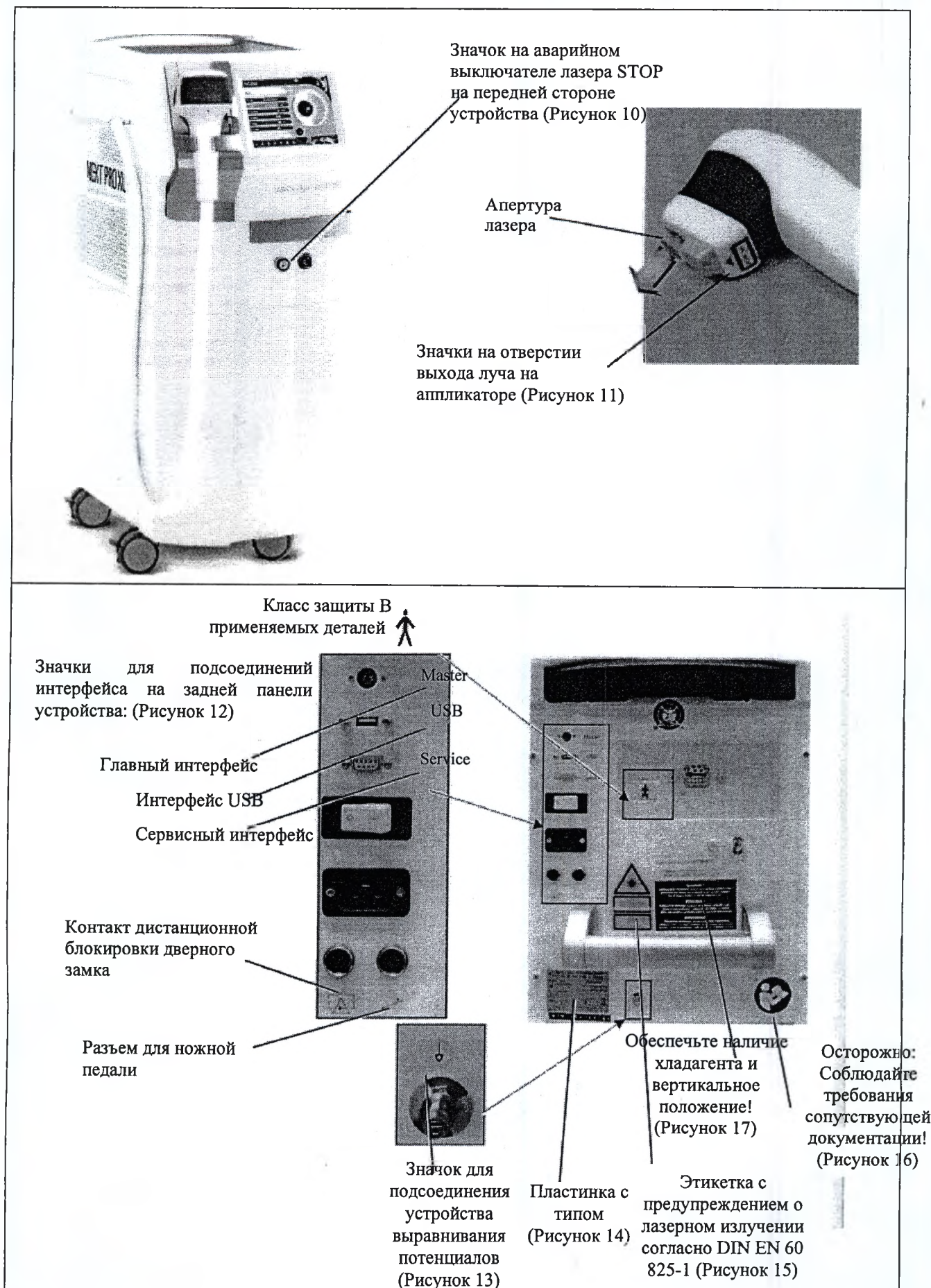


Рисунок 9: Значки на устройстве MeDioStar



Рисунок 10: Аварийный выключатель лазера STOP

Этим значком отмечен аварийный выключатель лазера STOP для быстрого выключения лазерного излучения или эмиссии модулей.



Рисунок 11: Отверстие выхода луча

Этим значком отмечено место выхода лазерного луча из системы трансмиссии.

- ① Master
- ② USB
- ③ Service
- ④
- ⑤

Figure 12: Подсоединения интерфейсов!

Предупреждение: Чрезвычайно важно, чтобы здесь было подключено вспомогательное оборудование, выпущенное компанией «Асклепион Лейзер Текнолоджис» (Asclepion Laser Technologies). Подключением главного, сервисного и USB интерфейса, должен заниматься авторизованный персонал.

- ① Главный интерфейс
- ② Интерфейс USB
- ③ Сервисный интерфейс
- ④ Разъем контакта дистанционной блокировки замка
- ⑤ Разъем для ножной педали



Рисунок 13: Соединение устройства выравнивания потенциалов

Этот контакт используется для дополнительного подсоединения устройства к системе выравнивания потенциалов.

Модель  
Серийный номер  
Дата выпуска  
(год-месяц-дата)  
  
ОСТОРОЖНО:  
Придерживайтесь  
сопроводительных  
документов!

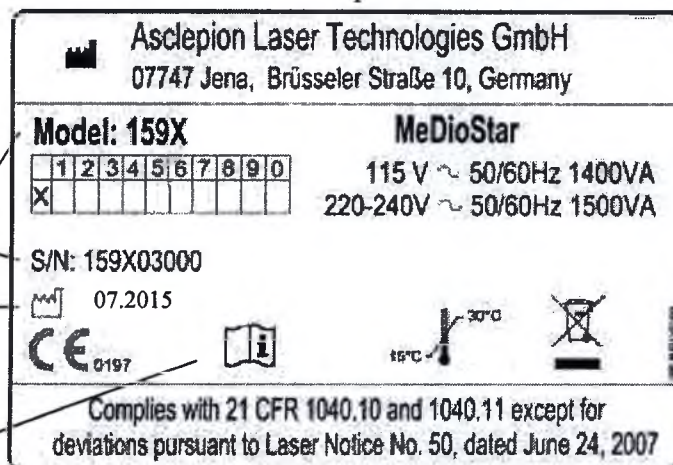


Рисунок 14: Этикетка лазера MeDioStar – на примере модель 1591

Этикетка с указанием типа и индивидуальных данных, таких как серийный номер и дата выпуска





Рисунок 15: Значок предупреждения о работающем лазере EN 60 825-1

Этот значок представляет информацию об опасностях, максимальных величинах излучаемой энергии и классификации источника лазерного излучения.



Рисунок 16: Внимание: Соблюдайте требования прилагаемых документов!

Этот значок предупреждает пользователя о том, что перед применением устройства должны быть тщательно изучены все документы, поставляемые вместе с устройством.

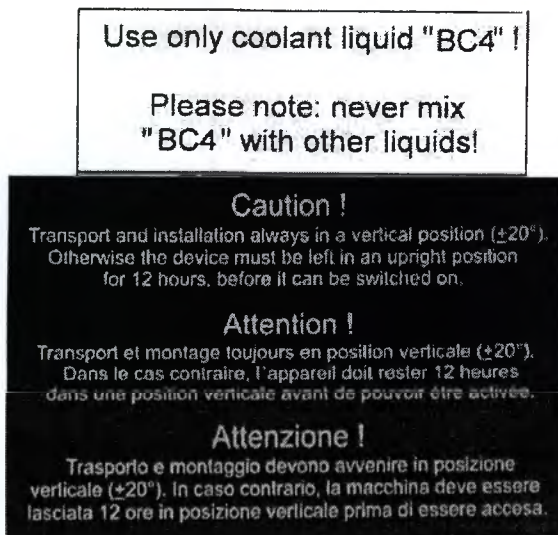


Рисунок 17: Обеспечьте наличие охлаждающей жидкости и вертикальное положение при транспортировке!

Этот значок предупреждает пользователя о том, что в качестве охлаждающей жидкости должна применяться специально разработанная компанией «Асклепион» (Asclepion) жидкость (обладающий функциями защиты от коррозии, антибактериальный, незамерзающий эффективный охладитель)!

Никогда не смешивайте этот охладитель с дистиллированной водой!

Этот значок предупреждает пользователя о том, что устройство должно находиться в вертикальном положении (угол наклона не более 20°).

### 5.2.3. Общие рекомендации по установке



#### ПРЕДУПРЕЖДЕНИЕ

Лазерное устройство испускает мощное излучение в инфракрасном диапазоне и работает от линейного напряжения. Поэтому требуется соблюдение мер электромагнитной совместимости (ЭМС). Несоблюдение этих мер может привести к серьезным травмам пациентов и персонала пользователя при неправильной установке и установке устройства.

Установка и установка устройства должна быть проведена с соблюдением всех инструкций, приведенных в разделе *Безопасность, Технические характеристики, Спецификации* и Приложение по ЭМС.

#### ВАЖНАЯ ИНФОРМАЦИЯ



После каждого перемещения устройства из более холодной в более теплую среду с различием температуры больше, чем 5 °C, дайте аппарату приспособиться к комнатной температуре в распакованном состоянии в течение следующего времени:

минимум 2 часа при различии температур до 10 °C

минимум 4 часа при различии температур до 15 °C

минимум 8 часов при различии температур больше, чем 20 °C.

Затем включите питание и дайте аппарату поработать без подключения аппликатора в течение 30 минут.

Убедитесь, что среда, в которой устанавливается и должно эксплуатироваться устройство, соответствует разрешенным условиям среды, указанным в главе *«Технические характеристики / Спецификации»*.

Неисполнение этих требований может привести к поломке аппарата.

Для обеспечения оптимальной вентиляции оставьте, по крайней мере, 20 см свободного пространства между стенами помещения и задней и боковыми панелями



#### ПРЕДУПРЕЖДЕНИЕ

Лазерное устройство испускает мощное излучение в инфракрасном диапазоне. Это излучение может вызвать серьезные травмы глаз при несоответствующей эксплуатации устройства.

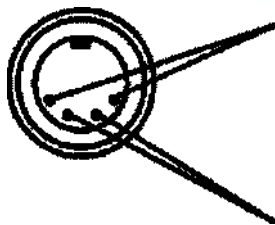
Каждый вход в зону работающего лазера (обычно, это помещение, в котором проводится лазерная терапия) должен быть оборудован предупреждающими лампочками, которые горят (или мигают) в течение времени действия лазерного излучения, чтобы предупредить лиц о запрете входа в помещение.

### 5.2.4 Подсоединение дверного прерывателя

На задней панели устройства, предусмотрен разъем для подсоединения к устройству контакта блокировки дверного замка (смотри Рисунок ниже).

В качестве порта можно использовать круглый штыревой контакт, который можно ввинтить, типа (x)V 40, в соответствии с IEC 60130-9, например, Lumberg WSV 40 (в соответствии с поставкой).

(x): в зависимости от типа, напр. для WS поставляется угловой контакт.



Контакт блокировки дверного замка (значения для подключения приведены в разделе *Технические характеристики*)

Релейный выключатель лазерной эмиссии (значения для подключения приведены в разделе *Технические характеристики*)

Рисунок 18: Подсоединения для дистанционной блокировки дверного замка и лампы, предупреждающей о работающем лазере.



Осуществляя два подключения – *контакта дистанционной блокировки дверного замка* и *наружного контакта двери*, вы можете предотвратить эмиссию лазерного излучения при открывании двери в помещение, где работает лазер.

Эта защитная система служит для автоматического отключения хирургического луча при открывании двери, тем самым, исключая какой-либо риск для лица, входящего в помещение.

Включенный в комплект штырь контакта оборудован перемычкой на заводе. Для подключения контакта удаленной блокировки эту перемычку нужно снять и подсоединить удаленный контакт блокировки к тем же разъемам. Наружный контакт должен быть выполнен в виде плавающего контакта. Если Вы не хотите использовать контакт удаленной блокировки, штепсель нужно соединить с перемычкой на заводе.



#### Важная информация

Штырь контакта может быть подсоединен только при отключенном устройстве, отсоединенном от источника напряжения. Несоблюдение этого указания может стать причиной повреждения устройства.

Контакты для дистанционной системы блокировки дверного замка и ножной педали никогда не должны подключаться к линейной мощности, поскольку это может привести к серьезному повреждению системы. Подсоединяйте эти разъемы только так, как описано в этом разделе.



#### Совет

Если вы подсоединили контакт блокировки дверного замка к входной двери, каждый день проверяйте, прежде чем начать процедуру, чтобы лазер нельзя было переключить на режим *READY* при открытом состоянии этой двери. В случае неисправности, сообщите об этом в Техническую службу.

Внешний источник напряжения для низковольтной предупреждающей лампочки можно подключить через два дополнительных контакта этого разъема. Установленный внутри релейный переключатель рассчитан на максимальное напряжение или максимальный ток (см. рис. выше). Безусловно соблюдайте следующие требования техники безопасности для подключения наружной предупреждающей лампочки.



#### ПРЕДУПРЕЖДЕНИЕ

Для исключения риска поражения электрическим током с последующими серьезными проблемами для здоровья, а также – опасности возгорания трансформатора, если вы используете внешний трансформатор для системы питания лампы, обратите внимание: Необходимо выбирать защитный трансформатор, соответствующий IEC / EN 61558-2-6.

Внутреннее реле устройства закрыто, если устройство находится в режиме *READY*.

Рекомендованная лампа, предупреждающая о работающем лазере, может, конечно, включаться и выключаться также и с помощью обычно выключателя, если работает лазер.

### 5.2.5 Ножная педаль

Теперь, подсоедините ножную педаль к разъему ножной педали, предусмотренному на задней панели устройства (обратитесь к Рисунку *Подсоединения на задней панели устройства*). Убедитесь, что штекер вставлен глубоко, до упора. Затем зафиксируйте его, повернув накидную гайку в направлении по часовой стрелке. Ножную педаль следует разместить в непосредственной близости от устройства.

Чтобы позже можно было активировать ножную педаль, сначала нужно нажать на крышку так, чтобы она открылась (обратитесь к Разделу *Технические данные/Защитные блоки*). Таким образом, можно открыть доступ к фактическому выключателю (черного цвета), который можно привести в действие ногой, чтобы лазерная эмиссия соответствовала режиму *READY*.



## 5.2.6 Аппликаторы

Различные аппликаторы, имеющие одинаковые разъемы для подключения к устройству (см. раздел *Технические данные/Аппликаторы*). Этот разъем необходимо аккуратно подключить к разъему на задней панели устройства и надавить до срабатывания замков справа и слева (характерный звук). При этом происходит как подключение источника питания диодного излучателя, так и жидкостной магистрали для системы охлаждения Пельтье (см. также Раздел *Работа устройства/Замена аппликатора*).

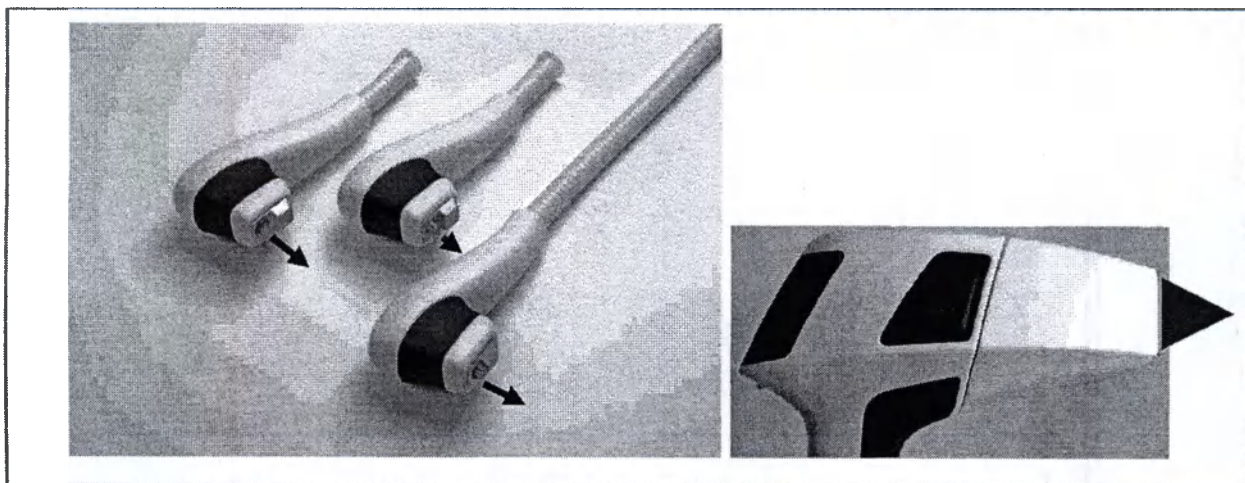


Рисунок 19: Аппликаторы MeDioStar с различными размерами пятна с указанием направления излучения (красными стрелками). Слева направо приведены аппликаторы ST, HP, VAS и XLL/S.

## 5.2.7 Подключение к сети

### Важная информация



При выборе сетевой розетки, учитывайте все технические данные вашей локальной сети и устройства. Сначала, убедитесь, что доступная линейная мощность соответствует указанным требованиям к источнику питания (линейная мощность указана на пластинке с указанием типа). Если устройство подключено к несоответствующему источнику питания, это может привести к его повреждению.

Обеспечивайте соответствие требованиям, указанным в ваших национальных правилах / стандартах, в соответствии с вносимыми в них поправками и дополнениями.

Перед подключением к сети убедитесь, что главный выключатель находится в положении «0» (прибор не под напряжением). Сначала подключите кабель питания к разъему на задней панели аппарата, затем включите его в розетку. Для работы лазера требуется, чтобы аппарат был подсоединен к однофазному источнику питания, защищенному плавким предохранителем с номиналом не менее 1500 ВА.

## 5.2.8 Линия для выравнивания потенциалов

Линия для выравнивания потенциалов может быть подключена к разъему на задней панели устройства, и к соответствующим разъемам других устройств и к стационарной системе. Выравнивание потенциалов не заменяет необходимость заземления устройства.

### Важная информация



Обеспечивайте соответствие требованиям Инструкции IEC/EN 60601-1 относительно медицинского электрооборудования.

### 5.3 Включение

Перед тем, как включить устройство, убедитесь в том, что удовлетворяются следующие требования:

- Устройство находится в безупречном состоянии (отсутствуют повреждения).
- Напряжение, указанное на этикетке, соответствует линейному напряжению, к которому можно подключиться в месте установки.
- Штекер устройства вставлен в соответствующую сетевую розетку.
- Штекер ножной педали соответствующим образом подсоединен к гнезду ножной педали на задней панели устройства и завинчен.
- Штекер контакта двери соответствующим образом подсоединен и привинчен к своей клемме на задней панели устройства.
- Аппликатор подсоединен.
- Предупреждающие лампы включены на каждом входе в помещение, где работает лазер.

Убедитесь в том, что приняты все меры предосторожности.

Затем переходите к выполнению следующих действий:

1. Переведите силовой выключатель на задней панели устройства в положение I (Вкл).
2. Удостоверьтесь, что *Аварийный выключатель лазера Stop* деактивирован (не нажат)
3. Затем, вставьте ключ защиты в выключатель с ключом и поверните его по часовой стрелке до упора.

В то время как устройство автоматически проверяет важные и относящиеся к обеспечению безопасности детали, на дисплее появляется экран запуска. На экране появляется главное меню.

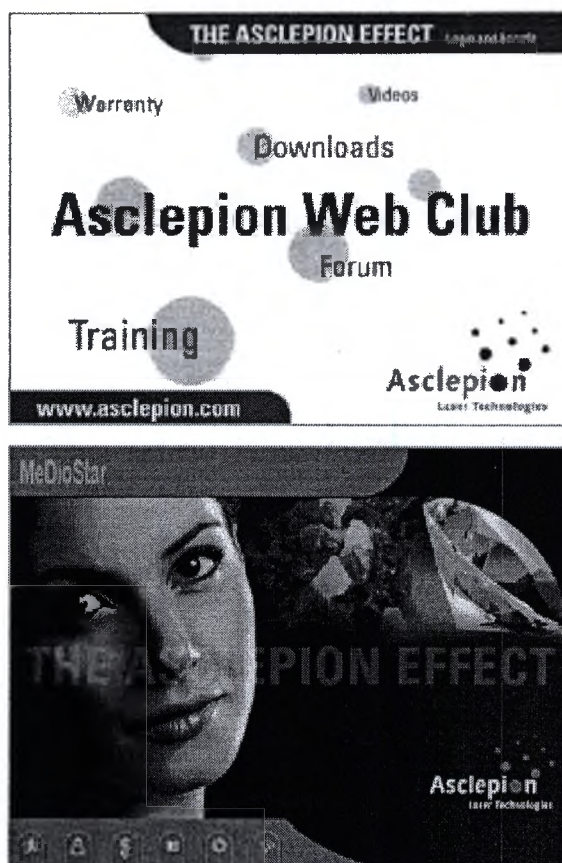


Рисунок 20: Экран запуска



## 6 Работа устройства



### ПРЕДУПРЕЖДЕНИЕ

Использование иных устройств управления или иное осуществление регулировок или иное выполнение процедур, чем указанные в данном документе, может привести к опасному воздействию излучения.

Безоговорочно соблюдайте инструкции, включенные в это Руководство пользователя, в отношении оборудования, и порядок выполнения действий при эксплуатации, техническом обслуживании, проверке или калибровке.

Устройство работает от линейного напряжения. Есть опасность поражения электрическим током!

Устройство удовлетворяет указанным предельным значениям токов утечки. Тем не менее, убедитесь, что контакт с пациентом и устройством происходит не одновременно, когда устройство включено.

### 6.1 Общая информация о работе

Параметры проведения процедуры должны быть заданы с помощью сенсорного экрана на дисплее передней панели (смотри рисунок *Передняя панель устройства*). Настройка не вызывает затруднений и не требует пояснений.

- Программное обеспечение устройства автоматически определяет и выводит на дисплей подключенный к нему аппликатор с указанием размера пятна. Размер пятна можно изменить заменой наконечника при использовании аппликатора XL, для остальных аппликаторов размер пятна фиксирован.
- Чтобы выбрать функцию, нажмите на соответствующие области на дисплее. Нажимая на клавиши +/- на правой стороне дисплея, вы можете перемещаться по перечням, состоящим из нескольких страниц (например, перечни показаний).
- Чтобы выбрать параметры, нажмите на область соответствующего параметра активированной функции. Области с темным фоном (функциональные области) можно выбрать, тогда как области со светлым фоном (области показаний) используются только для информации.  
Нажимая на клавиши +/- на правой стороне дисплея, вы можете изменить заданные диаметры. Если вы будете удерживать клавишу нажатой некоторое время, это обеспечит автоматический просмотр параметров. Загрузка новых параметров осуществляется при нажатии ОК.
- Успешное нажатие на клавишу подтверждается коротким сигналом зуммера.
- Устройство активируется при нажатии на клавишу *STANDBY/READY* (ОЖИДАНИЕ/ГОТОВ). Если устройство переключено в режим *READY*, на дисплее будет дополнительно отображен желтый предупредительный знак.

Обзор основных функциональных клавиш

| Функция/ Параметр     | Обозначение на дисплее                                                              | Пояснение                                                                                           |
|-----------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Выключение устройства |    | Выключение устройства переключательным элементом (аналоговый выключатель с ключом).                 |
| Быстрый запуск        |    | Вход в меню быстрого запуска. Позволяет непосредственно запустить лазер.                            |
| База данных пациентов |    | Выбор и хранение в памяти историй процедур с соответствующими параметрами.                          |
| Показания             |    | Отображение и выбор всех доступных показаний.                                                       |
| Библиотека            |    | Содержит информацию, включая фото- и видеоматериалы.                                                |
| Установка             |    | Общие установки устройства можно настроить на дисплее.                                              |
| Асклепион             |    | Узнайте о преимуществах Asclepion Web Club.                                                         |
| Инструменты           |   | Выбор сохраненных специальных функций лазера.                                                       |
| Сохранить             |  | Запоминание установок процедуры.                                                                    |
| Домашнее меню         |  | Возврат к начальному меню                                                                           |
| Кнопки                |  | Просмотр и изменение установок.                                                                     |
| Назад                 |  | Возврат к предыдущему меню без изменения установок.                                                 |
| Отмена/Удалить        |  | Выход из текущих показателей/статистики пациент/избранного. Стирание.                               |
| ОК                    |  | Подтверждение установок.                                                                            |
| Готов/Ожидание        |  | Активный режим выделен белым фоном. Желтый знак лазерной опасности появляется в режиме <i>Готов</i> |



## 6.2 Настройки / Установка

Вы можете изменить общие настройки дисплея, т.е. язык и громкость. Для этого нажмите кнопку *Setup* в основном меню вызовите меню «Установка». При этом откроется окно «Установка» (см. рис. ниже).

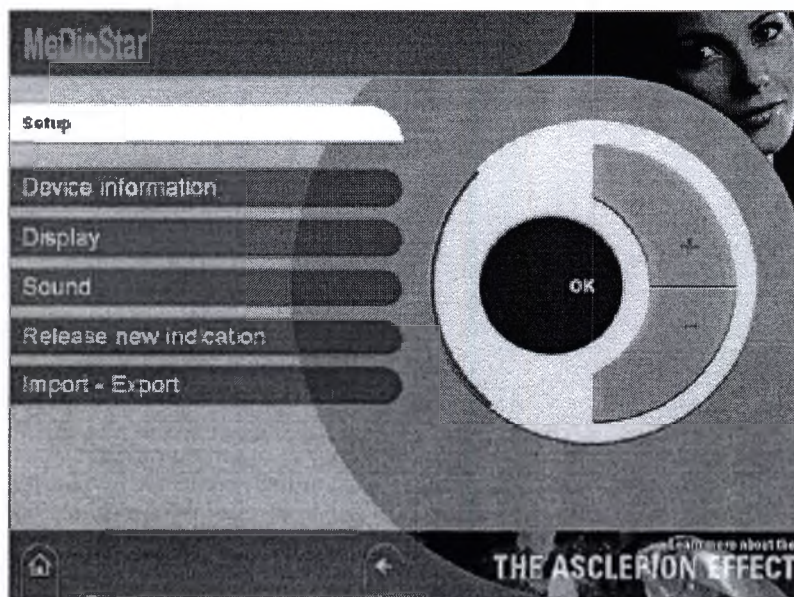


Рисунок 21: Меню «Установка»

Следующие функции доступны при нажатии соответствующих клавиш:

| Функция/<br>Параметр         | Обозначение на<br>дисплее | Пояснение                                                                                                                   |
|------------------------------|---------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Информация                   | Device information        | Данные о версии программного обеспечения                                                                                    |
| Язык                         | Display                   | Выбор языка                                                                                                                 |
| Звук                         | Sound                     | Установка громкости звука                                                                                                   |
| Очистить для новых показаний | Release new indication    | Новые показания должны быть разрешены                                                                                       |
| Импорт/Экспорт               | Import - Export           | Позволяет экспортировать и импортировать базу данных пациентов, список указаний и библиотеку на флеш-накопитель или с него. |



### Совет

Использование интерфейса USB возможно только в режиме *STANDBY* и только для экспорта и импорта данных с соответствующего флеш-накопителя USB или на нее, например, от «Асклепион Лейзер Текнолоджис» (Asclepion Laser Technologies).

Резервное копирование данных о пациенте должно выполняться через регулярные интервалы времени, с использованием соответствующего флеш-накопителя USB, чтобы не допустить потерю данных в случае возможного дефекта устройства!

Эти данные можно считывать только на дисплее устройства.



### 6.3 База данных пациентов

Вы можете сохранить информацию о проведенных процедурах и добавить новых пациентов в Базу данных. Для этого войдите в Базу данных, нажав клавишу «База данных» в главном меню.

Появится экран «База данных» (см. рис. ниже).



Рисунок 22: Меню «База данных» пациентов

| Функция/ Параметр | Обозначение на дисплее                                                              | Пояснение                                                                                                                  |
|-------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| Новый пациент     |  | Добавление нового пациента в Вашу базу данных. При нажатии этой клавиши на дисплее появится клавиатура для ввода данных.   |
| Информация        |  | Здесь вы можете вызвать текст комментариев или информацию о пациенте (аллергические реакции, реакция на процедуры и т.д.). |



Рисунок 23: Экранная клавиатура для ввода данных

Для написания инициалов заглавными буквами, нажмите один раз на клавишу *Shift*, но не удерживайте ее нажатой. После написания одной буквы, клавиатура автоматически снова возвращается к прописным буквам.

Вы можете переключить клавиатуру на заглавные буквы, нажав на клавишу *Cap*.

Активируя клавишу *Shift* или *Cap*, вы можете добавить специальные символы.

Используйте клавишу *äü*, чтобы добавить специальные символы иностранных языков. Здесь вы также можете нажать на клавиши *Shift* или *Cap*, чтобы перейти к написанию заглавных букв. Чтобы вернуться к первоначальной раскладке клавиатуры, снова нажмите на клавишу *äü*.



#### Важная информация

Убедитесь в том, что дата рождения пациента введена полностью, **четырьмя цифрами**, и имеет смысл. В противном случае, вводимая вами информация не будет сохранена.

## 6.4 Библиотека

Этот раздел содержит информацию о различных показаниях, включая применение, методы проведения процедур, побочные эффекты, а также фотографии до и после и видеоматериалы. Для входа в меню «Библиотека» нажмите клавишу «Библиотека» в главном меню.



Рисунок 24: Библиотека



Доступная информация:

| Функция/ Параметр    | Обозначение на дисплее                                                            | Пояснение                                                                             |
|----------------------|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Показание            | Epilation BASIC                                                                   | Выберите показание, по которому вы желаете посмотреть информацию (например, эпиляция) |
| Фотографии           |  | Фотографии до и после (если есть)                                                     |
| Видео                |  | Видеоматериалы проведения процедур (если есть)                                        |
| Показания            | Indications                                                                       | Область применения данной процедуры                                                   |
| Противопоказания     | Contraindications                                                                 | Противопоказания                                                                      |
| Подготовка           | Preparation                                                                       | Замечания по подготовке пациента                                                      |
| Проведение процедуры | Therapy Procedure                                                                 | Замечания по проведению процедуры                                                     |
| Постпроцедурный уход | Aftercare                                                                         | Замечания по проведению постпроцедурного ухода                                        |
| Замечания            | Notes                                                                             | Замечания общего характера                                                            |

Примеры доступной информации:

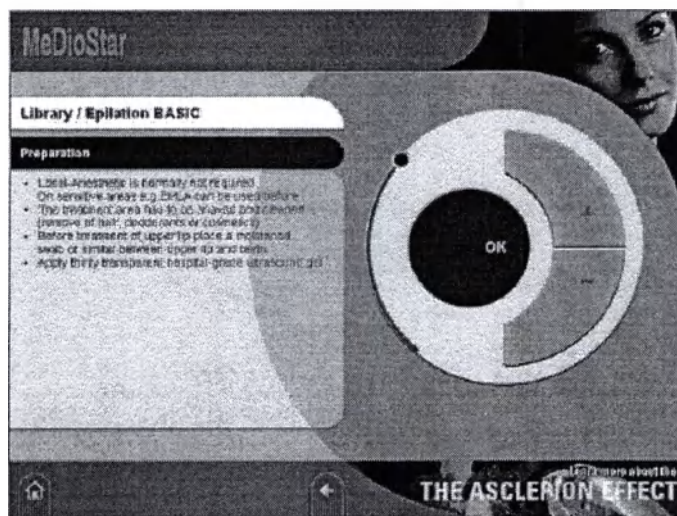


Рисунок 25: Терапевтическая информация



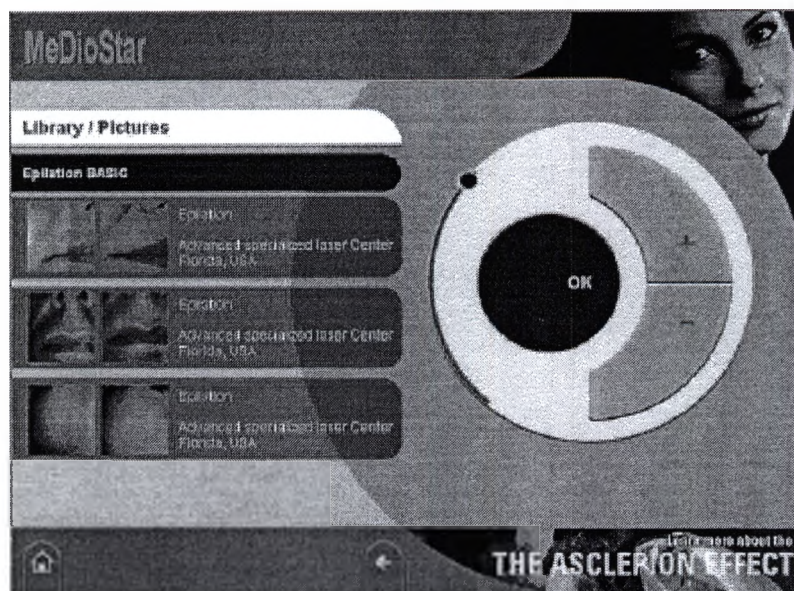


Рисунок 26: Библиотека фотографий



Рисунок 27: Библиотека видеоматериалов

Для того чтобы увеличить фотографии или запустить видео, прикоснитесь к фотографии или видео.



## 6.5. Асклепион Эффект

Асклепион Эффект – это философия поддержки пользователей и пациентов.

Асклепион Эффект предоставляет вам информацию о компании «Асклепион Лейзер Текнолоджис» (Asclepion Laser Technologies), стратегии ее бизнеса и инструментов маркетинга.

Вы уже стали членом нашего эксклюзивного Web Club? Если нет, то это возможность ознакомиться с нашими предложениями.

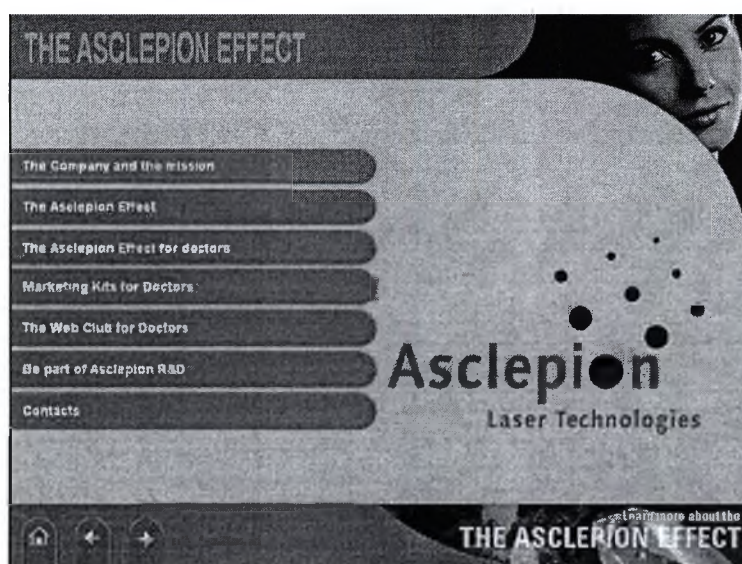


Рисунок 28: Асклепион Эффект

## 6.6 Начало процедуры

Ваше устройство предназначено для различных применений.

Чтобы можно было начать процедуру, вам необходимо перейти к экрану Treatment (Процедура) (смотри ниже пример для начала с перечня показаний).

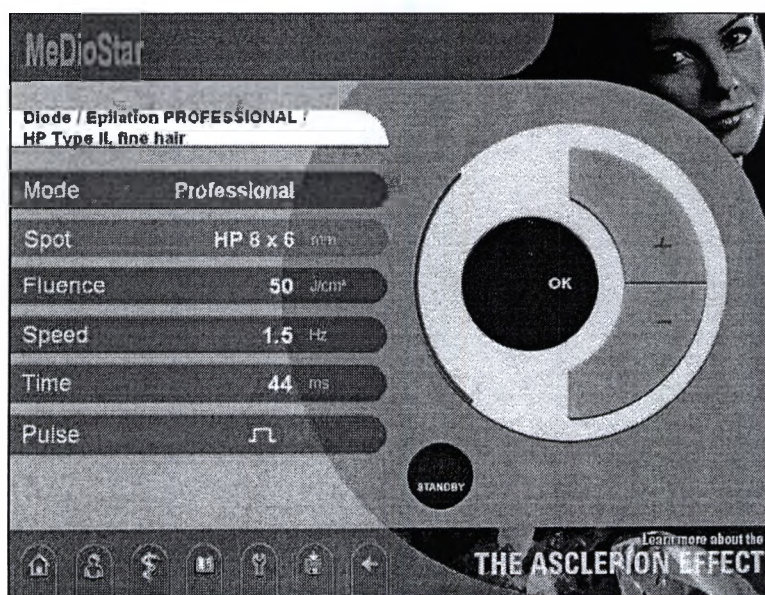


Рисунок 29: Меню Treatment (Процедура)



Перейти к экрану Процедура через перечень показаний можно только в случае, если подсоединен соответствующий аппликатор. Если аппликатор не подсоединен, или подсоединен несоответствующий аппликатор, на дисплее появится сообщение об этом.

У вас есть несколько опций для перехода от главного меню к экрану Процедура:

- Начало работы через **Быстрый запуск**   
(Выбранные пользователем параметры могут быть непосредственно заданы на дисплее в соответствии с выбранным режимом – Основной, Профессиональный, Однородный импульс, Форсированный или Сосудистый).
- Начало работы через **Перечень показаний**   
(В соответствии с выбранным показанием, соответствующие параметры уже отображены для пробной процедуры. В зависимости от реакции на пробную процедуру, их нужно уменьшить или увеличить. См. главу *Применение*.)
- Начало работы через **Базу данных пациентов**   
(Эта опция рекомендуется для продолжения лечения).

#### 6.6.1 Начало работы через Быстрый запуск

Чтобы перейти к экрану *Быстрого запуска*, нажмите на клавишу *Quickstart* (Быстрый запуск) в главном меню.

Для открытия этого окна системе потребуется несколько секунд.

Через меню Быстрого запуска (*Рисунок, Экран быстрого запуска, пример Базового режима*) вы можете запустить свое лазерное устройство.



Рисунок 30: Меню быстрого запуска

Обратитесь к главе *Настройка и сохранение параметров* для настройки параметров.

На дисплее в меню Быстрого запуска вы можете также выбрать различные режимы – Основной, Профессиональный, Однородный импульс, Форсированный или Сосудистый – если они разрешены для подсоединенного аппликатора. (Смотри раздел *Применение*, где приведены инструкции по применению.)



### 6.6.2 Начало работы через Перечень показаний

Нажмите на кнопку *Перечень показаний* в главном меню, чтобы открыть экран с перечнем показаний (смотри Рисунок ниже).

Указаны все показания, которые разрешены для вашего устройства.



Рисунок 31: Меню показаний

Выберите свое показание, нажав на соответствующую область. Откроется экран процедур для данного показания. Обратитесь к главе *Настройка и сохранение параметров* для настройки параметров.

### 6.6.3 Начало работы через меню Базы данных пациентов

Начало работы через меню Базы данных пациентов полезно, когда Вы ранее уже провели процедуру пациенту и Вы хотите воспроизвести прежние параметры этой процедуры. Для этого нажмите клавишу «База данных пациентов» для входа в базу данных пациентов. При этом на дисплей будет выведено меню *База данных пациентов*.



Рисунок 32: Меню «База данных» пациентов

Нажмите на клавишу с именем пациента, при этом на дисплее появится запись с параметрами процедуры.

Пациента выбирают путем нажатия на название программы на левой стороне. Для «включения» экрана, используют клавиши +/- . При подтверждении нажатием на ОК, вы открываете *Экран процедур*. Обратитесь к главе *Настройка и сохранение параметров* для настройки параметров.

## 6.7 Настройка и сохранение параметров

В этой главе описано, как задать параметры для индивидуального лечения и как их сохранить. Сначала, активируйте экран Процедуры.

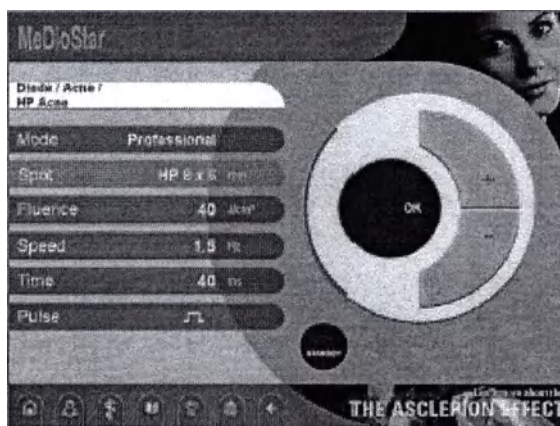


Рисунок 33: Экран Процедуры

Выберите параметр, который вы хотите изменить, нажав на область. Выбранный параметр будет визуально отмечен (темнее). Для осуществления изменений пользуйтесь клавишами +/-.

Нажмите ОК, чтобы сохранить измененные настройки.

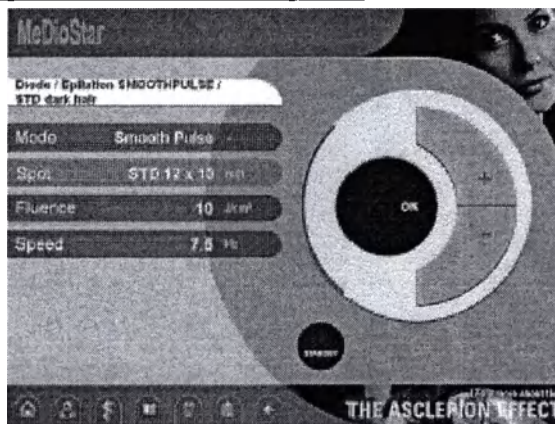


Рисунок 34: Экран лазерного устройства в режиме ожидания

Теперь, вы можете сохранить измененные настройки, нажав на кнопку *Save* (Сохранить). У вас есть выбор сохранения настроек для пациента или для показания. Чтобы выполнить это, нажмите на клавишу *Patient database* (База данных пациентов) или на клавишу *Indications list* (Перечень показаний).

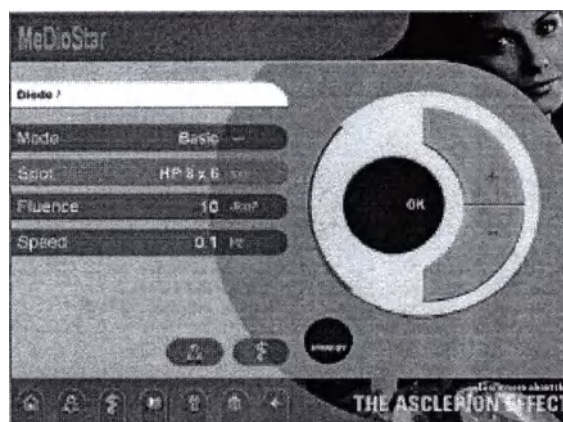


Рисунок 35: Сохранение параметров

#### Сохранение информации в базе данных пациентов:

Для сохранения параметров в базе данных пациентов сначала выберите: сохраняете ли Вы информацию о новом пациенте или ранее зарегистрированном. Если пациент ранее был зарегистрирован, Вы можете, либо создать для него новый файл, либо сохранить запись в существующем файле. В этом случае файл будет перезаписан.

Для вывода на дисплей сохраненных параметров войдите в базу данных пациентов (см. Раздел База данных пациентов).

#### Сохранение в перечень показаний:

Приняв решение сохранить установки в перечне показаний, Вы можете либо выбрать ранее записанные, либо новые. В случае выбора ранее записанных показаний, их содержание будет перезаписано.

Для возврата к предыдущим параметрам войдите в список показаний (см. Раздел Начало работы Перечень показаний).

## 6.8 Настройки для вашего лазерного устройства

Параметры, которые можно настроить, зависят от режима и выбранного аппликатора.

#### Основной режим:

можно настроить плотность энергии (Fluence) и скорость обработки (Speed)

Примечание: В этом режиме, будет использоваться самая короткая из возможных длительностей импульса (Time) для заданной плотности, всегда со двоянным импульсом.

Для двоянного импульса плотность и время всегда относятся к сумме двух частей двоянного импульса (промежутки между импульсами не учитываются).

#### Профессиональный режим:

можно настроить плотность, скорость, время, а также – одиночный или двоянный импульс

#### Сосудистый режим:

можно настроить плотность, скорость, время

Примечание: всегда одиночный импульс



#### Режим однородного импульса:

Можно настроить плотность и скорость

Примечание: всегда одиночный импульс, всегда самое короткое из возможного времени для заданной плотности  
низкая плотность, высокая частота  
в противоположность другим режимам, всегда необходимо несколько проходов (смотри *Применение/Эпиляция*)

#### Форсированный режим:

Можно настроить плотность, скорость, время, количество импульсов (Pulse) и паузу между импульсами

Примечание: - заданная Общая плотность распределяется на количество импульсов (отдельные части прикладываются к одной и той же точке)  
- Время относится к продолжительности одного частичного импульса (не сумма)  
- Пауза – это время между отдельными частичными импульсами (не сумма)



#### Совет

Обратите внимание, что

- для конкретного аппликатора могут быть активированы только подходящие режимы. Это означает, что не все режимы можно настроить для каждого аппликатора.
- Большинство параметров технически зависят друг от друга. Это означает, что, например, самая высокая плотность не возможна одновременно с самой короткой продолжительностью импульса.

Размер пятна можно изменить путем замены аппликаторов или, в случае использования аппликатора XL, путем замены наконечника. Размер пятна автоматически распознается устройством и отображается на дисплее.

В дополнение к выбранным параметрам, отображается статус устройства [STANDBY или READY] и, если применимо, сообщения о неисправностях открытым текстом.

Кроме того, дополнительно указываются энергия импульса, номер испускаемого в настоящий момент импульса и общее количество импульсов (смотри Раздел *Специальные функции/Инструменты*).

Излучение энергии лазером осуществляется при нажатии на ножную педаль.

### 6.8.1 Параметры

| Функция/ Параметр     | Обозначение на дисплее | Пояснение                                                                                                                                                                                      |
|-----------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Плотность энергии     | Fluence                | Устанавливает плотность энергии (флюенс) (полный флюенс в <i>форсированном</i> режиме)                                                                                                         |
| Скорость процедуры    | Speed                  | Устанавливает скорость процедуры (частоту повторения импульсов)                                                                                                                                |
| Размер пятна          | Spot                   | Показывает размер пятна, установленный на аппликаторе                                                                                                                                          |
| Длительность импульса | Time                   | Устанавливает длительность импульса<br><i>Профессиональный режим:</i> для двойного импульса – сумма двух частей импульса<br><i>Форсированный:</i> длительность импульса при частичном импульсе |
| Режим работы          | Mode                   | Режим работы                                                                                                                                                                                   |
| Импульс               | Pulse                  | <i>Профессиональный режим:</i> Переключение одиночного импульса на двойной.<br><i>Форсированный:</i> несколько импульсов                                                                       |
| Импульс-пауза         | Pause                  | Только в <i>Форсированном</i> режиме: регулировка паузы между частичными импульсами.                                                                                                           |

## 6.8.2 Специальные функции/Инструменты

Нажатием клавиши Инструменты можно перейти в меню «Инструменты»

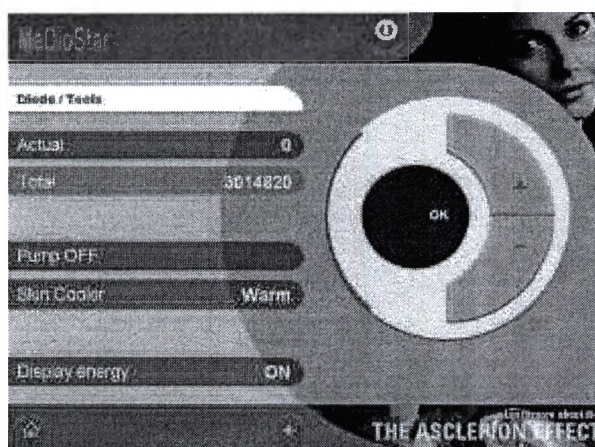


Рисунок 36: Экран «Инструменты»

| Функция/<br>Параметр        | Обозначение на<br>дисплее | Пояснение                                                                                                                       |
|-----------------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| Счетчик импульсов           | Actual                    | Может быть установлен на 0 нажатием клавиши (до звукового сигнала) и автоматически устанавливается на 0 после выключения лазера |
| Счетчик импульсов           | Total                     | Показывает суммарное количество импульсов                                                                                       |
| Насос охлаждения воды       | Pump OFF                  | См. информацию ниже                                                                                                             |
| Температура охлаждения кожи | Skin Cooler               | Холодная/средняя/теплая (рекомендуется: холодная)                                                                               |
| Индикация энергии           | Display energy            | Показывает величину импульсной энергии на дисплее                                                                               |

### ВАЖНАЯ ИНФОРМАЦИЯ



Перед сменой аппликатора или наконечника аппликатора XL, насос воды охлаждения должен быть всегда выключен путем выключения лазера (рекомендовано) или нажатием кнопки *Pump off* (ВЫКЛЮЧЕНИЕ НАСОСА) в меню «Инструменты». Таким образом можно предотвратить утечку хладагента. Когда аппликатор сменен, насос включается автоматически.

### ВАЖНАЯ ИНФОРМАЦИЯ



Перед окончанием ресурса подключенного аппликатора (зависит от аппликатора) эта информация появится на дисплее несколько раз.



### 6.8.3 Активация режима готовности лазера и эмиссия лазерного луча

Смотри также главу *Применение*!

После активации клавиши Быстрого запуска или показания из перечня показаний, лазер находится в режиме *STANDBY (ОЖИДАНИЕ)*. На клавише *READY/STANDBY* режим ожидания подсвечивается белым.

Снова убедитесь в том, что:

- аппликатор подсоединен корректно, а наконечник аппликатора чист и продезинфицирован.
- предприняты все меры предосторожности по обеспечению защиты от лазера.
- контакт блокировочного устройства дверцы функционирует соответствующим образом, если оно вами установлено: Откройте дверцу; должно быть невозможно перевести лазер в режим *READY* (появляется сообщение об ошибке, которое должно быть подтверждено).

Настраивайте необходимые параметры в соответствии с пояснениями, приведенными в предыдущих главах.



#### ПРЕДУПРЕЖДЕНИЕ

Прямое и рассеянное лазерное излучение может привести к серьезным травмам глаз. Во время идущей лазерной операции все лица, присутствующие в помещении, где работает лазер, должны носить очки для защиты глаз или козырьки для защиты глаз пациентов, соответствующие этому лазеру, как указано в главе *Технические данные*. Другие типы средств для защиты глаз от лазерного излучения могут не обеспечить необходимую степень защиты!

Перед тем, как нажать на клавишу *READY*, лечащий пользователь должен проверить это. В режиме *READY* вы можете также активировать лазерный импульс, непреднамеренно нажав на ножную педаль! В связи с этим, лазерное устройство необходимо переключать в режим *STANDBY* во время пауз между лечебными процедурами и в конце лечебного сеанса. Лазерный луч можно выпустить только в том случае, если аппликатор точно направлен на обрабатываемую область кожи. В случае опасных неисправностей, необходимо сразу же активировать кнопку аварийного останова ЛАЗЕРА.

Нажимая на клавишу *READY/STANDBY*, вы переходите к режиму *READY*; при этом, в нижнем правом углу дисплея появляется желтый индикатор с предупреждением о лазере. Сначала система выполняет испытание безопасности аппаратного оборудования, что занимает около 2 секунд (смотри рисунок Запуск аппаратного оборудования).



Рисунок 37: Режим *READY (ГОТОВ)* лазера



Кроме того, система проверяет, является ли температура охлаждающей насадки аппликатора достаточно низкой. Если температура охлаждения после запуска аппаратного оборудования еще не достигнута, появляется экран Охлаждения аппликатора. Его индикатор выполнения отражает процесс охлаждения охлаждающей насадки. Если охлаждающая насадка холодная, этот экран исчезает. (То же самое применяется для активации устройства после 15 минут его бездействия.)

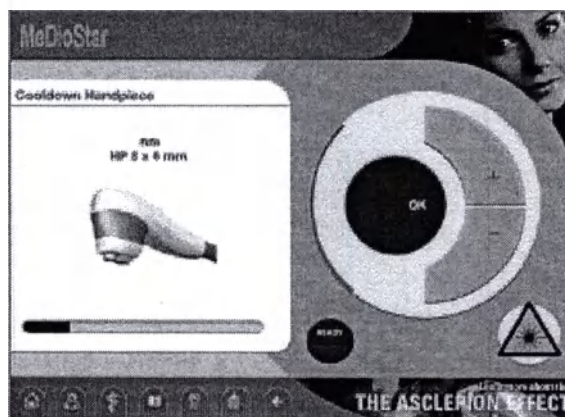


Рисунок 38: Охлаждение аппликатора

Если нажать на ножную педаль, происходит высвобождение лазерного излучения из лазерного наконечника аппликатора. Если отпустить ножную педаль, эмиссия лазерного излучения мгновенно прекращается.

На эмиссию лазерного излучения указывает акустический сигнал в виде предупреждающего зуммера и оптический сигнал – в виде зеленого мигающего индикатора лазерной эмиссии на дисплее.

Когда вы меняете любой параметр в режиме *READY*, устройство автоматически переключается на режим *STANDBY*, т.е. вы должны еще раз нажать на клавишу *STANDBY/READY*, чтобы вернуться к режиму *READY*.

Во время лечебной процедуры небольшое повышение температуры охлаждающей насадки является нормальным, особенно для больших участков. Если достигнут верхний предел температуры охлаждения, эмиссия лазерного излучения будет прервана, и постепенно появится экран охлаждения аппликатора. Процедуру можно будет продолжить, как только охлаждающая насадка снова станет достаточно холодной.

Устройство MeDioStar оснащено удобным для пользователя аварийным ВЫКЛЮЧАТЕЛЕМ лазера, который находится на передней панели устройства. В аварийной ситуации, лазер немедленно деактивируется при нажатии на эту кнопку, и, таким образом, устраняется любая лазерная опасность для пользователя и пациента.

После разрешения проблемы, связанной с аварийной ситуацией, восстановите функциональность устройства, слегка повернув ручную аварийный переключатель лазера в направлении против часовой стрелки до его нормального положения.



#### ОСТОРОЖНО

Если во время генерирования лазерного излучения в области Fluence (Плотность) появляется «Δ» или «▽», значит, устройство обнаружило отклонение от выходных значений на величину, большую или меньшую, чем 20%.

Более высокие значения могут вызвать нежелательные побочные эффекты, тогда как более низкие значения могут снизить эффективность лечебной процедуры.

Если это отклонение сохраняется, сообщите об этом в Техническую службу.

Если вы закончили процедуру, переключите лазер на режим *STANDBY*, нажав еще раз на клавишу *READY/STANDBY*. Если вы намереваетесь на некоторое время прервать процедуру, также переключите лазер на режим *STANDBY*. В этом режиме, невозможно непреднамеренно включить лазерную эмиссию.

После длительного нахождения в состоянии бездействия в режиме *READY*, устройство автоматически переключается на режим *STANDBY*.

## 6.9 Замена аппликатора и изменение размера пятна на аппликаторе XL

Замена аппликатора, принципиально, должна происходить в отключенном состоянии устройства. Если это невозможно или при замене наконечника на аппликаторе XL, необходимо в обязательном порядке деактивировать охлаждающий насос, прежде чем извлечь аппликатор из устройства или наконечник отключить от аппликатора XL. Чтобы это выполнить, нажмите на клавишу Pump off (Выключение насоса) в меню Инструменты (смотри раздел *Специальная функция/Инструменты*) для выключения насоса, при этом, гаснет светодиодная лампочка на аппликаторе. Только теперь разъем аппликатора или наконечник (аппликатора XL) можно отключить. Помпа автоматически включится после подключения наконечника.



### Важная информация

Частая замена наконечников аппликатора XL приводит к потере охлаждающей жидкости. Это может привести к появлению на дисплее сообщения о необходимости дозаправки системы охлаждения. Для того, чтобы ограничить потери несколькими каплями соблюдайте инструкцию, приведенную выше.

Аппликатор XL рекомендуется держать вертикально наконечником вниз, чтобы при смене наконечника из аппликатора капало. Если внутри устройства на диодном окне будут остатки, их следует удалить тканью из микроволокна (см. главу «Очистка и дезинфекция»).

Дозаправка хладагента легко осуществляется пользователем. (см. главу «Плановое техническое обслуживание»).

Для Замены аппликатора требуется охватить многофункциональный разъем аппликатора таким образом, чтобы надавить на металлические кнопки слева и справа его корпуса. Это можно сделать большим и указательным пальцами либо двумя руками. Ответная часть многофункционального разъема расположена на задней панели устройства; разъем содержит как электрические подключения к источнику питания диода, так и подключение к системе подачи охлаждающей жидкости. Разъем может быть затем разомкнут. Разъем следует совместить с ответной частью, надавить на него и покачивать справа налево. При этом можно услышать два характерных щелчка.

Для Замены наконечника на аппликаторе XL также требуется одновременно надавить на две кнопки слева и справа на его корпусе (см. рисунок ниже) и снять наконечник. Затем другой наконечник устанавливают также, как описано выше. Очень важно убедиться в том, что внутренние поверхности аппликатора, особенно оптика, абсолютно не имеют загрязнений (см. также Раздел *Чистка и дезинфекция*).

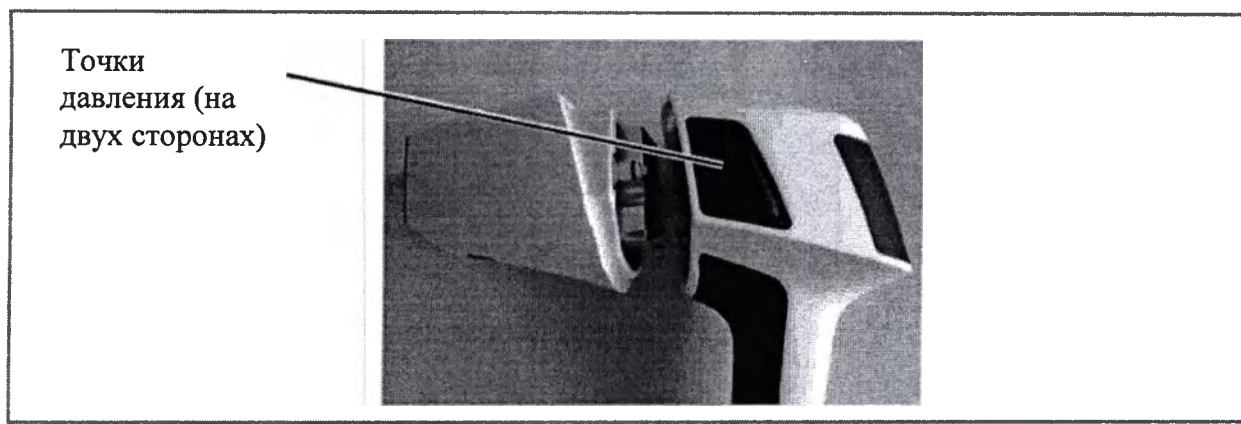


Рисунок 39: Аппликатор XL после нажатия на точки давления открыт для замены наконечника

#### 6.10 Выключение устройства

Выйдите из режима *READY* и переключитесь на режим *STANDBY*, нажав на клавишу *STANDBY/READY*.

Чтобы выключить лазерное устройство, поверните выключатель с ключом в направлении против часовой стрелки до упора. Только после этого вы можете выключить выключатель питания на задней панели устройства (обратитесь к рисунку: *Подсоединения на задней панели устройства*). При переводе выключателя питания в положение «0» (ВЫКЛ) устройство полностью отсоединено от источника напряжения.



#### ПРЕДУПРЕЖДЕНИЕ

Прямое и рассеянное лазерное излучение может привести к серьезным травмам глаз.

Никогда не оставляйте устройство без надзора, когда оно включено. Полностью отключайте устройство с помощью выключателя питания.

После того, как выключите устройство, убедитесь, что вы вынули ключ из выключателя с ключом. Храните ключ в безопасном месте, чтобы не допустить несанкционированного использования устройства.



## 7 Применение

### 7.1 Общая информация

Настоящее руководство содержит подробную информацию о работе и применении лазерного устройства. Разумеется, данные инструкции не могут служить альтернативой профессиональным знаниям медицинского применения лазеров, тщательного изучения соответствующей литературы, личного опыта, полученного под контролем, и критической оценки текущей ситуации.

С другой стороны, данное руководство может помочь тем, кто начинает работу, и тем, кто регулярно не работает с этим лазером.

По этой причине перед началом лечения пациентов мы рекомендуем изучение литературы и консультации с практикующими врачами, работающими с этим видом лазерного оборудования, чтобы ознакомиться с методами лечения, использующими лазер.

Мы с удовольствием поможем вам в установлении контактов с другими пользователями. Представитель, ответственный за продажи, обслуживающий ваш регион, обеспечит вас подробной информацией.

#### Требования, предъявляемые к пользователю

Следуйте Разделу *Назначение/Требования к персоналу*

Перед началом эксплуатации Пользователь должен пройти обучение по безопасному и эффективному использованию аппарата, содержащемуся в этом руководстве. Инструктаж, проведенный авторизованным «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) персоналом на основе этого руководства, отражается в регистрационном журнале медицинского устройства. Пользователь должен быть ознакомлен со следующими разделами:

- Назначение аппарата и основы работы на нем, включая практические навыки.
- Принципы работы и действие аппарата при различных уровнях энергии.
- Регулировка всех рабочих элементов.
- Показания по всем доступным процедурам.
- Противопоказания и побочные эффекты.
- Значения всех предупреждающих сообщений во всех режимах работы.
- Знакомство с проведением функциональной проверки.

Остальные требования различны для разных стран. Соответствие инструктажа действующим положениям местных законов остается на ответственности Пользователя.



#### ПРЕДУПРЕЖДЕНИЕ

Лазерное излучение от устройства может вызвать тепловые изменения в структурах тканей. Убедитесь в том, что вами поняты принципы взаимодействия лазера с тканью, соотношение между параметрами отдельного применения, технические приемы применения, а также основы техники безопасности при работе с лазером.

При наличии даже самых малых сомнений, проконсультируйтесь с одним или более коллегами, обладающими практическим опытом, и/или специалистами дистрибьютора или «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH), прежде чем приступить к лазерной процедуре.

## 7.2 Общая информация по лечению



### ОСТОРОЖНО

Воздействие лазерного излучения на кожу может привести к тепловым повреждениям структур тканей – намеренно, в соответствии с показанием, или не намеренно.

Врач несет ответственность за точное определение показания, зоны лечения и параметров лечения, а также – за корректное позиционирование аппликатора.

Кроме того, во время лечения необходимо рукой проверять температуру охлаждающей насадки, а также – отрегулированную плотность энергии на дисплее.



### ОСТОРОЖНО

Во время процедуры и после нее в зоне обработки могут наблюдаться побочные эффекты. Степень проявления этих побочных эффектов варьируется от пациента к пациенту; обычно она очень низкая.

В связи с этим, в любом случае должна быть выполнена пробная процедура на небольшом участке поверхности, как описано ниже, чтобы одновременно минимизировать побочные эффекты и оптимизировать эффективность лечебной процедуры.

Важно помнить о том, что побочные эффекты могут проявляться более сильно при обработке больших поверхностей, чем при обработке пробной поверхности меньшего размера.

Кроме того, пациенты получают лучшее впечатление от процедуры лечебной терапии и могут лучше решить – «за» или «против» лечения, прежде чем дать свое согласие.



### Совет

Во время предоперационного обсуждения, пациента следует проинформировать обо всех рисках, которые могут быть обусловлены лазерной терапией и предоперационным и послеоперационным уходом. Более того, пациент должен получить всю информацию о механизме лазерной терапии, альтернативных процедурах, времени, необходимом для лечения, перспективах успешного лечения и о режиме после лазерной терапии.

Вам рекомендуется составить отчет об этой беседе и предложить пациенту подписать специальную форму согласия по этому брифингу. Рекомендуется также сделать фотоснимки до и после лечения.



### ПРЕДУПРЕЖДЕНИЕ

Контактная поверхность аппликатора контактирует с кожей пациента во время лечения.

Существует риск переноса микроорганизмов.

Выбранный аппликатор необходимо продезинфицировать перед каждым применением, а также – очищайте и дезинфицируйте его после каждого сеанса применения, как описано в главе *Очистка и дезинфекция*.



### ОСТОРОЖНО

Любое абсорбирующее загрязнение на лазерном наконечнике аппликатора генерирует локальный перегрев и может обусловить повышение побочных эффектов и дефектов аппликатора!

Убедитесь в том, что лазерный наконечник аппликатора остается чистым также и во время обработки!



## 7.2.1 Взаимодействие лазерного луча и ткани

Целью терапии в области дерматологии и эстетической медицины является удаление нежелательных патологий без побочных эффектов. Концепция лечения, известная как **селективный фототермолиз**, представленная Андерсеном и Пэрришем в 1983 году, обеспечивает эффективного разрушения мишени с одновременной защитой окружающей кожи.

Ниже перечислены основные факторы, обеспечивающие успех терапии:

### Поглощение лазерного излучения – длина волны

Поглощение лазерного излучения в мишени (т.е. в меланине волоса или в крови в сосуде) должно быть выше, чем в окружающих тканях кожи, в основном состоящих из воды. Чем больше поглощение в мишени, тем больше тепловыделение; чем меньше поглощение в окружающих тканях, тем меньше нежелательный нагрев окружающих тканей.

Диапазон длины волны в устройстве MeDioStar в ближней области спектра инфракрасного излучения (IR) характеризуется относительно высокой абсорбцией меланина и крови. Длины волн различных аппликаторов оптимально приспособлены в рамках этого диапазона к индивидуально запланированному показанию.

Тем не менее, следует также учитывать поглощение в меланине, содержащемся в эпидермисе темной кожи, что всегда нежелательно (кроме удаления пигментных патологий) и может привести к побочным эффектам в виде гипо- и гиперпигментации. Это означает, что длины волн менее 800 нм менее удобны для работы с темными типами кожи ввиду относительно высокой степени поглощения меланином и совсем не применимы для VI фототипа (см. *Противопоказания*). Аппликаторы с длинами волн 800- 950 нм более удобны для темной кожи. С другой стороны, из-за высокого поглощения меланином более короткие волны более удобны для светлых волос и пациентов с I и II фототипами кожи.

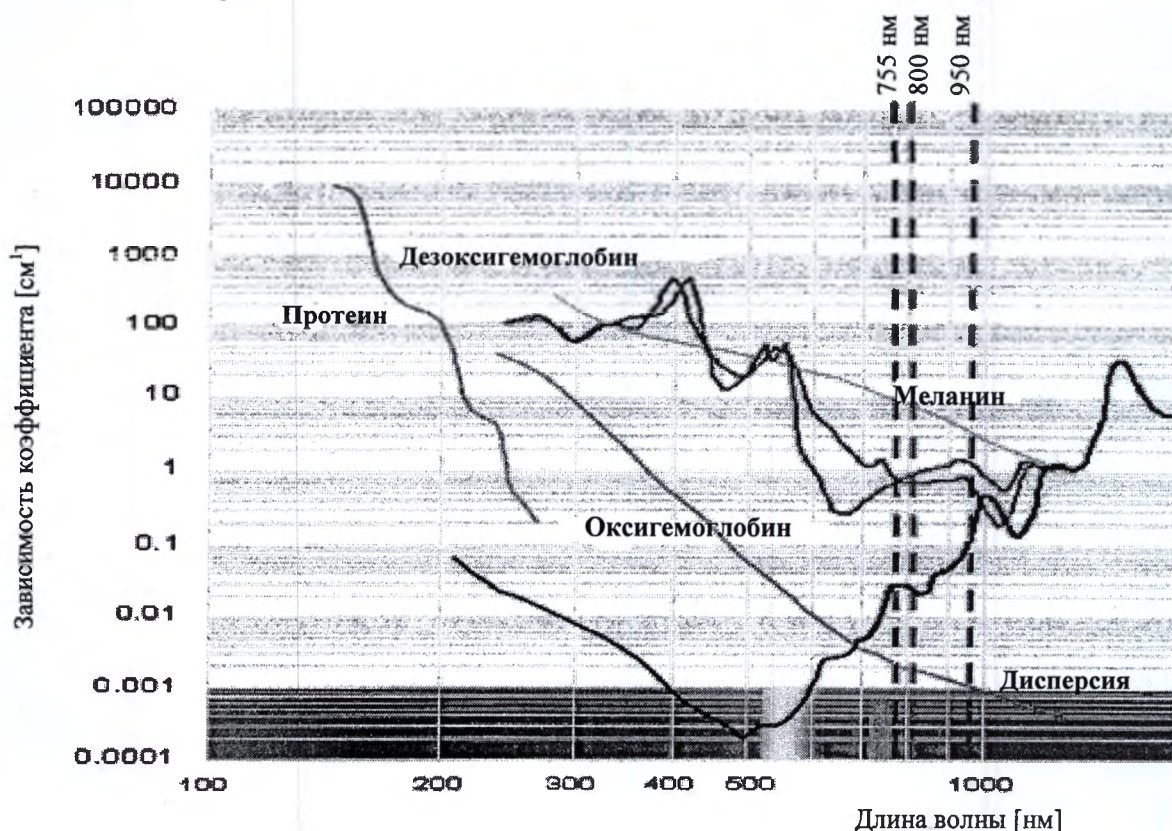


Рисунок 40: Зависимость коэффициента поглощения от длины волны лазера

### Размер пятна

Размер пятна должен быть настолько большим, чтобы объект нацеливания, расположенный на глубине нескольких миллиметров под поверхностью кожи (например, корень волоса или сосуд) был достигнут с достаточно высокой плотностью энергии (FLUENCE). Это требование выполняется лазерным устройством MeDioStar.

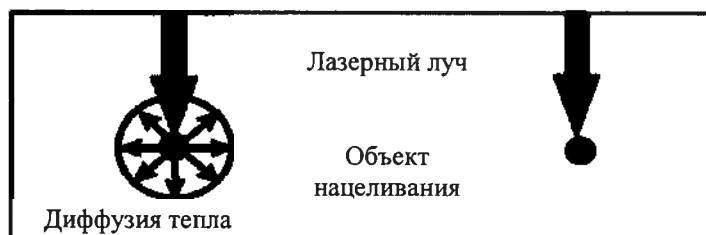
Должно быть принципиально обеспечено, чтобы большее пятно нагревало больший объем в коже. В соответствии с этим, для больших пятен необходимая плотность энергии ниже.



### Длительность импульса

Длительность импульса лазера должна быть меньше или, по крайней мере, не значительно превышать время тепловой релаксации объекта нацеливания (например, волос или кровеносного сосуда). Время тепловой релаксации – это время, за которое объект нацеливания отдает 50% тепла окружающей среде.

Тонкие структуры (волосы, сосуды) отдают тепло гораздо быстрее, чем толстые структуры. Чтобы достичь нужной температуры в тонких объектах нацеливания, необходимо доставить требуемую энергию как можно быстрее. Если импульс слишком продолжительный, потеря тепла в кожу, окружающую объект нацеливания, должна быть компенсирована более высокой плотностью энергии, что обуславливает, по тенденции, большее количество побочных эффектов.



Длительность импульса  
превышает время  
тепловой релаксации

Длительность импульса  
меньше времени  
тепловой релаксации

Рисунок 41: Время тепловой релаксации и длительность импульса лазерного луча

| Цель                            | Диаметр           | Время тепловой релаксации |
|---------------------------------|-------------------|---------------------------|
| Расширенные сосуды              | 10 мкм – 50 мкм   | 50 мксек – 1 мксек        |
|                                 | 100 мкм           | 5 мксек                   |
|                                 | 300 мкм           | 45 мксек                  |
|                                 | 500 мкм           | 125 мксек                 |
|                                 | 1 мм              | (500 мксек)               |
| Волосяное варикозное расширение | Прим. 300 мкм     | Прим. 45 мксек            |
| Меланосома                      | Прим. 0.5 – 1 мкм | Прим. 0.05 мксек          |

Рисунок 42: Время тепловой релаксации для разных диаметров объекта нацеливания (примеры)

Однако, для эффективного лечения, в первую очередь определяют необходимую плотность энергии и размер пятна. Только после этого настраивают самый короткий из возможных импульсов для тонких структур и светлой кожи.

Для обработки тонких волос на участках малой площади, напр. на лице, лучше всего подходит аппликатор типа НР (поз. 4022). Благодаря небольшому размеру пятна устройство способно выдавать короткие импульсы с необходимой плотностью излучения, сравнимым со стандартным аппликатора типа ST. Поэтому время эмиссии лазера также меньше.

Для темной кожи важно учитывать, что меланин в эпидермисе не будет нагреваться, т.е. следует выбирать большую продолжительность импульса – с толстыми структурами нет проблем.

При обработке тонких волос/сосудов пациентов с темной кожей необходимо прибегнуть к компромиссу. Импульс, который должен быть выбран, продолжительнее, чем для светлой кожи и тонкого объекта нацеливания, но короче, чем для темной кожи и более толстых структур. Это решение является приемлемым, потому что тепловое проявление у тонких объектов нацеливания значительно ниже, чем у толстых объектов. Более того, устройство MeDioStar обеспечивает эффективное охлаждение эпидермиса (смотри ниже).

Эпидермис может быть дополнительно защищен прерыванием импульса (сдвоенным импульсом). В режиме БАЗОВЫЙ всегда испускается сдвоенный импульс, в режиме ПРОФЕССИОНАЛЬНЫЙ он может быть активирован на дисплее.

### Охлаждение эпидермиса

Во избежание нежелательных побочных эффектов, необходимо обеспечить эффективное охлаждение эпидермиса (особенно важно для типов темной кожи из-за абсорбции ими меланина).

Система охлаждения кожи устройства MeDioStar встроена в аппликатор. Контакт эпидермиса с холодной металлической насадкой является крайне эффективным из-за высокой теплопроводности (в 8 раз лучше, чем для механизма охлаждения на сапфировой основе). Более того, температура охлаждения системы охлаждения кожи автоматически контролируется в любой момент времени.

## 7.2.2 Классификация типов кожи

| Тип кожи                           |                                                                                    |                                              |
|------------------------------------|------------------------------------------------------------------------------------|----------------------------------------------|
| I<br>(«Ирландский» тип<br>кожи)    | Очень светлая кожа, белые или рыжие волосы,<br>веснушки, голубые или зеленые глаза | Всегда обгорает, никогда не<br>загорает      |
| II<br>(Центрально-<br>Европейский) | Светлая кожа, белые волосы, веснушки, голубые или<br>зеленые глаза                 | Обычно обгорает, редко<br>загорает           |
| III                                | Серые или коричневые волосы, карие глаза                                           | Иногда обгорает, обычно<br>загорает          |
| IV<br>(средиземноморский<br>тип)   | Слегка темная кожа, черные волосы, темные глаза                                    | Редко обгорает, легко<br>загорает            |
| V<br>(Индия, Южная<br>Америка)     | Коричневая кожа, черные волосы, темные глаза                                       | Редко обгорает, очень легко<br>загорает      |
| VI<br>(Африка, Индия)              | Коричневая или черная кожа, черные волосы, темные<br>глаза                         | Никогда не обгорает, очень<br>легко загорает |

Рисунок 43: Классификация типов кожи по Фицпатрику

## 7.2.3 Обзор зон, чувствительных к боли

### Лицо:

Сильная боль

Умеренная боль

Слабая боль

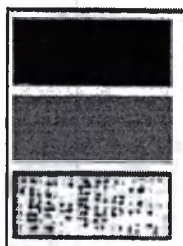


Рисунок 44: Чувствительные зоны лица

Тело:

Сильная боль

Умеренная боль

Слабая боль

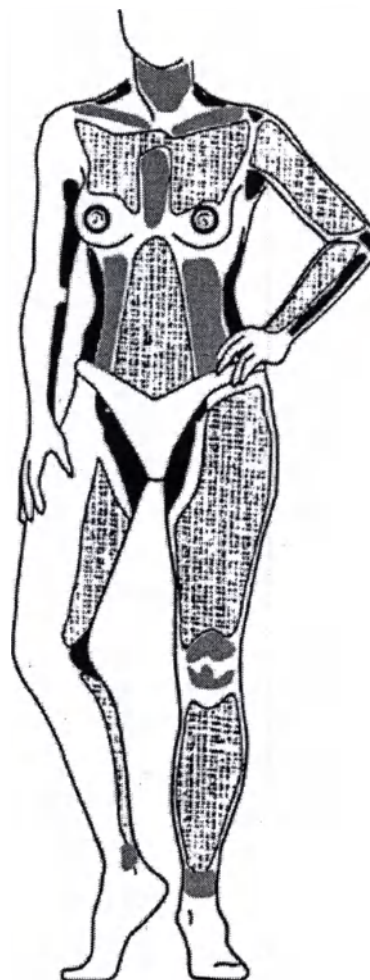
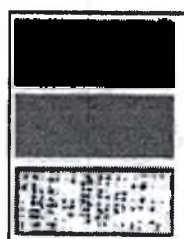


Рисунок 45: Чувствительные зоны тела

#### 7.2.4. Параметры применения

Для импульсного лазера, такого как MeDioStar, главным параметром для лечения является плотность энергии (флюенс). Регулируется прямо на экране. Чем больше флюенс, тем более эффективно лечение, но возможны более сильные побочные эффекты. Поэтому, при повышении флюенса необходимы также тестовые сеансы обработки.

Имеют место следующие математические соотношения:

$$\text{Плотность энергии} = \frac{\text{Энергия [Дж]} }{\text{Диаметр пятна (см}^2\text{)}} \\ [\text{Дж/см}^2]$$

$$\text{Мощность [Ватт]} = \frac{\text{Энергия [Дж]} }{\text{Длительность импульса [сек]}}$$



**Используемый размер пятна** (в зависимости от аппликатора) автоматически учитывается устройством. Как описано выше, для пятен меньшего размера необходима более высокая плотность энергии.

**Длительность импульса** может быть настроена в режимах *Профессиональный*, *Сосудистый* и *Форсированный*, в соответствии с приведенным выше пояснением: меньшая продолжительность (с достаточной плотностью энергии) для тонких волос и сосудов, а также – при лентигинозе, а большая продолжительность – для защиты темной кожи. Паузы между частичными импульсами (сдвоенный импульс, пакет импульсов) также обеспечивают более щадящую обработку для меланина в эпидермисе.

**Режимы Базовый и Профессиональный** предназначены для эпиляции, *Профессиональный* используется также для процедуры омоложения (помимо лентигиноза). Режим *Сосудистый* предназначен для обработки сосудов и доброкачественного лентигиноза (с использованием небольшого пятна от аппликатора VAS). Режим *Форсированный* также может использоваться для обработки сосудов.

Режим Однородного импульса может также использоваться для эпиляции на больших поверхностях. Этот режим рекомендуется, поскольку он более комфортен и вызывает меньше побочных эффектов. В отличие от всех прочих видов обработки, в этом режиме аппликатор с заданной последовательностью импульсов (скорость) и низкой плотностью энергии быстро перемещают по обрабатываемой зоне. Однако необходимо выполнить несколько проходов, чтобы иметь возможность видеть околофолликулярную эритему.

Для обеспечения достаточного охлаждения эпидермиса, аппликатор всегда перемещают в направлении охлаждающей металлической насадке во всех видах процедур (кроме лентигиноза) так, чтобы лазерный импульс всегда попадал на предварительно охлажденную кожу. Единственным исключением является лечение лентигиноза, потому что в эпидермисе должен быть разрушен меланин.

Заданная последовательность импульсов (скорость) в Гц (импульсов в секунду) определяет скорость процедуры и не влияет на эффективность лечения. Для чувствительных областей уменьшение может быть менее болезненным.

### 7.3 Типичные показания - обзор

- эпиляция
- лечение сосудов
- инверсные акне
- акне
- Актинический эластоз (омолаживание)

Следующие разделы посвящены инструкциям по показаниям.

## 7.4 Эпиляция

Удаление нежелательного роста волос - несомненно, одно из самых старых косметических операций, выполняемых человеком. В течение последних лет популярность этого значительно увеличивается. Методы варьируются от регулярно повторяемого бритья до более длительной, хотя очень болезненной эпиляции воском, отнимающему чрезвычайно много времени удалению волос посредством электроэпиляции, которые с другой стороны могут проводить к довольно длительному успеху.

Каждый из этих методов, и, естественно, более приятный метод лазерной эпиляции, стремится удалять волосы с максимально длительным эффектом.

### 7.4.1 Цель: анатомия волоса

Как каждый знает из собственного опыта, длительное удаление волос не может быть достигнуто просто выдергиванием нежелательных волос снаружи. Они вырастут снова. Это означает, что должны быть разрушены структуры, ответственные за рост волос.

Исследователи сегодня фактически единодушны, что папилла в более низкой части волос, герминативные ячейки вокруг него, и так называемые фолликулы волос - факторы, способствующие росту волос, и что поэтому они должны быть разрушены или, по крайней мере, ослаблены.

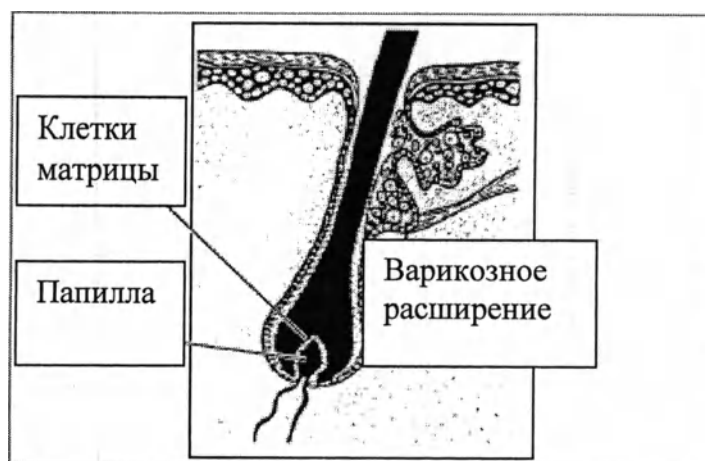


Рисунок 46. Анатомия волосяного фолликула

В зависимости от части тела, корни волос могут быть размещены до 5 мм вглубь под кожей. Именно поэтому размер пятна должен быть как можно большим, чтобы обеспечить эффективность лазера.

Клиническое исследование \* (20 пациентов, прямое сравнение, участок обработки на ноге), проведенное с помощью MeDioStar, показало, размер пятна 12 мм достаточен для эффективного лечения волос на ногах. Дальнейшее увеличение пятна до 14 мм не дало лучших результатов. Размер пятна меньше 8 мм привел к снижению эффективности примерно на 10%, даже при более высокой плотности излучения лазера.

*Bäumler et al: The effect of different spot sizes on the efficacy of hair removal using a long-pulsed diode laser; DermatolSurg 2002;28; 118-121*

Необходимо помнить, что, например, над верхней губой корни волос находятся не очень глубоко в коже, и поэтому пятно меньшего размера может быть абсолютно эффективным и соответствующим для данного применения. Использование пятен меньшего размера рекомендуется, в частности, для более тонких волос, потому что более короткие импульсы могут быть настроены с меньшим размером пятна.

#### 7.4.2 Фазы роста волос

Очень тонкие волосы, растут уже на стадии эмбриона, но в младенчестве они очень тонкие. У них ещё нет папулы, однако, они растут из более глубокого эпидермиса, и благополучно перемещаются в дерму. Позже, волосы с папулой формируются под влиянием гормонов. Их количество задается генетически. С этого времени и далее, человеческие волосы подчинены циклам роста, которые могут проходить от нескольких месяцев до нескольких лет (в зависимости от области тела).

Активная стадия роста называется "анаген", в то время как "телоген" - стадия небольшого роста или отсутствия роста. Принимая во внимание высокие требования к питающим веществам, фаза перехода к переросту кажется особенно подходящей для достижения эффективного лазерного лечения.

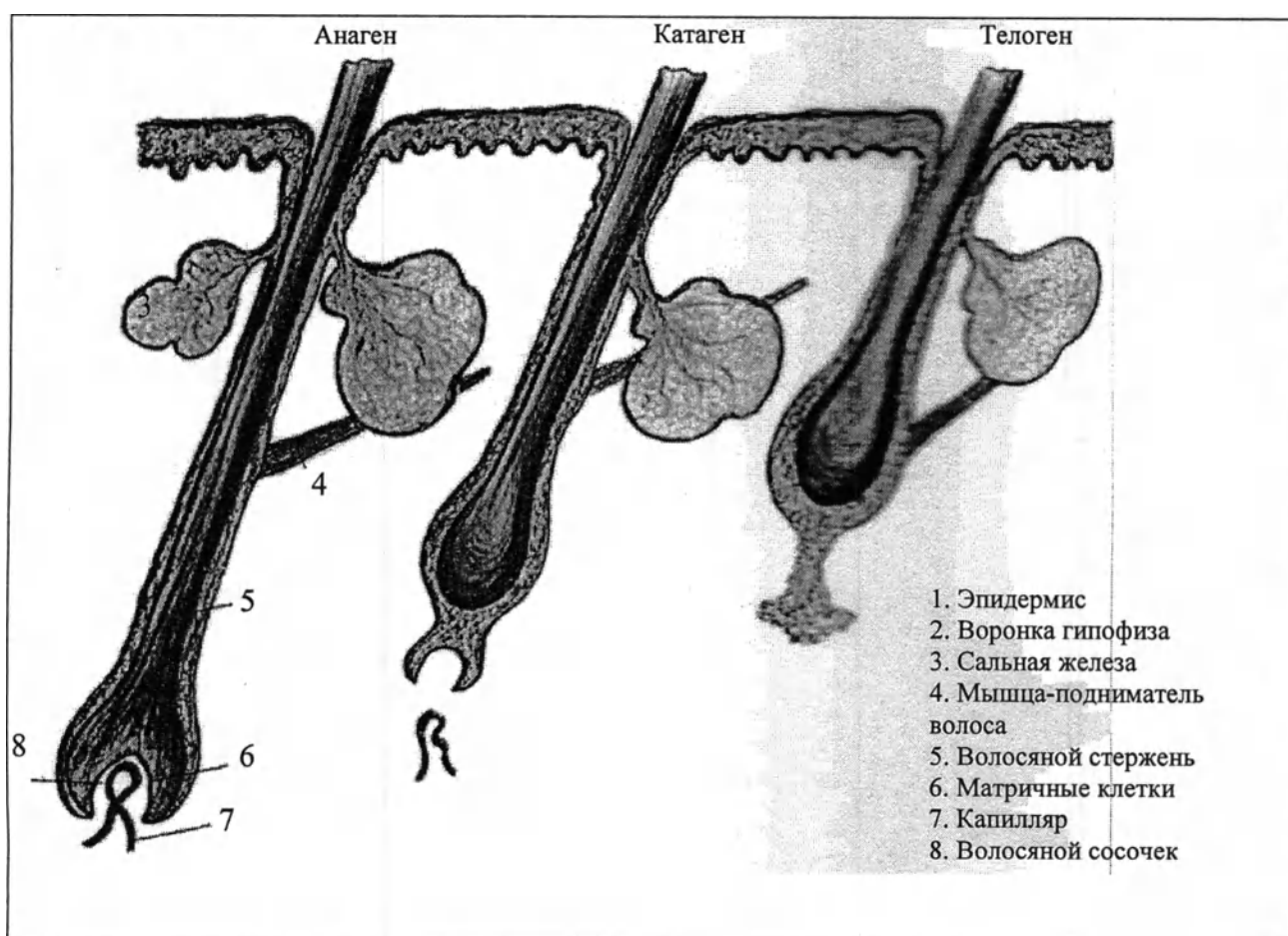


Рисунок 47: Циклы роста волос

У людей, фазы для различных волос не синхронизированы, т.е. различные виды волос находятся в различных фазах. В определенной области только определенный процент волос реагирует на лазерную обработку. В соответствии с этим, всегда необходима серия лазерных сеансов.

Чем короче фаза телогена по сравнению с фазой анагена, тем быстрее происходит рост волос в определенной зоне. Вот почему необходимо брить бороду чаще, чем другие части тела. Следовательно, интервал между последующими лазерными обработками также должен быть короче.



|                   | Примерная глубина фолликула анагена | Продолжительность телогена | Продолжительность анагена | Число фолликулов/См <sup>2</sup> | Общее число фолликулов | Дневная величина роста |
|-------------------|-------------------------------------|----------------------------|---------------------------|----------------------------------|------------------------|------------------------|
| <b>ГОЛОВА</b>     |                                     |                            |                           |                                  | 1 миллион              |                        |
| ВЕРХНЯЯ ГУБА      | 1-2,5 мм                            | 6 недель                   | 4 месяца                  | 500                              |                        |                        |
| БОРОДА-ПОДБОРОДОК | 2-4 мм                              | 10 недель                  | 1 год                     | 500                              |                        | 0,38 мм                |
| ЩЕКИ              | 2-4 мм                              |                            |                           | 880                              |                        | 0,32 мм                |
| БРОВИ             | 2-2,5 мм                            | 3 месяца                   | 4-8 недель                |                                  |                        | 0,16 мм                |
| УХО               |                                     | 3 месяца                   | 4-8 недель                |                                  |                        |                        |
| КОЖА ЧЕРЕПА       | 3-5 мм                              | 3-4 месяца                 | 2-6 лет                   | 350                              |                        | 0,35 мм                |
| <b>ТЕЛО</b>       |                                     |                            |                           |                                  |                        |                        |
| ПОДМЫШКИ          | 3,5-4,5 мм                          | 3 месяца                   | 4 месяца                  | 65                               |                        | 0,3 мм                 |
| НОГИ, БЕДРА       | 2,5-4 мм                            | 5 месяцев                  | 4 месяца                  | 60                               | 370 000                | 0,21 мм                |
| ЛОБКОВАЯ ЗОНА     | 3,5-5 мм                            | 3 месяца                   | 4 месяца                  | 70                               |                        |                        |
| РУКИ              |                                     | 4 месяца                   | 3 месяца                  | 80                               | 220 000                | 0,3 мм                 |
| ГРУДЬ             | 3-4,5 мм                            |                            |                           | 65                               |                        | 0,35 мм                |
| ТУЛОВИЩЕ          | 2-4,5 мм                            |                            |                           | 70                               | 425 000                | 0,3 мм                 |

Рисунок 48: Рост волос (выдержка из таблицы Richards - Meharg)

#### 7.4.3 Выбор пациентов

Как показывает практика, применение диодного лазера позволяет достигать значительной задержки роста волос, как у женщин, так и у мужчин.

Лазерная эпиляция темных волос особенно эффективна, потому что темные волосы имеют повышенное содержание меланина. Светлые волосы обычно требуют более высоких плотностей энергии, что допускается, поскольку обычно кожа светлее волос. Для светлых волос рекомендуется аппликатор с более короткими длинами волн, начиная с 755 нм. Однако, успех лечения не может быть предсказан в каждом отдельном случае. Как ни странно, хорошие результаты наблюдались даже для белых волос. С другой стороны, бывают негативные исключения для особо стойких темных волос.

Очень светлые волосы, рыжеватые волосы (содержат феомеланин) и седые волосы очень слабо реагируют или вообще не реагируют на лазерную обработку. То же самое относится к очень тонким волосам.

Работа с аппликатором с более короткой длиной волны, начиная с 755 нм, требует особой осторожности, см. раздел *Пробная процедура*.

Перед лечением женщин с очень сильным ростом волос, следует проконтролировать гормональный статус.

Гормональный статус мужчин – транссексуалов (стремящихся изменить свой пол из мужского в женский) также следует проконтролировать перед тем, как приступить к процедуре.

Полное удаление волос не может быть достигнуто, обычно тонкие светлые волосы нельзя удалить. Важно проинформировать пациентов об этих фактах!

#### Области, подходящие для эпиляции:

- \* Усыки/верхняя губа
- \* Волосы на лице
- \* Подбородок / верхняя часть шеи
- \* Бедро
- \* Линия бикини
- \* Нижняя часть ног
- \* Верхняя часть рук
- \* Нижняя часть рук
- \* Грудь
- \* Спина
- \* Руки
- \* Нос/Уши (процедуру проводить осторожно)

#### 7.4.4 Противопоказания

Следует следовать Противопоказаниям из Раздела *Назначение*, (за исключением паукообразных вен). Отсрочка на 4 – 6 недель также рекомендуется после проведения других процедур с целью эпиляции, таких как восковая депиляция или выщипывание, потому что хромофор объекта, «объект нацеливания» более не является доступным, и, таким образом, лазерная обработка не является эффективной.

Не следует проводить обработку в зоне имеющихся татуировок! В противном случае татуировки могут быть повреждены, а также возможны проявление более серьезных побочных эффектов (высокая абсорбция темными частицами красителя)!

#### 7.4.5 Возможные побочные эффекты

Все побочные эффекты являются менее значительными для светлой кожи и светлых волос, и становятся более интенсивными для более темных, более толстых и густых волос. Эти эффекты также становятся сильнее в случае с аппликаторами с более короткой длиной волны лазера, начиная с 755 нм и, конечно, при повышенной плотности потока излучения для отдельной ситуации (пробная процедура!).

Таким образом, начальные значения для пробных процедур должны выбираться тем более низкими, чем темнее кожа (и обычно с учетом цвета волос).

Во время процедуры пациенты испытывают ощущение покалывания с одновременным теплом.

После процедуры можно наблюдать незначительную околофолликулярную эритему. Если волосы темные и толстые, возможно также образование околофолликулярного отека. При работе в режиме *Гладкого импульса* наоборот, незначительная околофолликулярная эритема менее выражена, а общая – более выражена.

Эти эффекты являются нормальными и сохраняются в течение периода времени от нескольких часов до 2 дней.

Если устройство используется в соответствии с его предназначением, и соблюдается предписанный режим терапии, то водяные пузыри, корки, а также пигментные изменения у пациентов возникают редко (защита от света!). Обычно водяные пузыри и корки вылечиваются без каких-либо последствий в течение примерно одной недели. Пигментные изменения могут наблюдаться в течение нескольких месяцев.

Не проходящие пигментные изменения и рубцы проявляются очень редко.

В редких случаях темные волосы могут обесцвечиваться и затем больше не удаляться с помощью лазера / в связи с отсутствием поглощения.

В редких случаях также встречается необычный рост волос, особенно у пациентов с темной кожей и вызвано стимуляцией роста волос (также см. Совет в главе *Лечение*).

#### 7.4.6 Подготовка к лазерной эпиляции

В качестве обязательного предварительного условия, область, подлежащая обработке, должна быть абсолютно выбритой и чистой. Удалите также следы дезодорантов и прочей косметической продукции.

Перед обработкой верхней губы, между ней и зубами нужно разместить увлажненный тампон. Это делается для предотвращения попадания небольшой части излучения, прошедшего через верхнюю губу, и нагревания зубов (может быть болезненным).

Для документирования лечения область обработки должна быть сфотографирована.

Обычно анестезия не требуется, потому что лазерная эпиляция, проводимая с помощью устройства MeDioStar, вызывает относительно небольшие болевые ощущения, благодаря интегрированной в аппликатор системе охлаждения кожи. Особо следует отметить, что, в режиме *Гладкого импульса*, пациенты почти ничего не чувствуют.

Для чувствительных участков или очень распространенных участков лечения, можно использовать местное обезболивающее средство, напр. эутектическую смесь местных анестетиков, в зависимости от переносимости и формы применения (охлаждение кожи!). Тем не менее, анестетики не следует применять во время пробного или начального лечения (если вообще возможно), так как ощущения во время процедур дают возможность уверенно оценить ожидаемые побочные эффекты.

Клинически протестированный **бесцветный** ультразвуковой гель оптимизирует введение лазерного луча в кожу за счет снижения отражения и рассеяния лазерного луча. Таким образом, достигается более высокая эффективность.

Тонкий слой прозрачного ультразвукового геля следует нанести на участок, где будет проводиться обработка. Это также снижает уровни образующегося дыма/запаха.



#### 7.4.7 Тестовая процедура

Если пациент принимает решение в пользу лазерной эпиляции после получения информации от врача и оформления согласия, всегда следует провести тестовую процедуру в области, где затем будет проводиться основная процедура. Индивидуальная реакция кожи пациентов и чувствительность к боли могут различаться. Помимо особо чувствительных и особо болевых толерантных пациентов, ощущение боли является хорошим показателем оценки для ожидаемых побочных эффектов.

Тестовую процедуру начинают на небольшом участке с начальными параметрами, рекомендованными для соответствующего основной области типа кожи, даже, если воздействие не чувствуется пациентом. Если предполагается обработка чувствительных зон (таких как бикини или верхняя часть голени), тестовую процедуру следует проводить в этой зоне.

Чем темнее кожа пациента, тем более низкая начальная плотность энергии и большая длительность импульса должны быть выбраны в *Профессиональном* режиме. Последнее не является проблемой для более толстых волос. Для тонких волос импульс не должен быть таким длительным, чтобы можно было обеспечить эффективность обработки. Благодаря низкой абсорбирующей «массе», побочные эффекты для тонких волос обычно бывают менее значительными.

Аппликатор с длиной волны 755 нм рекомендован только для I и II фототипов кожи, поскольку его наиболее важным преимуществом является немного более высокая эффективность для светлых волос, которая обычно ассоциируется со светлой кожей, а меланин в эпидермисе в темной коже вызывает больше побочных эффектов. Если это наконечник использовать для темной кожи, флюенс должен быть еще ниже, чем при использовании стандартного наконечника. Лечение пациентов с типом кожи IV и типа кожи V должно быть сделано только (если вообще допустимо) в режиме *Однородного импульса* и только тогда, когда терапевт имеет достаточный опыт работы с фототипом кожи III (и IV и V). Процедуры для фототипа кожи VI и загорелой кожи противопоказаны!

Способ воздействия, используемый для тестовой процедуры, должен также использоваться и для последующей реальной процедуры.

Аппликатор всегда следует перемещать по коже с небольшим давлением, что уменьшает расстояние до корня волоса (повышение эффективности). Убедитесь, что холодная насадка для охлаждения кожи остается в контакте с кожей во время процедуры, чтобы гарантировать предварительное охлаждение эпидермиса. Практически, аппликатор следует держать в контакте с кожей, и не следует заново на нее устанавливать. Благодаря ультразвуковому гелю, легко можно видеть точку, на которую должно быть помещено пятно для следующей линии.



#### ПРЕДУПРЕЖДЕНИЕ

Лазерное излучение может привести к серьезным травмам глаз.

Во время сеанса лазерной терапии все лица, присутствующие в помещении, где работает лазер, должны носить очки для защиты глаз, в соответствии с инструкциями, приведенными в главе *Технические данные*!

Выбранные и установленные на дисплее параметры необходимо контролировать до и в процессе проведения процедуры.

Во время процедуры необходимо также контролировать работу системы охлаждения!

MeDioStar переключают на режим *READY* с необходимой ПЛОТНОСТЬЮ ЭНЕРГИИ, расположите аппликатор на желаемой зоне и, если необходимо, немного подождите, когда установится режим *READY* (система охлаждения должна установить заданную температуру – информация отображается на дисплее).

Рекомендуется использовать режим *Однородного импульса* (низкий Флюенс, высокая частота, многократные проходы), если его использование возможно с анатомической точки зрения по отношению к размеру используемого аппликатора – но особенно для темной кожи. Это более комфортно, но столь же эффективно. (Время, требуемое для процедуры примерно одинаково. Аппликатор перемещается быстрее в этом режиме, но требуются многократные проходы).

Для тестовой процедуры в Режиме *Однородного импульса* аппликатор быстро перемещают по участку площадью около 10 см<sup>2</sup> (примерно 10 см в секунду). При выполнении этого действия, по возможности не допускайте пропусков и всегда перемещайте аппликатор в направлении охлаждающей насадки.



Для светлой кожи, то это должно быть повторено четыре раза, три раза для темной кожи (3-4 прохода). Следует остановиться, если процедура становится болезненной, в противном случае следует увеличить количество проходов.

Конечная цель: легкая эритема.

Режимы Основной и Профессиональный больше предназначены для анатомически сложных зон, однако, могут быть применены везде. При использовании этих режимов, при тестовом флюенсе необходимо сделать по меньшей мере 4-6 пятен в виде квадрата, так как отдельные пятна могут вызвать меньшую реакцию (окружающая кожа может лучше охлаждаться).

В начале работы, холодную насадку аппликатора на короткое время помещают на первую точку, где должна проводиться обработка. Затем аппликатор перемещают на величину пятна так, что лазерный наконечник размещается на предварительно охлажденном участке (и одновременно охлаждается следующая точка). После этого, при нажатии на ножную педаль, начинается лазерная эмиссия.

Перемещайте аппликатор в направлении насадки, охлаждающей кожу, на размер пятна в соответствии с установленной частотой. Звуковой сигнал, соответствующий этой частоте может служить ориентиром. Если по завершении тестовой процедуры через несколько минут реакции кожи не наблюдается, флюенс можно постепенно увеличить (проводите тест на новом участке).

Конечная цель: перифоликулярная эритема.

Если процедура становится болезненной, флюенс следует уменьшить. При этом не рекомендуется применение анестетиков.

После полной лазерной обработки участка, устройство необходимо переключить в режим *STANDBY*.

#### 7.4.8 Обработка

После подготовки зоны обработки, ее можно разметить белым карандашом (например, карандаш для подводки глаз). Это полезно для разбиения больших зон на малые участки (Нанесите ультразвуковой гель на участки для предотвращения потери влаги).

Это обеспечивает равномерную обработку участка лазером.

Татуировки и пигментные патологии, не диагностированные как доброкачественные не должны подвергаться обработке!

Проводите процедуру как описано в предыдущем разделе.



##### Совет

Если лазер работает по большим площадям, то для уменьшения боли, область нужно обрабатывать последовательно, когда это возможно, особенно в случае темной кожи и густых волос.

При обработки больших площадей ножной переключатель должен быть освобожден после каждой "линии" (прерывания лазерного излучения) и снова включен со следующей "линии". "Линия" может быть также шириной 10 см в режиме *Однородного импульса*, например, если процедура выполняется спиралевидными движениями, как показано на рисунке.

Этот процесс не только более комфортен для пациентов, но также меньше нагружает систему охлаждения кожи. Система лучше охлаждает во время прерывания, так что процедуру не нужно останавливать даже при длительных обработках.

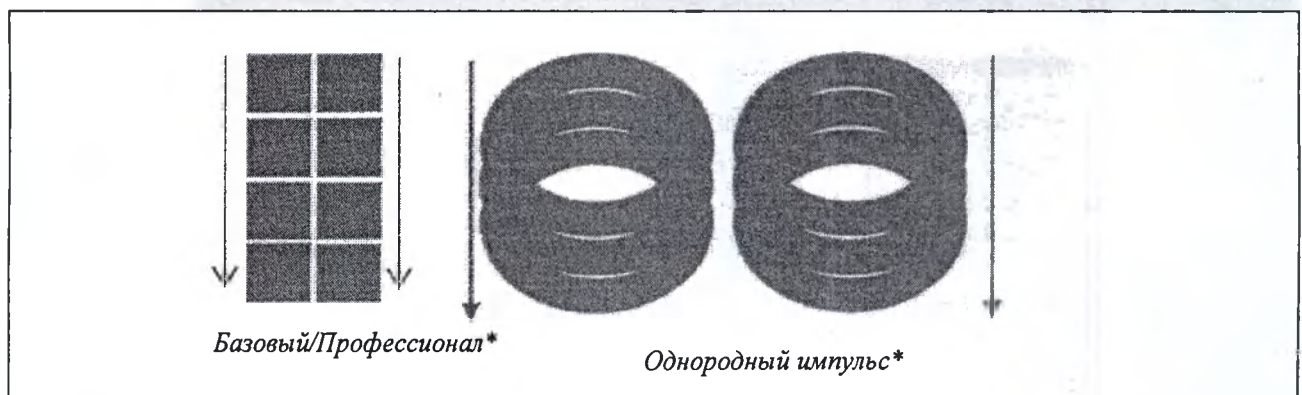


Рисунок 49: Направление проведения процедуры – следующий проход сверху.

\* По возможности следует исключать пропуски между точками и «линиями». Более того, лучше делать небольшое перекрытие, чтобы не осталось необработанных «линий».

Для режима Однородный импульс рекомендуется спиралевидный процесс лечения (справа), описанный выше. При этом также возможно перемещение по «линии» или в форме меандра, если перемещать быстро (приблизительно 10 см в секунду). Из-за большого размера пятна для аппликатора XL самый простой способ состоит в быстром перемещении по «линиям».

Производите то количество проходов, которое было определено в тестовой процедуре. Если, несмотря на это, процедура является болезненной, необходимо ее прервать и охладить кожу.

При использовании режимов Базовый или Профессиональный, устанавливайте флюенс, который хорошо переносился в ходе тестовой процедуры.

Затем обрабатывайте область, как описано выше, и всегда перемещайте аппликатор в направлении охладителя кожи. На каждой вновь начатой «линии» первая точка всегда должна быть предварительно охлаждена.

Если процедура остается болезненной, необходимо снизить плотность энергии, и, если это необходимо прекратить процедуру и немедленно охладить кожу.

Если процедура прерывается на короткий период или если обработка области завершена, переключите лазер в режим *Ожидания*.

#### ОСТОРОЖНО



Пыль, осевшая на лазерный наконечник, может загореться под воздействием лазерного излучения и вызвать побочные эффекты, такие как покраснение, возможное образование водяных пузырей, образование корки, редко рубцы! Обеспечьте, чтобы лазерный наконечник аппликатора всегда оставался чистым!

Самый простой способ поддерживать чистоту лазерного наконечника даже во время процедуры - это вытирать его увлажненным тампоном каждый раз после реализации "линии". Звуки потрескивания при обработке темных, густых волос обычно означают, что на наконечнике есть волосы. В этом случае наконечник должен быть протерт незамедлительно. В любом случае, если продолжать процедуру, волосы могут пригореть к поверхности наконечника и тогда удалить их будет труднее.

#### Совет



В некоторых случаях, в зонах, прилегающих к зоне обработки, появляются новые волосы (парадоксальный рост волос). Исследованием \* установлено, что этот эффект может быть предотвращен путем интенсивного охлаждения вокруг обрабатываемой области до и во время процедуры, например, охлаждающими пакетами, и очень агрессивным проведением процедуры в зоне обработки, то есть 2 проходами (в режимах *Базовый* или *Профессиональный*). Авторы предположили, что парадоксальный рост волос обусловлен субтерапевтическими уровнями тепловой энергии.

### 7.4.9 Послеоперационная терапия

Сразу же после завершения лазерной обработки, кожу следует охладить в течение длительного времени, особенно при темных волосах и темной коже. Постоянное охлаждение может значительно уменьшить побочные эффекты! Это можно легко сделать с помощью холодных тампонов, которые пациент может использовать в зависимости от ситуации.

После достаточного охлаждения кожи можно нанести противовоспалительную мазь. В случае передозировки лекарственных препаратов, показан локальный антибиотик, при этом, мониторинг лечения является абсолютно необходимым.

#### ОСТОРОЖНО



Если после проведения процедуры обработанный участок будет подвергаться воздействию солнечного излучения, могут проявиться более значительные побочные эффекты, в частности, пигментные изменения.

В связи с этим, необходимо избегать воздействия такого излучения в течение 6 недель, или, по меньшей мере, пользоваться солнцезащитным кремом с коэффициентом защиты не ниже 20.

Не следует допускать получения травм на обработанном участке в течение 2 – 3 дней.

\* Willey et al: Hair stimulation following laser and IPL photo epilation: review of 543 cases and ways to manage it / Lasers in Surgery in Medicine 39: 297-301 (2007).



Можно поддерживать отслоение, используя лосьон.

Следует поставить пациентов в известность о том, что через два дня после процедуры из отверстий волосяных фолликул может выделяться тканевая жидкость. Корочку, которая может образоваться, следует удалять путем обычного умывания и использования лосьонов для кожи.

#### 7.4.10 Последующие процедуры обработки

Следует уведомить пациентов о том, что в некоторых случаях – в частности, для толстых волос – удаление волос после процедуры произойдет примерно через две недели.

Если во время последнего сеанса процедура переносилась хорошо, то количество проходов (режим Однородного импульса) или плотность энергии можно постепенно увеличивать во время последующих процедур. Это увеличение рекомендуется также и потому, что волосы становятся все менее и менее густыми, и более тонкими. Следовательно, необходима более высокая плотность энергии, которая будет хорошо переноситься.

Количество необходимых процедур зависит от нескольких факторов:

- генетической предрасположенности
- гормонального фона
- обрабатываемого участка тела (различное количество волос в анагенной фазе)
- типа волос и кожи
- результата, желательного для пациента (зачастую, остающиеся тонкие волоски являются приемлемыми)
- интервала между процедурами

Для достижения удовлетворительного результата, может потребоваться в среднем от четырех до семи сеансов терапии. Особенно для области бороды и для людей с очень сильным ростом волос требуется даже большее количество сеансов.

То же самое относится к мужчинам с волосами на спине или груди, которые выросли только недавно. В этом случае кажется, что лазерная обработка не производит никакого эффекта, но без обработки рост волос был бы еще более интенсивным. Полезно задать пациенту вопрос о росте волос у его отца или дяди в этом возрасте.

Интервалы между сеансами не должны быть слишком короткими (4 – 6 недель; в случае отсутствия регенерации волос, временной интервал может быть больше), чтобы для как можно большего количества волос состояние покоя сменилось фазой анагена.

В общем случае, интервал для обработки области бороды должен быть короче (примерно 4 недели), а для обработки других участков – больше (примерно 6 недель), в соответствии с объяснением в главе *Фазы роста волос*.

Обычно, интервал выбирают длиннее после нескольких сеансов, потому что заново вырастает меньшее количество волос.

Однако если после лазерной обработки начался интенсивный рост, рекомендуется повторить обработку через короткий временной интервал, потому что очень много волос находится в фазе анагена, и они демонстрируют хорошую реакцию на терапию.

Для пациентов с нормальным ростом волос достигнутый результат может быть стабильным в течение нескольких лет. Для пациентов с генетически обусловленным интенсивным ростом волос, можно рассчитывать на то, что последующая обработка будет необходима каждый год, но с меньшим количеством сеансов.



## 7.4.11 Ожидаемые результаты

Ожидаемые результаты для эпиляции:

| Исследованное | Тип кожи | Цвет волос                     | Флюенс [Дж/см <sup>2</sup> ] | Зона                                       | Размер пятна и длительность импульса              | Кол-во процедур | Эффективность                                                                                                                                                                                                            |
|---------------|----------|--------------------------------|------------------------------|--------------------------------------------|---------------------------------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A             | I-III    |                                | 35 (I/II)<br>30 (III)        | Подмышечная впадина                        | Mediostar miXT: 12 мм<br>Mediostar NeXT: 10x14 мм | 3               | Среднее уменьшение волос, %<br>Для фототипа I/II:<br>Mediostar NeXT: 64.3%<br>Mediostar miXT: 50.1%<br>Для фототипа III:<br>Mediostar NeXT: 65.1%<br>Mediostar miXT: 61.6%<br>Однородный импульс в Mediostar NeXT: 67.1% |
| B             | I-III    | Русые, от коричневых до черных | 33-44                        | Ноги                                       | 8-14 мм<br>2x60 мс                                | 3               | Средний процент возобновления роста волос (после 3 месяцев):<br>67% для 8 мм<br>54% для 12 мм<br>55% для 14 мм<br>11% черных волос<br>26% коричневых волос<br>31% русых волос<br>Толщина волос уменьшилась на 85%        |
| C             | II-IV    | От светло-коричневых до черных | 35                           | Верхняя губа                               | 12 мм<br>2x45 мс                                  | 3               | Среднее уменьшение волос после 6 месяцев<br>49%                                                                                                                                                                          |
| D             | II-IV    | От светло-до темно-коричневых  | 25-35                        | Лицо, подмышечные, усы, подбородок, бикини | 12 мм<br>50 мс                                    | 3               | Среднее уменьшение волос после 6 месяцев<br>70%<br>Гистология:<br>Снижение доли фазы анагена (роста) к остальным: по крайней мере, 1: 1 (по сравнению с нормальным 8: 2)                                                 |
| E             | I-VI     |                                | 10-36                        | Различная локализация                      | 12 мм                                             | 3-11            | Среднее уменьшение волос после 5.4 месяца:<br>26% после 1 процедуры<br>47% после 2 процедур<br>64% после 3 процедур                                                                                                      |

\*Как указано выше, нельзя ожидать долговременных результатов только после 3 процедур (см. исследование E)

Справочная литература:

A: Steps, A.: Diode laser hair removal: a study with a new high power system; White paper 2013

B: W. Bäumler, PhD; K. Scherer, MD; C. Abels, MD; S. Neff, MD; M. Landthaler, MD and R.-M. Szeimies, MD. The Effect of Different Spot Sizes on the Efficacy of Hair Removal Using a Long-Pulsed Diode Laser. Dermatolog Surg 2002; 28: 118-121

C: E. J. Fiskerstrand, MD, PhD; L.O. Svaasand, PhD; J.S. Nelson, MD, PhD. Hair Removal with Long Pulsed Diode Lasers: A Comparison Between Two Systems With Different Pulse Structures. Lasers in Surgery and Medicine 32: 399-404 (2003)

D: N.S. Sadick, MD, FACP, FAACS; V.G. Prieto, MD, PhD. The Use of a New Diode Laser for Hair Removal. Dermatol Surg 2003; 29: 30-34

E: Albert J. Nemeth MD, FAAD, FASLMS, FASDS, FISHRS. Impressive Laser Hair Removal with an 810 nm Powerpulsed Diode Laser: Safety and Efficacy. Presentation EADV 2004

## 7.5 Лечение сосудов

Для лазерного лечения телеангиоэктазии используется пятно меньшего размера, приспособленное для сосудов (дополнительный аппликатор).

Лазерное лечение поверхностных растянутых сосудов, в частности, на лице, но также и в других местах, проходит очень успешно на протяжении более 20 лет – особенно с использованием лазерных устройств, которые излучают свет в желтом и зеленом диапазонах (лазеры на аргоне, контрастном веществе, калий-титанил-фосфате и бромиде меди).

Эти лазеры очень хорошо подходят для коагуляции очень мелких сосудов, потому что их длина волны очень сильно поглощается кровью, но очень слабо водой, содержащейся в окружающей коже (смотри кривую абсорбции). Методика селективного фототермолиза обеспечивает эффективное повреждение кровеносного сосуда и одновременную защиту окружающей его кожи. Глубина проникновения лазерного излучения является достаточной для очень мелких сосудов.

Из-за более глубокого проникновения лазерного излучения, лазеры с длиной волны в **инфракрасном диапазоне** – как диодный лазер MeDioStar – лучше подходят для сосудов большего диаметра, например, для типичных вен на ногах, которые, в основном, больше и расположены глубже под поверхностью кожи, и для ангиомы. Более низкая абсорбция воды по сравнению с лазером Nd:YAG (1064 нм) является преимуществом, потому что обычно развивается меньше побочных эффектов.

В современных отчетах описано успешное лечение капиллярных гемангиом с помощью лазеров в ближней инфракрасной области спектра, которые плохо реагируют на проводимое лечение лазерами в зеленом и желтом диапазонах.

Относительно большой диаметр пятна (что является возможным благодаря высокой мощности устройства MeDioStar) также играет важную роль: эффективность проникновения лазерного излучения тем выше, чем больше пятно.

Телеангиоэктазии ногных вен все еще является косметической проблемой частого обращения. Методикой выбора является уплотнение ткани. Эффективность этой терапии проявила себя на протяжении десятилетий, однако, многие пациенты предпочитают лазерную терапию.

В общем случае, степень успешности лазерного лечения ногных вен ниже, чем применения лазера для лечения, например, телеангиоэктазии на лице, потому что вены находятся под гидростатическим давлением и значительно изменяются в диаметре и в насыщенности кислородом. Степень успешности, которая может быть достигнута, составляет около 70%.

Абсорбция лазерного излучения в меланин у темнокожих пациентов является меньшей для длины волны устройства MeDioStar, чем для лазеров, работающих в зелено-желтом диапазоне (смотри кривую абсорбции). Чтобы свести к минимуму нежелательные побочные эффекты, это, тем не менее, необходимо учитывать во время обработки, путем достаточного охлаждения поверхности кожи.

Помимо длины волны, **плотность энергии (ФЛЮЕНС)** и время воздействия лазерного излучения (продолжительность импульса) являются решающими параметрами для успешного лечения. Плотность энергии необходимо выбирать таким образом, чтобы, с одной стороны, сосуд был закрыт, а, с другой стороны, не появлялись нежелательные побочные эффекты (терапевтическое окно).

Продолжительность импульса должна быть сходной или более короткой, чем **время тепловой релаксации** сосуда (это – время, которое необходимо объекту нацеливания, чтобы испустить 50% тепла, получаемого при абсорбции), чтобы следовать концепции лечения селективного фототермолиза, упомянутой выше. Если продолжительность импульса слишком велика, кожа, окружающая сосуд, будет нагреваться больше, эффективность будет снижена, и риск побочных эффектов возрастет.

### 7.5.1 Выбор пациентов

Пациенты с типом кожи от I до III, не загорелой в области, подлежащей обработке, могут проходить лечебную процедуру со следующими ограничениями.

Терапия лазером MeDioStar наиболее успешна при расширении сосудов с диаметром от 0,5 до 2 мм. Также возможно успешная деструкция гемангиом.

Сосуды ног можно разделить на красные и синие. Красные сосуды характеризуются меньшим диаметром, более поверхностной локализацией и большей насыщенностью кислородом (расширение артериальной капиллярной петли).

Синие сосуды являются результатом расширения венозных капилляров с пониженной скоростью кровотока. Более крупные сосуды лучше реагируют на лечение этим лазером, чем мелкие.

Перед лазерной обработкой вен в области бедер или голеней, все вены, особенно боковые ветви должны быть проверены на наличие варикозов методами доплеровской диагностики, или следует провести хирургическое лечение или склеротерапию.

Ретикулярные варикозные расширения вен могут подвергаться лазерному лечению, только если они идентифицированы как одиночные варикозные расширения, или если они не проходят глубоко.

### 7.5.2 Противопоказания

Следуйте Противопоказаниям из Раздела *Назначение*, (включая противопоказания для паукообразных вен).



#### ОСТОРОЖНО

Более высокая плотность энергии, необходимая для лечения дилатированных сосудов, и более интенсивная абсорбция из-за величины диаметра сосуда могут вызвать более интенсивные побочные эффекты (например, по сравнению с удалением волос). Поэтому, загорелые участки или пациенты с типом кожи IV, V или VI вообще не должны подвергаться терапии.



#### Полезная информация

Злоупотребление курением и/или ожирение могут снизить терапевтический эффект.

### 7.5.3 Возможные побочные эффекты

Более высокая плотность энергии, необходимая для лечения дилатированных (расширенных) сосудов, и более интенсивная абсорбция из-за величины диаметра сосуда могут вызвать более интенсивные побочные эффекты (по сравнению с удалением волос).

Поэтому достаточное охлаждение кожи, в соответствии с приведенным далее описанием, является абсолютно необходимым и более важным, чем для процедур удаления волос.

Все побочные эффекты являются менее интенсивными для пациентов со светлой кожей и более тонкими сосудами, но становятся интенсивнее для более толстых сосудов и более темной кожи и, конечно, если используемая плотность энергии является слишком высокой для отдельного случая (пробная процедура!).

В связи с этим, исходные значения для пробной обработки кожи типа III должны быть ниже (более темные типы кожи не должны подвергаться терапии).

Во время процедуры, пациенты ощущают покалывание вместе с теплом. Это может быть ощущение горения в случае более толстых сосудов.

После процедуры может наблюдаться эритема по месту прохождения сосудов. Если сосуды толще, возможно также образование отека вдоль сосудов. Эти эффекты являются нормальными и длятся в течение периода от нескольких часов до 2 дней. Иногда появляются водяные пузыри, образуется корка и временные пигментные изменения, но более часто, по сравнению с эпиляцией (защита от света!).

Обычно водяные пузыри и образующаяся корка излечиваются без негативных последствий в течение примерно одной недели. Пигментные изменения могут оставаться в течение периода вплоть до нескольких месяцев.

Непреходящие пигментные изменения и рубцы появляются крайне редко, если устройство работает в соответствии с предназначением, и, если лечение индивидуально подобрано для пациента.



#### 7.5.4 Подготовка к лазерной терапии

В качестве обязательного предварительного условия, участок, на котором должна проводиться процедура, должен быть очищен. Удалите также следы косметических продуктов. Волосы, если они существуют, должны быть тщательно удалены.

Следует сделать фотоснимки исходного состояния, чтобы документально зафиксировать успешность лечения.

Процедура может вызвать боль, особенно для более толстых сосудов. Однако анестезия обычно не является необходимой, если перед процедурой и после нее участок будет достаточно охлажден. Использование локальных анестетиков, таких как EMLA, не уменьшает ощущение боли.

Тонкий слой прозрачного, бесцветного ультразвукового геля должен быть нанесен на участок обработки.

Можно наложить холодные тампоны (из холодильника, не замороженные!).

#### 7.5.5 Пробная процедура

Если пациент принимает решение в пользу лазерного лечения после получения информации от врача, после этого в любом случае должна быть проведена пробная процедура.

Из-за большого количества различных диаметров сосудов, на практике оптимальная плотность энергии может быть найдена только эмпирическим путем при обработке пробных участков, и должна быть определена заново для каждого участка, на котором другой диаметр сосуда (цвет/изменение структуры).



##### ОСТОРОЖНО

Более высокая плотность энергии, необходимая для лечения дилатированных сосудов, и более интенсивная абсорбция из-за величины диаметра сосуда могут вызвать более интенсивные побочные эффекты (например, по сравнению с удалением волос).

Поэтому, достаточное охлаждение перед процедурой и после нее является очень важным для того, чтобы свести к минимуму побочные эффекты!

После подготовки участка обработки, пробный участок, на котором будет проводиться обработка, предварительно охлаждают в течение нескольких секунд с использованием холодных тампонов (примерно 4 - 8°C). После этого охлаждающую насадку аппликатора перемещают назад и вперед в продольном направлении над сосудом, который будут обрабатывать, без воздействия лазером.

Пробная плотность энергии для кожи типа III должна быть задана ниже, чем для светлой кожи, продолжительность импульса – как можно короче для заданной плотности для меньших сосудов и более длительной для сосудов большего размера и кожи типа III. Скорость обработки, в основном используемая в начале, устанавливают равной 0,5 Гц (SPEED). Эта настройка позволяет оценить ситуацию после только одного импульса, потому что можно деактивировать ножную педаль после одного импульса.

Более того, чем ниже скорость обработки, тем больше время предварительного охлаждения для следующей области обработки.



##### ПРЕДУПРЕЖДЕНИЕ

Лазерное излучение может привести к серьезным травмам глаз.

Во время сеанса лазерной терапии все лица, присутствующие в помещении, где работает лазер, должны носить очки для защиты глаз, в соответствии с инструкциями, приведенными в главе *Технические данные*!

Во время процедуры и после нее необходимо контролировать заданную плотность энергии! Всегда необходимо проверять, что система охлаждения работает.

Устройство MeDioStar переключают в режим *READY* с необходимой плотностью энергии.



#### Совет

В отличие от процедур эпиляции, к аппликатору НЕ прикладывают давление. Рекомендуется выдерживать расстояние примерно в 1 мм между лазерным наконечником и кожей. В то же время, холодная насадка системы охлаждения кожи должна находиться в контакте с кожей (слегка наклоните аппликатор).

К пробному участку подводят 2 – 3 импульса; лазерный наконечник перемещают к месту охлаждения кожи. После этого, оценивают состояние обработанного участка.

Если сосуд исчез (более характерно для мелких сосудов) или становится темнее (более характерно для крупных сосудов), плотность энергии будет поддерживаться, при этом, пятно за пятном помещают вдоль сосуда.

Сразу же после лазерной обработки, используют охлаждающую насадку для последующего охлаждения участка в течение нескольких секунд.

Если не наблюдается никакой реакции, подождите несколько минут, чтобы увидеть, не возникает ли воспалительная реакция. В это время можно также протестировать сосуд другого размера в одной и той же процедуре.

Чем больше сосуд, тем обычно нужна меньшая плотность энергии.

Если даже после некоторого ожидания реакция не наблюдается, **НОВЫЙ (!)** пробный участок снова предварительно охлаждают с помощью охлаждающей насадки, а затем обрабатывают лазером с наложением, или тот же самый участок дважды, прежде чем увеличить плотность энергии, если необходимо. Риск возникновения побочных эффектов меньше в случае работы с наложением, чем при слишком высокой плотности энергии!

Важно, чтобы пробные участки охлаждались предварительно и после процедуры, снова и снова, с использованием охлаждающей насадки.

После процедуры лазер переключают в режим *STANDBY*.

При выполнении пробной процедуры можно также оценить риск пигментных изменений, подсушивание и риск появления последующих рубцов.

Более того, пациент может получить впечатление от того, каким образом происходит обработка поврежденного участка.

### 7.5.6 Процедура обработки

Участок, который должен быть обработан первым предварительно охлаждают в течение нескольких секунд холодными тампонами. Затем первый сосуд охлаждают металлической насадкой, как описано выше.

Первый участок обрабатывают лазером с параметрами, определенными во время пробной процедуры (возможно, различными для разных сосудов), а затем используют насадку для последующего охлаждения обработанного сосуда. Если один участок полностью обработан, используют холодные тампоны для последующего охлаждения. Затем таким же образом обрабатывают следующий участок.

Необходимо обеспечить, чтобы насадка всегда находилась в контакте с кожей (без оказания давления), и чтобы аппликатор всегда перемещался к охлаждающей насадке.

После лечения лазер необходимо переключить на режим *STANDBY*.

Весь обрабатываемый участок оставить охлаждаться не менее чем на 10 минут.

Благодаря последующему охлаждению, эта процедура ведет к снижению ощущению боли и к снижению побочных эффектов.

### 7.5.7 Послелечебная обработка

После достаточного охлаждения кожи, нанесите противовоспалительную мазь, которую не нужно удалять до следующего дня.

В случае передозировки показан локальный антибиотик, и абсолютно необходимо контролировать процесс заживления.



**ОСТОРОЖНО**

Если после проведения процедуры обработанный участок будет подвергаться воздействию солнечного излучения, могут проявиться более значительные побочные эффекты, в частности, пигментные изменения.

В связи с этим, необходимо избегать воздействия такого излучения в течение 6 недель, или, по меньшей мере, пользоваться солнцезащитным кремом с коэффициентом защиты не ниже 20.

Не следует допускать получения травм на обработанном участке в течение 2 – 3 дней.

Более того, пациенты на протяжении непродолжительного периода времени должны обходиться без экстремальных физических или сосудистых стрессов, таких как бег трусцой, спортивные занятия в фитнес-студии, сауны, горячие ванны и т.д.

**7.5.8 Последующие процедуры**

Если сосуды не исчезли непосредственно, нажмите пальцем на сосуд и посмотрите, течет ли кровь назад, чтобы оценить результаты.

В зависимости от результата лечения, индивидуальной реакции кожи и интересов пациента, можно, при необходимости, наметить время для дальнейшей процедуры, с более высокой плотностью энергии.

Интервал между сеансами не должен быть меньше 12 недель. Из отчетов следует, что даже через несколько месяцев сосуды исчезают. Вплоть до этого времени некоторые сосуды могут быть темнее, чем прежде (коагуляция крови). Пациентов необходимо поставить в известность об этих фактах.

Более трех процедур не показано для ножных вен. Как упомянуто, может быть достигнут уровень успешности, соответствующий 70%.

**7.5.9 Ожидаемые результаты**

Ожидаемые результаты при лечении сосудов:

| Исследование                                                                                                                                                  | Методика                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Результаты                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| K. Kykalova: Vascular treatments with MeDioStar high power diode laser from Asclepion Laser Technologies Institute of Aesthetic Medicine, Prague, Czech, 2002 | <p>Исследование, клинический случай</p> <p><b>Пациенты:</b><br/>Группа 1 (2001): 9 пациентов в возрасте 33-65<br/>Группа 2 (2002): 24 пациента в возрасте 27-60<br/>Фототип кожи I-III</p> <p><b>Параметры:</b><br/>Mediostar 810 нм. 6 мм (сосудистый наконечник)<br/>Флюенс для группы 1: 130-150 Дж/см<sup>2</sup><br/>Флюенс для группы 2: 90-100 Дж/см<sup>2</sup><br/>Количество процедур: 2-5, интервал 2 месяца</p> <p><b>Методика:</b><br/>Процедура вплоть до получения клинического результата – склерозирования сосуда или коагуляции крови (потемнение сосуда)<br/>Следующая процедура при отсутствии результата после 2 месяцев (индивидуально)</p> | <p>Для группы 2 снижение флюенса сопровождалось уменьшением побочных эффектов при сохранении высоких результатов!</p> <p><u>Малые сосуды: 1-2 мм</u><br/>после третьей процедуры почти 70% полностью склерозировались без возврата (последний контроль 2 месяца после процедуры)</p> <p><u>Средние сосуды: 2-3 мм</u><br/>после третьей процедуры 50% полностью коагулировались без возврата (последний контроль 2 месяца после процедуры)</p> <p><u>Крупные сосуды: 4 мм*</u><br/>Требуется более 3 процедур, после 3 процедуры возврат около 70%, поэтому требуется больше процедур и более высокая энергия.</p> <p><b>*Замечание:</b><br/>В разделе Назначение этого Руководства процедуры с сосудах более 3 мм указаны как противопоказание!</p> |



| Исследование                                                                                                                                                                                                                             | Методика                                                                                                                                                                                                                                                                                                                                  | Результаты                                                                                                                                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V. Tsepkenko, S. Khaustov, A. Burov<br>“Our experience in vessels’ laser coagulation”<br>Clinic of plastic and aesthetic surgery “VIRTUS”<br>Odessa, Ukraine<br>(перевод с русского языка)                                               | <b>Цель:</b><br>Эффективность селективной лазерной коагуляции у пациентов с синими венами (до 3 мм)<br><b>Параметры:</b><br>Mediostar («Асклепион» (Asclepion), Германия),<br>Длина волны 810 нм, размер пятна 6 мм, плотность энергии 80-160 Дж/см <sup>2</sup><br><b>Пациенты:</b><br>105 пациентов с синими сосудами диаметром до 3 мм | Полное склерозирование – 75% (79 пациентов),<br>Значительное улучшение – 20% (21 пациент),<br>Умеренное улучшение – 4% (4 пациента),<br>Незначительное улучшение – 1% (1 пациент).                          |
| Wollina U, Konrad H, Schmidt WD, Haroske G, Astafeva LG, Fassler D.<br>Response of spider leg veins to pulsed diode laser (810 nm): a clinical, histo-logical and remission spec-troscopy study.<br>J Cosmet Laser Ther<br>2003;5:154-62 | 35 пациентов с паукообразными венами ног,<br>2 процедуры через 2 недели,<br>диодный лазер с длиной волны 810 нм,<br>Размер пятна 12 мм,<br>длительность импульса 60 мс, плотность энергии 80-100 Дж/см <sup>2</sup><br>Биопсия кожи<br>Спектроскопия                                                                                      | Полное очищение после первой процедуры у 15 из 35 пациентов, у 20 из 35 значительное улучшение, ситуация стабильна после 6 месяцев,<br>У 2 пациентов склерозирование средней степени без побочных эффектов. |

## 7.6 Лечение акне

**Акне** является одним из наиболее частых заболеваний, с которыми приходится сталкиваться в дерматологической практике. В основном, лечение бывает длительным и частично связано со значительными побочными эффектами.

Большинство юных пациентов, которых это касается, очень страдают от него.

В большинстве случаев, это – заболевание фолликулов, относящихся к волосу и к сальной железе, которые, главным образом, расположены на лице, на спине и на груди. Сначала, они образуют черные головки, не находящиеся в воспаленном состоянии, но на более поздних стадиях могут также появиться ряд воспалительных высыпаний, таких как папулы, пустулы и узелки. Acne vulgaris или «обычное акне» вызвано повышенным влиянием андрогена в пубертатный период и исчезает, самое позднее, к началу третьего десятилетия жизни.

Инфракрасное излучение устройства MeDioStar, как и при эпиляции проникает достаточно глубоко в кожу, чтобы достичь сальные железы и фолликулы.

Лечение, а также – противопоказания, побочные эффекты и сама процедура обработки идентичны эпиляции (смотри соответствующие главы).

Но в отличие от процедуры эпиляции, процедура обработки акне состоит из 3 – 4 проходов в прямой последовательности и затем лучше всего непрерывно охлаждать кожу охлаждающей маской. Из-за воспаления, процедура является болезненной.

Необходимо выполнить от 3 до 5 процедур с интервалом в одну неделю.

**Инверсные акне**<sup>(1)</sup> представляет собой воспаление сальных желез. Оно начинается с сальных желез и вторично поражает апокринные потовые железы. Мужчины и женщины страдают в равной степени. Это заболевание часто возникает в период созревания, но может также начаться и в любой момент позже.

Предрасположенными зонами особенно являются подмышечные области и пахово-лобковая область, также имеет место распространение и на ягодичную область. Спина и живот поражаются менее часто, и редко – зоны, типичные для акне, такие как лицо.

(1) Courtesy of Dr. med. C. Passos Pereira, Hürth-Hermühlheim, published in DERMAforum, Sept. 2003 (перевод с немецкого языка)

В пораженных зонах сначала развиваются узелковые одиночные очаги воспаления, а в ходе болезни они демонстрируют рецидив и слияние с образованиями, сходными с чирьями. Часто появляются плоские пластинки шрамов толщиной в сантиметрах. Они имеют кожные/подкожные фистулы, которые можно удалить только оперативным путем. Стресс для пациента обусловлен не только болями, связанными с воспалительным процессом, моторными ограничениями из-за образования шрамов, но также повторными дурно пахнущими инфекциями.

Причиной заболевания может быть генетическая предрасположенность, ее развитие в сочетании с прочими заболеваниями (М. Доулинг-Дегос), дефектами кератинизации фолликулярных протоков, себорея, особая бактериальная колонизация пропионовых бактерий и стафилококка. На ауреузин, курение и ожирение тоже ложится ответственность за развитие этого заболевания.

В соответствии с анамнезом болезни, в отношении некоторых пациентов развитие этого заболевания можно, вероятно, объяснить интенсивной флуктуацией гормонов (временная вторичная аменорея из-за значительной потери веса), но болезнь не проходит с окончанием этой возможной причины.

Принимаемыми терапевтическими мерами на настоящий момент являются многократное лечение антибиотиками и антисептиками, вскрытие абсцессов и эксцизия шрамов, устранение дефектов с помощью пересадки тонких лоскутов кожи. Недостатками этой процедуры является неоднократное развитие повторных проявлений, повторные хирургические процедуры на небольших или больших участках, боль, необходимая смена банджа, потери рабочего времени из-за больничных листов, а также – психологический стресс с возможным последующим ограничением социальных контактов.

Альтернативным терапевтическим выбором является лазерное лечение с использованием диодного лазера, такого как MeDioStar. Лазерное излучение, предназначенное для целей эпиляции, проникает глубоко под поверхность кожи и его эффект обусловлен абсорбцией светового излучения чаще всего пигментами или подобными светочувствительными структурами. Волосные фолликулы испытывают воздействие в первую очередь. Они приводятся в состояние обратного развития из-за полученного теплового повреждения после нескольких сеансов обработки.

Бактерии, образующие порфирин, и грибы, которые считаются локальными причинами инверсных акне, также разрушаются во время этой процедуры. После обычной процедуры эпиляции, этот эффект становится очевидным по уменьшенному образованию запаха из подмышечной области.

Лечение пораженных участков проводится при 810 нм с 30 – 40 Дж/см<sup>2</sup>. Сначала, выполняется одиночная процедура для пораженного участка (обратите внимание: однократная обработка включает в себя ряд сессий, как и при эпиляции). В самом благоприятном случае, лечение должно проводиться на стадии первичной пустулы или абсцесса, без образования рубца.

За последние три года лечение проводилось на 20 пациентах. Их заболевания продемонстрировали самые различные стадии развития, начиная от рецессивного образования абсцесса в паховой области вплоть до обширного наблюдения с частично значительными осложнениями (повторные операции, состояние после сепсиса с образованием вертебрального абсцесса).

Все пациенты продемонстрировали положительную реакцию на терапию. В лучшем случае, новые абсцессы были излечены в течение нескольких дней без необходимости дополнительных антибиотических терапевтических средств. В случае воспалительных реакций, которые уже существовали в течение длительного времени (более 6 месяцев), лечение воспаления проходило в течение 6 недель. В случае обширных полостей в результате рубца на месте абсцесса, мог быть достигнут антисептический эффект, но не заживление полости; здесь следует ожидать рецессивные симптомы.

Пациенты, у которых еще не было обширных рубцов, или еще не зарубцевались участки, продемонстрировали хорошую рецессивную профилактику. В течение самого длительного периода, составившего около трех лет, можно было наблюдать полную свободу рецессивных симптомов, после отделения абсцесса, проведенного под общей анестезией за месяц до этого. В качестве дополнительного решения, было уменьшено распространение запаха.

По сравнению с предыдущими исследованиями, можно сказать, что существует дополнительный терапевтический вариант для лечения инверсных акне. К нему можно прибегнуть в начале развития заболевания и, в благоприятных случаях, обойтись без оперативного вмешательства.

В случаях прогрессирующего заболевания, может быть достигнуто значительное усовершенствование диагностики и общего состояния пациентов. Здесь, не требуются первичные радикальные операции с устранением дефекта, а вместо этого – необходим только минимум операций, поэтому пациенты могут лучше перенести заболевание.

Ожидаемые результаты при терапии инверсные акне:

| Исследование                                                                                                                                                                                                                                                                                                         | Методики                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Результаты                                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Bechara et al.:<br>Prospective study<br>comparing laser<br>epilation treatment<br>versus no treatment of<br>mild and moderate<br>Hidradenitis<br>suppurativa/ Acne<br>inversa (HS/ AI)<br>Lecture at 44th annual<br>conference of<br>DGPRAC<br>September 2013,<br>Münster, Germany<br>(перевод с<br>немецкого языка) | Рандомизированное сравнительное<br>исследование<br><b>Цель:</b><br>В прогрессирующей стадии HS / AI терапией<br>выбора является хирургическое удаление<br>всех пораженных участков. Возможной<br>причиной может быть разрушение<br>волосных фолликулов на ранних стадиях.<br><b>Пациенты:</b><br>68 пациентов с HS/AI включая 58<br>проведенных процедур и<br>40 с оценкой после 12 месяцев<br><b>Параметры и методика:</b><br>Сравнительный анализ после процедуры,<br>проведенной аппаратом Medistar и без<br>процедуры.<br>Размер пятна 12 мм, плотность энергии и<br>длительность импульса в зависимости от<br>фототипа кожи (как при эпиляции)<br>6 процедур с интервалом 4 недели<br><b>Оценка:</b><br>Оценка по баллам HS до и после 12 месяцев | Деструкция волосных<br>фолликулов при лазерной<br>эпиляции представляется<br>эффективным лечением при<br>средней и умеренной<br>HS/AI.<br><br><b>Детали:</b><br>После процедуры:<br>Среднее уменьшение<br>баллов HS<br>47,62%<br><br>Среднее уменьшение<br>баллов HS после 12<br>месяцев:<br>77,33% |

## 7.7 Лечение старческого эласто́за

Под лечением старческого эласто́за следует понимать улучшение состояния кожи, вызванного главным образом инсоляцией, это означает улучшение структуры кожи (лифтинг, уменьшение размера пор), очищение от пигментаций и уменьшение мелких морщинок, что обеспечивает омоложение общего внешнего вида (также упрощенно называют "омоложение кожи").

В отношении этого, лечение, противопоказания, побочные эффекты и процедура обработки сходны с процедурами эпиляции. (Смотри соответствующие главы.)

Но в отличие от процедуры эпиляции, процедура состоит из 3 последовательных проходов в режиме *Профессиональный*, а затем лучше всего постоянно охлаждать кожу с помощью охлаждающей маски. Необходимы 3 процедуры с интервалами в один месяц.

Если, однако, возрастные пятна становятся ярче (диагноз должен быть абсолютно надежным, чтобы исключить раковые и предраковые поражения!), для лечения должно использоваться пятно небольшого размера на расстоянии около 1 мм от поверхности кожи. После процедур сначала происходит потемнение веснушек! Обязательно соответствующим образом поставьте в известность об этом своих пациентов.

Лекция, прочитанная Сью МакКой, доктором медицинских наук, на объединенной лазерной конференции в Эдинбурге, 2004 г.

**Лечение ленти́гиноза диодным лазером при 808 нм**  
С. МакКой; Лазер, клиника кожи и вен, Северная Аделаида, Южная Австралия

### Предпосылка

Ленти́гиноз представляют собой обычные доброкачественные эпидермические кожные патологические изменения, которые появляются, главным образом, на участках, подверженных воздействию солнечных лучей, у лиц со светлой (Фицпатрик, типы I – III) кожей, с увеличением случаев их появления в зрелом возрасте. Гистологически, солнечный ленти́гиноз, связанный с солнечным воздействием, проявляется в удлинении эпидермальных выростов в толщу соединительной ткани, увеличении числа меланоцитов и количества эпидермального пигмента.



Использовалось множество различных лазеров с высокой степенью эффективности и низким уровнем появления неблагоприятных эффектов, включая Nd:YAG с Q-переключением, рубином и александритом, Nd:YAG с двойной частотой и продолжительным импульсом, Erbium YAG, с ультракоротким импульсом CO<sub>2</sub> и другие. В этом исследовании дана оценка лечения лентигиноза диодным лазером с продолжительным импульсом, 808 нм, находящимся в общем клиническом использовании для уменьшения роста волос.

#### Материалы и методики

В этом эксперименте участвовали двенадцать взрослых добровольцев женского пола, в возрасте от 44 до 74 лет, с многочисленным лентигинозом (по меньшей мере, 10) на тыльной части кистей и/или предплечий. Длинноимпульсный диодный лазер 808 нм (MeDioStar, Карл Цейс Meditec, Йена, Германия) использовали только в режиме «Pro 2» - с одиночным импульсом без интервала. Вначале проводилась обработка трех пациенток с применением пятна 12 мм. Обработка остальных 9 пациенток проводилась с применением пятна 6 мм, что обеспечило возможность использования более высокой плотности энергии с меньшей длительностью импульса. Процедура проводилась с силиконовой дистанционной втулкой для создания круглых плоских зон на расстоянии 1 мм от поверхности кожи (в противоположность рекомендованной методике лечения при эпиляции, в соответствии с которой обеспечивается контакт с кожей и используется прозрачный гель).

Все пациентки проходили обработку с величинами энергии, начиная с 25 Дж/см<sup>2</sup> и с повышением приращением по 5 Дж/см<sup>2</sup>, пока не стало наблюдаться потемнение лентигиноза в течение 5 минут обработки. Остальная часть поражений проходила обработку при этой плотности энергии.

Один лентигиноз на пациента, расположенный на тыльной стороне руки, проходил обработку при предварительно выбранной плотности энергии, при этом, сразу же после процедуры была произведена проба на биопсию. Всего проводилось исследование 12 проб на биопсию, по 2 на каждую плотность энергии от 25 до 50 Дж/см<sup>2</sup>. Через последующие 4 недели подсчитанный процент исчезновения лентигиноза составил 0 – 25%, 51 – 75% и 76 – 100%. Осуществлялась запись любых отрицательных явлений.

#### Результаты

Все пациентки продемонстрировали 50% или большее уменьшение лентигиноза за один месяц, за исключением одной пациентки, которая подвергалась обработке с применением пятна размером 12 мм и 30 Дж и продемонстрировал только 25 – 50%. Отмечалось слабое соотношение между зазором и плотностью энергии, но устойчивое соотношение между зазором и цветом первоначальных патологических изменений и более темными патологическими изменениями, соответствующими большему зазору. В течение одного месяца не наблюдалось образование рубцов, но некоторые патологические изменения продемонстрировали остаточную эритему за этот короткий интервал после проведения процедуры. Гистология последовательно показывала обесцвечивание ядерного хроматина пигментированных основных кератиноцитов, расщепление тонкого верхнего обода папиллярного дермального коллагена. Эффекты были более выраженными с пятном размером 6 мм, чем 12 мм.

#### Заключение

Диодный лазер с излучением в диапазоне от 25 до 50 Дж/см<sup>2</sup> при 808 нм способен индуцировать ограниченный и фокальный некроз лентигиноза, вызванного воздействием солнечных лучей на коже предплечья кавказских женщин с удовлетворительными клиническими результатами. Процедура проводится быстро и хорошо переносится. Результаты являются в большей степени зависимыми от цвета лентигиноза, чем от плотности лазерной энергии. Мнение оператора и его опыт являются важными при получении хороших результатов.

## 8. Принадлежности



### ПРЕДУПРЕЖДЕНИЕ

Использование принадлежностей, не прошедших тестирование и не разрешенных «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) для использования с данным лазерным устройством может привести к серьезному поражению глаз или электрическому удару.

Для данного устройства используйте только принадлежности и кабели, указанные в настоящем руководстве пользователя.

Все принадлежности и кабели, предназначены только для этого устройства и могут применяться только с этим устройством.

Мы настоятельно предостерегаем от использования принадлежностей от других производителей. Даже если они сертифицированы уполномоченным органом сертификации как безопасные для применения, «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) не несет никакой ответственности за их применение.

По запросу, «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) предоставит вам обновленный список.

## 9 Чистка и дезинфекция

### 9.1 Общие правила

#### Устройство



#### ПРЕДУПРЕЖДЕНИЕ

Лазер работает с линейным напряжением. Существует риск поражения электрическим током!

Отсоедините линейный кабель питания от сетевой розетки, чтобы прервать подвод энергии к системе, прежде чем приступать к работе по очистке.

Пользователь может проводить очистку только наружных поверхностей системы.

Для чистки и дезинфекции допускается использование только слегка увлажненных мягких салфеток, например, «Кодан» (Kodan) или «Бациллол» (Bacillol). Запрещается проводить очистку влажной тканью или распылением дезинфицирующих средств.

Устройство следует очищать и дезинфицировать, по крайней мере, ежедневно после его использования. Если устройство не используется каждый день, его следует накрыть чистой тканью.

#### Методика проведения:

- Выключите устройство выключателем с ключом и выключателем питания. Отключите устройство от сети, вынув кабель питания из электрической розетки.
- Наденьте одноразовые перчатки.
- Все доступные внешние поверхности очищаются с помощью слегка влажной мягкой салфеткой. При очистке, соединения на задней стороне устройства пропускайте.
- Для удаления стойких загрязнений используйте салфетки «Кодан» (Kodan) или «Бациллол» (Bacillol). Абразивные средства не должны использоваться!
- После этого, все доступные внешние поверхности тщательно продезинфицируйте салфетками «Кодан» (Kodan) или «Бациллол» (Bacillol).

Соблюдайте инструкции производителей дезинфекции.

При дезинфекции, соединения на задней стороне устройства пропускайте.

Воздержитесь от использования агрессивных дезинфицирующих средств.

#### Аппликаторы



#### ПРЕДУПРЕЖДЕНИЕ

Контактная поверхность аппликатора контактирует с кожей пациента во время процедуры. Существует риск переноса микроорганизмов.

Детали аппликаторов необходимо тщательно очищать и дезинфицировать вручную сразу же после использования и перед применением на пациенте.

Если появляется необходимость очистки устройства в время процедуры, его необходимо переключить в режим ОЖИДАНИЯ, прежде чем приступать к работам по очистке! Не используйте спирт или изопропиловый спирт вблизи места проведения процедуры, потому что это обуславливает риск возгорания, если после этого активируют лазер!



#### ОСТОРОЖНО

Пыль, осевшая на оптическую поверхность, может загореться под воздействием лазерного излучения и вызвать побочные эффекты, такие как покраснение, возможное образование водяных пузырей, образование корки, редко рубцы!

Обеспечьте, чтобы все доступные оптические поверхности не были поврежденными и были чистыми после процесса очистки и оставались чистыми во время проведения процедуры.

Необходимо следовать инструкциям по проведению процедур, приведенным в следующих разделах.



## 9.2 Общие рекомендации по чистке и дезинфекции аппликаторов



### Важная информация

Запрещается проводить очистку аппликаторов влажной тканью или под струей воды или распылением дезинфицирующих средств. Это может привести к разрушению внутренней оптики и электроники. Следует использовать только влажные салфетки «Кодан» (Kodan) или «Бациллол» (Bacillol). (Аппликаторы можно повредить сильными кислотными или щелочными растворами!)

Аппликаторы нельзя стерилизовать.

Часто проводимая чистка и дезинфекция оказывают незначительное влияние на аппликаторы. Цвета могут стать более светлыми, или измениться, но это не влияет на эксплуатацию.

Окончание срока службы изделия обычно определяется износом и повреждениями, обусловленными его эксплуатацией.

Если аппликаторы не используются в течение длительного периода времени, их необходимо защитить от загрязнения

### ИНСТРУКЦИИ

#### Рабочее место

Рабочее место должно быть чистым и продезинфицированным все необходимые инструменты должны быть в наличии.

Оборудование: Нетканые салфетки; микрофибровые салфетки, поставляемые «Асклепион» (Asclepion) или чистящие салфетки для очков такого же типа; дезинфицирующие салфетки (например, «Кодан» (Kodan) или «Бациллол» (Bacillol); Одноразовые перчатки.

#### Подготовка к чистке

Аппарат должен быть выключен.

Чистка аппликаторов должна проводиться как можно скорее после его эксплуатации (в течение 30 минут).

Вскрытие или разборка аппликаторов запрещена.

Единственное исключение:

Для аппликатора XL отсоединение наконечника от корпуса для изменения размеров пятна (см. главу «Работа устройства / Замена аппликатора и изменение размера пятна на аппликаторе XL»).

Не является ни необходимым, ни рекомендуется отсоединять аппликатор от устройства для очистки и дезинфекции.

Лазерный аппарат должен быть расположен таким образом, чтобы находиться в непосредственной близости к рабочему месту. При необходимости, для этого можно отсоединить вилку. Теперь можно производить чистку, поскольку длина шланга аппликатора позволяет это.

Наденьте перчатки.

До начала чистки аппликатор не нужно удалять из держателя. Прочно удерживайте его одной рукой (в перчатке) за рукоятку на протяжении всего процесса, в то время как другой рукой производите чистку и дезинфекцию. Это предотвратит падение аппликатора.

#### Чистка: вручную

##### 1. Процедура для корпуса аппликатора:

Доступные поверхности корпуса аппликатора и охлаждающего наконечника сначала очищают грубо от геля с помощью нетканой салфетки. Затем очищают слегка увлажненной тканью или салфеткой. Ткань не должна быть мокрой, и с нее не должны стекать капли.

Вы можете использовать дезинфицирующие салфетки для удаления стойких загрязнений.

## ИНСТРУКЦИИ

Чистка:  
вручную

**2. Процедура для оптических поверхностей наконечников и оптических поверхностей аппликатора XL, которые доступны после отсоединения наконечника:**

Доступные оптические поверхности должны быть абсолютно чистыми. Сначала, на поверхность нужно подышать, а затем очистить тканью из микрофибры.

В случае сильных загрязнений, сначала используйте дезинфицирующие салфетки, затем микрофибровую ткань.

Не поцарапайте оптические поверхности.

Чистка:  
автоматическая

Невозможна и запрещена.

Дезинфекция

После очистки доступные наружные поверхности должны быть продезинфицированы с помощью дезинфицирующей ткани (например, ткань «Кодан» (Kodan) или «Бациллол» (Bacillol)). Не поцарапайте оптические поверхности. Визуально проверьте их без каких-либо инструментов (смотрите на оптические поверхности горизонтально).

Стерилизация

Невозможна, не требуется и запрещена.

Хранение и  
транспортировка

Детали должны храниться и транспортироваться в чистом состоянии и быть защищенными от загрязнения. Обеспечьте, чтобы соблюдались параметры соответствующих допустимых окружающих условий, указанных в главе *Технические данные*.

После того как обработка аппликатора завершена, продолжают удерживать его, пока вы очистите и продезинфицируете держатель аппликатора на устройстве, как описано для корпуса аппликатора. Только после этого аппликатор следует установить в держатель на устройстве для безопасного хранения.

Изготовитель подтвердил, что вышеприведенные инструкции ПРИГОДНЫ для подготовки деталей вспомогательного оборудования к их повторному использованию.

### ПРЕДУПРЕЖДЕНИЕ



Контактная поверхность аппликатора контактирует с кожей пациента во время процедуры. Существует риск переноса микроорганизмов.

Лицо, занимающееся очисткой, несет полную ответственность за то, чтобы фактически выполненные работы по очистке и дезинфекции с помощью оборудования и материалов и с привлечением соответствующего персонала обеспечили получение желаемых результатов.

Обычно требуется узаконенный мониторинг процедур. Следует также проводить оценку эффекта и отрицательных последствий каждого отклонения от представленных инструкций.

Обработка может осуществляться только обученным и уполномоченным персоналом.

Производитель не несет ответственности за любые прямые или косвенные убытки, если обработка была произведена неправильно.



### 9.3 Специальные рекомендации по чистке и дезинфекции аппликаторов



Рисунок 50: Аппликатор ST

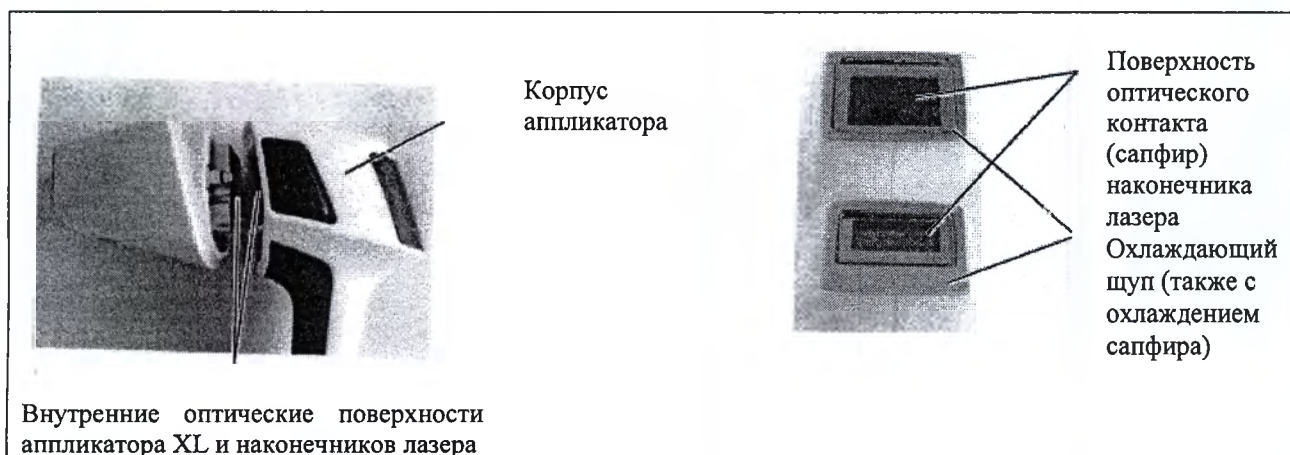


Рисунок 51: Аппликатор (слева) с наконечником XLL (сверху) и XLS (внизу)

#### Во время процедуры:

При использовании рекомендованных технических приемов, оптические контактные поверхности лазерного наконечника, в значительной степени, хорошо защищены от загрязнения. Тем не менее, их следует содержать в чистом состоянии также и во время проведения процедуры (в частности, при обработке более толстых и темных волос)!

По этой причине, необходимо регулярно проверять состояние оптической контактной поверхности и очищать ее с помощью чистой, без ворсовой влажной ткани. Вы можете, например, быстро протереть поверхность тампоном каждый раз после лазерной обработки линии, прежде чем переходить к лазерной обработке следующей линии. Эта методика позволяет исключить пригорания возможного существующего загрязнения при продолжении лазерной обработки.

Внутренние оптические поверхности должны содержаться в чистоте при замене лазерных наконечников аппликатора XL.



## 10. Сообщения об ошибках и устранение неисправностей



### ПРЕДУПРЕЖДЕНИЕ

Лазер работает при линейном напряжении и излучает инфракрасное излучение. Существует риск удара током и повреждения глаз!

Процедуры поиска неисправностей, указанные ниже должны неукоснительно соблюдаться. Любое отклонение от указанных методик и, конечно, любое вскрытие устройства или аппликаторов запрещено (кроме замены лазерных наконечников для аппликатора XL).



### ВАЖНАЯ ИНФОРМАЦИЯ

Неправильное использование или техническое обслуживание лазерной системы может привести к потере гарантии, предоставляемой «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH).

По любым вопросам, не указанным в данном руководстве, обратитесь к представителю по обслуживанию клиентов (смотри раздел *Техническая поддержка пользователя (сервис)*).

### 10.1 Общая информация

Если аппарат не реагирует на поворот ключа в положение ВКЛЮЧЕНО, убедитесь в следующем:

1. Аппарат включен в сеть питания.
2. Основной выключатель на задней панели аппарата находится в положении ВКЛЮЧЕНО
3. Аварийный выключатель лазера разблокирован. Если он заблокирован, поверните красную ручку аварийного выключения против часовой стрелки до тех пор, пока переключатель не выпрыгнет.

Как отмечалось выше, программное обеспечение направляет Ваши действия по устранению неисправностей посредством сообщений, отображаемым на дисплее.

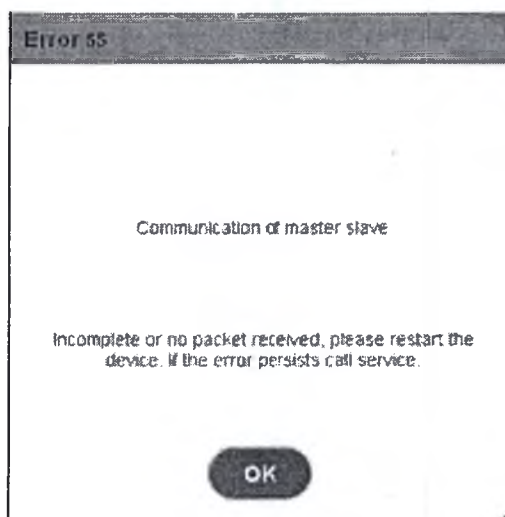


Рисунок 52: Сообщение об ошибке (пример)

При возникновении какой-либо неисправности на дисплее появится сообщение об ошибке с пояснениями относительно дальнейших действий. Некоторые неисправности могут быть

устранены пользователем, для этого необходимо следовать инструкциям, выводимым на дисплей.

В случае появления ошибок, связанных с безопасностью, аппарат самостоятельно выключится в течение миллисекунд. В этом случае отображение сообщения об ошибке невозможно. Если это случится, или возникнет какая-либо другая неисправность, не описанная в этом руководстве, необходимо отключить аппарат от сети.

В данном разделе содержится информация о причинах неисправности системы MeDioStar. Действия по устранению неисправностей предпринимаются эксплуатационным персоналом, за исключением сообщений, содержащих специальное указание о том, что их устранение возможно только персоналом «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) или персоналом, им авторизованным.

## 10.2 Сообщения об ошибках и устранение неисправностей

Аппарат MeDioStar оборудован системой аварийной сигнализации. При возникновении опасной ситуации аппарат переключается в безопасный режим, и излучение становится невозможным. Для самостоятельного устранения возникшей неисправности необходимо ознакомиться с нижеприведенной таблицей. Если неисправность осталась, свяжитесь с «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) или техническим персоналом, авторизованным «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH).

Перед тем как обратиться в сервисную службу «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH), обязательно запишите текст сообщения об ошибке и ее код.

| Сообщение об ошибке                                           | Объяснение/ действие                                                                                                                                                                                                                                                                        |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Охладитель</b><br>(ошибка 513)                             | Охлаждающую жидкость BC4 следует заливать с помощью заправочного комплекта (поставляемого в комплекте с устройством) через соединения на тыльной стороне устройства (см. раздел «Текущее техническое обслуживание»).                                                                        |
| <b>Коммуникационная ошибка</b><br>(все ошибки с кодом 50 XXX) | Связь прервана<br><br>Перезагрузите аппарат. Продолжайте работать, если неисправность осталась – обратитесь в Сервисную службу.                                                                                                                                                             |
| <b>Температурная ошибка</b><br>(все ошибки с кодом 150 XXX)   | Температура слишком мала или слишком велика.<br><br>Проверьте, поступает ли воздух через вентиляционные отверстия. Перезагрузите аппарат. Если неисправность исчезла – продолжайте работать, если осталась – обратитесь в Сервисную службу.                                                 |
| <b>Ножная педаль</b><br>(ошибки с кодом 400 XXX)              | Отпустите педаль.<br>(не включайте ножную педаль раньше времени, подождите, пока на дисплее появится надпись <i>READY (ГОТОВ)</i> с желтым оповещением)                                                                                                                                     |
| <b>Дверной прерыватель</b><br>(ошибки с кодом 600 601)        | Контакты дверного замка открыты, разъем дверного замка не подключен. Если дверь была подсоединена к дверному замку, дверь открыта.<br><br>Правильно подключите контакты дверного замка или включите переключатель дверного замка. Если дверь подключилась к дверному замку, закройте дверь. |
| <b>Ошибка аппликатора</b><br>(все ошибки с кодом 61XX)        | Проверьте соединение аппликатора.<br><br>Перезапустите аппарат. Если неисправность осталась – обратитесь в Сервисную службу.                                                                                                                                                                |

Возможные неисправности

| Неисправность                                                                 | Объяснение/ устранение                                                                                                                                                                                                                                                                                            |
|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Отсутствует питание                                                           | <p>Проверьте, подключен ли кабель питания к розетке.</p> <p>Установлен ли переключатель в положение «I» или (Включено)?</p> <p>Проверьте, не нажата ли кнопка аварийного выключения.</p> <p>Проверьте предохранители внутренней системы электропитания.</p>                                                       |
| Функциональные клавиши дисплея не отвечают на нажатия (или отвечают частично) | <p>Неисправность калибровки сенсорного дисплея.</p> <p>Калибровка должна проводиться авторизованным инженером по обслуживанию. Обратитесь к поставщику или напрямую к «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) (см. главу <i>Техническая поддержка пользователя (сервис)</i>).</p> |
| Лазерное излучение отсутствует при нажатой педали                             | <p>Проверьте надежность подключения кабеля ножной педали.</p> <p>Аппарат находится в режиме <i>STANDBY</i> (Ожидание). Для переключения в режим <i>READY</i> (Готов) нажмите кнопку <i>READY</i>.</p>                                                                                                             |



## 11. Техническая поддержка пользователя



### ПРЕДУПРЕЖДЕНИЕ

Лазер работает с линейным напряжением. Существует риск поражения электрическим током и повреждения глаз!

Не открывайте устройство и не пытайтесь самостоятельно производить ремонт устройства, в случае неисправности лазера.

Устройство не содержит встроенных частей, обслуживаемых пользователем.

К обслуживанию устройства допускаются только инженеры, являющиеся нашими сотрудниками или инженеры, обученные и уполномоченные нами. Это же относится к предписанным ежегодным проверкам безопасности.



### ПРЕДУПРЕЖДЕНИЕ

При проведении процедуры аппликатор контактирует с травмированной кожей пациента. Существует риск переноса микроорганизмов.

При необходимости осмотра или ремонта аппликаторов, или основного блока устройства в медицинском учреждении или у производителя они должны быть заранее очищены и продезинфицированы!

Если вам требуется помощь технической службы, обратитесь по адресу и телефону, приведенным ниже. При обращении в представительство «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) всегда указывайте модель и серийный номер аппарата. Эти данные указаны на идентификационной табличке, расположенной на задней панели аппарата.

«Асклепион Лейзер Текнолоджис ГмбХ»  
(Asclepion Laser Technologies GmbH)  
Брюсселер Штр., 10  
D - 07747 ЙЕНА  
Германия  
[www.asclepion.com](http://www.asclepion.com)

Отдел работы с клиентами:

Тел.: +49 (0) 3641 / 7700 - 401

Факс: +49 3641/7700-402

Электронная почта: [service@asclepion.com](mailto:service@asclepion.com)

Пожалуйста, имейте в виду, что производитель, поставщик или импортер не считают себя ответственными за безопасность, надёжность и эксплуатационные качества аппарата, если не выполняются следующие рекомендации:

- Установка, настройка, модернизация или ремонт должны выполняться авторизованным компанией персоналом.
- Электрооборудование кабинета должно соответствовать требованиям IEC 64 с учетом поправок.
- Аппарат используется в соответствии с инструкциями, приведенными в настоящем руководстве.

## 12. Техническое обслуживание, проверка безопасности и калибровка

Лазер не содержит никаких встроенных компонентов, подлежащих обслуживанию пользователем.



### ПРЕДУПРЕЖДЕНИЕ

Предупреждение - Использование иных устройств управления или иное осуществление регулировок или иное выполнение процедур, чем указанные в данном документе, может привести к опасному воздействию излучения и поражению электрическим током.

Любое отклонение от указанных методик и, конечно, любое вскрытие устройства или аппликаторов (за исключением замены наконечников аппликатора XL) запрещено.

Перед обслуживанием необходимо отключить устройства от сети отсоединением кабеля питания от розетки.

К обслуживанию устройства допускаются только инженеры, являющиеся нашими сотрудниками или инженеры, обученные и уполномоченные нами. Это же относится к предписанным ежегодным проверкам безопасности и калибровке. Это же относится к предписанным ежегодным проверкам безопасности и калибровке.

Кроме того, лица, осуществляющие обслуживание должны иметь необходимое оборудование (например, лазерные измерительные приборы, предназначенные для этого лазера). Работы по обслуживанию должны быть выполнены правильно и должны быть задокументированы.

Работы по обслуживанию и ремонту устройства, требующие его включения, должны производиться в зоне лазера. Должны быть соблюдены все предосторожности, указанные в разделе Безопасность/Лазер.

Неисправные или поврежденные узлы должны быть немедленно заменены. Используйте только запасные части, поставляемые «Асклепион Лейзер Текнолоджис» (Asclepion Laser Technologies). Безопасность не гарантируется при использовании запасных частей других производителей, даже если они сертифицированы.

Любая модификация устройства строго запрещена.



### ОСТОРОЖНО

Слишком высокая выходная мощность лазера может вызвать побочные эффекты!

Выходная мощность терапевтического лазера должна проверяться обслуживающим техником «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH) или квалифицированным техником дистрибьютора в рамках проверки безопасности не реже одного раза в год; также при необходимости необходимо проводить калибровку устройства. Результаты проверки должны быть задокументированы в учетном журнале медицинского устройства.

После калибровки следует провести очень аккуратно пробную процедуру.

Вполне возможно, что реальная плотность энергии будет немного выше, чем раньше (относительно заводских настроек), даже для тех же настроек. Технический персонал должен проинформировать существует ли отклонение после калибровки. То же самое относится к чистке аппликаторов.

### ВАЖНАЯ ИНФОРМАЦИЯ



Чтобы гарантировать высокую надежность и длительный срок службы, необходимо использовать только охлаждающую жидкость, специально разработанную компанией «Асклепион» (Asclepion) для этого устройства (защита от коррозии, антибактериальная, антифриз, эффективное охлаждение)! Эту охлаждающую жидкость нельзя смешивать с дистиллированной водой. Пожалуйста, обратите внимание на соответствующие этикетки на устройстве (см. раздел Установка / Значки на устройстве).



#### ВАЖНАЯ ИНФОРМАЦИЯ

Компания «Асклепион» (Asclepion) дает гарантию для устройства на один год. Гарантия может быть продлена при условии прохождения регистрации на нашем сайте.

Тщательно произведенная чистка, как описано в главе *Очистка и дезинфекция* и в этой главе, обеспечивает длительный срок службы устройства.

Максимальное число импульсов может быть ограничено в зависимости от версии аппликатора.

Неправильное обращение во время работы, технического обслуживания, проверки безопасности или калибровки может привести к аннулированию гарантии. По любым вопросам не ответили в данном руководстве, обратитесь к представителю по обслуживанию клиентов (смотри раздел *Техническая поддержка пользователя (сервис)*).

Для предоставления расширенной гарантии требуется проведение ежегодной проверки устройства

Расходные детали не покрываются гарантией. Список расходных деталей можно запросить в отделе обслуживания клиентов.

### 12.1 Регламент технического обслуживания

Нижеприведенные проверки могут проводиться персоналом клиники или больницы:

#### Проверка внешнего вида аппарата

Проверьте все кабели на наличие и надежность подключения.

Периодичность: Ежедневно

Проверка проводится: Персоналом клиники или больницы

#### Проверка системы охлаждения

Проверьте, свободны ли вентиляционные решетки системы охлаждения аппарата.

Периодичность: Ежедневно

Проверка проводится: Персоналом клиники или больницы

#### Проверка аппликатора

Проверьте состояние аппликатора.

Периодичность: Перед каждым использованием

Проверка проводится: Персоналом, работающим на лазере.



#### ВАЖНАЯ ИНФОРМАЦИЯ

Несколько напоминаний будет отображаться на дисплее перед окончанием ресурса подключенного аппликатора (зависит от аппликатора). Это позволяет предсказать ожидаемую замену.

#### Заправка охлаждающей жидкости

Комплект для заправки охлаждающей жидкости (BC4) поставляется с аппаратом.



#### ВАЖНАЯ ИНФОРМАЦИЯ

Для заправки лазера используйте только эту жидкость!

BC 4 – готовая к применению жидкость, и ее не следует смешивать с другими жидкостями.

BC 4 не допускается смешивать с ионообменными веществами.



### ОСТОРОЖНО



Жидкость и пар ВС4 являются горючими веществами и вызывают сильное раздражение глаз. ВС4 необходимо держать вдали от источников тепла, горячих поверхностей, искр, открытого огня и других источников воспламенения. Запрещается курить и тара с ВС4 должна храниться закрытой. В частности, после заполнения устройства ВС4, пары должны быть удалены полностью с помощью вентиляции, прежде чем лазер активирован!

Во время заполнения должна быть использована защита глаз/защита лица.

В случае попадания жидкости или паров ВС4 в глаза, помимо мер предосторожности, глаза необходимо осторожно промыть в течение нескольких минут. Контактные линзы должны быть удалены. Продолжайте полоскание. В случае раздражения глаз, необходима консультация окулиста.

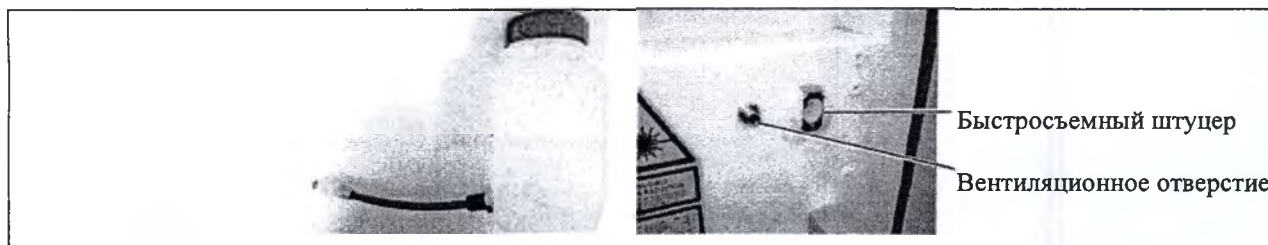


Рисунок 53: Комплект для заправки охлаждающей жидкости (слева) и быстросъемный штуцер (справа)

Заправка системы охлаждения должна производиться, как указано ниже, при появлении на дисплее сообщения или как минимум после 1-2 месяцев эксплуатации.

- Выключите лазер
- Заполните заправочную емкость примерно на 2/3 охлаждающей жидкостью
- Снимите защитный колпачок с воздушного штуцера (на задней панели устройства)
- Подключите к воздушному штуцеру прозрачную трубку, второй конец трубки поместите в стакан с водой
- Подключите к быстросъемному заправочному штуцеру синюю трубку
- Горловина заправочной емкости должна быть открыта
- Тщательно заполняйте охлаждающую жидкость до тех пор, пока не прекратится поступление воздушных пузырьков из прозрачной трубки и пойдет только охлаждающая жидкость (это можно наблюдать в стакане с водой)
- Отключите синий шланг от устройства нажатием кнопок быстросъемного клапана
- Включите лазер и проверьте: осталось ли сообщение о необходимости заполнить охладитель.
- Если сообщения нет – процесс заправки окончен
- Если сообщение остается (недостаточно охладителя из-за наличия воздушных пузырьков), повторите процедуру. Полезно поднять немного левую сторону передней панели устройства (если смотреть спереди) подложив под него подставку толщиной 1-2 см (например, крышку заправочной емкости).
- закройте колпачком воздушный штуцер

## 12.2 Регулярная проверка безопасности

### ОБЪЕМ ЕЖЕГОДНОЙ ПРОВЕРКИ БЕЗОПАСНОСТИ

По крайней мере, указанные ниже проверки должны быть выполнены в соответствии с национальными нормативами, а также с международным стандартом для медицинского электронного оборудования – текущая периодическая проверка и проверка после ремонта медицинского электрооборудования (IEC 62353).

Проверка должна производиться в следующем порядке:

- визуальный осмотр лазерного устройства и вспомогательного оборудования
- измерение сопротивления защитного заземляющего провода
- испытание на утечку в землю
- измерение сопротивления изоляции
- функциональное испытание

Дополнительно следует произвести:

- Измерение фактической выходной энергии лазерных модулей на выходе аппликаторов; при необходимости калибровка выходной лазерной энергии



**Совет**

Чтобы получить информацию об объеме и выполнении проверок безопасности, свяжитесь со своим дистрибьютором или непосредственно с компанией «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH).

**Дополнительная информация**

По запросу, изготовитель предоставит схемы контуров, перечни деталей компонентов, описания, инструкции по калибровке или иную информацию, не включенную в это Руководство пользователя, чтобы оказать содействие техническому персоналу, обладающему соответствующей квалификацией, при ремонте тех деталей устройства, которые обозначены изготовителем как ремонтпригодные. В этом контексте, «технический персонал, обладающий соответствующей квалификацией», означает персонал, прошедший курс изготовителя по обучению обслуживанию этого устройства, и санкционированный на выполнение его ремонта.

### 13 Утилизация

Утилизация устройства должна проводиться в соответствии с распоряжением 2002/96/ЕС Европейского Совета для Отходов электрического и электронного оборудования [WEEE].



#### **ПРЕДУПРЕЖДЕНИЕ**

Во время лечения аппликаторы находятся в контакте с неповрежденной кожей пациента. Существует опасность переноса микроорганизмов. Перед утилизацией в соответствии с актами, указанными выше, аппликаторы должны быть очищены и продезинфицированы!

Обратитесь к нашей Технической службе, если у вас появятся какие-либо вопросы, касающиеся утилизации.



#### 14. ЕС Декларация соответствия

Декларация соответствия выпускается на ограниченное время. Действующую версию можно получить в нашей службе технической поддержки.

**«Асклепион  
Лейзер Текнолоджис» (Asclepion Laser Technologies)**

Декларация ЕС о соответствии

**«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)**  
Брюсселер Штрассе, 10  
07747 Йена  
Германия

Мы заявляем о соответствии медицинского прибора

**MeDioStar**

**ALT - артикул №:**

1591; 1592

**Классификация:**

Класс II b в соответствии с 93/42/EEC  
Приложение IX

Со стандартами Медицинского оборудования 93/42/EEC Приложение II  
(орган технической экспертизы: «ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH), Тилли штр., 2, 90431 Нюрнберг, № 0197, регистрационный номер: HD 60105768 0001).

Любая модификация изделия, не разрешенная «Асклепион Лейзер Текнолоджис ГмбХ», сделает эту декларацию недействительной.

на основе технического документа: ALT M 03/14

Согласованные стандарты:

Основные требования Директивы 93/42/EEC, Приложение 1, со всеми соответствующими согласованными стандартами.

Йена, 3 декабря 2015 года

«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)

От лица

/Подпись/

Пиетро Аматулли

Технический директор

Настоящая декларация действительна до: 02.12.2020

«Асклепион  
Лейзер Текнолоджис» (Asclepion Laser Technologies)

Декларация ЕС о соответствии

«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)  
Брюсселер Штрассе, 10  
07747 Йена  
Германия

Мы заявляем о соответствии медицинского прибора

**MeDioStar**

*ALT - артикул №:* 1590

Классификация: Класс II b в соответствии с 93/42/EEC  
Приложение IX

Со стандартами Медицинского оборудования 93/42/EEC Приложение II  
(орган технической экспертизы: «ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH), Тилли штр., 2, 90431 Нюрнберг, № 0197, регистрационный номер: HD 60105768 0001).

Любая модификация изделия, не разрешенная «Асклепион Лейзер Текнолоджис ГмбХ», сделает эту декларацию недействительной.

на основе технического документа: ALT M 03/14

Согласованные стандарты:

Основные требования Директивы 93/42/EEC, Приложение 1, со всеми соответствующими согласованными стандартами.

Йена, 3 декабря 2015 года

«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)

От лица

/Подпись/

Пиетро Амагулли

Технический директор

Настоящая декларация действительна до: 02.12.2020

А. Приложение: Декларация производителя по электромагнитной совместимости



**ВАЖНАЯ ИНФОРМАЦИЯ**

Применение принадлежностей, трансформаторов или кабелей, иных, нежели указаны в настоящем Руководстве, за исключением приобретенных у производителя в качестве запасных частей, может привести к увеличению помех или снижению защищенности аппарата.

| Модель устройства                              | Описание                                                                                         |
|------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Mediostar, #1590<br>(Модель Mediostar NeXT)    | Диодный лазер высокой мощности (основной блок)<br>Примечание: для аппликаторов ST, HP, VAS и ALX |
| Mediostar, #1591<br>(Модель Mediostar NeXTPRO) | Диодный лазер высокой мощности (основной блок)<br>Примечание: для всех аппликаторов              |

| Принадлежность/назначение                                                                                                                                                                                                                 | Номер              | Длина/размеры |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------------|
| Ножная педаль с кабелем                                                                                                                                                                                                                   | 6608 06 008        | <3,0 м        |
| Линия системы охлаждения                                                                                                                                                                                                                  | 5507 04 013        | <3,0 м        |
| Разъем дверной блокировки                                                                                                                                                                                                                 | 1601 01 078        | -             |
| Аппликатор ST                                                                                                                                                                                                                             | 4020 00 000        | <3,0 м        |
| Аппликатор VAS                                                                                                                                                                                                                            | 4021 00 000        | <3,0 м        |
| Аппликатор HP                                                                                                                                                                                                                             | 4022 00 000        | <3,0 м        |
| Аппликатор с наконечником XLS <sup>1</sup>                                                                                                                                                                                                | 4070 с 4071 00 000 | <3,0 м        |
| Аппликатор с наконечником XLL <sup>1</sup>                                                                                                                                                                                                | 4070 с 4072 00 000 | <3,0 м        |
| Примечание: MeDioStar 1590 может быть использован со всеми принадлежностями, указанными выше, за исключением принадлежностей, отмеченных значком (1).<br>MeDioStar 1591 может быть использован со всеми принадлежностями, указанными выше |                    |               |

**ВАЖНАЯ ИНФОРМАЦИЯ**

Настоящее устройство требует соблюдения особых условий сетевых подключений. Максимально допустимый импеданс сети питания:

$Z_{\max} = 0,1753 \text{ Ом}$  для Mediostar 1590 и

$Z_{\max} = 0,3911 \text{ Ом}$  для Mediostar 1591

в точке подключения источника питания.

При необходимости следует обратиться в службу, обеспечивающую электропитанием, чтобы убедиться, что сеть питания имеет импеданс не более  $Z_{\max}$ .



**ВАЖНАЯ ИНФОРМАЦИЯ**

Использование принадлежностей или кабеля от другого медицинского электрооборудования, нежели MeDioStar может привести к увеличению излучения или снижению помехозащищенности оборудования / системы.



**ВАЖНАЯ ИНФОРМАЦИЯ**

MeDioStar нельзя ставить или размещать рядом с другими приборами. Если MeDioStar используется в непосредственной близости с другими приборами, то необходимо постоянно следить за его корректной работой.



## ВАЖНАЯ ИНФОРМАЦИЯ



Для MeDioStar определены следующие существенные эксплуатационные характеристики EMC:

- независимый выход из предустановленного режима работы
- независимое изменение предварительной выбранной выходной энергии
- независимое (непреднамеренное) излучение выходного излучения

## A.1 Электромагнитные излучения помех

Аппарат MeDioStar предназначен для использования при электромагнитных условиях, приведенных ниже. Заказчик и/или Пользователь аппарата MeDioStar должен обеспечить нижеуказанные электромагнитные условия.

| Измерение излучения                                 | Соответствие     | Электромагнитная совместимость                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Радиочастотное излучение согласно CISPR 11          | Группа 1         | MeDioStar использует радиочастотную энергию только для своего внутреннего функционирования. Поэтому его радиоизлучение очень слабое и не может оказывать какое-либо влияние на соседнее электронное оборудование.                                                                                                                                          |
| Радиочастотное излучение согласно CISPR 11          | Класс В          | MeDioStar предназначен для использования во всех учреждениях, в том числе в автономных учреждениях и тех, которые подключены непосредственно к сети общественного электропитания, которая снабжает здания, используемые для бытовых целей.                                                                                                                 |
| Излучение гармоник согласно IEC 61000-3-2           | Класс А          | Для гармоник:<br>MeDioStar предназначен для использования во всех учреждениях, в том числе в автономных учреждениях и тех, которые подключены непосредственно к сети общественного электропитания, которая снабжает здания, используемые для бытовых целей.                                                                                                |
| Колебания напряжения /фликер согласно IEC 61000-3-3 | Соответствует 1* | Для фликеров:<br>Во время работы влияние питающей сети, не может быть абсолютно исключено. При необходимости, должно быть обеспечено - после консультации с поставщиком электроэнергии - что максимально допустимый импеданс сети питания:<br>$Z_{\max} = 0,1753 \text{ Ом}$ (для Mediodstar 1590)<br>$Z_{\max} = 0,3911 \text{ Ом}$ (для Mediodstar 1591) |

1\*) в соответствии с соотв. IEC 61000-3-11:2000 максимально допустимый импеданс сети питания:

$Z_{\max} = 0,1753 \text{ Ом}$  для Mediodstar 1590.

$Z_{\max} = 0,3911 \text{ Ом}$  для Mediodstar 1591.

## А.2 Электромагнитная помехоустойчивость

Аппарат MeDioStar предназначен для использования при электромагнитных условиях, приведенных ниже. Заказчик и/или Пользователь аппарата MeDioStar должен обеспечить нижеуказанные электромагнитные условия.

| Тест-невосприимчивости                                                                                   | Тестовое значение по IEC 60601-1-2                                                                                                                                                             | Соответствие                         | Электромагнитная обстановка - рекомендации                                                                                                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Электростатический разряд IEC 61000-4-2                                                                  | +/- 6 кВ контактный заряд<br>+/- 8 кВ разряд воздуха                                                                                                                                           | +/- 6 кВ<br>+/- 8 кВ                 | Полы должны быть деревянными или из керамической плитки. Если полы покрыты синтетическими материалами, относительная влажность должна быть не менее 30%                                                                                                               |
| Быстрые электрические помехи/всплески IEC 61000-4-4                                                      | +/- 2 кВ для цепей питания<br>+/- 1 кВ для входных/выходных цепей                                                                                                                              | +/- 2 кВ<br>+/- 1 кВ                 | Качество напряжения сетей должно соответствовать обычным требованиям для коммерческого и/или медицинского применения.                                                                                                                                                 |
| Скачки IEC 61000-4-5                                                                                     | +/- 1 кВ в дифференциальном режиме<br>+/- 2 кВ в обычном режиме                                                                                                                                | +/- 1 кВ<br>+/- 2 кВ                 | Качество напряжения сетей должно соответствовать обычным требованиям для коммерческого и/или медицинского применения.                                                                                                                                                 |
| Падения напряжения, прерывания и флуктуации напряжения во входных цепях источника питания IEC 61000-4-11 | <5% $U_t$ для полуволны (прерывание >95%)<br><br>40% $U_t$ для 5 циклов (падение $U_t$ 60%)<br><br>70% $U_t$ для 25 циклов (падение $U_t$ 30%)<br><br><5% $U_t$ (падение $U_t$ >95%) для 5 сек | <5%<br><br>40%<br><br>70%<br><br><5% | Питание должно соответствовать обычным требованиям для медицинского оборудования.<br>Если пользователю аппарата необходимо работать на аппарате в условиях прерывания напряжения питания, рекомендуется использовать источник бесперебойного питания или аккумулятор. |
| Величина магнитного поля частоты 50/60 Гц по IEC 61000-4-8                                               | 3 А/м                                                                                                                                                                                          | 3 А/м                                | Сила магнитных полей должна быть на уровне, типичном для коммерческого и/или медицинского применения.                                                                                                                                                                 |
| Примечание: $U_t$ – это напряжение в сети переменного тока перед тестированием                           |                                                                                                                                                                                                |                                      |                                                                                                                                                                                                                                                                       |

Аппарат MeDioStar предназначен для использования при электромагнитных условиях, приведенных ниже. Заказчик и/или Пользователь аппарата MeDioStar должен обеспечить нижеуказанные электромагнитные условия.

| Тест невосприимчивости                            | Тестовое значение по IEC 60601-1-2 | Соответствие | Электромагнитная обстановка - рекомендации                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---------------------------------------------------|------------------------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Кондуктивные высокочастотные помехи IEC 61000-4-3 | 3 Veff<br>От 150 Гц до 80 МГц      | 3 В          | <p>Портативные и мобильные средства коммуникации, в том числе кабели, не должны использоваться ближе к любой части аппарата, чем рекомендованное удаление, рассчитанное из уравнения частоты излучателя</p> <p><b>Рекомендованное удаление</b></p> $d = \left[ \frac{3,5}{3V} \right] \sqrt{P}$                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Излученные высокочастотные помехи IEC 61000-4-3   | 3 В/м<br>От 80 МГц до 2,5 ГГц      | 3 В/м        | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$ <p>от 80 МГц до 800 МГц</p> $d = \left[ \frac{7}{3} \right] \sqrt{P}$ <p>от 800 МГц до 2,5 ГГц</p> <p>где <math>P</math> — это номинальная мощность излучателя в Вт, заявленная производителем, а <math>d</math> — это рекомендуемое удаление в метрах (м).</p> <p>Напряженность поля от фиксированных источников, как указано в отчете об электромагнитной совместимости<sup>a</sup>, должна быть меньше уровня соответствия в каждом частотном диапазоне<sup>b</sup>.</p> <p>Вблизи оборудования, обозначенного следующим символом, может наблюдаться интерференция</p> <p>«(*)»</p>  |

Примечание 1. При 80 МГц и 800 МГц выбирается более высокая частота.

Примечание 2. Данные рекомендации могут выполняться не во всех ситуациях. На распространение электромагнитных волн влияет поглощение и отражение от окружающих предметов и людей.

<sup>a</sup> Напряженность поля от фиксированных излучателей, например, радиоприемников, телефонов (сотовых, беспроводных), мобильных и любительских радиоприемников, АМ, FM и TV приемников не может быть теоретически предсказана с высокой точностью. Для оценки электромагнитной среды с учетом фиксированных радиочастотных передатчиков следует учесть необходимость проведения электромагнитных изысканий на объекте. Если измеренная напряженность поля на участке, где используется Mediostar, превышает допустимые уровни радиочастотного излучения, приведенные выше, то необходимо следить за его работой, чтобы обеспечить его нормальное функционирование. В случае ненормального функционирования возможна необходимость принятия дополнительных мер, таких как переориентация или перемещение прибора Mediostar.

<sup>b</sup> В диапазоне частот от 150 кГц до 80 МГц напряженность поля должна быть менее 3 В / м.



### А.3 Рекомендованное безопасное удаление

Рекомендованное удаление портативных и мобильных средств коммуникации от аппарата MeDioStar в соответствии с нормами IEC 60 601-1-2.

Аппарат MeDioStar предназначен для использования при электромагнитных условиях, при которых излучаемые радиочастотные помехи контролируются. Заказчик или пользователь MeDioStar может помочь предотвратить электромагнитных помехи, соблюдая минимальное расстояние между портативным и мобильным радиочастотным коммуникационным оборудованием (передатчиками) и MeDioStar как рекомендовано ниже, в соответствии с максимальной выходной мощностью оборудования связи

| Частота излучателя                                                                                                                                                                                                                                                      | От 150 кГц до 80 МГц                        | От 150 кГц до 800 МГц                       | От 800 МГц до 2,5 ГГц                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------------------------------------------|-------------------------------------------|
| Соотношение                                                                                                                                                                                                                                                             | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$ | $d = \left[ \frac{3,5}{3} \right] \sqrt{P}$ | $d = \left[ \frac{7}{3} \right] \sqrt{P}$ |
| Номинальная<br>выходная мощность<br>излучателя, Вт                                                                                                                                                                                                                      | Безопасное расстояние, м                    | Безопасное расстояние, м                    | Безопасное расстояние, м                  |
| 0,01                                                                                                                                                                                                                                                                    | 0,12                                        | 0,12                                        | 0,23                                      |
| 0,1                                                                                                                                                                                                                                                                     | 0,37                                        | 0,37                                        | 0,74                                      |
| 1                                                                                                                                                                                                                                                                       | 1,17                                        | 1,17                                        | 2,33                                      |
| 10                                                                                                                                                                                                                                                                      | 3,70                                        | 3,70                                        | 7,37                                      |
| 100                                                                                                                                                                                                                                                                     | 11,70                                       | 11,70                                       | 23,30                                     |
| Для излучателей с максимальной выходной мощностью, не указанной выше, рекомендуемую дальность d в метрах (м) можно высчитать уравнением, применимому к частоте передатчика, где P – максимальная выходная мощность излучателя в ваттах (Вт), заявленная производителем. |                                             |                                             |                                           |
| Примечание 1. При 80 МГц и 800 МГц удаление выбирается исходя из более высокой частоты.                                                                                                                                                                                 |                                             |                                             |                                           |
| Примечание 2. Данные рекомендации могут выполняться не во всех ситуациях. На распространение электромагнитных волн влияет поглощение и отражение от окружающих предметов и людей.                                                                                       |                                             |                                             |                                           |

|                             |                                                           |                   |                                                                     |
|-----------------------------|-----------------------------------------------------------|-------------------|---------------------------------------------------------------------|
| ТР 7338/Индекс изменений: С | <b>Предписание по упаковке<br/>MeDioStar Familie 159x</b> |                   | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
|                             | Номер документа: <b>1590 08 004</b>                       | Версия: <b>06</b> | Страница 1 из 9<br>159008004 Packinstruct MS 159x<br>V06.doc        |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                        |                          |          |                    |        |                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------------|----------|--------------------|--------|-----------------|
| <b>Предписание по упаковке для приборов семейства MeDioStar , включая компоненты и принадлежности, для перевозки грузовым и воздушным транспортом</b>                                                                                                                                                                                                                                                                                                                                                                                     |                        |                          |          |                    |        |                 |
| Обозначение приборов<br>согл. заводской<br>табличке                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | MeDioStar              |                          | MOTUS LD | The Epi Lab        | Pronto | SmoothPulse PRO |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | (NeXT <sup>PRO</sup> ) | (NeXT <sup>PROmo</sup> ) |          |                    |        |                 |
| Артикульный номер                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 1591<br>1592<br>1595   | 15912                    | 15913    | 15911<br><br>15951 | 15921  | 15922           |
| <p><u>Получатели:</u>            производственный отдел<br/>                                  отдел сбыта<br/>                                  сервисный отдел<br/>                                  отдел разработок</p> <p><u>Место сборки:</u>        производство отдела реализации / логистики<br/>                                  сервисная зона<br/>                                  помещения заказчика</p> <p><u>Применяемые</u>            DMR-Index 1591 08 010<br/><u>документы:</u>            DMR-Index 1595 08 010</p> |                        |                          |          |                    |        |                 |

**Составлено:**

| Версия | Краткое описание изменений                                                                                                                                                                      | Дата       | Имя      | Подпись   |
|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|----------|-----------|
| 06     | Обновление изображений и процесса упаковки, добавлена упаковка для MS Derivate, добавлена табличка «Ограниченное количество» и стрелка для выравнивания, обновлены актуальные варианты приборов | 23.05.2016 | Т. Клосс | /Подпись/ |

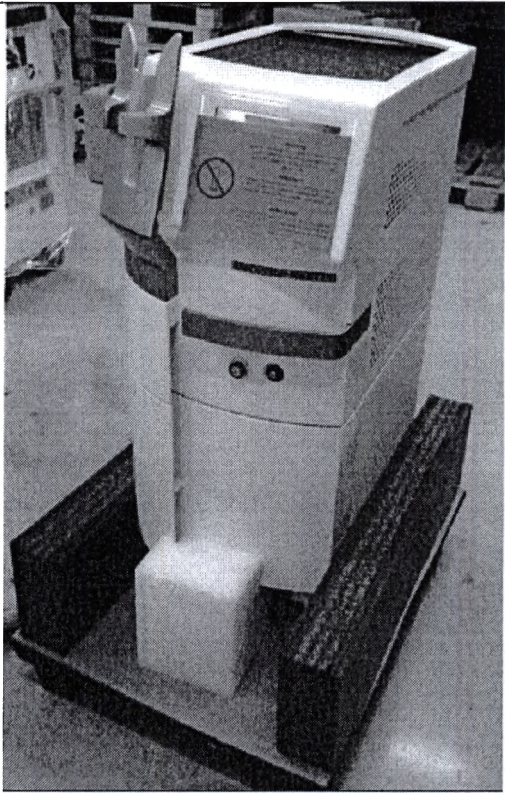
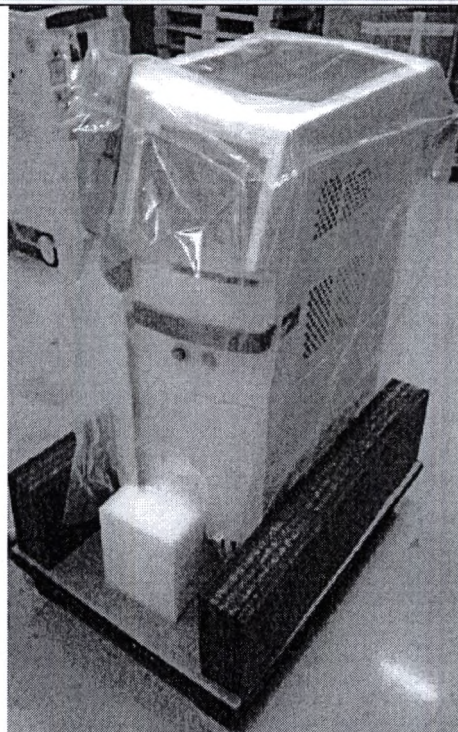
|                              |      |                   |           |           |
|------------------------------|------|-------------------|-----------|-----------|
| <b>Проверка и одобрение:</b> | Зона | Дата              | Имя       | Подпись   |
| Проверено                    | FuE  | <b>23.05.2016</b> | А. Винтер | /Подпись/ |
| Одобрено                     | F    | <b>24.05.2016</b> | Р. Шлисер | /Подпись/ |

|                             |                                                           |            |                                                                     |
|-----------------------------|-----------------------------------------------------------|------------|---------------------------------------------------------------------|
| ТР 7338/Индекс изменений: С | <b>Предписание по упаковке<br/>MeDioStar Familie 159x</b> |            | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
|                             | Номер документа: 1590 08 004                              | Версия: 06 | Страница 2 из 9<br>159008004 Packinstruct MS 159x<br>V06            |

| Условия монтажа                        |                                             |
|----------------------------------------|---------------------------------------------|
| Инструменты и вспомогательные средства |                                             |
| № п/п                                  | Название                                    |
| Инструмент                             |                                             |
| 1                                      | Инстр. 1 Устройство для спайки стяжных лент |
| Вспомогательное средство               |                                             |
|                                        | Нет                                         |
| Используемые сокращения:               |                                             |
|                                        | см. Руководство по менеджменту качества     |
| Особые условия монтажа:                |                                             |
|                                        | Особые требования отсутствуют               |

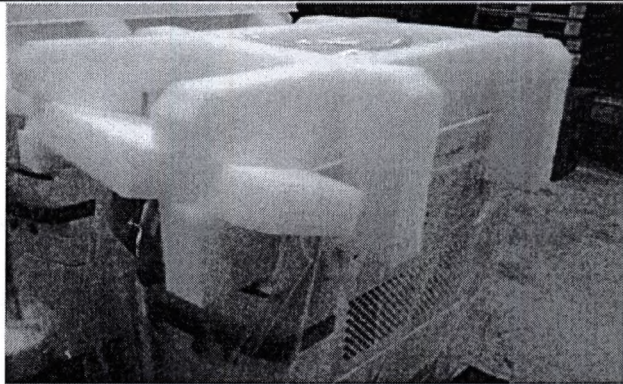
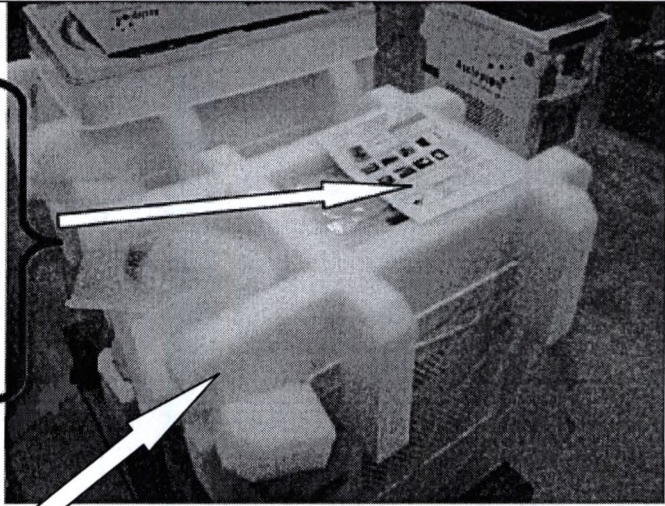


|                             |                                                   |            |                                                                     |
|-----------------------------|---------------------------------------------------|------------|---------------------------------------------------------------------|
| ТР 7338/Индекс изменений: С | Предписание по упаковке<br>MeDioStar Familie 159x |            | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
|                             | Номер документа: 1590 08 004                      | Версия: 06 | Страница 3 из 9<br>159008004 Packinstruct MS 159x<br>V06            |

| МП | Монтажная операция                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Примечание                                                                           |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 1  | <ul style="list-style-type: none"> <li>- Подготовить упаковку MeDioStar (826-0900-000) (состоит из поддона, картонной выкройке, пакета с боковыми фальцами, верхней части картона, набора деталей из пеноматериала и таблички)</li> <li>- Уложить нижний кусок пеноматериала (866-0805-245) на картонную выкройку</li> <li>- Установить прибор на кусок пеноматериала - при этом <u>не наклонять более чем на 20°!</u></li> <li>- Если отсутствует, наклеить указательную табличку (1590-99-046) «Подождать 12 часов перед включением NeXT» на дисплей</li> </ul> |   |
| 2  | <ul style="list-style-type: none"> <li>- Натянуть пакет с боковыми фальцами (866-0805-226) на прибор</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |

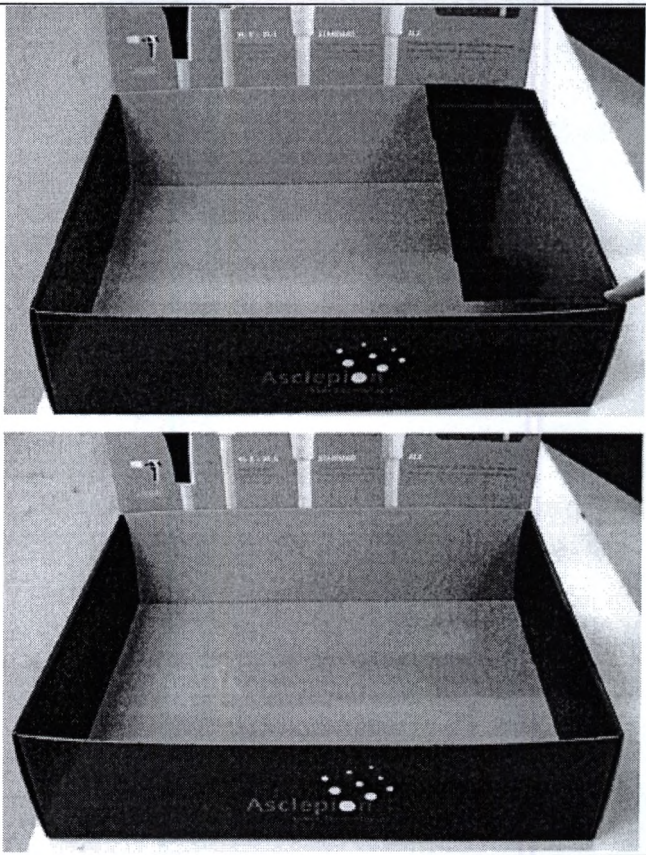


|                             |                                                           |                   |                                                                     |
|-----------------------------|-----------------------------------------------------------|-------------------|---------------------------------------------------------------------|
| ТР 7338/Индекс изменений: С | <b>Предписание по упаковке<br/>MeDioStar Familie 159x</b> |                   | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
|                             | Номер документа: <b>1590 08 004</b>                       | Версия: <b>06</b> | Страница 4 из 9<br>159008004 Packinstruct MS 159x<br>V06            |

| МП      | Монтажная операция                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Примечание                                                                           |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 3       | <ul style="list-style-type: none"> <li>- Надеть верхний пеноматериал (866-0805-246) правильным образом согласно изображению</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |    |
| 4       | <p>Упаковать принадлежности согласно соответствующим упаковочному листу и передаточной ведомости, а также клиентскому заказу. Они включают в себя, например:</p> <ul style="list-style-type: none"> <li>- Ножной переключатель</li> <li>- При необходимости – очки для защиты от лазера, защиту глаз пациента</li> <li>- Упаковать сетевой кабель, ключ, систему блокировки дверей и стилус в пузырчатую упаковку</li> <li>- охлаждающую жидкость и ПЭТ-шланг, копию упаковочного листа и передаточной ведомости, добавить комплект для запуска</li> <li>- Завернуть пакуемый набор в пузырчатую упаковку</li> </ul> |   |
| 5       | <b>Упаковка ручных блоков</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                      |
| 5.1     | <b>Упаковка ручных блоков 4020-4028 (например, ST, VAS, HP) и 4070 (XL) в блистерную упаковку или упаковку из пеноматериала</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                      |
| 5.1.1   | <b>Блистерная упаковка (если имеется)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                      |
| 5.1.1.1 | <ul style="list-style-type: none"> <li>- Уложить ручной блок в блистере (866-0805-181; 866-0805-192) на прибор</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |

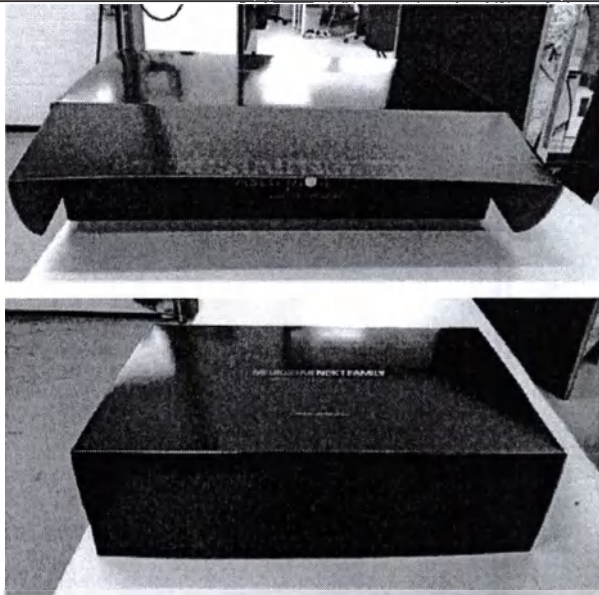


|                             |                                                   |            |                                                                     |
|-----------------------------|---------------------------------------------------|------------|---------------------------------------------------------------------|
| ТР 7338/Индекс изменений: С | Предписание по упаковке<br>MeDioStar Familie 159x |            | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
|                             | Номер документа: 1590 08 004                      | Версия: 06 | Страница 5 из 9<br>159008004 Packinstruct MS 159x<br>V06            |

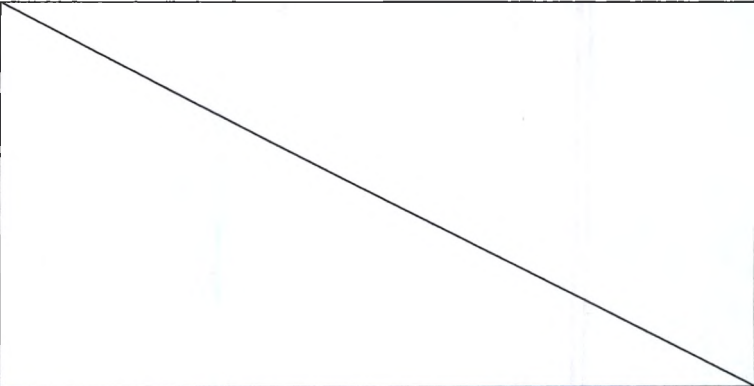
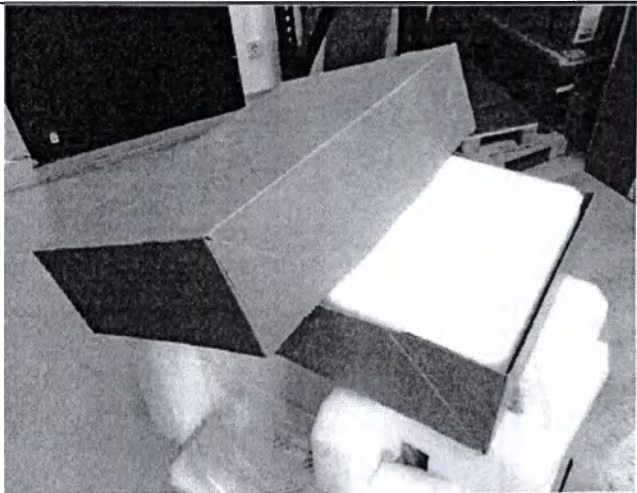
| МП      | Монтажная операция                                                                                                                                                 | Примечание                                                                          |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 5.1.2   | <b>Упаковка из пеноматериала с упаковочным картоном</b> (если имеется)                                                                                             |                                                                                     |
| 5.1.2.1 | <ul style="list-style-type: none"> <li>Поднять переднюю стенку и заднюю стенку (с крышкой) упаковочного картона (866-0805-221) и сложить боковые стенки</li> </ul> |   |
| 5.1.2.2 | <ul style="list-style-type: none"> <li>Согнуть боковые стенки и зафиксировать в поверхности дна</li> </ul>                                                         |  |



|                             |                                                   |            |                                                                     |
|-----------------------------|---------------------------------------------------|------------|---------------------------------------------------------------------|
| ТР 7338/Индекс изменений: С | Предписание по упаковке<br>MeDioStar Familie 159x |            | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
|                             | Номер документа: 1590 08 004                      | Версия: 06 | Страница 6 из 9<br>159008004 Packinstruct MS 159x<br>V06            |

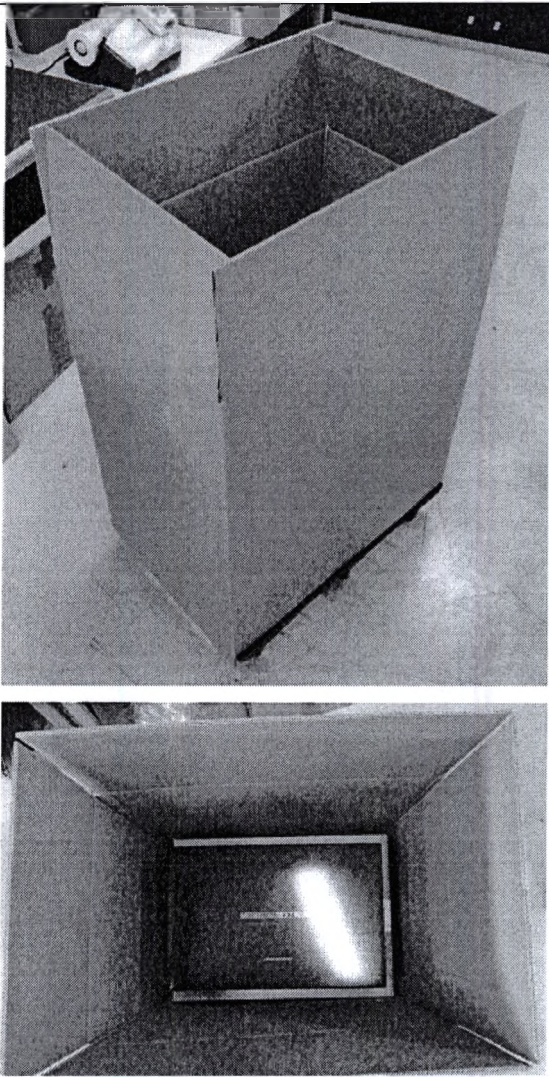
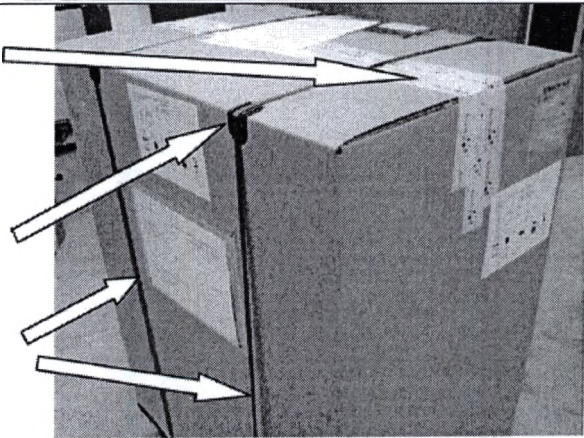
| МП      | Монтажная операция                                                                                                                                                                                                                                                                                                                                                                                                                          | Примечание                                                                           |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 5.1.2.3 | <ul style="list-style-type: none"> <li>- Уложить вкладыш из полиэтиленового пеноматериала вместе с ручным блоком в упаковку</li> <li>- Уложить полиэтиленовую крышку</li> </ul> <p><b>Замечание:</b></p> <ul style="list-style-type: none"> <li>- вкладыш из полиэтиленового пеноматериала для ручного блока 4070 XL: 866-0805-218</li> <li>- вкладыш из полиэтиленового пеноматериала для ручных блоков 4020-4028: 866-0805-258</li> </ul> |   |
| 5.1.2.4 | <ul style="list-style-type: none"> <li>- закрыть крышку картонной упаковки и задвинуть картонные направляющие по бокам</li> </ul>                                                                                                                                                                                                                                                                                                           |  |

|                             |                                                           |            |                                                                     |
|-----------------------------|-----------------------------------------------------------|------------|---------------------------------------------------------------------|
| ТР 7338/Индекс изменений: С | <b>Предписание по упаковке<br/>MeDioStar Familie 159x</b> |            | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
|                             | Номер документа: 1590 08 004                              | Версия: 06 | Страница 7 из 9<br>159008004 Packinstruct MS 159x<br>V06            |

| МП      | Монтажная операция                                                                                                                                                                                                                                                                                                                                                | Примечание                                                                           |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 5.1.2.5 | - уложить упаковку на прибор                                                                                                                                                                                                                                                                                                                                      |    |
| 5.2     | <b>Упаковка ручных блоков 4060-4068 и 40709 (XL) для приборов:<br/>The Epi Lab/Pronto/Smoothpulse PRO</b>                                                                                                                                                                                                                                                         |                                                                                      |
| 5.2.1   | <ul style="list-style-type: none"> <li>- собрать складную картонную коробку (866-0805-259) с вкладышем из полиэтиленового пеноматериала аналогично пунктам 5.1.2.1 - 5.2.2.5 и уложить на прибор</li> </ul> <p><b>Внимание:</b> Ручной блок XL для Derivate (40709) упаковывать также в складную картонную коробку для ручных блоков Derivate (866-0805-259)!</p> |  |
| 5.3     | <b>Ручной блок 4079 для приборов: MeDioStar PROmo и MOTUS LD</b>                                                                                                                                                                                                                                                                                                  |                                                                                      |
| 5.3.1   | <ul style="list-style-type: none"> <li>- сложить нейтральную картонную коробку (ratioform: SA60) и уложить ручной блок 10x10 (4079) в полиэтиленовом вкладыше (866-0805-218)</li> </ul>                                                                                                                                                                           |  |

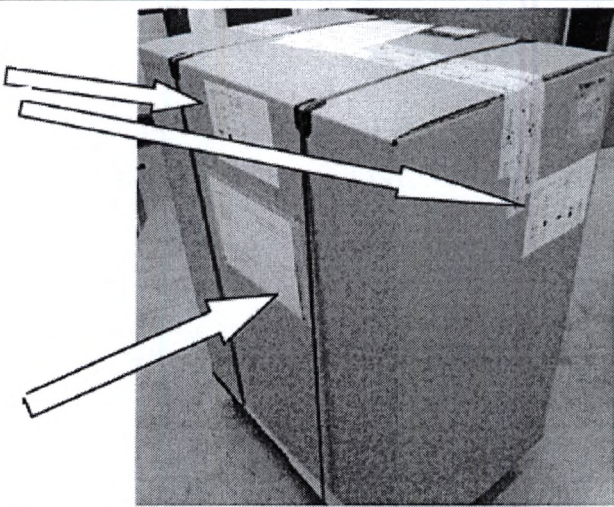
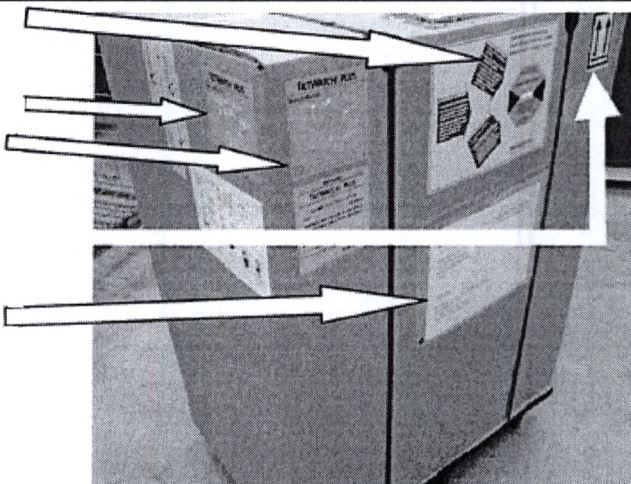


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|-----------------------------|---------------------------------------------------|------------|---------------------------------------------------------------------|
| ТР 7338/Индекс изменений: С | Предписание по упаковке<br>MeDioStar Familie 159x |            | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
|                             | Номер документа: 1590 08 004                      | Версия: 06 | Страница 8 из 9<br>159008004 Packinstruct MS 159x<br>V06            |

| МП | Монтажная операция                                                                                                                                                                                                                                                                                                                                                                                                          | Примечание                                                                           |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 6  | <p>- установить картонную упаковку (866-0805-247)</p>                                                                                                                                                                                                                                                                                                                                                                       |   |
| 7  | <p><b>Закреть верхнюю часть картона</b></p> <ul style="list-style-type: none"> <li>- Верхнюю часть картона запечатать скотчем</li> </ul> <p><b>Внимание!</b><br/>Для MOTUS LD использовать только нейтральный или «ДЕКА»-скотч!</p> <ul style="list-style-type: none"> <li>- Установить уголки для защиты краев с шипами</li> <li>- Опоясать стенки верхнего картона двумя стреппинг-лентами при помощи Инстр. 1</li> </ul> |  |



|                             |                                                           |            |                                                                     |
|-----------------------------|-----------------------------------------------------------|------------|---------------------------------------------------------------------|
| ТР 7338/Индекс изменений: С | <b>Предписание по упаковке<br/>MeDioStar Familie 159x</b> |            | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
|                             | Номер документа: 1590 08 004                              | Версия: 06 | Страница 9 из 9<br>159008004 Packinstruct MS 159x<br>V06            |

| МП       | Монтажная операция                                                                                                                                                                                                                                                                                                                                                                                               | Примечание                                                                          |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>8</b> | <b>Завершающие работы / Нанесение наклеек</b>                                                                                                                                                                                                                                                                                                                                                                    |                                                                                     |
| 8.1      | <ul style="list-style-type: none"> <li>Приклеить две наклейки «Транспортная упаковка» (817-3099-004) и вписать артикул и серийный номер прибора водостойким маркером</li> </ul> <p><b>Внимание!</b><br/>Для MOTUS LD применять наклейку «Транспортная упаковка MOTUS» (815-9199-038)!</p> <ul style="list-style-type: none"> <li>Прикрепить первый конверт для транспортных документов (866-0805-260)</li> </ul> |   |
| 8.2      | <ul style="list-style-type: none"> <li>Прикрепить индикатор удара (866-0604-029)</li> <li>Прикрепить два индикатора наклона (866-0604-031) по углам и закрепить степлером</li> <li>Приклеить наклейку «Не ронять, верх» (866-0604-127)</li> <li>Прикрепить второй конверт для транспортных документов (866-0805-260)</li> </ul>                                                                                  |  |
| 8.3      | <ul style="list-style-type: none"> <li>При перевозке в страны за пределами Германии необходимо иметь в виду специфические для каждой страны таблички согласно АА 7756!</li> </ul>                                                                                                                                                                                                                                |                                                                                     |

По выбору  
4070 XLHP  
4071 XLS  
4072 XLL

4073 CXS  
4074 CSL

По выбору  
4020 HSST  
4021 HSVAS  
4022 HSHP  
4024 ALX 14 x 10

4023 COS  
4028 ALX 14 x 10

153099024 Наклейка  
«Ручной блок с лазерной  
апертурой»

159099029 Наклейка с  
серийным номером

660604120  
Индикатор  
наклона плюс

Y  
1:1

660604097 Наклейка  
«Экстренное  
выключение лазера»

Маркировка  
ВКЛ/ВЫКЛ на  
замке-  
выключателе

153099024 Наклейка  
(самоклеющаяся этикетка)

Передняя сторона приборов

159199023 Наклейка  
«MSPRO ETA 3120-F»

MeDioStar NeXT<sup>PRO</sup>

C - C

159199024 Крышка  
для надписи  
MSNeXT PRO  
(Стандарт HS)

Чертеж этикеток для MeDioStar NeXT<sup>PRO</sup> 1591, 1592, 1595

|                                                  |       |                                                                                   |                |             |
|--------------------------------------------------|-------|-----------------------------------------------------------------------------------|----------------|-------------|
| 02                                               | L5136 | Изм. В12 159099028 в 159199023 [7.8A] согласно (153099024) 1 2F1 660604120 [3.4C] | 02.04.15       | MU          |
| 01                                               | L5124 | согласно 660604115 в 660604116 [1,2E]                                             | 19.01.15       | MU          |
| Индекс                                           |       | Др.                                                                               | Когда          | Кем         |
| Собств. Директиве по ограничению вредных веществ |       |                                                                                   |                | Про/ИНЖЕНЕР |
| При приемке размеры проверяются особо            |       |                                                                                   |                | Мастерск.:  |
| Допуск свободного размера: ISO 2768 m K          |       | ДБР<br>ПРОВ<br>НОРМА                                                              | 28.08.14       | Ка          |
| КАЧЕСТВО ПОВЕРХНОСТИ СОГЛАСНО ISO 1301           |       |                                                                                   |                |             |
| МАСШТАБ: 3:10                                    |       | 159199020                                                                         | ЭТИКЕТКИ MSPRO |             |



Главный сервисный  
USB разъем  
Трафаретная печать по  
чертежу 159001003

## Задняя сторона приборов

170199031  
Указательная табличка Рабочая  
часть В только для 1591/1592

Маркировка ВКЛ/ВЫКЛ  
на переключателе

159099038  
Наклейка на задней панели ВС4.

Разъем для ножного  
переключателя  
(Трафаретная печать  
по чертежу 159001003)

159099032  
Наклейка «Осторожно»

Разъем для блокировочного  
контакта(Трафаретная  
печать по чертежу  
159001003)

По выбору 159199041  
Laser-K14 MSPRO/EN  
или для MSPRO cos.  
159599023 Laser-K14  
MSPRO cos / EN

660604109  
Табличка прибора  
«Следовать инструкции по  
эксплуатации»

1234-921  
Табличка «Произведено»

Сюда относятся: 159099037 Этикетка ВС4 «Наливная  
горловина»  
159099040 Наклейка «Земля»

По выбору 660604115 CE-  
знак 0197 для 1591/1592  
или для MSPRO cos.  
660604108 CE-знак для  
1595

550206141  
Штекер POAG-S6/25

## Чертеж этикеток для MeDioStar NeXT<sup>PRO</sup> 1591, 1592, 1595

159199021  
Заводская табличка MeDioStar

159099036  
Наклейка с серийным номером

X  
1:1

660604036

Наклейка «Выравнивание потенциалов»

|                                        |      |                                                                                                                   |             |                |
|----------------------------------------|------|-------------------------------------------------------------------------------------------------------------------|-------------|----------------|
| 02                                     | 5136 | Изм. В12 159099028 в 159199023(7.8A) согласно (153099024) и 159199023(7.8A) согласно 660604115 в 660604116 [1,2E] | 02.04.15    | MU             |
| 01                                     | 5124 |                                                                                                                   | 19.01.15    | MU             |
| ИНДЕКС                                 |      | Др.                                                                                                               | Когда Кем   |                |
| Допуск. посадочного размера            |      | Соотв. Директиве по ограничению                                                                                   | Про/ИНЖЕНЕР |                |
| Допуск свободного размера              |      | При приемке размеры проверяются особо                                                                             | Мастерск.:  |                |
| ISO 2768 m K                           |      | ОБРАТНОЕ                                                                                                          | 28 Окт 14   | Кл             |
| КАЧЕСТВО ПОВЕРХНОСТИ СОГЛАСНО ISO 1302 |      | ПРОВ                                                                                                              |             |                |
|                                        |      | НОРМА                                                                                                             |             |                |
| МАСШТАБ: 3:10                          |      | 159199020                                                                                                         |             | ЭТИКЕТКИ MSPRO |



|               |                                                      |                                                                   |                                                                          |
|---------------|------------------------------------------------------|-------------------------------------------------------------------|--------------------------------------------------------------------------|
| Форма 7302    | Анализ и контроль рисков согласно EN ISO 14971: 2009 |                                                                   | «Асклепион<br>Лейзер<br>Технологии»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: F | Идентификационный номер:                             | RH/14/11/10-01<br>Код участника/год/месяц/день - порядковый номер | FB 7302 RAaC MSPRO V03<br>RH141110-01                                    |

|                                                  |   |                                             |                          |                      |                          |                                                    |
|--------------------------------------------------|---|---------------------------------------------|--------------------------|----------------------|--------------------------|----------------------------------------------------|
| Медицинское изделие: MeDioStar                   | X | Директива 93/42/ЕЕС по медицинским изделиям | X                        | IEC 60 601-2-22:2007 | <input type="checkbox"/> | Перед проведением научно-исследовательских работ   |
| Номер изделия: 1591/1592                         | X | IEC/ EN 60601-1:2006                        | X                        | EN 60 825-1:2007     | <input type="checkbox"/> | Во время проведения научно-исследовательских работ |
| Установленный уровень разработки: предсерийный   | X | IEC/ EN 60 601-1-2:2007                     | <input type="checkbox"/> | .....                | X                        | после проведения научно-исследовательских работ    |
| Редакция руководства пользователя: 159099001-V06 | X | IEC/ EN 62304:2006                          | <input type="checkbox"/> | .....                | X                        | перед серийным производством                       |
| 159099002-V06                                    | X | IEC/ EN 62366:2008                          | <input type="checkbox"/> | .....                | <input type="checkbox"/> | после производства                                 |

Примечание: Управление рисками устройства было проведено согласно EN ISO 14971:2009. В настоящее время проводится анализ соблюдения стандарта EN ISO 14971:2012. Для этой цели был выполнен анализ просчетов при предыдущем управлении рисками.

Справочные документы:

Составлено:

| Вер. | Описание изменения                                                                                                               | Дата               | Имя, фамилия | Подпись         |
|------|----------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------|-----------------|
| 01   | Первая редакция: Начальная версия включая анализ рисков, оценку первых рисков и предложение мер по управлению рисками            | 04 февраля 2014 г. | М. Мёллер    | подписал Мёллер |
| 02   | обновить управление рисками / Осуществление контрмер / Оценка остаточного риска                                                  | 20 августа 2014 г. | М. Мёллер    | подписал Мёллер |
| 03   | уточненные риски из-за недостаточно контролируемых процессов в проектировании, производстве и техническом обслуживании (глава 1) | 10 ноября 2014 г.  | Хербст       | /Подпись/       |

Проверил и выпустил:

|            | Отдел                                | Дата              | Имя, фамилия | Подпись   |
|------------|--------------------------------------|-------------------|--------------|-----------|
| Участник 1 | Отдел научно-исследовательских работ | 11 ноября 2014 г. | И. Штрайт    | /Подпись/ |
| Участник 2 |                                      |                   |              |           |
| Участник 3 |                                      |                   |              |           |
| Выпустил   | /неразборчиво/                       | 11 ноября 2014 г. | Тиме         | /Подпись/ |

Случай последней модификации формы: новая структура документа с электронной таблицей

|                                                         |              |                 |                                                                 |              |               |
|---------------------------------------------------------|--------------|-----------------|-----------------------------------------------------------------|--------------|---------------|
| Форма составлена Отделом научно-исследовательских работ |              |                 | Форма документа проверена и выпущена Отделом контроля качества: |              |               |
| 06.06.2013                                              | И. Штрайт    | подписал Штрайт | 10.06.2013                                                      | Р. Тиме      | подписал Тиме |
| Дата                                                    | Имя, фамилия | Подпись         | Дата                                                            | Имя, фамилия | Подпись       |

**Управление рисками по устройству**  
**Анализ рисков, оценка и контроль**  
**На основе анализа характера, последствий и важности отказов**

| №                                           | Анализ рисков                                      |                                                                                    |               |                                                                                                                                                                                       |            | Управление рисками                                                                                                                                                                                                                                                                                           |                                                            |                                   |             |                         |                        |                 |                    |                                                                                     |                                 |             |             |
|---------------------------------------------|----------------------------------------------------|------------------------------------------------------------------------------------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|-----------------------------------|-------------|-------------------------|------------------------|-----------------|--------------------|-------------------------------------------------------------------------------------|---------------------------------|-------------|-------------|
|                                             | Опасность                                          | Мед./технолог. Эффект                                                              | S             | Тяжесть нежелательности                                                                                                                                                               | A          | Меры предотвращения                                                                                                                                                                                                                                                                                          | Применимые стандарты                                       | Безопасность                      |             |                         | Осуществление контроля |                 |                    | Оценка остаточного риска                                                            |                                 |             |             |
| Конструкция                                 |                                                    |                                                                                    |               |                                                                                                                                                                                       |            |                                                                                                                                                                                                                                                                                                              |                                                            | Защитные меры                     | Информация  | Эффективность проверки? | Выполнение проверки?   | Запись (записи) | Ответственное лицо | A                                                                                   | Анализ соотношения рисков/выгод |             |             |
| 1 Опасности из-за недостаточности процессов |                                                    |                                                                                    |               |                                                                                                                                                                                       |            |                                                                                                                                                                                                                                                                                                              |                                                            |                                   |             |                         |                        |                 |                    |                                                                                     |                                 |             |             |
| HA10                                        | Опасности из-за недостаточности процессов          | Устройство не является безопасным                                                  | критически    | Риски, связанные с изделием, не определены.                                                                                                                                           | иногда     | Процесс управления рисками для этого устройства устанавливается соответствии с EN/ISO 14971:2009.                                                                                                                                                                                                            | IEC 60601-1:2005 4.2 [TRF]                                 | IEC 60601-1:2005/ EN 60601-1:2006 | да          | -                       | -                      | да              | да                 | Рабочая инструкция процесса RA730 /управление рисками                               | Компания «АЛТ» (ALT)            | невозможно  | неприменимо |
| HA20                                        | Опасности из-за недостаточности процессов          | Нежелательные побочные эффекты (умеренные)                                         | критически    | Определение основных эксплуатационных параметров отсутствует / неправильное.                                                                                                          | иногда     | Основные эксплуатационные параметры определяются в Отчете по управлению рисками.                                                                                                                                                                                                                             | IEC 60601-1:2005 4.3 [TRF]                                 | IEC 60601-1:2005/ EN 60601-1:2006 | да          | -                       | -                      | да              | да                 | Отчет об управлении рисками                                                         | Компания «АЛТ» (ALT)            | невозможно  | неприменимо |
| HA30                                        | неприменимо                                        | неприменимо                                                                        | несущественно | неприменимо                                                                                                                                                                           | невозможно | неприменимо, потому что: Отклонения от этого стандарта не используются. Без альтернативных средств.                                                                                                                                                                                                          | IEC 60601-1:2005 4.5 [TRF]                                 | IEC 60601-1:2005/ EN 60601-1:2006 | неприменимо | неприменимо             | неприменимо            | неприменимо     | неприменимо        | неприменимо                                                                         | неприменимо                     | неприменимо | неприменимо |
| HA40                                        | Опасности из-за недостаточности процессов          | Устройство не является безопасным                                                  | критически    | Устройство не является безопасным при единичном нарушении. Остальные риски не являются приемлемыми, согласно определению в главе 4.2                                                  | невозможно | Возможные условия единичного нарушения описаны кодом [SFC] в соответствующих опасностях в рамках процесса анализа рисков                                                                                                                                                                                     | IEC 60601-1:2005 4.7 [TRF]<br>4.7 a) [TRF]<br>4.7 b) [TRF] | IEC 60601-1:2005/ EN 60601-1:2006 | да          | -                       | -                      | да              | да                 | FB 7302 RAaC (см. этот документ)                                                    | Компания «АЛТ» (ALT)            | невозможно  | неприменимо |
| HA41                                        | Опасности из-за недостаточной разработки процессов | Недостаточная функция: травмы пациента, оператора или третьей стороны, пожар       | критически    | Неудовлетворительное качество внешних процессов НИОКР при разработке, проверке и подтверждении правильности                                                                           | часто      | Формулировка компанией ALT задач при разработке. Окончательная проверка, подтверждение правильности, документирование и выпуск результатов разработки компанией ALT                                                                                                                                          | Руководство по управлению качеством RA 732-735             | неприменимо                       | -           | да                      | -                      | да              | да                 | Проверка и выпуск документов для технических спецификаций                           | Отдел НИОКР                     | невозможно  | неприменимо |
| HA42                                        | Опасности из-за недостаточной разработки процесса  | Утрата безопасности - непредсказуемый характер изменений при использовании системы | критически    | Неадекватная маркировка - неадекватные данные маркировки могут привести к неправильной установке системы, неверной информации для пользователя и неправильному использованию системы. | иногда     | Адекватность этикеток системы проверяется на стадии выпуска проекта и во время заключительных испытаний.                                                                                                                                                                                                     | Руководство по управлению качеством RA 731 -737            | неприменимо                       | -           | да                      | -                      | да              | да                 | Директивные документы: DMR<br>Схема маркировки<br>Протокол заключительных испытаний | F                               | невозможно  | неприменимо |
| HA43                                        | Опасности из-за недостаточной разработки процесса  | Неправильное использование системы                                                 | критически    | Неудовлетворительные правила по применению                                                                                                                                            | часто      | Предполагаемое использование каждой системы ясно обозначено в нескольких документах DHF: Клиническая оценка (основной документ), руководство пользователя (UM), документы по управлению рисками, DMR/DHR                                                                                                     | Руководство по управлению качеством RA 730-737             | неприменимо                       | -           | да                      | -                      | да              | да                 | Контрольный список, руководство пользователя<br>Документы DHF                       | ZI<br>PJL                       | невозможно  | неприменимо |
| HA44                                        | Опасности из-за недостаточной разработки процесса  | Неправильная плотность мощности и, возможно, неадекватная защита глаз              | незначительно | Неудовлетворительная спецификация на комплектующие изделия и компоненты, используемые с устройством                                                                                   | часто      | Дополнительные принадлежности системы указаны с кодовым номером. В процедурах заключительных испытаний идентифицированы все дополнительные принадлежности, а их доставка проверяется для каждого блока. Дополнительные принадлежности указаны в руководстве по эксплуатации и ясно обозначено их применение. | Руководство по управлению качеством RA 730-737             | неприменимо                       | -           | да                      | -                      | да              | да                 | Контрольный список, руководство пользователя<br>Документы DHF<br>Главный DHR        | ZI<br>PJL                       | невозможно  | неприменимо |

Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| №    | Анализ рисков                             |                                            |               |                                                                                                                                                           |        | Управление рисками                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                |                                                                 |             |               |            |                         |                                                                                                                                                                                                                                                                                             |                                                                                                                                                          |                      |                  | Оценка остаточного риска   |                                 |
|------|-------------------------------------------|--------------------------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-------------|---------------|------------|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|----------------------------|---------------------------------|
|      | Опасность                                 | Мех./Анализ/Эффект                         | S             | Типичная неисправность                                                                                                                                    | A      | Первая оценка                                                                                                                                                                                                                                                                                                                                                                                          | Меры предотвращения                                                                                                                                                                                                                                                                            | Применяемые стандарты                                           | Конструкция | Защитные меры | Информация | Эффективность проверки? | Выполнение проверки?                                                                                                                                                                                                                                                                        | Данные (записи)                                                                                                                                          | Отвественное лицо    | A                | Снижение остаточного риска | Анализ соотношения рисков/выгод |
| HA50 | Опасности из-за недостаточности процессов | Устройство не является безопасным          | незначительно | Типовое испытание не проведено                                                                                                                            | иногда | Меры предотвращения                                                                                                                                                                                                                                                                                                                                                                                    | Выполнение типового испытания MedioStar в соответствии с 60601-1<br>У готовой продукции должны быть следующие минимальные проверяемые параметры (в протоколе заключительных испытаний):<br>- ток утечки<br>- диэлектрическая прочность<br>- защитное заземление<br>- выходное излучение лазера | IEC 60601-1:2005 5.1 [TRF]<br>IEC 00601-1:2005/ EN 60601-1:2006 | да          | -             | -          | да                      | да                                                                                                                                                                                                                                                                                          | Типовое испытание: Протокол испытаний согласно IEC 60601-1<br><br>Заключительные испытания при производстве: 1591 08 200 JPA MSPRO 1591 08 201 FTR MSPRO | Компания «АЛТ» (ALT) | если ли возможно |                            | неприменено                     |
| HA60 | Опасности из-за недостаточности процессов | Нежелательные побочные эффекты (умеренные) | критически    | Невозможна техническая условия испытаний                                                                                                                  | иногда | Наименее благоприятные условия эксплуатации следующие:<br>Напряжение питания: 115 В (115 В переменного тока из-за преобразования подачи питания)<br>Частота сети: 50 Гц<br><br>Температура: 30 °C<br>Относительная влажность: 70% (без конденсации)<br>Давление воздуха: макс. 2 000 м над уровнем моря<br><br>Проведение испытаний согласно пункта 5.4 а)                                             | IEC 60601-1:2005 5.4 а) [TRF]<br>IEC 60601-1:2005/ EN 60601-1:2006                                                                                                                                                                                                                             | да                                                              | -           | -             | да         | да                      | Протокол испытаний согласно IEC 60601-1                                                                                                                                                                                                                                                     | «ЛП А» (LGA)                                                                                                                                             | невозможно           |                  | неприменено                |                                 |
| HA70 | Опасности из-за недостаточности процессов | Нежелательные побочные эффекты (умеренные) | критически    | Отказ встроенных программ / программного обеспечения и/или невыполнение требующихся операций и/или отсутствующая / некачественная / неполная документация | иногда | неприменно, потому что требования этого пункта 14 применяются к ПЭМС (соответствие определяется по требованиям в главах 14.2 - 14.13)<br>Разработка программного обеспечения согласно EN 60601-1:2006, пункт 14 / EN 62304: 2006 / AC:2008                                                                                                                                                             | IEC 60601-1:2005 14.1 [TRF]<br>IEC C0601-1:2005/ EN 60601-1:2006                                                                                                                                                                                                                               | да                                                              | -           | -             | да         | да                      | Разработка программного обеспечения для рабочей инструкции процесса<br><br>Уровень обозначенности                                                                                                                                                                                           | IS<br>RH                                                                                                                                                 | невозможно           |                  | неприменено                |                                 |
| HA80 | Опасности из-за недостаточности процессов | Нежелательные побочные эффекты (умеренные) | критически    | Данные отсутствуют / недостаточная безопасность данных                                                                                                    | иногда | В настоящем документе рассмотрены опасности, связанные с программными и аппаратными аспектами программируемой электронной медицинской системы, включая опасности, которые связаны со связностью сетей/данных, компонентами сторонних поставщиков и неисследованными подсистемами                                                                                                                       | IEC 60601-1:2005 14.6.1 [TRF]<br>IEC 60601-1:2005/ EN 60601-1:2006                                                                                                                                                                                                                             | да                                                              | -           | -             | да         | да                      | РА730 Управление рисками<br><br>Разработка программного обеспечения для рабочей инструкции процесса<br><br>FB 7302 RAaC (см. данный документ, HA1450/ HA1470 / HA1481 / HA1482 / HA760 / HA780 / HA1480 / HA690 / HA700 / HA710 / HA720 / HA770 / HA790 / HA800)                            | IS                                                                                                                                                       | невозможно           |                  | неприменено                |                                 |
| HA90 | Опасности из-за недостаточности процессов | Нежелательные побочные эффекты (умеренные) | критически    | Неправильные результаты анализа из-за отсутствующих или неправильных средств                                                                              | иногда | В дополнение к подпункту 6.1 ISO 14971, будут выбраны и идентифицированы надлежащим образом подтвержденные средства и процедуры для реализации каждого действия по управлению рисками. Эти средства и процедуры должны быть надлежащими, чтобы гарантировать, что каждое действие по управлению рисками удовлетворительным образом снижает уровень идентифицированных рисков<br><br>разработка удобной | IEC 60601-1:2005 14.6.2 [TRF]<br>IEC 606011:2005/ EN 60601-1:2006                                                                                                                                                                                                                              | да                                                              | -           | -             | да         | да                      | Рабочая инструкция процесса РА730 Управление рисками<br><br>Концепция управления рисками и отчет<br><br>FB 7302 RAaC (см. данный документ, HA1450 / HA1470 / HA1481 / HA1482 / HA760 / HA780 / HA1480 / HA690 / HA700 / HA710 / HA720 / HA770 / HA790 / HA800)<br><br>Протоколы верификации | IS<br><br>Мно<br>Мно                                                                                                                                     | невозможно           |                  | неприменено                |                                 |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков |                                            |                                            |            |                                                                                                                                                           |        | Управление рисками                                                                                                                                                                                                                                                                                      |                              |                                   |             |               |                        |                         |                       |                                                                                                                                                                                                                                                                                                                                                                                                                   |                          |                          |                                 |
|---------------|--------------------------------------------|--------------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------------|-------------|---------------|------------------------|-------------------------|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|---------------------------------|
|               |                                            |                                            |            |                                                                                                                                                           |        | Безопасность                                                                                                                                                                                                                                                                                            |                              |                                   |             |               | Осуществление контрмер |                         |                       |                                                                                                                                                                                                                                                                                                                                                                                                                   | Оценка остаточного риска |                          |                                 |
| №             | Опасность                                  | Мед./технолог. Эффект                      | S          | Причина неисправности                                                                                                                                     | A      | Первая оценка                                                                                                                                                                                                                                                                                           |                              | Применяемые стандарты             | Конструкция | Защитные меры | Информация             | Эффективность проверки? | Выполнение проверено? | Запись (записи)                                                                                                                                                                                                                                                                                                                                                                                                   | Ответственное лицо       | Анализ остаточного риска | Анализ соотношения рисков/выгод |
|               |                                            |                                            |            |                                                                                                                                                           |        | Меры противодействия                                                                                                                                                                                                                                                                                    |                              |                                   |             |               |                        |                         |                       |                                                                                                                                                                                                                                                                                                                                                                                                                   |                          |                          |                                 |
| HA100         | Опасности из-за недостаточности процессов. | Нежелательные побочные эффекты (умеренные) | критически | Техническое требование отсутствует / недостаточно                                                                                                         | иногда | Для ПЭМС и каждой из ее подсистем (например, для PESS) должна быть документирована спецификация требований:<br>- ТЭПО (только одна ПЭМС)<br>- SDS (два PESS, главный + подчиненный)<br>- Меры по управлению рисками только в подчиненном                                                                | IEC 60601-1:2005 14.7 [TRF]  | IEC 60601-1:2005/ EN 60601-1:2006 | да          | -             | -                      | да                      | да                    | Спецификация требований по программному обеспечению<br><br>Схема архитектуры<br>Спецификация на архитектуру программного обеспечения                                                                                                                                                                                                                                                                              | RH                       | невозможно               | исприменно                      |
| HA110         | Опасности из-за недостаточности процессов. | Нежелательные побочные эффекты (умеренные) | критически | Отсутствует спецификация архитектуры                                                                                                                      | иногда | Для ПЭМС и каждой из ее подсистем, должна быть указана, архитектура, которая должна удовлетворять спецификации требований:<br>- ТЭПО (только одна ПЭМС)<br>- SDS (два PESS, главный + подчиненный)                                                                                                      | IEC 60601-1:2005 14.8 [TRF]  | IEC 60601-1:2005/ EN 60601-1:2006 | да          | -             | -                      | да                      | да                    | Спецификация на архитектуру программного обеспечения                                                                                                                                                                                                                                                                                                                                                              | RH                       | невозможно               | исприменно                      |
| HA120         | Опасности из-за недостаточности процессов. | Нежелательные побочные эффекты (умеренные) | критически | Отказ встроенных программ / программного обеспечения и/или невыполнение требующихся операций и/или отсутствующая / некачественная / неполная документация | иногда | Конструкция была разбита на следующие подсистемы<br>- Главный процесс<br>- Подчиненный процесс<br><br>Для каждой подсистемы должны быть подготовлены спецификации на проект и испытания.                                                                                                                | IEC 60601-1:2005 14.9 [TRF]  | IEC 60601-1:2005/ EN 60601-1:2006 | да          | -             | -                      | да                      | да                    | Управление конфигурацией программного обеспечения<br><br>Спецификация требований по программному обеспечению:<br>Схема архитектуры<br>Проект программного обеспечения<br>Спецификация:<br>ГИП, центральный блок<br>ГИП, диод<br>ГИП, служба<br>Апликатор<br>Подчиненный, начальная нагрузка<br>Подчиненный, система охлаждения<br>Подчиненный, диод<br>Подчиненный, оборудование<br>Подчиненный, центральный блок | RH                       | невозможно               | исприменно                      |
| HA130         | Опасности из-за недостаточности процессов. | Нежелательные побочные эффекты (умеренные) | критически | Отсутствует / недостаточное планирование верификации                                                                                                      | иногда | Верификация должна быть проведена для всех функций, которые реализуют основные меры безопасности, основные показатели или действия по управлению рисками.<br>Верификация должна быть выполнена в соответствии с планом верификации.<br>Результаты верификации должны быть зафиксированы в документации. | IEC 60601-1:2005 14.10 [TRF] | IEC 60601-1:2005/ EN 60601-1:2006 | да          | -             | -                      | да                      | да                    | Программное обеспечение для проверки                                                                                                                                                                                                                                                                                                                                                                              | RH                       | невозможно               | исприменно                      |
| HA140         | Опасности из-за недостаточности процессов  | Нежелательные побочные эффекты (умеренные) | критически | Отсутствует / недостаточное планирование валидации                                                                                                        | иногда | План подтверждения ПЭМС должен указывать подтверждение базовой безопасности и основные параметров производительности, и должен требовать проверки случайного срабатывания ПЭМС.<br>Верификация ПЭМС должна                                                                                              | IEC 60601-1:2005 14.11 [TRF] | IEC 60601-1:2005/ EN 60601-1:2006 | да          | -             | -                      | да                      | да                    | Программное обеспечение для проверки                                                                                                                                                                                                                                                                                                                                                                              | CaM                      | невозможно               | исприменно                      |

Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| №     | Анализ рисков                                                                                                                                    |                                                                                                                        |                   |                                                                                                             |                       | Управление рисками                                                                                                                                                                                                                                                                |                                                                                                                              |                                                     |                        |               |              |                         |                          |                                                                                                                                              |                    |                   |                           |                                 |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|------------------------|---------------|--------------|-------------------------|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|---------------------------|---------------------------------|
|       |                                                                                                                                                  |                                                                                                                        |                   |                                                                                                             |                       | Безопасность                                                                                                                                                                                                                                                                      |                                                                                                                              |                                                     | Осуществление контрмер |               |              |                         | Оценка остаточного риска |                                                                                                                                              |                    |                   |                           |                                 |
|       | №                                                                                                                                                | Опасность                                                                                                              | Механизмы эффекта | S                                                                                                           | Причина неисправности | A                                                                                                                                                                                                                                                                                 | Меры предотвращения                                                                                                          | Применимые стандарты                                | Конструкция            | Защитные меры | Информация   | Эффективность проверки? | Выполнение проверки?     | Данные (таблица)                                                                                                                             | Ответственное лицо | A                 | Степень остаточного риска | Анализ соотношения рисков/выгод |
|       |                                                                                                                                                  |                                                                                                                        |                   |                                                                                                             |                       |                                                                                                                                                                                                                                                                                   | Бить выполнена в соответствии с планом верификации ПЭМС. Результаты верификации ПЭМС должны быть зафиксированы в документах. |                                                     |                        |               |              |                         |                          |                                                                                                                                              |                    |                   |                           |                                 |
| HA150 | Опасности из-за недостаточности процессов                                                                                                        | Нежелательные побочные эффекты (умеренные)                                                                             | критически        | Отсутствует спецификация на условия сети                                                                    | невозможно            | неприменяемо, потому что ПЭМС не предназначена для использования в сети. Нет сетевого интерфейса                                                                                                                                                                                  | IEC 60601-1:2005 14.13 [TRF]                                                                                                 | IEC 60601-1:2005/ EN 60601-1:2006                   | неприменяемо           | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо             | неприменяемо                                                                                                                                 |                    | неприменяемо      | невозможно                | неприменяемо                    |
| HA165 | Опасности из-за неудовлетворительного процесса закупок                                                                                           | Поступающие товары не соответствуют требованиям, что нарушает производственный процесс                                 | незначительно     | Неудовлетворительный контроль за материалами и недостаточно информации о совместимости материалов           | часто                 | Покупка деталей с опубликованными документами в соответствии с процедурами компании ALT. Входной контроль выбранных деталей                                                                                                                                                       | Руководство по управлению качеством RA 737 RA 7410 RA 7412-14 RA 8242                                                        | неприменяемо                                        | -                      | да            | -            | да                      | да                       | Протоколы о публикации документов<br>Протоколы входного контроля                                                                             | F                  | невозможно        |                           | неприменяемо                    |
| HA166 | Опасности из-за неудовлетворительного процесса закупок                                                                                           | Поступающие товары не соответствуют требованиям, что нарушает производственный процесс                                 | незначительно     | Недостаточный контроль субподрядчиков                                                                       | часто                 | Анализ стандартных неполадок<br>Оценка поставщиков<br>Аудит поставщиков                                                                                                                                                                                                           | Руководство по управлению качеством RA 720 RA 7412-14 RA 8242                                                                | неприменяемо                                        | -                      | да            | -            | да                      | да                       | Недостаточная статистическая оценка документов поставщиков<br>Заключения аудиторов                                                           | F                  | невозможно        |                           | неприменяемо                    |
| HA170 | Недостаточная спецификация на эксплуатацию и техническое обслуживание (неправильное обращение)                                                   | Нарушение процедуры лечения                                                                                            | незначительно     | Недостаточное описание использования и техобслуживания                                                      | иногда                | Описание процедур по эксплуатации и техническому обслуживанию<br>Проверка эксплуатационной пригодности (процедура)                                                                                                                                                                | EN 62366:2008 4.1, 5.3, 6                                                                                                    | EN 60601-1-6:2010<br>EN 62366:2008/ IEC 62366:2007  | да                     | -             | да           | да                      | да                       | Руководство пользователя<br>Файл эксплуатационной пригодности                                                                                | ZI                 | сдана ли возможно |                           | неприменяемо                    |
| HA186 | Недостаточная спецификация на эксплуатацию и техническое обслуживание (снижение качества оборудования)                                           | Неправильные процедуры применения, поломки устройства, нанесение ущерба                                                | незначительно     | Неудовлетворительно техническое обслуживание                                                                | иногда                | Описание процедуры технического обслуживания<br>Проверка эксплуатационной пригодности (техническое обслуживание)                                                                                                                                                                  | EN 62366:2008 4.1, 5.3, 6                                                                                                    | EN 60601-1-6:2010<br>EN 62366:2008 / IEC 62366:2007 | да                     | -             | да           | да                      | да                       | Руководство пользователя<br>Файл эксплуатационной пригодности<br>Руководство по обслуживанию                                                 | ZI                 | сдана ли возможно |                           | неприменяемо                    |
| HA190 | Отсутствует или недостаточная спецификация на техническое обслуживание (неправильные выходные значения, опасность поражения электрическим током) | Отсутствует или слишком незначительный герметизирующий эффект поражения электрическим током<br>Передозировка процедуры | критически        | Разная оптика аппликаторов, недостаточное техобслуживание, не допускается открытие устройства пользователем | иногда                | Описание процедуры технического обслуживания.<br>Простота очистки устройства.<br>В руководстве пользователя определена ежегодная проверка на безопасность. Уполномоченный персонал для настройки и обслуживания. Проверка эксплуатационной пригодности (техническое обслуживание) | EN 62366:2008 4.1, 5.3, 6                                                                                                    | EN 60601-1-6:2010<br>EN 62366:2008 / IEC 62366:2007 | да                     | -             | да           | да                      | да                       | Руководство пользователя<br>Контрольный список, руководство пользователя<br>Файл эксплуатационной пригодности<br>Руководство по обслуживанию | ZI                 | невозможно        |                           | неприменяемо                    |
| HA201 | Опасности из-за недостаточного техобслуживания и обслуживания процессов                                                                          | Ухудшение безопасности или эксплуатационных характеристик устройства                                                   | незначительно     | Неудовлетворительно техническое обслуживание                                                                | иногда                | Техобслуживание предоставляется или напрямую компанией ALT (Германия, Австрия) или оптовым торговцем. Со всеми оптовыми торговцами заключены договоры на обслуживание с предоставлением техобслуживания.                                                                          | Руководство по управлению качеством                                                                                          | неприменяемо                                        | -                      | да            | -            | да                      | да                       | Договоры на обслуживание, протоколы установки и обслуживания                                                                                 | Набор              | сдана ли возможно |                           | неприменяемо                    |
| HA210 | Отсутствует указание на срок службы (разрушение аппликатора или оптики)                                                                          | Отсутствует или слишком незначительный герметизирующий эффект<br>Побочные эффекты                                      | незначительно     | Истечение срока аппликатора из-за продолжительного использования                                            | иногда                | Указание предполагаемого срока эксплуатации в руководстве пользователя или руководстве по обслуживанию - медицинское электрооборудование: 5 - 6 лет - Контактные части, 12 месяцев - выполнение раз в год ежегодного техобслуживания и технической проверки на безопасность       | IEC 60601-1:2005 4.4 [TRF]<br>EN 62366:2008 4.1, 5.3                                                                         | EN 60601-1-6:2010<br>EN 62366:2008 / IEC 62366:2007 | да                     | -             | -            | да                      | да                       | Отчет об управлении рисками, руководство пользователя                                                                                        | Мно<br>ZI          | невозможно        |                           | неприменяемо                    |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| №     | Анализ рисков                                                   |                                                                                |                       |                                                                                           |                       | Управление рисками |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                     |                        |             |               |            |                         |                          |                                                                                                                                                                     |                   |            |                    |                                 |
|-------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|-----------------------|-------------------------------------------------------------------------------------------|-----------------------|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|------------------------|-------------|---------------|------------|-------------------------|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------|--------------------|---------------------------------|
|       |                                                                 |                                                                                |                       |                                                                                           |                       | Безопасность       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                     | Осуществление контроля |             |               |            |                         | Оценка остаточного риска |                                                                                                                                                                     |                   |            |                    |                                 |
|       | №                                                               | Опасность                                                                      | Мед./технолог. Эффект | S                                                                                         | Причина неисправности | A                  | Первая оценка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Меры противодействия                                                | Применяемые стандарты  | Конструкция | Защитные меры | Информация | Эффективность проверки? | Выполнение проверено?    | Запись (записи)                                                                                                                                                     | Отвественное лицо | A          | Оценки остаточного | Анализ соотношения рисков/выгод |
| HA211 | Опасности из-за неудовлетворительных производственных процессов | Недостаточная функция<br>Травмы пациента, оператора или третьей стороны, пожар | критически            | Неудовлетворительное качество внешних производственных процессов                          | иногда                |                    | Поставщик, чьи производственные процессы были определены и проверены (например, согласно ISO 9001 и т.п.).<br>Оценка поставщиков компанией ALT и, при необходимости, проведения аудиторских проверок<br>Поставщик с многолетним опытом работы с медицинской продукцией или с долгосрочным сотрудничеством с компанией ALT<br>Проверка готовых изделий согласно утвержденным процедурам и окончательная приемка компанией ALT                                                                                                             | Руководство по управлению качеством<br>РА 7412-7414                 | исприменено            | -           | да            | -          | да                      | да                       | Отчеты об оценке поставщиков<br>Заключения аудиторов<br>Протоколы испытаний поставщика, протоколы испытаний компании ALT                                            | F                 | невозможно |                    | исприменено                     |
| HA212 | Опасности из-за неудовлетворительных производственных процессов | Недостаточная функция<br>Травмы пациента, оператора или третьей стороны, пожар | критически            | Неудовлетворительное качество поставленных деталей, компонентов                           | иногда                |                    | Проверка поставщика по градуированной шкале уровней опасности продукции<br>Критически важные детали со свидетельством об испытаниях, сертификацией и наблюдением за производством владельца проверяемой торговой марки<br>Оценка поставщиков компанией ALT и, при необходимости, проведения аудиторских проверок<br>Поставщик с многолетним опытом работы с медицинской продукцией или с долгосрочным сотрудничеством с компанией ALT<br>Проверка готовых изделий согласно утвержденным процедурам и окончательная приемка компанией ALT | Руководство по управлению качеством<br>РА 7412-7414<br>РА 7410      | исприменено            | -           | да            | -          | да                      | да                       | Сертификаты<br>Протоколы испытаний поставщика, протоколы испытаний компании ALT, отчеты об оценке поставщиков<br>Заключения аудиторов                               | F                 | невозможно |                    | исприменено                     |
| HA213 | Опасности из-за неудовлетворительных производственных процессов | Недостаточная функция<br>Травмы пациента, оператора или третьей стороны, пожар | критически            | Неадекватные или неправильные изготовление и испытания                                    | иногда                |                    | Спецификации для производства и испытаний согласно разработке проекта и процессам изменений компании ALT, а также соблюдение стандартов проверены и опубликованы.<br>Эффективность и соответствие постоянно контролируются через непрерывное наблюдение за рынком и получение обратной связи от отделов обслуживания, продаж, поставки и пр. согласно системе контроля качества компании ALT                                                                                                                                             | Руководство по управлению качеством<br>РА 73-1-737<br>РА 8242, 8243 | исприменено            | -           | да            | -          | да                      | да                       | Файл соответствия<br>Проверка и публикация документов DHR DMR                                                                                                       | F                 | невозможно |                    | исприменено                     |
| HA214 | Опасности из-за неудовлетворительных производственных процессов | Недостаточная функция<br>Травмы пациента, оператора или третьей стороны, пожар | критически            | Неадекватные или неправильные изготовление и испытания<br>Недостаточно обученный персонал | иногда                |                    | Привлечение только специалистов (инженеров, техников)<br>Хорошо обученный персонал в проверяемой компании, с многолетним опытом работы при изготовлении и испытаниях такой продукции.<br>100% проверка готовых изделий / записей операций по                                                                                                                                                                                                                                                                                             | Руководство по управлению качеством<br>РА 6101<br>РА 6221           | исприменено            | -           | да            | -          | да                      | да                       | Протоколы обучения и квалификационные аттестаты занятию на производстве персонала<br>100% проверка готовых изделий и протоколы испытаний системой контроля качества | F OS              | невозможно |                    | исприменено                     |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков                                                                                             |                                                                         |                                                                             |               |   |                                                                                                                                                                                     |            |                                                                                                                                                                                                                                                                                   |                                                            |                                    | Управление рисками     |              |                         |                       |                           |                                                                                                                                                    |                           |                           |                                 |  |
|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|-----------------------------------------------------------------------------|---------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|------------------------------------|------------------------|--------------|-------------------------|-----------------------|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------------|---------------------------------|--|
|                                                                                                           |                                                                         |                                                                             |               |   |                                                                                                                                                                                     | Исходность |                                                                                                                                                                                                                                                                                   |                                                            |                                    | Осуществление контрмер |              |                         |                       | Уровень остаточного риска |                                                                                                                                                    |                           |                           |                                 |  |
| №                                                                                                         | Зародыш                                                                 | Идентификация                                                               | Эффект        | S | Причина неисправности                                                                                                                                                               | A          | Меры противодействия                                                                                                                                                                                                                                                              | Применены ли стандарты                                     | Конструкция                        | Защитные меры          | Информация   | Эффективность проверки? | Выполнение проверено? | Запись (записи)           | Ответственное лицо                                                                                                                                 | A                         | Уровень остаточного риска | Анализ соотношения рисков/выгод |  |
|                                                                                                           |                                                                         |                                                                             |               |   |                                                                                                                                                                                     |            | Меры противодействия                                                                                                                                                                                                                                                              |                                                            |                                    |                        |              |                         |                       |                           |                                                                                                                                                    |                           |                           |                                 |  |
| HA215                                                                                                     | Опасности из-за недостаточного техобслуживания и обслуживания процессов | Недостаточная функция Гравим пациента, оператора или третьей стороны, пожар | критически    |   | не отвечает требованиям Техническое обслуживание и обслуживание из-за отсутствия спецификаций или из-за их несоответствия                                                           | иногда     | Использование только утвержденной документации обслуживания. Перед присылкой продукции все внесенные изменения проходят всеобъемлющие испытания, которые осуществляются опытными сотрудниками                                                                                     | Руководство по управлению качеством PA 731 PA 737          | неприменяемо                       | -                      | да           | -                       | да                    | да                        | Руководство по обслуживанию Изменение и публикация документов                                                                                      | Набор                     | невозможно                | неприменяемо                    |  |
| HA216                                                                                                     | Опасности из-за недостаточного техобслуживания и обслуживания процессов | Недостаточная функция Гравим пациента, оператора или третьей стороны, пожар | критически    |   | не отвечает требованиям Техническое обслуживание и обслуживание персонала без достаточной квалификации и уровня обучения                                                            | иногда     | Работы выполняет только должным образом обученный персонал (компания ALT, оптовые торговцы), прошедший обучение у опытных техников компании ALT. Обучение персонала внутри компании сотрудниками отдела научно-исследовательских работ                                            | Руководство по управлению качеством PA 6221 PA 6222        | неприменяемо                       | -                      | да           | -                       | да                    | да                        | Протоколы обучения и квалификационные тесты сотрудников компании и технических специалистов со стороны. Руководство по обслуживанию                | Набор                     | невозможно                | неприменяемо                    |  |
| HA217                                                                                                     | Опасности из-за неудовлетворительных процессов транспортировки          | Недостаточная функция Гравим пациента, оператора или третьей стороны, пожар | незначительно |   | Не отвечающая требованиям упаковка может привести к механическим повреждениям, повреждением из-за вибрации или слюна жидкости.                                                      | иногда     | Утвержденная упаковка. Испытания во время установки.                                                                                                                                                                                                                              | Руководство по управлению качеством PA 731 PA 7651 PA 7552 | неприменяемо                       | -                      | да           | -                       | да                    | да                        | Проверка упаковки, инструкции по упаковке                                                                                                          | F                         | невозможно                | неприменяемо                    |  |
| HA218                                                                                                     | Опасности из-за неудовлетворительных производственных процессов         | Гравим пациентов и/или операторов                                           | незначительно |   | Система не соответствует требованиям из-за недостаточного контроля за производственными процессами - неправильная или устаревшая документация для сборки и заключительных испытаний | часто      | Управление документацией, применяемой при производстве и заключительные испытания выполняются в соответствии с внутренними процедурами компании. Квалифицированный производственный персонал 100% проверка готовых изделий системой контроля качества                             | Руководство по управлению качеством PA 4242 PA 4243        | неприменяемо                       | -                      | да           | -                       | да                    | да                        | Опубликованные и директивные производственные документы (DMR, DHR). Подписанные записи DHR после окончательной проверки системой контроля качества | F Отдел контроля качества | невозможно                | неприменяемо                    |  |
| HA219                                                                                                     | Опасности из-за неудовлетворительных производственных процессов         | Ухудшение безопасности или эксплуатационных характеристик устройства        | незначительно |   | Недостаточный контроль изменений производственных процессов                                                                                                                         | часто      | Управление изменениями в соответствии с утвержденными процедурами                                                                                                                                                                                                                 | Руководство по управлению качеством PA 737                 | неприменяемо                       | -                      | да           | -                       | да                    | да                        | Изменение и публикация документов DMR. Главный DHR                                                                                                 | F                         | невозможно                | неприменяемо                    |  |
| 2. Опасность поражения электрическим током                                                                |                                                                         |                                                                             |               |   |                                                                                                                                                                                     |            |                                                                                                                                                                                                                                                                                   |                                                            |                                    |                        |              |                         |                       |                           |                                                                                                                                                    |                           |                           |                                 |  |
| 2.1 Опасность сетевого напряжения                                                                         |                                                                         |                                                                             |               |   |                                                                                                                                                                                     |            |                                                                                                                                                                                                                                                                                   |                                                            |                                    |                        |              |                         |                       |                           |                                                                                                                                                    |                           |                           |                                 |  |
| 2.1.1 Сетевое напряжение на проводящих частях корпуса (защитное заземление)                               |                                                                         |                                                                             |               |   |                                                                                                                                                                                     |            |                                                                                                                                                                                                                                                                                   |                                                            |                                    |                        |              |                         |                       |                           |                                                                                                                                                    |                           |                           |                                 |  |
| HA221                                                                                                     | Опасность сетевого напряжения                                           | Гравим в результате удара электрическим током                               | крайне опасно |   | нет защитного заземления на движущихся частях                                                                                                                                       | невозможно | неприменяемо, так как защитное заземление на движущихся частях устройства отсутствует                                                                                                                                                                                             | IEC 60601-1:2005 8.6.3 [TRF]                               | IEC 60601-1:2005 / EN 60601-1:2006 | неприменяемо           | неприменяемо | неприменяемо            | неприменяемо          | неприменяемо              | неприменяемо                                                                                                                                       | неприменяемо              | невозможно                | неприменяемо                    |  |
| HA231                                                                                                     | Опасность сетевого напряжения                                           | Гравим в результате удара электрическим током                               | крайне опасно |   | высокая влажность в течение длительного времени                                                                                                                                     | невозможно | неприменяемо, потому что устройство не подвергается воздействию высокой влажности в течение длительного времени и не предназначен для использования на открытом воздухе. В устройстве не размещаются чувствительные к влажности детали, которые могут привести к опасному случаю. | IEC 60601-1:2005 5.7 [TRF]                                 | IEC 60601-1:2005 / EN 60601-1:2006 | неприменяемо           | неприменяемо | неприменяемо            | неприменяемо          | неприменяемо              | неприменяемо                                                                                                                                       | неприменяемо              | невозможно                | неприменяемо                    |  |
| 2.1.2 Сетевое напряжение на внутренних токопроводящих частях (которые доступны через отверстия в корпусе) |                                                                         |                                                                             |               |   |                                                                                                                                                                                     |            |                                                                                                                                                                                                                                                                                   |                                                            |                                    |                        |              |                         |                       |                           |                                                                                                                                                    |                           |                           |                                 |  |

Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| №     | Анализ рисков                 |                                               |               |                                  |                  | Управление рисками                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                              |                                    |             |               |            |                         |                       |                                                                           |                    | Оценка остаточного риска |                                 |
|-------|-------------------------------|-----------------------------------------------|---------------|----------------------------------|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------|-------------|---------------|------------|-------------------------|-----------------------|---------------------------------------------------------------------------|--------------------|--------------------------|---------------------------------|
|       | Опасность                     | Мед./технолог. Эффект                         | S             | Причина неисправности            | A                | Первичная оценка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Меры противодействия                                                         | Применяемые стандарты              | Конструкция | Защитные меры | Информация | Эффективность проверки? | Выполнение проверено? | Запись (записи)                                                           | Ответственное лицо | A                        | Анализ соотношения рисков/выгод |
| HA240 | Опасность сетевого напряжения | Травма в результате удара электрическим током | крайне опасно | Неправильный дизайн устройства   | иногда           | Меры противодействия:<br>На изделии MedioStar имеется емкость для жидкости. Жидкость находится в замкнутом контуре. Заполнение водой и перелив за пределы устройства. Испытание на переполнение согласно IEC 60601-1, п. 11.6.2.<br>Тип жидкости: BC4<br>Объем: 150 мл (15% от 1000 мл)<br>Продолжительность разлива: 1 минута<br>устройство: наклонено под углом 15° в наименее желательном направлении по сравнению с положением при нормальном использовании<br>После этих процедур, устройство должно пройти необходимую проверку на диэлектрическую прочность и на токи утечки | IEC 60601-1:2005 11.6.2 [TRF]                                                | IEC 60601-1:2005/EN 60601-1:2006   | да          | да            | -          | да                      | да                    | Протокол испытаний согласно IEC 60601-1<br>Проверка Разлив/перелив/утечка | «ЛГА» (LGA)<br>ММО | нельзя                   | исприменно                      |
| HA250 | Опасность сетевого напряжения | Травма в результате удара электрическим током | крайне опасно | Неправильный дизайн устройства   | часто            | Разлив на медицинском электрооборудовании. Закрытый корпус. Только с ультразвуковым гелем при нормальном использовании. Испытание на разлив согласно IEC 60601-1, п. 11.6.3.<br>Тип жидкости: BC4<br>Объем: 200 мл<br>Продолжительность разлива: 1 минута<br>- кремниевый лоток (в верхней части устройства)<br>Тип жидкости: ультразвуковой гель<br>Объем: 10 мл<br>Продолжительность разлива: 1 мин<br>- испытания с гелем на аппликаторе<br>После этих процедур, устройство должно пройти необходимую проверку на диэлектрическую прочность и на токи утечки                     | IEC 60601-1:2005 11.6.3 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005 / EN 60601-1:2006 | да          | да            | -          | да                      | да                    | Протокол испытаний согласно IEC 60601-1<br>Проверка Разлив/перелив/утечка | «ЛГА» (LGA)<br>ММО | нельзя                   | исприменно                      |
| HA260 | Опасность сетевого напряжения | Травма в результате удара электрическим током | крайне опасно | Неправильный дизайн устройства   | иногда           | Заземление жидкостной контура<br>Испытание на калегационность всех шланговых соединений для имитации одной неполадки (протекающее уплотнение)                                                                                                                                                                                                                                                                                                                                                                                                                                       | IEC 60601-1:2005 13.2.6 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/EN 60601 1:2006   | да          | -             | -          | да                      | да                    | Протокол(ы) верификации<br>Проверка Разлив/перелив/утечка                 | «ЛГА» (LGA)        | нельзя                   | исприменно                      |
| HA270 | Опасность сетевого напряжения | Травма в результате удара электрическим током | крайне опасно | Неверное обращение с устройством | едва ли возможно | Выявление опасности из-за неправильного соединения доступных разъемов. Определены следующие интерфейсы:<br>- USB интерфейс<br>- Службный интерфейс (PS2,                                                                                                                                                                                                                                                                                                                                                                                                                            | IEC 60601-1:2005 15.4.1 [TRF]                                                | IEC 60601 1:2005 / EN 60601-1:2006 | да          | -             | -          | да                      | да                    | Протокол(ы) верификации<br>Устройство для проверки                        | ММО                | нельзя                   | исприменно                      |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| на основе анализа характера, последствий и важности отказов |                                                                       |                                               |               |                                                                                                                    |                  |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                  |                                    |             |               |            |                          |                                                               |                                                                    |                        |                    |                                 |
|-------------------------------------------------------------|-----------------------------------------------------------------------|-----------------------------------------------|---------------|--------------------------------------------------------------------------------------------------------------------|------------------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|------------------------------------|-------------|---------------|------------|--------------------------|---------------------------------------------------------------|--------------------------------------------------------------------|------------------------|--------------------|---------------------------------|
| №                                                           | Анализ рисков                                                         |                                               |               |                                                                                                                    |                  | Управление рисками |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                  |                                    |             |               |            |                          |                                                               |                                                                    |                        |                    |                                 |
|                                                             |                                                                       |                                               |               |                                                                                                                    |                  | Безопасность       |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                  | Осуществление контрмер             |             |               |            |                          | Оценка остаточного риска                                      |                                                                    |                        |                    |                                 |
|                                                             |                                                                       |                                               |               |                                                                                                                    |                  | Первая оценка      |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                  |                                    | Конструкция | Защитные меры | Информация | Эффективность проверена? | Выполнение проверено?                                         | Запись (записи)                                                    | Ответственное лицо     | Оценки остаточного | Анализ соотношения рисков/выгод |
| №                                                           | Опасность                                                             | Мед./технолог. Эффект                         | S             | Причина неисправности                                                                                              | A                |                    | Меры противодействия                                                                                                                                                                                                                                                                                                                                                                                                                               | Применяемые стандарты                                                            |                                    |             |               |            |                          |                                                               |                                                                    |                        |                    |                                 |
|                                                             |                                                                       |                                               |               |                                                                                                                    |                  |                    | Sub D)<br>- Сетевой вход<br>- Блокировка дверцы<br>- Интерфейс ножного переключателя<br>- защитное заземление<br>- Интерфейс аппликатора<br><br>Применение разъемов различной формы. Опасность перепутать разъемы для пользователей, пациентов и других лиц отсутствует.<br><br>у источников питания будут разъемы-розетки, у неснабжаемых энергией контактных частей будут разъемы-вилки                                                          |                                                                                  |                                    |             |               |            |                          |                                                               |                                                                    |                        |                    |                                 |
| HA280                                                       | Опасность сетевого напряжения                                         | Травма в результате удара электрическим током | крайне опасно | Попадание жидкости(жидкостей) в устройство. Попадание твердых материалов в устройство.                             | едва ли возможно |                    | Определение класса IP: - IPX0<br><br>Директива 93/42/EEC по медицинским изделиям                                                                                                                                                                                                                                                                                                                                                                   | IEC 60601-1:2005 11.6.5 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601 -1:2006 | да          | -             | да         | да                       | да                                                            | Устройство для проверки<br>Протокол испытаний согласно IEC 60601-1 | ММo<br><br>«ЛГА» (LGA) | невозможно         | испринено                       |
| 2.1.3 Короткое замыкание изоляционного слоя                 |                                                                       |                                               |               |                                                                                                                    |                  |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                  |                                    |             |               |            |                          |                                                               |                                                                    |                        |                    |                                 |
| HA290                                                       | Повышение температуры в оборудовании                                  | Ожоги (незначительные)                        | незначительно | повреждение теплоизоляции                                                                                          | иногда           |                    | испринено, потому что у устройства компактный металлический корпус. Передняя и верхняя панель из пластика только для дизайна. Эти пластиковые части изготовлены из сырья, перечисленного в списке UL. изоляционные детали<br>- Пластиковая крышка аппликатора<br>- бак для жидкости системы охлаждения<br>- металлические трубы контура охлаждения<br><br>Испытание на твердость вдавливанием шарика должно быть выполнено для крышки аппликатора. | IEC 60601-1:2005 8.8.4.1 [TRF]                                                   | IEC 60601-1:2005/ EN 60601-1:2006  | да          | -             | -          | да                       | да                                                            | Протокол испытаний согласно IEC 60601-1                            | «ЛГА» (LGA)            | невозможно         | испринено                       |
| HA300                                                       | Опасное напряжение при физическом контакте (Источник питания)         | Поражение электрическим током<br>Возгорание   | критически    | Контакт с токоведущими частями под сетевым напряжением<br>Пробой основной изоляции                                 | едва ли возможно |                    | - 1xMOPP, защитное заземление корпуса<br>- 2xMOPP до контактных частей<br>- Корпус устройства можно открыть только с помощью инструментов                                                                                                                                                                                                                                                                                                          | Директива 93/42/EEC по медицинским изделиям                                      | да                                 | -           | -             | да         | да                       | Протокол испытаний согласно IEC 60601-1<br><br>Схема изоляции | «ЛГА» (LGA)<br><br>ММo                                             | невозможно             | испринено          |                                 |
| HA310                                                       | Опасное напряжение при физическом контакте                            | Ожоги (незначительные)                        | критически    | Контакт с током короткого замыкания в устройстве и на корпусе, повреждение изоляции, повреждение основной изоляции | едва ли возможно |                    | - 1xMOPP, защитное заземление корпуса<br>- 1xMOPP, SIP/SOP<br>- 2xMOPP до контактных частей<br>- Сетевой предохранитель                                                                                                                                                                                                                                                                                                                            | Директива 93/42/EEC по медицинским изделиям                                      | да                                 | -           | -             | да         | да                       | Протокол испытаний согласно IEC 60601-1<br><br>Схема изоляции | «ЛГА» (LGA)<br><br>ММo                                             | невозможно             | испринено          |                                 |
| HA320                                                       | Опасное напряжение при физическом контакте (Обрыв провода заземления) | Поражение электрическим током                 | критически    | Контакт с опасным напряжением                                                                                      | едва ли возможно |                    | - 1xMOPP, защитное заземление корпуса<br>- 1xMOPP, SIP/SOP<br>- 2xMOPP до контактных частей<br>- Корпус устройства можно открыть только с помощью инструментов.                                                                                                                                                                                                                                                                                    | Директива 93/42/EEC по медицинским изделиям                                      | да                                 | -           | -             | да         | да                       | Протокол испытаний согласно IEC 60601-1<br><br>Схема изоляции | «ЛГА» (LGA)<br><br>ММo                                             | невозможно             | испринено          |                                 |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| №                          | Анализ рисков                                                                       |                                               |               |                                                                                                                                                        |                 | Управление рисками |                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                           |              |               |             |                         |                       |                                                           |                    | Оценка остаточного риска |                                 |
|----------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|--------------|---------------|-------------|-------------------------|-----------------------|-----------------------------------------------------------|--------------------|--------------------------|---------------------------------|
|                            | Опасность                                                                           | Мед./технолог. Эффект                         | S             | Причина неисправности                                                                                                                                  | A               | Первая оценка      | Меры противодействия                                                                                                                                                                                                                                                                                                                                                                                 | Применимые стандарты                                                                      | Безопасность |               |             | Осуществление контроля  |                       |                                                           |                    | Отчетное лицо            | Анализ соотношения рисков/выгод |
|                            |                                                                                     |                                               |               |                                                                                                                                                        |                 |                    |                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                           | Конструкция  | Защитные меры | Информация  | Эффективность проверки? | Выполнение проверено? | Запись (записи)                                           |                    |                          |                                 |
| HA330                      | Опасное напряжение при физическом контакте (Напряжение питания на контактной части) | Поражение электрическим током                 | критически    | Внешний источник питания в условиях единичного нарушения                                                                                               | сда ли возможно | Первая оценка      | - 1xMOPP, защитное заземление корпуса<br>- 1xMOPP, SIP/SOP<br>- 2xMOPP до контактных частей                                                                                                                                                                                                                                                                                                          | Директива 93/42/EEC по медицинским изделиям                                               | да           | -             | -           | да                      | да                    | Протокол испытаний согласно IEC 60601-1<br>Схема изоляции | «ЛГА» (LGA)<br>ММО | невозможно               | неприменимо                     |
| HA340                      | Опасное напряжение при физическом контакте                                          | Травма в результате удара электрическим током | крайне опасно | [SFC] Не закреплены кабели / провода                                                                                                                   | иногда          | Первая оценка      | Крепление проводки с помощью хомутов, зажимов, разъемов с фиксаторов или винтов                                                                                                                                                                                                                                                                                                                      | IEC 60601-1:2005 8.10.2 [TRF]<br>4.7 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | -            | да            | -           | да                      | да                    | Чертежи                                                   | КІ                 | невозможно               | неприменимо                     |
| HA350                      | Опасное напряжение при физическом контакте                                          | Травма в результате удара электрическим током | крайне опасно | Отсутствует / недостаточна оценка того, имеются ли части, которые могут соприкасаться с пациентом, но не поддаются под определение контактных частей   | невозможно      | Первая оценка      | неприменимо, потому что Пациент не находится в бессознательном состоянии или под анестезией и не утратил трудоспособность. Пациент может непреднамеренно коснуться устройства, но характеристики самого устройства отличаются от характеристик контактных частей. Риск для пациента в этом случае не больше, чем для оператора.<br>меры профилактики:<br>- заземление устройства/корпуса<br>- 2xMOPP | IEC 60601-1:2005 4.6 [TRF]                                                                | неприменимо  | неприменимо   | неприменимо | неприменимо             | неприменимо           | неприменимо                                               | неприменимо        | невозможно               | неприменимо                     |
| HA360                      | Опасное напряжение при физическом контакте                                          | Травма в результате удара электрическим током | крайне опасно | [SFC] Движущиеся механические части, острые углы или кромки могут создать опасную ситуацию вследствие повреждения изоляции при сборке или эксплуатации | иногда          | Первая оценка      | - Внутренние кабели и проводка достаточно защищены от трения об острые углы или кромки.<br>- Острые углы и края исключены<br>- Использование дополнительной защиты деталей<br>- Следует соблюдать безопасное расстояние от устройства<br>- Крепление проводки с помощью хомутов, зажимов, разъемов с фиксаторами или винтов                                                                          | IEC 60601-1:2005 8.10.5 [TRF]<br>4.7 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | -            | да            | -           | да                      | да                    | Чертежи                                                   | КІ                 | невозможно               | неприменимо                     |
| 2.2 Опасности токов утечки |                                                                                     |                                               |               |                                                                                                                                                        |                 |                    |                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                           |              |               |             |                         |                       |                                                           |                    |                          |                                 |
| HA370                      | Опасности токов утечки                                                              | Травма в результате удара электрическим током | крайне опасно | Классификация контактной части (частей)                                                                                                                | невозможно      | Первая оценка      | неприменимо, потому что нет других контактных частей кроме аппликаторов (см. 4.6), которые обозначены как части, контактирующие с пациентом и классифицированные как тип В                                                                                                                                                                                                                           | IEC 60601-1:2005 8.3 [TRF]                                                                | неприменимо  | неприменимо   | неприменимо | неприменимо             | неприменимо           | неприменимо                                               | неприменимо        | невозможно               | неприменимо                     |

Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков |                                                                                                    |                                               |               |                                                                                                                                               |                  | Управление рисками                                                                                                                                                                                                                                                                                                         |                                                                                   |                                   |               |                        |                        |                     |                                                                                                                                                                                                                                                |                           |                                 |              |
|---------------|----------------------------------------------------------------------------------------------------|-----------------------------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------|---------------|------------------------|------------------------|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------------------|--------------|
|               |                                                                                                    |                                               |               |                                                                                                                                               |                  | Безопасность                                                                                                                                                                                                                                                                                                               |                                                                                   |                                   |               | Осуществление контроля |                        |                     |                                                                                                                                                                                                                                                | Уровень остаточного риска |                                 |              |
| №             | Описание                                                                                           | Мод./функция/Эффект                           | S             | Потенциальная неисправность                                                                                                                   | A                | Меры противодействия                                                                                                                                                                                                                                                                                                       | Применимые стандарты                                                              | Конструкция                       | Защитные меры | Информация             | Эффективность проверки | Выполнение проверки | Записи (записи)                                                                                                                                                                                                                                | Одобрение лица            | Анализ соотношения рисков/выгод |              |
| HA380         | Опасности токов утечки (в Sub-D/PS2/USB интерфейсу на задней стороне устройства можно прикасаться) | Травма в результате удара электрическим током | крайне опасно | SFC) Прямой или опосредованный контакт пациента с доступными частями, у которых превышен допустимый ток утечки                                | едва ли возможно | Стыки дополнительно закрыты.                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 8.4.2 c) [TRF] 4.7 [TRF]                                         | IEC 60601-1:2005/ EN 60601-1:2006 | -             | да                     | -                      | да                  | Протокол испытаний согласно IEC 60601-1                                                                                                                                                                                                        | «П А» (LGA)               | невозможно                      | неприменяемо |
| HA390         | Опасности токов утечки                                                                             | Травма в результате удара электрическим током | крайне опасно | Прямой или опосредованный контакт пациента с доступными частями, у которых превышен допустимый ток утечки                                     | невозможно       | неприменяемо, потому что пределы, указанные в 8.4.2 b), относятся к                                                                                                                                                                                                                                                        | IEC 60601 1:2005 8.4.2 c) [TRF]                                                   | IEC 60601-1:2005/ EN 60601-1:2006 | неприменяемо  | неприменяемо           | неприменяемо           | неприменяемо        | неприменяемо                                                                                                                                                                                                                                   | неприменяемо              | невозможно                      | неприменяемо |
| HA400         | неприменяемо                                                                                       | неприменяемо                                  | несущественно | неприменяемо                                                                                                                                  | невозможно       | неприменяемо, так как устройство не относится к медицинской технике.                                                                                                                                                                                                                                                       | IEC 60601 1:2005 16.1 [TRF]                                                       | IEC 60601-1:2005/ EN 60601-1:2006 | неприменяемо  | неприменяемо           | неприменяемо           | неприменяемо        | неприменяемо                                                                                                                                                                                                                                   | неприменяемо              | невозможно                      | неприменяемо |
| HA410         | неприменяемо                                                                                       | неприменяемо                                  | несущественно | неприменяемо                                                                                                                                  | невозможно       | неприменяемо, так как устройство не относится к медицинской технике.                                                                                                                                                                                                                                                       | IEC 60601 1:2005 16.9.1 [TRF]                                                     | IEC 60601-1:2005/ EN 60601-1:2000 | неприменяемо  | неприменяемо           | неприменяемо           | неприменяемо        | неприменяемо                                                                                                                                                                                                                                   | неприменяемо              | невозможно                      | неприменяемо |
| HA420         | неприменяемо                                                                                       | неприменяемо                                  | несущественно | неприменяемо                                                                                                                                  | невозможно       | неприменяемо, потому что электрические элементы управления не могут быть удалены без инструментов. Поэтому они не считаются контактными. Маловероятно, что будут случайно отсоединены в течение предполагаемого срока эксплуатации.                                                                                        | IEC 60601 1:2005 5.9.2.3 [TRF]                                                    | IEC 60601-1:2005/ EN 60601-1:2006 | неприменяемо  | неприменяемо           | неприменяемо           | неприменяемо        | неприменяемо                                                                                                                                                                                                                                   | неприменяемо              | невозможно                      | неприменяемо |
| HA430         | Опасное напряжение при физическом контакте                                                         | Общие травмы (умеренный)                      | критически    | Применяются нестандартные знаки                                                                                                               | едва ли возможно | Стандартные знаки безопасности используются на оборудовании согласно IEC 60601-1 п. 7.5.<br>- Следуйте инструкции по использованию (D 2 рис. 10)<br>- Шаблон для создания предупреждающего знака (D 2, рис. 1)                                                                                                             | IEC 60601 1:2005 7.5 [TRF]                                                        | IEC 60601-1:2005/ EN 60601-1:2006 | да            | -                      | да                     | да                  | Схема маркировки<br>Контрольный список этикетки устройства<br>Оценка, EN 980 / EN ISO 15223-1                                                                                                                                                  | MMo                       | невозможно                      | неприменяемо |
| HA440         | Опасное напряжение при физическом контакте                                                         | Травма в результате удара электрическим током | крайне опасно | SFC) Доступная токопроводящая часть (части) недостаточно изолирована от контактной части (частей) типа B, не связанной с защитным заземлением | никогда          | неприменяемо, потому что доступные металлические части физически неразрывно связаны с контактной частью и могут рассматриваться как часть контактной части.<br>- Аппликатор / лазерная насадка - это контактная часть типа B.<br>- Контактные части снабжены защитным заземлением и доступные металлические части (корпус) | IEC 60601-1:2005 8.5.2.2 [TRF] 4.7 [TRF]                                          | IEC 60601-1:2005/ EN 60601-1:2006 | неприменяемо  | неприменяемо           | неприменяемо           | неприменяемо        | неприменяемо                                                                                                                                                                                                                                   | неприменяемо              | невозможно                      | неприменяемо |
| HA450         | неприменяемо                                                                                       | неприменяемо                                  | несущественно | неприменяемо                                                                                                                                  | невозможно       | Никакие провода пациента не идентифицированы как содержащие токопроводящий материал.                                                                                                                                                                                                                                       | IEC 60601-1:2005 8.5.2.3 [TRF]                                                    | IEC 60601-1:2005/ EN 60601-1:2006 | неприменяемо  | неприменяемо           | неприменяемо           | неприменяемо        | неприменяемо                                                                                                                                                                                                                                   | неприменяемо              | невозможно                      | неприменяемо |
| HA460         | Опасное напряжение при физическом контакте                                                         | Травма в результате удара электрическим током | крайне опасно | Неправильный дизайн ножного переключателя / неправильный класс защиты IP                                                                      | никогда          | Имеется ножной переключатель.<br>Класс IP: IPX8                                                                                                                                                                                                                                                                            | IEC 60601 1:2005 15.4.7 3 b) [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006 | да            | да                     | -                      | да                  | протокол испытаний ножного переключателя, см. Список защитных материалов и компонентов Объявление медицинских специалистов Steute IEC 60601-1, -2-22 TR, TÜV + Объявление медицинских специалистов Steute IEC 60601-1, -2-22 TR, TÜV Ergänzung | Mmo (Steute)              | невозможно                      | неприменяемо |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков                                           |                                              |                                                                                                     |               |                                                                                       |                  | Управление рисками |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                      |                                                                            |               |              |                         |                       |                 |                                                                 | Оценка остаточного риска |                          |                                 |
|---------------------------------------------------------|----------------------------------------------|-----------------------------------------------------------------------------------------------------|---------------|---------------------------------------------------------------------------------------|------------------|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|----------------------------------------------------------------------------|---------------|--------------|-------------------------|-----------------------|-----------------|-----------------------------------------------------------------|--------------------------|--------------------------|---------------------------------|
| №                                                       | Опасность                                    | Мед./технолог. Эффект                                                                               | S             | Причина неисправности                                                                 | A                | Первая оценка      | Меры противодействия                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Применяемые стандарты                                | Безопасность                                                               |               |              | Осуществление контрмер  |                       |                 |                                                                 | Оценка остаточного риска |                          |                                 |
|                                                         |                                              |                                                                                                     |               |                                                                                       |                  |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                      | Конструкция                                                                | Защитные меры | Информация   | Эффективность проверки? | Выполнение проверено? | Записи (записи) | Остаточное значение                                             | А                        | Оценка остаточного риска | Анализ соотношения рисков/выгод |
| HA470                                                   | Опасное напряжение при физическом контакте   | Травма в результате удара электрическим током                                                       | крайне опасно | Отказ компонентов, важных для безопасности                                            | невозможно       | Первая оценка      | Меры противодействия: Все компоненты, включая проводку, используются в соответствии с указанными номинальными значениями. Идентификация соответствующих компонентов устройства в списке критически важных компонентов.                                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 4.8 [TRF] 4.8 a) [TRF] 4.8 b) [TRF] | IEC 60601-1:2005/ EN 60601-1:2006                                          | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо          | неприменяемо    | неприменяемо                                                    | невозможно               | неприменяемо             | неприменяемо                    |
| HA480                                                   | Опасное напряжение при физическом контакте   | Травма в результате удара электрическим током                                                       | несущественно | Неполадки компонентов с высокими требованиями к надежности                            | невозможно       | Первая оценка      | Компоненты с высокими требованиями к надежности отсутствуют.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | IEC 60601-1:2005 4.9 [TRF]                           | IEC 60601-1:2005/ EN 60601-1:2006                                          | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо          | неприменяемо    | неприменяемо                                                    | невозможно               | неприменяемо             | неприменяемо                    |
| HA490                                                   | Опасное напряжение при физическом контакте   | Травма в результате удара электрическим током                                                       | крайне опасно | [SFC] Дизайн устройства не представляет особых требований к безопасности              | едва ли возможно | Первая оценка      | Отсутствуют разъемы или проводники, идентифицированные как источник потенциальной опасности в данном устройстве в случае разделения, неслучайного перемещения или отсоединения.<br>- отсоединить 24 В = выключить устройство<br>- отсоединить управляющую линию = выводится сообщение об ошибке (слабые активные сигналы)<br>- отсоединить диодную линию = считывание текущего напряжения и сравнение заданных и измеренных значений<br><br>потенциальная опасность отсутствует, потому что:<br>- устройство выключено или показывает сообщение об ошибке<br>- заземленные корпус и контактная часть | IEC 60601-1:2005 8.1 [TRF] 4.7 [TRF]                 | IEC 60601-1:2005/ EN 60601-1:2006                                          | -             | да           | -                       | да                    | да              | Протокол испытаний согласно IEC 60601-1                         | «ЛГА» (LGA)              | невозможно               | неприменяемо                    |
| 2.3 Электромагнитные опасности (согласно IEC 60601-1-2) |                                              |                                                                                                     |               |                                                                                       |                  |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                      |                                                                            |               |              |                         |                       |                 |                                                                 |                          |                          |                                 |
| HA500                                                   | Опасности, связанные с электрическими полями | Прекращение процедуры (продолжение не представляется возможным, требуются дополнительные процедуры) | критически    | Электромагнитные помехи между компонентами системы и внешними компонентами            | иногда           | Первая оценка      | Проведение испытаний устройства на излучение и защищенность согласно IEC 60601-1, п. 17 и 60601-1-2.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | IEC 60601-1:2005 17 [TRF]                            | IEC 60601-1:2005/ EN 60601-1:2006                                          | -             | да           | -                       | да                    | да              | Отчет по ЭМС согласно IEC 60601-1-2                             | SLG                      | невозможно               | неприменяемо                    |
| HA510                                                   | Опасности, связанные с электрическими полями | Жалоба                                                                                              | незначительно | Отсутствует таблица (таблицы) в руководстве пользователя                              | едва ли возможно | Первая оценка      | Примечание в руководстве пользователя: Руководство пользователя содержит ЭМС-таблицы по излучению и помехозащищенности согласно DIN EN 60601-1-2                                                                                                                                                                                                                                                                                                                                                                                                                                                     | IEC 60601-1:2005 17 [TRF]                            | IEC 60601-1:2005/ EN 60601-1:2006                                          | да            | -            | да                      | да                    | да              | Отчет по ЭМС согласно IEC 60601-1-2<br>Руководство пользователя | SLG<br>ZI                | невозможно               | неприменяемо                    |
| HA520                                                   | Электричество (Контактные части)             | Опасное напряжение при физическом контакте                                                          | критически    | Индукция электрических полей изоляции под действием электрических или магнитных полей | невозможно       | Первая оценка      | действия не требуются, так как риск на приемлемом уровне                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2007      | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN 60601-1-2:2007 | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо          | неприменяемо    | неприменяемо                                                    | невозможно               | неприменяемо             | неприменяемо                    |
| HA530                                                   | Электричество (Источники питания)            | Пробой изоляции на сигнальных линиях                                                                | критически    | электромагнитное воздействие<br>Поврежденная изоляция                                 | невозможно       | Первая оценка      | действия не требуются, так как риск на приемлемом уровне                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2008      | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN                | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо          | неприменяемо    | неприменяемо                                                    | невозможно               | неприменяемо             | неприменяемо                    |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков                           |                                                                               |                                                                                                                  |               |                                                                                       |                  | Управление рисками                                                                                   |                                                                  |                                                                            |              |               |              |                         |                      |                                     |                | Оценка остаточного риска |                |                                  |
|-----------------------------------------|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|---------------|---------------------------------------------------------------------------------------|------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----------------------------------------------------------------------------|--------------|---------------|--------------|-------------------------|----------------------|-------------------------------------|----------------|--------------------------|----------------|----------------------------------|
| №                                       | Опасности                                                                     | Мед./технолог. Эффект                                                                                            | В             | Полноценная неисправность                                                             | A                | Последствия                                                                                          | Меры                                                             | Данные по к. стандарты                                                     | Конструкция  | Защитные меры | Информация   | Эффективность проверки? | Выполнение проверки? | Запись (записи)                     | Оценочное лицо | A                        | Оценочное лицо | Анализ соответствия рисков/выгод |
|                                         |                                                                               |                                                                                                                  |               |                                                                                       |                  |                                                                                                      |                                                                  | 60601-1-2:2007                                                             |              |               |              |                         |                      |                                     |                |                          |                |                                  |
| HA54                                    | Электричество (Источники питания)                                             | Повышенный ток утечки в землю                                                                                    | критически    | Индукция электрических помех изоляции под действием электрических или магнитных полей | невозможно       | действия не требуются, так как риск на приемлемом уровне                                             | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2007                  | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN 60601-1-2:2007 | неприменяемо | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо         | неприменяемо                        | неприменяемо   | невозможно               |                | неприменяемо                     |
| HA55                                    | Аблучаемое тепло (внутренняя система охлаждения)                              | Перегрев                                                                                                         | критически    | Помехи в работе под действием электрических или магнитных полей                       | невозможно       | действия не требуются, так как риск на приемлемом уровне                                             | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2007                  | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN 60601-1-2:2007 | неприменяемо | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо         | неприменяемо                        | неприменяемо   | невозможно               |                | неприменяемо                     |
| HA56                                    | Неионизирующее излучение (внутренняя электроника, включая электронный затвор) | Непреднамеренное изменение скорректированных параметров                                                          | критически    | Индукция энергии Помехи в работе под действием электрических или магнитных полей      | едва ли возможно | Экранирование устройства, Фильтрация выводов, узел ESD                                               | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2007                  | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN 60601-1-2:2007 | да           | -             | -            | да                      | да                   | Отчет по ЭМС согласно IEC 60601-1-2 | SLG            | невозможно               |                | неприменяемо                     |
| HA57                                    | Магнитные поля (магнитные датчики)                                            | Типичные неисправности                                                                                           | критически    | Помехи в работе под действием внешних магнитных полей                                 | едва ли возможно | Экранирование устройства, Фильтрация выводов, узел ESD<br>Конструкция системы согласно IEC 60601-1-2 | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2007                  | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN 60601-1-2:2007 | да           | -             | -            | да                      | да                   | Отчет по ЭМС согласно IEC 60601-1-2 | SLG            | невозможно               |                | неприменяемо                     |
| HA58                                    | Помехи от электромагнитных полей (помехозащищенность)                         | Неисправность устройства<br>Неконтролируемый выброс импульсов конструирующего излучения / неправильные параметры | критически    | Недостаточный скрининг в отношении к внешней ЭМС                                      | никогда          | Экранирование устройства, Фильтрация выводов, узел ESD<br>Конструкция системы согласно IEC 60601-1-2 | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2007                  | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN 60601-1-2:2007 | да           | -             | -            | да                      | да                   | Отчет по ЭМС согласно IEC 60601-1-2 | SLG            | невозможно               |                | неприменяемо                     |
| HA59                                    | Электромагнитные поля (Излучение)                                             | Опасности неисправности в результате неисправности других устройств ЭМС для пользователя/ владельцев             | критически    | Помехи от электромагнитных полей (связанные с сетью, воздух)                          | никогда          | Экранирование устройства, Фильтрация выводов, узел ESD<br>Конструкция системы согласно IEC 60601-1-2 | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2007                  | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN 60601-1-2:2007 | да           | -             | -            | да                      | да                   | Отчет по ЭМС согласно IEC 60601-1-2 | SLG            | невозможно               |                | неприменяемо                     |
| HA60                                    | Ошибка в передаче данных (Повреждение процессора в аппаратной части)          | Неправильные выходные параметры                                                                                  | критически    | Индукция электрических помех в работе под действием электрических или магнитных полей | едва ли возможно | Экранирование устройства, Фильтрация выводов, узел ESD<br>Конструкция системы согласно IEC 60601-1-2 | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2007                  | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN 60601-1-2:2007 | да           | -             | -            | да                      | да                   | Отчет по ЭМС согласно IEC 60601-1-2 | SLG            | невозможно               |                | неприменяемо                     |
| HA61                                    | Ошибка в передаче данных (Повреждено программное обеспечение)                 | Неправильные выходные параметры                                                                                  | критически    | Индукция электрических помех в работе под действием электрических или магнитных полей | едва ли возможно | Экранирование устройства, Фильтрация выводов, узел ESD<br>Конструкция системы согласно IEC 60601-1-2 | IEC 60601-1:2005 17 [TRF]<br>IEC 60601-1-2:2007                  | IEC 60601-1:2005/ EN 60601-1:2006<br>IEC 60601-1-2:2007/ EN 60601-1-2:2007 | да           | -             | -            | да                      | да                   | Отчет по ЭМС согласно IEC 60601-1-2 | SLG            | невозможно               |                | неприменяемо                     |
| 3. Опасности излучения                  |                                                                               |                                                                                                                  |               |                                                                                       |                  |                                                                                                      |                                                                  |                                                                            |              |               |              |                         |                      |                                     |                |                          |                |                                  |
| 3.1 Опасности неионизирующего излучения |                                                                               |                                                                                                                  |               |                                                                                       |                  |                                                                                                      |                                                                  |                                                                            |              |               |              |                         |                      |                                     |                |                          |                |                                  |
| 3.1.1 Опасности излучения               |                                                                               |                                                                                                                  |               |                                                                                       |                  |                                                                                                      |                                                                  |                                                                            |              |               |              |                         |                      |                                     |                |                          |                |                                  |
| HA62                                    | неприменяемо                                                                  | неприменяемо                                                                                                     | несущественно | неприменяемо                                                                          | невозможно       | неприменяемо, так как MedioStar не генерирует рентгеновское излучение                                | IEC 60801-1:2005 10.1.2 [TRF]<br>IEC 60601-1:2005 12.4.5.2 [TRF] | IEC 60601-1:2005/ EN 60601-1:2006                                          | неприменяемо | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо         | неприменяемо                        | неприменяемо   | невозможно               |                | неприменяемо                     |

Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| На основе анализа характера, последствий и важности отказов                        |               |                                                 |                                |             |                                                                            |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                   |                                   |                                    |                        |             |                         |                      |                                                                    |                    |                          |             |
|------------------------------------------------------------------------------------|---------------|-------------------------------------------------|--------------------------------|-------------|----------------------------------------------------------------------------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------|------------------------|-------------|-------------------------|----------------------|--------------------------------------------------------------------|--------------------|--------------------------|-------------|
| №                                                                                  | Анализ рисков |                                                 |                                |             |                                                                            | Первая оценка         | Управление рисками                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                   |                                   |                                    |                        |             |                         |                      |                                                                    |                    |                          |             |
|                                                                                    | Опасность     | Мед./технолог.                                  | Эффект                         | S           | Причина неисправности                                                      |                       | A                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Безопасность                                                                                      |                                   |                                    | Осуществление контрмер |             |                         |                      | Оценка остаточного риска                                           |                    |                          |             |
|                                                                                    |               |                                                 |                                |             |                                                                            |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                   |                                   |                                    |                        |             |                         |                      |                                                                    |                    |                          |             |
|                                                                                    | №             | Опасность                                       | Мед./технолог.                 | Эффект      | S                                                                          | Причина неисправности | A                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Меры противодействия                                                                              | Применяемые стандарты             | Конструкция                        | Защитные меры          | Информация  | Эффективность проверки? | Выполнение проверки? | Запись (записи)                                                    | Ответственное лицо | Оценка остаточного риска |             |
|                                                                                    | HA630         | неприменимо                                     | неприменимо                    | неприменимо | несущественно                                                              | неприменимо           | невозможно                                                                                                                                                                                                                                                                                                                                                                                                                                                          | неприменимо, так как устройство не генерирует радиотерапевтическое излучение                      | IEC 60601-1:2005 12.4.5.3 [TRF]   | IEC 60601-1:2005 / EN 60601-1:2006 | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо                                                        | неприменимо        | неприменимо              |             |
| 3.1.2 Альфа, бета, гамма излучение, нейтронное излучение и излучение других частиц |               |                                                 |                                |             |                                                                            |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                   |                                   |                                    |                        |             |                         |                      |                                                                    |                    |                          |             |
|                                                                                    | HA640         | неприменимо                                     | неприменимо                    | неприменимо | несущественно                                                              | неприменимо           | невозможно                                                                                                                                                                                                                                                                                                                                                                                                                                                          | неприменимо, так как MedioStar не излучает альфа, бета, гамма частицы, нейтроны и другие частицы. | IEC 60601-1:2005 10.2 [TRF]       | IEC 60601-1:2005/ EN 60601-1:2006  | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо                                                        | неприменимо        | неприменимо              |             |
| 3.2 Опасности неионизирующего излучения                                            |               |                                                 |                                |             |                                                                            |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                   |                                   |                                    |                        |             |                         |                      |                                                                    |                    |                          |             |
| 3.2.1 Опасности излучения в видимом диапазоне                                      |               |                                                 |                                |             |                                                                            |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                   |                                   |                                    |                        |             |                         |                      |                                                                    |                    |                          |             |
|                                                                                    | HA645         | неприменимо                                     | неприменимо                    | неприменимо | несущественно                                                              | неприменимо           | невозможно                                                                                                                                                                                                                                                                                                                                                                                                                                                          | неприменимо, так как другое видимое электромагнитное излучение отсутствует                        | IEC 60601-1:2005 10.5 [TRF]       | IEC 60601-1:2005/ EN 60601-1:2006  | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо                                                        | неприменимо        | неприменимо              |             |
| 3.2.2 Опасности излучения в инфракрасном диапазоне                                 |               |                                                 |                                |             |                                                                            |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                   |                                   |                                    |                        |             |                         |                      |                                                                    |                    |                          |             |
|                                                                                    | HA650         | Инфракрасное излучение слишком высокой мощности | Общая травма (средней тяжести) | критически  | Отсутствует оценка риска для диагностического и терапевтического излучения | часто                 | Устройство генерирует терапевтическое излучение. Измерение излучения согласно IEC 60825 и IEC 60601-2-22. Соответствие требованиям. Все риски рассматриваются в настоящем анализе рисков.                                                                                                                                                                                                                                                                           | IEC 60601-1:2005 12.4.5.4 [TRF]                                                                   | IEC 60601-1:2005/ EN 60601-1:2006 | да                                 | -                      | -           | да                      | да                   | Протокол испытаний согласно IEC 60601-2-22                         | «ЛГ А» (LGA)       | неприменимо              |             |
|                                                                                    | HA660         | Инфракрасное излучение слишком высокой мощности | Общая травма (средней тяжести) | критически  | Превышение пределов безопасности                                           | невозможно            | неприменимо, потому что нет преднамеренного превышения пределов безопасности. Пределы безопасности не регулируются, диапазоны задаются через ГАП (плотность энергии, длительность импульса, частота повторения импульсов)<br><br>дополнительная защита благодаря:<br>- Кнопка отключения лазера на передней части корпуса<br>- Устройство сигнализации о неисправностях<br>- Процедура ожидания / готовности<br>- Уведомление: Защитные очки от лазерного излучения | IEC 60601-1:2005 12.4.1 [TRF]                                                                     | IEC 60601-1:2005/ EN 60601-1:2006 | неприменимо                        | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо                                                        | неприменимо        | неприменимо              | неприменимо |
|                                                                                    | HA670         | Инфракрасное излучение слишком высокой мощности | Общая травма (средней тяжести) | критически  | не указаны параметров, имеющие отношение к безопасности                    | иногда                | Все пределы безопасности регулируются с выводом на экран через графический интерфейс пользователя. Пределы безопасности:<br>- Плотность энергии<br>- Длительность импульса<br>- Частота повторения импульсов<br><br>дополнительная защита благодаря:<br>- предупреждение об излучении с помощью звукового сигнала и визуального индикатора<br>- отображение символов с предупреждениями о лазерном излучении                                                        | IEC 60601-1:2005 12.4.2 [TRF]                                                                     | IEC 60601-1:2005/ EN 60601-1:2006 | -                                  | да                     | -           | да                      | да                   | Анализ отслеживаемости Программное обеспечение для проверки, HA120 | RH                 | неприменимо              |             |
|                                                                                    | HA671         | Инфракрасное излучение слишком высокой мощности | Общая травма (средней тяжести) | критически  | Случайный выбор повышенных выходных значений                               | часто                 | Все пределы безопасности регулируются с выводом на экран через графический интерфейс пользователя и должны быть подтверждены.<br>- подтверждение                                                                                                                                                                                                                                                                                                                    | IEC 60601-1:2005 12.4.3 [TRF]                                                                     | IEC 60601-1:2005/ EN 60601-1:2006 | -                                  | да                     | -           | да                      | да                   | Анализ отслеживаемости Программное обеспечение для проверки, HA120 | RH                 | неприменимо              |             |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков |                                                        |                                                                       |            |                                                                                                                                                                                         |        | Управление рисками                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                           |                                          |               |                        |                         |                      |                                                                                                               |                          |                                 |
|---------------|--------------------------------------------------------|-----------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|------------------------------------------|---------------|------------------------|-------------------------|----------------------|---------------------------------------------------------------------------------------------------------------|--------------------------|---------------------------------|
|               |                                                        |                                                                       |            |                                                                                                                                                                                         |        | Безопасность                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                           |                                          |               | Осуществление контроля |                         |                      |                                                                                                               | Оценка остаточного риска |                                 |
| Идентификатор | Описание                                               | Механизм / Эффект                                                     | С          | Детали некорректности                                                                                                                                                                   | А      | Планы предотвращения                                                                                                                                                                                                                                                                                                                                                                                                   | Примечательные стандарты                                                                  | Конструкция                              | Защитные меры | Информация             | Эффективность проверки? | Выполнение проверки? | Данные (записи)                                                                                               | Отчетное лицо            | Анализ соотношения рисков/выгод |
|               |                                                        |                                                                       |            |                                                                                                                                                                                         |        | Исходные параметры /<br>- процедура ожидания /<br>- кнопки переключения для<br>активации лазерных<br>импульсов                                                                                                                                                                                                                                                                                                         |                                                                                           |                                          |               |                        |                         |                      |                                                                                                               |                          |                                 |
| HA680         | Инфракрасное излучение<br>слишком высокой<br>мощности  | Общая травма (средней<br>тяжести)                                     | критически | Неправильный выходной<br>сигнал                                                                                                                                                         | часто  | Пределы безопасности<br>(плотность энергии,<br>длительность импульса,<br>частота повторения<br>импульсов) контролируются<br>аппаратными и программными<br>средствами.<br>- Избыточный контроль за<br>выходными параметрами<br>(контроль мощности).<br>- отклонения отображаются на<br>дисплее (интерфейс<br>пользователя)                                                                                              | IEC 60601-1:2005<br>12.4.4 (TRF)                                                          | IEC 60601-<br>1:2005/ EN<br>60601-1:2006 | -             | да                     | -                       | да                   | Анализ отслеживаемости<br><br>Программное обеспечение<br>для проверки, HA120                                  | RH                       | невозможно<br><br>исприменно    |
| HA690         | Нет ионизирующего<br>излучения – лазерное<br>излучение | Повреждение/травма<br>глаз, травмы от испуга                          | критически | Автоматическая активация<br>(сбой программного<br>обеспечения)                                                                                                                          | иногда | - электронный затвор<br>управляется ножным<br>переключателем, независимо<br>от программного обеспечения<br>- процедура ожидания /<br>готовности<br>- Блокировка дверей                                                                                                                                                                                                                                                 | IEC 60601-1:2005<br>14.6.1<br>(непреднамеренные<br>взаимодействия<br>внутри и среди PESS) | EN 62304: 2006                           | -             | да                     | -                       | да                   | Анализ отслеживаемости<br><br>Программное обеспечение<br>для проверки, HA 120                                 | RH                       | невозможно<br><br>исприменно    |
| HA700         | Нет ионизирующего<br>излучения – лазерное<br>излучение | Повреждение / травма<br>глаз, травма от испуга,<br>травма третьих лиц | критически | Непреднамеренное нажатие на<br>ножной переключатель<br>(лазерное излучение)                                                                                                             | иногда | - процедура ожидания /<br>готовности<br>- Блокировка дверей<br>- Избыточное срабатывание<br>программного и аппаратного<br>обеспечения<br>- ножной переключатель с<br>крышкой<br>- Отклонение лазера в<br>направлении неактивности                                                                                                                                                                                      | IEC 60601-1:2005<br>14.6.1<br>(непреднамеренные<br>взаимодействия<br>внутри и среди PESS) | EN 62304 : 2006                          | -             | да                     | -                       | да                   | Анализ отслеживаемости<br><br>Программное обеспечение<br>для проверки, HA 120                                 | RH                       | невозможно<br><br>исприменно    |
| HA710         | Нет ионизирующего<br>излучения – лазерное<br>излучение | Повреждение / травма<br>глаз, травма от испуга,<br>травма третьих лиц | критически | При размыкании ножного<br>переключателя лазерное<br>излучение не прекращается (в<br>случае неисправности ножного<br>переключателя и/или<br>короткого замыкания на<br>сигнальных линиях) | иногда | - Дублирующее срабатывание<br>программного обеспечения и<br>аппаратных средств (для<br>независимых контактов)<br>- аварийный выключатель<br>лазера                                                                                                                                                                                                                                                                     | IEC 60601-1:2005<br>14.6.1<br>(непреднамеренные<br>взаимодействия<br>внутри и среди PESS) | EN 62304: 2006                           | -             | да                     | -                       | да                   | Анализ отслеживаемости<br><br>Программное обеспечение<br>для проверки, HA 120                                 | RH                       | невозможно<br><br>исприменно    |
| HA720         | Нет ионизирующего<br>излучения – лазерное<br>излучение | Повреждение / травма<br>глаз, травма от испуга,<br>травма третьих лиц | критически | Непреднамеренный выброс<br>лазерного излучения при<br>переключении в режим<br>готовности из-за нажатия<br>ножного переключателя                                                         | иногда | В случае переключения в<br>режим READY (готовность)<br>при нажатии ножным<br>переключателем лазерное<br>излучение не подается.                                                                                                                                                                                                                                                                                         | IEC 60601-1:2005<br>14.6.1<br>(непреднамеренные<br>взаимодействия<br>внутри и среди PESS) | EN 62304: 2006                           | -             | да                     | -                       | да                   | Анализ отслеживаемости<br><br>Программное обеспечение<br>для проверки, HA120                                  | RH                       | невозможно<br><br>исприменно    |
| HA730         | Нет ионизирующего<br>излучения – лазерное<br>излучение | Повреждение глаз /<br>травма, травма третьих<br>лиц                   | критически | Люди, находящиеся в<br>помещении без защитных<br>очков во время лазерных<br>процедур                                                                                                    | часто  | Звуковая и оптическая<br>индикация излучения на<br>дисплее<br>Время на закрытие глаз при<br>активации режима готовности<br>(1 - Акустический сигнал<br>после активации состояния<br>готовности. 2 - Активация<br>лазера возможна через две<br>секунды после активации<br>состояния готовности)<br>Примечание в руководстве<br>пользователя для защитных<br>очков (предполагаемое<br>использование и<br>характеристики) |                                                                                           | EN 62304: 2006                           | -             | да                     | да                      | да                   | Программное обеспечение<br>для проверки, HA 120<br><br>Анализ отслеживаемости<br><br>Руководство пользователя | RH<br><br>ZI             | невозможно<br><br>исприменно    |
| HA750         | Нет ионизирующего<br>излучения – лазерное<br>излучение | Повреждение глаз /<br>травма, травма третьих<br>лиц                   | критически | Доступ третьих лиц во время<br>лазерного лечения                                                                                                                                        | иногда | - Блокировка дверей<br>- Световая сигнализация<br>(лампы) лазерного излучения                                                                                                                                                                                                                                                                                                                                          |                                                                                           | EN 62304:2006                            | -             | да                     | -                       | да                   | Анализ отслеживаемости<br><br>Программное обеспечение<br>для проверки, HA120                                  | RH                       | невозможно<br><br>исприменно    |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков                                           |                                                  |                                                                           |               |                                                                                                                                      |                  | Управление рисками                                                                                                                                                                                     |                                                                                                |              |                        |              |                        |                     |                                                                                                      |                           |            |                                 |  |
|---------------------------------------------------------|--------------------------------------------------|---------------------------------------------------------------------------|---------------|--------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------------|------------------------|--------------|------------------------|---------------------|------------------------------------------------------------------------------------------------------|---------------------------|------------|---------------------------------|--|
|                                                         |                                                  |                                                                           |               |                                                                                                                                      |                  | Безопасность                                                                                                                                                                                           |                                                                                                |              | Осуществление контроля |              |                        |                     |                                                                                                      | Уровень остаточного риска |            |                                 |  |
|                                                         |                                                  |                                                                           |               |                                                                                                                                      |                  |                                                                                                                                                                                                        |                                                                                                |              |                        |              |                        |                     |                                                                                                      |                           |            |                                 |  |
| №                                                       | Опасность                                        | Мед./человеческий эффект                                                  | К             | Последствия неисправности                                                                                                            | А                | Меры предотвращения                                                                                                                                                                                    | Применимые стандарты                                                                           | Конструкция  | Защитные меры          | Информация   | Эффективность проверки | Выполнение проверки | Запись (записи)                                                                                      | Отслеживание              | А          | Анализ соотношения рисков/выгод |  |
| HA760                                                   | Нет ионизирующего излучения – лазерное излучение | • Передозировка процедуры<br>• Везикулы и/или рубцы                       | критически    | неправильный параметр лазера из-за неисправного программного обеспечения и/или аппаратных средств (аварийный отказ системы)          | иногда           | - Проверка достоверности параметра лазера подчиненным процессом<br>- Использование контрольной суммы в передаче данных между главным и подчиненным процессом<br>- Использование сторожевого устройства | IEC 60601-1:2005 14.6.1 (неверные данные)<br>EN 62304:2006                                     | да           | -                      | -            | да                     | да                  | Анализ отслеживаемости<br>Программное обеспечение для проверки, HA120                                | RH                        | невозможно | неприменяемо                    |  |
| HA770                                                   | Нет ионизирующего излучения – лазерное излучение | • Повреждения глаз<br>• Передозировка процедуры<br>• Везикулы и/или рубцы | критически    | Непреднамеренное включение лазерной системы                                                                                          | иногда           | - главный выключатель<br>- выключатель с ключом<br>- аварийный выключатель лазера<br>- режимы READY (готовность) и STANDBY (ожидание)<br>- возможный переключатель                                     | IEC 60601-1:2005 14.6.1 (непреднамеренные взаимодействия внутри и среди PESS)<br>EN 62304:2006 | да           | -                      | -            | да                     | да                  | Анализ отслеживаемости<br>Программное обеспечение для проверки, HA 120                               | RH                        | невозможно | неприменяемо                    |  |
| HA780                                                   | Нет ионизирующего излучения – лазерное излучение | • Передозировка процедуры<br>• Везикулы и/или рубцы                       | критически    | неправильный параметр лазера из-за ошибки считывания данных из постоянной памяти                                                     | иногда           | - Использование контрольной суммы                                                                                                                                                                      | IEC 60601-1:2005 14.6.1 (неверные данные)<br>EN 62304:2006                                     | да           | -                      | -            | да                     | да                  | Анализ отслеживаемости<br>Программное обеспечение для проверки, HA 120                               | RH                        | невозможно | неприменяемо                    |  |
| HA790                                                   | Нет ионизирующего излучения – лазерное излучение | • Повреждения глаз<br>• Передозировка процедуры<br>• Везикулы и/или рубцы | критически    | неправильный параметр выходного излучения лазера после замены источника питания / блока управления диодами                           | иногда           | - регулировка тока<br>- контроль выделяемой энергии<br><br>Примечание: в руководстве по обслуживанию<br>Измерение энергии лазера                                                                       | IEC 60601-1:2005 14.6.1 (неизвестные аспекты или качество сторонних PESS)<br>EN 62304:2006     | -            | да                     | да           | да                     | да                  | Программное обеспечение для проверки, HA120<br>Анализ отслеживаемости<br>Руководство по обслуживанию | RH<br>RW                  | невозможно | неприменяемо                    |  |
| HA800                                                   | Нет ионизирующего излучения – лазерное излучение | • Повреждения глаз<br>• Передозировка процедуры<br>• Везикулы и/или рубцы | критически    | неверный параметр лазерного излучения после замены лазерного аппликатора                                                             | иногда           | регулировка энергии при индивидуализации аппликатора и<br>Параметры, отображаемые через графический интерфейс пользователя.<br>- Плотность энергии<br>- тип аппликатора                                | IEC 60601-1:2005 14.6.1 (неизвестные аспекты или качество сторонних PESS)<br>EN 62304:2006     | -            | да                     | -            | да                     | да                  | Анализ отслеживаемости<br>Программное обеспечение для проверки, HA120                                | RH                        | невозможно | неприменяемо                    |  |
| HA810                                                   | Нет ионизирующего излучения – лазерное излучение | • Повреждения глаз<br>• Передозировка процедуры<br>• Везикулы и/или рубцы | критически    | Неисправность блока управления диодами<br>неправильный выходной параметр (неправильное значение силы тока или длительности импульса) | иногда           | - Контроль длительности импульса с помощью блокировки импульсов<br>- контроль энергии лазера                                                                                                           | EN 62304:2006                                                                                  | да           | -                      | -            | да                     | да                  | Анализ отслеживаемости<br>Программное обеспечение для проверки, HA 120                               | RH                        | невозможно | неприменяемо                    |  |
| HA820                                                   | Слишком высокая энергия излучения                | Общая травма (средней ожоги)                                              | критически    | Неожиданное инфракрасное излучение от медицинского электрооборудования                                                               | невозможно       | неприменяемо, потому что здесь только инфракрасное излучение от лазерного диода<br>Выполнены требования IEC 60825 и IEC 60601-2-22 по инфракрасному излучению                                          | IEC 60601-1:2005 10.6 [TRF]<br>IEC 60601-1:2005 / EN 60601-1:2006                              | неприменяемо | неприменяемо           | неприменяемо | неприменяемо           | неприменяемо        | неприменяемо                                                                                         | неприменяемо              | невозможно | неприменяемо                    |  |
| 3.2.3 Опасность ультрафиолетового излучения             |                                                  |                                                                           |               |                                                                                                                                      |                  |                                                                                                                                                                                                        |                                                                                                |              |                        |              |                        |                     |                                                                                                      |                           |            |                                 |  |
| HA830                                                   | неприменяемо                                     | неприменяемо                                                              | несущественно | неприменяемо                                                                                                                         | невозможно       | неприменяемо, так как нет ультрафиолетового излучения                                                                                                                                                  | IEC 60601-1:2005 10.7 [TRF]<br>IEC 60601-1:2005 / EN 60601-1:2006                              | неприменяемо | неприменяемо           | неприменяемо | неприменяемо           | неприменяемо        | неприменяемо                                                                                         | неприменяемо              | невозможно | неприменяемо                    |  |
| 3.2.4 Опасность микроволнового излучения                |                                                  |                                                                           |               |                                                                                                                                      |                  |                                                                                                                                                                                                        |                                                                                                |              |                        |              |                        |                     |                                                                                                      |                           |            |                                 |  |
| HA840                                                   | неприменяемо                                     | неприменяемо                                                              | несущественно | неприменяемо                                                                                                                         | невозможно       | неприменяемо, так как устройство не генерирует микроволновое излучение.                                                                                                                                | IEC 60601-1:2005 10.3 [TRF]<br>IEC 60601-1:2005 / EN 60601-1:2006                              | неприменяемо | неприменяемо           | неприменяемо | неприменяемо           | неприменяемо        | неприменяемо                                                                                         | неприменяемо              | невозможно | неприменяемо                    |  |
| 4. Опасность, связанная с тепловой энергией             |                                                  |                                                                           |               |                                                                                                                                      |                  |                                                                                                                                                                                                        |                                                                                                |              |                        |              |                        |                     |                                                                                                      |                           |            |                                 |  |
| 4.1 Опасность из-за высоких температур                  |                                                  |                                                                           |               |                                                                                                                                      |                  |                                                                                                                                                                                                        |                                                                                                |              |                        |              |                        |                     |                                                                                                      |                           |            |                                 |  |
| 4.1.1 Слишком высокая температура рядом с цепью питания |                                                  |                                                                           |               |                                                                                                                                      |                  |                                                                                                                                                                                                        |                                                                                                |              |                        |              |                        |                     |                                                                                                      |                           |            |                                 |  |
| HA850                                                   | Опасности, связанные с эксплуатацией устройства  | Нежелательные побочные эффекты (ушеренные)                                | критически    | Замена компонентов                                                                                                                   | едва ли возможно | Компоненты могут быть заменены только обслуживающим персоналом, используя инструмент.<br>Более конструктивные меры:<br>- маркировка разъемов<br>- трудно различимые разъемы<br>Хорошо обученный        | IEC 60601-1:2005 7.9.3.2 [TRF]<br>IEC 60601-1:2005 / EN 60601-1:2006                           | да           | -                      | да           | да                     | да                  | Чертежи<br>Руководство по обслуживанию                                                               | KI<br>Сервис              | невозможно | неприменяемо                    |  |

Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| №                                           | Анализ рисков                                   |                                            |               |                                                                                    |                  | Управление рисками                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                            |                                    |                        |               |            |                         |                      |                                                                                             |                    |                    |                                 |
|---------------------------------------------|-------------------------------------------------|--------------------------------------------|---------------|------------------------------------------------------------------------------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------|---------------|------------|-------------------------|----------------------|---------------------------------------------------------------------------------------------|--------------------|--------------------|---------------------------------|
|                                             |                                                 |                                            |               |                                                                                    |                  | Безопасность                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                            |                                    | Осуществление контрмер |               |            |                         |                      | Оценка остаточного риска                                                                    |                    |                    |                                 |
|                                             | Опасность                                       | Мед./технолог. Эффект                      | S             | Причина неисправности                                                              | A                | Первая оценка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Меры противодействия                                                                                                                                                                                                                       | Применяемые стандарты              | Конструктив            | Защитные меры | Информация | Эффективность проверки? | Выполнение проверки? | Запись (записи)                                                                             | Ответственное лицо | Оценка остаточного | Анализ соотношения рисков/выгод |
|                                             |                                                 |                                            |               |                                                                                    |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | обслуживающий персонал и Запасные части и разъяснения по замене частей описаны в Руководстве по обслуживанию - плавкие предохранители - аппликатор<br>Запасные части и разъяснения по замене частей описаны в Руководстве по обслуживанию. |                                    |                        |               |            |                         |                      |                                                                                             |                    |                    |                                 |
| HA860                                       | Опасности, связанные с эксплуатацией устройства | Нежелательные побочные эффекты (умеренные) | критически    | Замена компонентов                                                                 | едва ли возможно | Компоненты могут быть заменены только обслуживающим персоналом, использующим инструмент. Для замены предохранителей, шнур питания должен быть вытаски (в противном случае зажим плавкого предохранителя открыть нельзя)<br><br>Примечание в руководстве пользователя:<br>Не вскрывайте установку, если Вы не имеете профессиональной подготовки или соответствующего разрешения.<br><br>Примечание в руководстве по обслуживанию:<br>Перед заменой компонентов обязательно вытаскивайте вилку из розетки! | IEC 60601-1:2005 7.9.3.2 [TRF]                                                                                                                                                                                                             | IEC 60601-1:2005 / EN 60601-1:2006 | да                     | -             | да         | да                      | да                   | Чертежи<br>Руководство пользователя<br>Руководство по обслуживанию                          | KI<br>ZI<br>Сервис | нельзя             | исприменно                      |
| HA870                                       | исприменно                                      | исприменно                                 | несущественно | исприменно                                                                         | нельзя           | исприменно, так как в устройстве не используется внешний источник питания постоянного тока.                                                                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 8.2.2 [TRF]                                                                                                                                                                                                               | IEC 60601-1:2005 / EN 60601-1:2006 | исприменно             | исприменно    | исприменно | исприменно              | исприменно           | исприменно                                                                                  | исприменно         | нельзя             | исприменно                      |
| 4.1.2 Превышение температуры в оборудовании |                                                 |                                            |               |                                                                                    |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                            |                                    |                        |               |            |                         |                      |                                                                                             |                    |                    |                                 |
| HA880                                       | Превышение температуры в оборудовании           | Ожоги (незначительные)                     | незначительно | [SFC] Отказ вентилятора                                                            | иногда           | Применение разрешенного типа вентилятора:<br>Документирование в списке критически важных компонентов<br><br>Измерьте температуру в устройстве и отключите слишком нагретые компоненты                                                                                                                                                                                                                                                                                                                     | IEC 60601-1:2005 4.7 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям                                                                                                                                                              | IEC 60601-1:2005 / EN 60601-1:2006 | да                     | -             | -          | да                      | да                   | Список защитных материалов и компонентов<br><br>Программное обеспечение для проверки, HA120 | MMo<br>RH          | нельзя             | исприменно                      |
| HA890                                       | Опасность, связанная с тепловой энергией        | Ожоги (незначительные)                     | незначительно | [SFC] Отсутствуют или неподходящие предохранители и расцепители максимального тока | нельзя           | исприменно, потому что в устройстве нет предохранителей, только выключатель (Вкл./Выкл.) с термомангнитной защитой (расцепитель максимального тока)<br><br>Документирование в списке критически важных компонентов                                                                                                                                                                                                                                                                                        | IEC 60601-1:2005 8.11.5 [TRF]<br><br>4.7 [TRF]                                                                                                                                                                                             | IEC 60601-1:2005 / EN 60601-1:2006 | исприменно             | исприменно    | исприменно | исприменно              | исприменно           | исприменно                                                                                  | исприменно         | нельзя             | исприменно                      |
| HA900                                       | Превышение температуры в оборудовании           | Ожоги (незначительные)                     | незначительно | Слишком высокая температура на медицинском устройстве                              | часто            | В нормальных условиях эксплуатации в худших условиях (включая максимальную рабочую температуру окружающего воздуха) ни одна из частей не нагревается выше температур, указанных в таблицах 22, 23 и 24 в стандарте IEC 60601-1, п.                                                                                                                                                                                                                                                                        | IEC 60601-1:2005 11.1.1 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям                                                                                                                                                           | IEC 60601-1:2005 / EN 60601-1:2006 | -                      | да            | -          | да                      | да                   | Протокол испытаний согласно 60601-1                                                         | MMo                | нельзя             | исприменно                      |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков |                                      |                        |               |                                                                                                |                   | Управление рисками                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                         |                                    |                        |               |            |                          |                       |                          |                    |           |                          |                                 |
|---------------|--------------------------------------|------------------------|---------------|------------------------------------------------------------------------------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|------------------------------------|------------------------|---------------|------------|--------------------------|-----------------------|--------------------------|--------------------|-----------|--------------------------|---------------------------------|
|               |                                      |                        |               |                                                                                                |                   | Безопасность                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                         |                                    | Осуществление контрмер |               |            |                          |                       | Оценка остаточного риска |                    |           |                          |                                 |
| №             | Опасность                            | Мед./технолог. Эффект  | S             | Причина неисправности                                                                          | A                 | Первая оценка                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                         | Применимые стандарты               | Конструкция            | Защитные меры | Информация | Эффективность проверена? | Выполнение проверено? | Запись (записи)          | Ответственное лицо | A         | Оценки остаточного риска | Анализ соотношения рисков/выгод |
|               |                                      |                        |               |                                                                                                |                   | 11.1.<br>Допустимые максимальные температуры, при которых переносим контакт (Таблица 23):<br>- Интерфейс пользователя (1 - 10 с: резистивный сенсорный дисплей): Максимальная температура 66°C<br>- аппликатор (пластик): > 1 мин / 48°C<br>- устройство (пластик/металл): > 1 мин / 48 °C<br>Таблица 24:<br>- контактная часть (пластик/металл): > 10 мин / 43°C<br>Испытания согласно пункту 11.1.3 для устройства. |                                                                                         |                                    |                        |               |            |                          |                       |                          |                    |           |                          |                                 |
| HA901         | Повышение температуры в оборудовании | Ожоги (незначительные) | незначительно | инженерная оценка изготовителя, что температурные пределы не могут быть превышены              | сдвиг ли возможно | испринено, потому что на данный момент такая техническая оценка отсутствует<br>Нужно выполнять измерения с испытательным углом<br>- Интерфейс пользователя (1 - 10 с: резистивный сенсорный дисплей)<br>- аппликатор (пластик): > 10 мин<br>- устройство (пластик/металл): > 1 мин<br>Условия испытаний:<br>Максимальная температура окружающей среды 30°C<br>Испытания согласно пункту 11.1.3 для устройства.        | IEC 60601-1:2005 11.1.3 [TRF]<br>Директива 93/42/EEC по медицинским изделиям            | IEC 60601-1:2005/ EN 60601-1:2006  | испринено              | испринено     | испринено  | испринено                | испринено             | испринено                | испринено          | испринено | испринено                | испринено                       |
| HA910         | Повышение температуры в оборудовании | Ожоги (незначительные) | критически    | [SFC] Противопожарные кожухи медицинского электрооборудования не выдерживают контакта с огнем. | испринено         | испринено, потому что противопожарный кожух отсутствует                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 11.3 [TRF]<br>4.7 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601 1:2006  | испринено              | испринено     | испринено  | испринено                | испринено             | испринено                | испринено          | испринено | испринено                | испринено                       |
| HA920         | Повышение температуры в оборудовании | Ожоги (незначительные) | несущественно | испринено                                                                                      | испринено         | испринено, так как в устройстве отсутствуют термореле и расцепители максимального тока с автоматическим возвратом в исходное положение                                                                                                                                                                                                                                                                                | IEC 60601-1:2005 15.4.2.1a) [TRF]                                                       | IEC 60601-1:2005/ EN 60601 -1:2006 | испринено              | испринено     | испринено  | испринено                | испринено             | испринено                | испринено          | испринено | испринено                | испринено                       |
| HA930         | Повышение температуры в оборудовании | Ожоги (незначительные) | несущественно | испринено                                                                                      | испринено         | испринено, так как в устройстве отсутствуют термореле и выключатели с функцией безопасности, которые приходится возвращать в исходное положение путем пайки, что может повлиять на эксплуатационные значения в устройстве.                                                                                                                                                                                            | IEC 60601-1:2005 15.4.2.1b) [TRF]                                                       | IEC 60601-1:2005/ EN 60601-1:2006  | испринено              | испринено     | испринено  | испринено                | испринено             | испринено                | испринено          | испринено | испринено                | испринено                       |
| HA940         | Повышение температуры в оборудовании | Ожоги (незначительные) | несущественно | испринено                                                                                      | испринено         | испринено, так как в устройстве отсутствуют термостаты                                                                                                                                                                                                                                                                                                                                                                | IEC 60601-1:2005 15.4.2.1c) [TRF]                                                       | IEC 60601-1:2005/ EN 60601-1:2006  | испринено              | испринено     | испринено  | испринено                | испринено             | испринено                | испринено          | испринено | испринено                | испринено                       |
| HA950         | Повышение температуры в оборудовании | Ожоги (незначительные) | несущественно | испринено                                                                                      | испринено         | испринено, так как в устройстве отсутствуют термореле и выключатели и расцепители максимального                                                                                                                                                                                                                                                                                                                       | IEC 60601-1:2005 15.4.2.1d) [TRF]                                                       | IEC 60601-1:2005/ EN 60601-1:2006  | испринено              | испринено     | испринено  | испринено                | испринено             | испринено                | испринено          | испринено | испринено                | испринено                       |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
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| №                                                                                  | Анализ рисков                                                                |                                                     |               |                                                                                           |            | Управление рисками |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                       |                                   |               |             |                         |                       |                                                                                |                                                                        |            |                    |                                 |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------------------------|---------------|-------------------------------------------------------------------------------------------|------------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------|---------------|-------------|-------------------------|-----------------------|--------------------------------------------------------------------------------|------------------------------------------------------------------------|------------|--------------------|---------------------------------|
|                                                                                    |                                                                              |                                                     |               |                                                                                           |            | Безопасность       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                       | Осуществление контрмер            |               |             |                         |                       | Оценка остаточного риска                                                       |                                                                        |            |                    |                                 |
| №                                                                                  | Опасность                                                                    | Мед./технолог. Эффект                               | S             | Причина неисправности                                                                     | A          | Первая оценка      | Меры противодействия                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Применяемые стандарты                                                                                                 | Конструкция                       | Защитные меры | Информация  | Эффективность проверки? | Выполнение проверено? | Запись (записи)                                                                | Ответственное лицо                                                     | A          | Оценка остаточного | Анализ соотношения рисков/выгод |
|                                                                                    |                                                                              |                                                     |               |                                                                                           |            |                    | Меры противодействия тока                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                       |                                   |               |             |                         |                       |                                                                                |                                                                        |            |                    |                                 |
| HA960                                                                              | Превышение температуры в оборудовании                                        | Ожоги (незначительные)                              | несущественно | неприменимо                                                                               | невозможно |                    | неприменимо, так как в устройстве не предусмотрен трубчатый нагревательный элемент.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | IEC 60601-1:2005 15.4.2.1 b) [TRF]                                                                                    | IEC 60601-1:2005/ EN 60601-1:2006 | неприменимо   | неприменимо | неприменимо             | неприменимо           | неприменимо                                                                    | неприменимо                                                            |            | невозможно         | неприменимо                     |
| 4.1.3 Использование контактных частей, предназначенных для передачи тепла пациенту |                                                                              |                                                     |               |                                                                                           |            |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                       |                                   |               |             |                         |                       |                                                                                |                                                                        |            |                    |                                 |
| HA970                                                                              | Использование контактных частей, предназначенных для передачи тепла пациенту | Ожоги (незначительные)                              | незначительно | Непреднамеренные высокая температура контактных частей                                    | часто      |                    | В устройстве имеется контактная часть (аппликатор), не предназначенная для передачи тепла пациенту.<br><br>Допустимые максимальные температуры, при которых переносим контакт (Таблица 23):<br>- Аппликатор (t мин < t; пластик): Максимальная температура 48°C<br><br>Допустимые максимальные температуры при контакте с кожей (Таблица 24)<br>- лазерная насадка / аппликатор (t > 10 мин; металл): Максимальная температура 43°C<br>- лазерная насадка (t > 10 мин; стекло): Максимальная температура 43°C<br><br>Испытания согласно пункту 11.1.3 для устройства | IEC 60601-1:2005 11.1.2.1 [TRF]<br>IEC 60601-1:2005 11.1.2.2 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006 | -             | да          | -                       | да                    | да                                                                             | Протокол испытаний согласно 60601-1<br>Оценка риска, датчик охлаждения | ММ         | невозможно         | неприменимо                     |
| HA980                                                                              | Недостаточная подача охлаждающего агента или ограниченное охлаждение         | • Перелозировка процедуры<br>• Везикулы и/или рубцы | незначительно | • Неисправности регулировки элемента Пельтье по двум точкам<br>• Перегрев                 | иногда     |                    | - постоянные проверки температуры воды в блоке охлаждения аппликатора<br>- постоянные проверки температуры на холодной стороне блока охлаждения аппликатора<br>- постоянные проверки расхода воды в блоке охлаждения аппликатора<br>- Сообщение об ошибке из-за превышения температуры                                                                                                                                                                                                                                                                               | EN 62304: 2006                                                                                                        | -                                 | да            | -           | да                      | да                    | Программное обеспечение для проверки, HA120<br>Анализ отслеживаемости          | RH                                                                     | невозможно | неприменимо        |                                 |
| HA990                                                                              | Недостаточная подача охлаждающего агента или ограниченное охлаждение         | отек при контакте                                   | незначительно | • Неисправности регулировки элемента Пельтье по двум точкам<br>• Недостаточное охлаждение | иногда     |                    | - постоянные проверки температуры воды в блоке охлаждения аппликатора<br>- постоянные проверки температуры на холодной стороне блока охлаждения аппликатора<br>- постоянные проверки расхода воды в блоке охлаждения аппликатора<br>- Ограниченная охлаждающая мощность элементов Пельтье                                                                                                                                                                                                                                                                            | EN 62304: 2006                                                                                                        | -                                 | да            | -           | да                      | да                    | Программное обеспечение для проверки, HA120<br>Оценка риска, датчик охлаждения | RH                                                                     | невозможно | неприменимо        |                                 |
| 4.1.4 Использование в сочетании с легковоспламеняющимися веществами                |                                                                              |                                                     |               |                                                                                           |            |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                       |                                   |               |             |                         |                       |                                                                                |                                                                        |            |                    |                                 |
| HA 1000                                                                            | неприменимо                                                                  | неприменимо                                         | несущественно | неприменимо                                                                               | невозможно |                    | Устройство MedioStar не предназначено для использования в сочетании с легковоспламеняющимися веществами.                                                                                                                                                                                                                                                                                                                                                                                                                                                             | IEC 60601-1:2005 11.5 [TRF]                                                                                           | IEC 60601-1:2005/ EN 60601-1:2006 | неприменимо   | неприменимо | неприменимо             | неприменимо           | неприменимо                                                                    | неприменимо                                                            |            | невозможно         | неприменимо                     |
| 4.2 Опасность пожара или взрыва                                                    |                                                                              |                                                     |               |                                                                                           |            |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                       |                                   |               |             |                         |                       |                                                                                |                                                                        |            |                    |                                 |
| 4.2.1 Использование батарей                                                        |                                                                              |                                                     |               |                                                                                           |            |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                       |                                   |               |             |                         |                       |                                                                                |                                                                        |            |                    |                                 |

Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков                                                        |                       |                        |               |                                                                                                                                                                                                           |                  | Управление рисками                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                           |                                                                                                       |                        |               |             |                         |                          |                                      |                    |                                 |             |
|----------------------------------------------------------------------|-----------------------|------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|------------------------|---------------|-------------|-------------------------|--------------------------|--------------------------------------|--------------------|---------------------------------|-------------|
|                                                                      |                       |                        |               |                                                                                                                                                                                                           |                  | Безопасность                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                           |                                                                                                       | Осуществление контроля |               |             |                         | Оценка остаточного риска |                                      |                    |                                 |             |
| №                                                                    | Опасность             | Мед./технолог. Эффект  | S             | Последствия                                                                                                                                                                                               | A                | Первая оценка                                                                                                                                                                                                                                                                                                                                                 | Меры противодействия                                                                                                                                                                                                                                                                      | Применимые стандарты                                                                                  | Конструкция            | Защитные меры | Информация  | Эффективность проверки? | Выполнение проверки?     | Датасет (человек)                    | Отчетственное лицо | Анализ соотношения рисков/выгод |             |
| HA101                                                                | Использование батарей | Ожоги (незначительные) | незначительно | Тип батарей и режим установки не отмечены / не указываются. Предупреждение в случае литиевых батарей или гальванических элементов отсутствует, а неправильная замена может привести к неприемлемому риску | едва ли возможно | Батарея используется для питания буферных «часов CMOS» на основной плате. Батарея должна заменяться только специалистами по техническому обслуживанию. Информация о типе батарей и процедуре замены описана в руководстве по обслуживанию. Опасность для пациента, оператора и третьих лиц в результате неправильной установки / вставки батарей отсутствует. | Батарея используется для питания буферных «часов CMOS» на основной плате. Опасность для пациента, оператора и третьих лиц в результате неправильной установки / вставки батарей отсутствует. Короткое замыкание батарей невозможно из-за специальной формы зажима аккумуляторной батареи. | IEC 60601-1:2005 7.3.3 [TRF]                                                                          | да                     | -             | да          | да                      | да                       | Чертежи Руководство по обслуживанию  | KI<br>RW           | невозможно                      | неприемлемо |
| HA102                                                                | Использование батарей | Ожоги (незначительные) | незначительно | Неправильное использование Батарей во время обслуживания                                                                                                                                                  | едва ли возможно | Батарея (CR2032) используется для питания буферных «часов CMOS» на основной плате. Опасность для пациента, оператора и третьих лиц в результате неправильной установки / вставки батарей отсутствует. Короткое замыкание батарей невозможно из-за специальной формы зажима аккумуляторной батареи.                                                            | Батарея используется для питания буферных «часов CMOS» на основной плате. Опасность для пациента, оператора и третьих лиц в результате неправильной установки / вставки батарей отсутствует.                                                                                              | IEC 60601-1:2005 15.4.3.1 [TRF]<br>IEC 60601-1:2005 15.4.3.2 [TRF]                                    | да                     | -             | да          | да                      | да                       | Чертеж отска аккумуляторной батареи  | CB                 | невозможно                      | неприемлемо |
| HA103                                                                | Использование батарей | Ожоги (незначительные) | незначительно | [SFC] Избыточная зарядка Батарей                                                                                                                                                                          | едва ли возможно | Устройство не оборудовано защитой от перезарядки, так как отсутствует зарядный контур. Батарея используется для питания буферных «часов CMOS» на основной плате. Использование литиевой батареи не создает опасность для пациента, оператора и третьих лиц.                                                                                                   | Батарея используется для питания буферных «часов CMOS» на основной плате. Использование литиевой батареи не создает опасность для пациента, оператора и третьих лиц.                                                                                                                      | IEC 60601-1:2005 15.4.3.3 [TRF]<br>IEC 60601-1:2005 15.4.3.4 [TRF]<br>IEC 60601-1:2005 15.4.3.5 [TRF] | да                     | -             | да          | да                      | да                       | Спецификации часов реального времени | CB                 | невозможно                      | неприемлемо |
| HA1031                                                               | Использование батарей | Ожоги (незначительные) | незначительно | [SFC] Избыточная зарядка Батарей                                                                                                                                                                          | едва ли возможно | неприемлемо, потому что у MedioStar нет внутреннего источника электроэнергии. Резервная батарея доступна для технических специалистов с соответствующими инструментами. Ток разряда ограничен 0,3 А, измерено незначительное количество до 0,9 А, предохранитель не требуется.                                                                                | Батарея используется для питания буферных «часов CMOS» на основной плате. Использование литиевой батареи не создает опасность для пациента, оператора и третьих лиц.                                                                                                                      | IEC 60601-1:2005 15.4.3.5 [TRF]<br>4.7 [TRF]                                                          | неприемлемо            | неприемлемо   | неприемлемо | неприемлемо             | неприемлемо              | неприемлемо                          | неприемлемо        | невозможно                      | неприемлемо |
| 4.2.2 Опасность, связанная со средой с высоким содержанием кислорода |                       |                        |               |                                                                                                                                                                                                           |                  |                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                           |                                                                                                       |                        |               |             |                         |                          |                                      |                    |                                 |             |
| HA104                                                                | неприемлемо           | неприемлемо            | несущественно | неприемлемо                                                                                                                                                                                               | невозможно       | неприемлемо, так как устройство MedioStar не предусматривает использование в среде с высоким содержанием кислорода.                                                                                                                                                                                                                                           | неприемлемо, так как устройство MedioStar не предусматривает использование в среде с высоким содержанием кислорода.                                                                                                                                                                       | IEC 60601-1:2005 11.2.2.1 [TRF]                                                                       | неприемлемо            | неприемлемо   | неприемлемо | неприемлемо             | неприемлемо              | неприемлемо                          | неприемлемо        | невозможно                      | неприемлемо |
| 5. Опасность, связанная с механической энергией                      |                       |                        |               |                                                                                                                                                                                                           |                  |                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                           |                                                                                                       |                        |               |             |                         |                          |                                      |                    |                                 |             |
| 5.1 Опасность, связанная с силой тяжести                             |                       |                        |               |                                                                                                                                                                                                           |                  |                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                           |                                                                                                       |                        |               |             |                         |                          |                                      |                    |                                 |             |
| 5.1.1 Опасность неполадок из-за неустойчивости                       |                       |                        |               |                                                                                                                                                                                                           |                  |                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                           |                                                                                                       |                        |               |             |                         |                          |                                      |                    |                                 |             |
| HA 105                                                               | неприемлемо           | неприемлемо            | несущественно | неприемлемо                                                                                                                                                                                               | невозможно       | неприемлемо, потому что MedioStar не является переносным устройством.                                                                                                                                                                                                                                                                                         | неприемлемо, потому что MedioStar не является переносным устройством. Директива 93/42/ЕЕС по медицинским изделиям                                                                                                                                                                         | IEC 60601-1:2005 9.4.2.4.3 [TRF]                                                                      | неприемлемо            | неприемлемо   | неприемлемо | неприемлемо             | неприемлемо              | неприемлемо                          | неприемлемо        | невозможно                      | неприемлемо |



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| Анализ рисков                                   |                                             |                                                         |               |                                                   |            | Управление рисками                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                              |             |                        |             |                         |                     |                                         |                          |            |                 |
|-------------------------------------------------|---------------------------------------------|---------------------------------------------------------|---------------|---------------------------------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-------------|------------------------|-------------|-------------------------|---------------------|-----------------------------------------|--------------------------|------------|-----------------|
|                                                 |                                             |                                                         |               |                                                   |            | Безопасность                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                              |             | Осуществление контроля |             |                         |                     |                                         | Оценка остаточного риска |            |                 |
| №                                               | Опасность                                   | Мед. Технол. Эффект                                     | S             | Причина возникновения                             | A          | Меры предотвращения                                                                                                                                                                                                                                                                                                                                                                                                                            | Идентификация стандартов                                                     | Конструкция | Защитные меры          | Информация  | Эффективность проверки? | Бюджетная проверка? | Запись (вспомог.)                       | Оценочное число          | А          | Остаточный риск |
| HA1051                                          | неприменимо                                 | неприменимо                                             | незначительно | неприменимо                                       | никогда    | а) около 35 кг, но при нормальном использовании не поднимается<br>б) Две ручки для переноски<br>в) Прилагается усилие в 345 Н на каждый захват (2 элемента)                                                                                                                                                                                                                                                                                    | IEC 60601-1:2005 9.4.4 [TRF]<br>Директива 93/42/EEC по медицинским изделиям  | да          | -                      | -           | да                      | да                  | Зборочные чертежи                       | K1                       | невозможно | неприменимо     |
| HA1060                                          | неприменимо                                 | неприменимо                                             | несущественно | неприменимо                                       | невозможно | неприменимо, потому что MedioStar не является переносным устройством.                                                                                                                                                                                                                                                                                                                                                                          | IEC 60601-1:2005 15.3.5 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | неприменимо | неприменимо            | неприменимо | неприменимо             | неприменимо         | неприменимо                             | неприменимо              | невозможно | неприменимо     |
| 5.1.2 Опасности, связанные с подвижными грузами |                                             |                                                         |               |                                                   |            |                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                              |             |                        |             |                         |                     |                                         |                          |            |                 |
| HA1070                                          | Опасности связанные с механической энергией | Травма в результате чрезмерного усилия (незначительная) | незначительно | Непреднамеренное движение компонентов устройства. | никогда    | Закрепление и фиксация компонентов с защелкивающимися соединителями, хомутами и винтами.                                                                                                                                                                                                                                                                                                                                                       | IEC 60601-1:2005 8.10.1 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | -           | да                     | -           | да                      | да                  | Зборочные чертежи                       | K1                       | невозможно | неприменимо     |
| HA1080                                          | неприменимо                                 | неприменимо                                             | несущественно | неприменимо                                       | невозможно | неприменимо, так как система крепления отсутствует.                                                                                                                                                                                                                                                                                                                                                                                            | IEC 60601-1:2005 9.8.1 [TRF]                                                 | неприменимо | неприменимо            | неприменимо | неприменимо             | неприменимо         | неприменимо                             | неприменимо              | невозможно | неприменимо     |
| HA1090                                          | неприменимо                                 | неприменимо                                             | несущественно | неприменимо                                       | невозможно | неприменимо, так как система крепления отсутствует.                                                                                                                                                                                                                                                                                                                                                                                            | IEC 60601-1:2005 9.8.2 [TRF]                                                 | м           | неприменимо            | неприменимо | неприменимо             | неприменимо         | неприменимо                             | неприменимо              | невозможно | неприменимо     |
| HA1100                                          | неприменимо                                 | неприменимо                                             | несущественно | неприменимо                                       | невозможно | неприменимо, так как система крепления или подвески отсутствует.                                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 9.8.3.1 [TRF]                                               | неприменимо | неприменимо            | неприменимо | неприменимо             | неприменимо         | неприменимо                             | неприменимо              | невозможно | неприменимо     |
| HA1110                                          | неприменимо                                 | неприменимо                                             | несущественно | неприменимо                                       | невозможно | неприменимо, так как система крепления или подвески отсутствует.                                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 9.8.3.2 [TRF]                                               | неприменимо | неприменимо            | неприменимо | неприменимо             | неприменимо         | неприменимо                             | неприменимо              | невозможно | неприменимо     |
| HA1120                                          | неприменимо                                 | неприменимо                                             | несущественно | неприменимо                                       | невозможно | неприменимо, так как система крепления или подвески отсутствует.                                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 9.8.4.1a) [TRF]<br>IEC 60601-1:2005 9.8.4.1b) [TRF]         | неприменимо | неприменимо            | неприменимо | неприменимо             | неприменимо         | неприменимо                             | неприменимо              | невозможно | неприменимо     |
| HA 1130                                         | неприменимо                                 | неприменимо                                             | несущественно | неприменимо                                       | невозможно | неприменимо, так как система крепления или подвески отсутствует.                                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 9.8.4.3 [TRF]                                               | неприменимо | неприменимо            | неприменимо | неприменимо             | неприменимо         | неприменимо                             | неприменимо              | невозможно | неприменимо     |
| HA1140                                          | неприменимо                                 | неприменимо                                             | несущественно | неприменимо                                       | невозможно | неприменимо, так как система крепления или подвески отсутствует.                                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 9.8.5 [TRF]                                                 | неприменимо | неприменимо            | неприменимо | неприменимо             | неприменимо         | неприменимо                             | неприменимо              | невозможно | неприменимо     |
| HA1150                                          | Опасности связанные с механической энергией | Травма в результате чрезмерного усилия (незначительная) | незначительно | [SFC] Недостаточная механическая прочность        | часто      | У MedioStar достаточная механическая прочность, и нет неприемлемых рисков из-за испытаний на нажим согласно IEC 60601-1, пункт 15.3.2:<br>- Внешние части корпуса должны выдерживать усилие 250 Н +/- 10 Н в течение 5 с, приложенное к участку окружности диаметром 30 мм.                                                                                                                                                                    | IEC 60601-1:2005 15.3.2 [TRF]<br>4.7 [TRF]                                   | -           | да                     | -           | да                      | да                  | Протокол испытаний согласно IEC 60601-1 | «ЛГ А» (LGA)             | невозможно | неприменимо     |
| HA1160                                          | Опасности связанные с механической энергией | Травма в результате чрезмерного усилия (незначительная) | незначительно | [SFC] Недостаточная механическая прочность        | часто      | У MedioStar достаточная механическая прочность, и нет неприемлемых рисков из-за испытаний на удар согласно ISO 60601-1, пункт 15.3.3:<br>- сплошной стальной шарик (диаметром 55 мм, массой 500 г +/- 25 г) может быть брошен без усилия с высоты 1,3 м однократно на каждую соответствующую часть<br>-> корпус устройства<br>- Для испытания вертикальных поверхностей на шпуре подвешивают стальной шар, далее его сбрасывают с высоты 1,3 м | IEC 60601-1:2005 15.3.3 [TRF]<br>4.7 [TRF]                                   | -           | да                     | -           | да                      | да                  | Протокол испытаний согласно IEC 60601-1 | «ЛГ А» (LGA)             | невозможно | неприменимо     |



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| Анализ рисков                                                |                                             |                                                         |               |                                            |        | Управление рисками |                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                          |                                   |               |            |                         |                      |                 |                                                                                                                                                                                |                          |                                 |            |
|--------------------------------------------------------------|---------------------------------------------|---------------------------------------------------------|---------------|--------------------------------------------|--------|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------------------|---------------|------------|-------------------------|----------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|---------------------------------|------------|
| №                                                            | Опасность                                   | Мед./технолог. Эффект                                   | S             | Причина неисправности                      | A      | Первая оценка      | Меры противодействия                                                                                                                                                                                                                                                                                                                                                                                                        | Применимые стандарты                                                                     | Безопасность                      |               |            | Осуществление контроля  |                      |                 |                                                                                                                                                                                | Оценка остаточного риска |                                 |            |
|                                                              |                                             |                                                         |               |                                            |        |                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                          | Конструктивная                    | Защитные меры | Информация | Эффективность проверки? | Выполнение проверки? | Запись (записи) | Отчетное лицо                                                                                                                                                                  | Оценочный коэффициент    | Анализ соотношения рисков/выгод |            |
|                                                              |                                             |                                                         |               |                                            |        |                    | Меры противодействия<br>так, чтобы при падении смоделировать колебательное движение подобно матпенку и горизонтальный удар против каждой соответствующей части.<br>→ корпус устройства                                                                                                                                                                                                                                      |                                                                                          |                                   |               |            |                         |                      |                 |                                                                                                                                                                                |                          |                                 |            |
| HA1176                                                       | Опасности связанные с механической энергией | Травма в результате чрезмерного усилия (незначительная) | незначительно | [SFC] Недостаточная механическая прочность | часто  |                    | Устройство имеет достаточную механическую прочность, и не возникнут неприемлемые риски из-за испытаний сбрасыванием согласно ISO 60601-1, пункт 15.3.4.2.<br>Вес устройства около 35 кг (10 кг < m < 50 кг) и оно должно выдерживать три сбрасывания с высоты 3 см на плиту из толстой твердой древесины. Испытание не должно вызвать повреждение устройства.                                                               | IEC 60601-1:2005 15.3.4.2 [TRF]<br>4.7 [TRF]                                             | IEC 60601-1:2005/ EN 60601-1:2006 | да            | -          | -                       | да                   | Да              | Протокол испытаний согласно IEC 60601-1                                                                                                                                        | «ЛГА» (LGA)              | невозможно                      | исприменно |
| 5.2 Опасности, связанные с накопленной механической энергией |                                             |                                                         |               |                                            |        |                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                          |                                   |               |            |                         |                      |                 |                                                                                                                                                                                |                          |                                 |            |
| HA1180                                                       | Опасности связанные с механической энергией | Общая травма (средней тяжести)                          | критически    | Недостаточные размеры жидкостного контура  | иногда |                    | Насос вырабатывает максимальное давление 1,9 бар. Система шлангов и разъемных соединений выдерживает давление 6 бар минимум в нахлудных условиях. (коэффициент запаса прочности: 3)<br>Компрессор вырабатывает максимальное давление 17 бар. Компрессор защищен мембранным выключателем (открывается при 17,7 бар).                                                                                                         | IEC 60601-1:2005 9.7.4 [TRF]<br>Директива 93/42/EEC по медицинским изделиям              | IEC 60601-1:2005/ EN 60601-1:2006 | да            | да         | да                      | да                   | да              | Проверка функции охлаждения<br>Спецификация на насос<br>Спецификация на шланг<br>Спецификация на разъем(ы)<br>Спецификация компрессора<br>Спецификация мембранного выключателя | ММ                       | невозможно                      | исприменно |
| HA1190                                                       | Опасности связанные с механической энергией | Общая травма (средней тяжести)                          | критически    | [SFC] Потеря давления                      | иногда |                    | При потере давления будет недостаточное охлаждение аппликатора. Опасность отсутствует благодаря измеренным температурам в аппликаторе.<br>- постоянные проверки температуры воды в блоке охлаждения аппликатора<br>- постоянные проверки температуры на холодной стороне блока охлаждения аппликатора<br>- постоянные проверки расхода воды в блоке охлаждения аппликатора                                                  | IEC 60601-1:2005 9.7.2 [TRF]<br>4.7 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006 | да            | -          | -                       | да                   | да              | Программное обеспечение для проверки, HA120<br>Проверка функции охлаждения                                                                                                     | ММ                       | невозможно                      | исприменно |
| HA1200                                                       | Опасности связанные с механической энергией | Общая травма (средней тяжести)                          | критически    | [SFC] Выброс струи / утечки жидкости       | иногда |                    | В случае выброса струи из-за утечки жидкости в блоке охлаждения возможна утечка жидкости на соединения.<br>В случае ошибки:<br>- потеря давления;<br>- нет расхода воды<br>- капли жидкости на нижней части устройства<br>Следующие части могут быть влажными:<br>- Блок охлаждения (в нижней части устройства)<br>- Источник питания (внутри корпуса)<br>- 24 В / 48 В сторона соединения<br>- внутренняя часть устройства | IEC 60601-1:2005 9.7.2 [TRF]<br>4.7 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006 | да            | -          | -                       | да                   | да              | Чертежи<br>Проверка функции охлаждения                                                                                                                                         | ММ                       | невозможно                      | исприменно |

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Анализ рисков, оценка и контроль  
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| №                                                           | Анализ рисков                                           |                                |               |                                                                           |                    |                  | Управление рисками                                                                                                                                                                                                                                                          |                                                                                      |                                    |                        |             |                         |                      |                         |                    |            |                                 |             |
|-------------------------------------------------------------|---------------------------------------------------------|--------------------------------|---------------|---------------------------------------------------------------------------|--------------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|------------------------------------|------------------------|-------------|-------------------------|----------------------|-------------------------|--------------------|------------|---------------------------------|-------------|
|                                                             |                                                         |                                |               |                                                                           |                    |                  | Безопасность                                                                                                                                                                                                                                                                |                                                                                      |                                    | Осуществление контроля |             |                         |                      | Жизнь остаточного риска |                    |            |                                 |             |
| №                                                           | Опасность                                               | Мед./технолог. Эффект          | S             | Причина неадекватности                                                    | A                  | Первичная оценка | Меры противодействия                                                                                                                                                                                                                                                        | Применимые стандарты                                                                 | Конструкция                        | Защитные меры          | Информация  | Эффективность проверки? | Выполнение проверки? | Запись (даты)           | Ответственное лицо | A          | Анализ соотношения рисков/выгод |             |
|                                                             |                                                         |                                |               |                                                                           |                    |                  | (капли жидкости / отвод жидкости в нижнюю часть устройства)<br>потенциальная опасность отсутствует, потому что:<br>- 2 MORP<br>- заземленные корпус и контактная часть<br>- постоянные проверки расхода воды (блок охлаждения), в случае ошибки блок охлаждения выключается |                                                                                      |                                    |                        |             |                         |                      |                         |                    |            |                                 |             |
| 5.3 Опасности, связанные с движущимися частями              |                                                         |                                |               |                                                                           |                    |                  |                                                                                                                                                                                                                                                                             |                                                                                      |                                    |                        |             |                         |                      |                         |                    |            |                                 |             |
| HA1210                                                      | неприменимо                                             | неприменимо                    | несущественно | неприменимо                                                               | невозможно         |                  | Устройство не содержит движущихся частей согласно IEC 60601-1, п. 9.2.1                                                                                                                                                                                                     | IEC 60601-1:2005 9.2.1 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям      | IEC 60601-1:2005/ EN 60601-1:2006  | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо             | неприменимо        | невозможно | неприменимо                     |             |
| HA1220                                                      | неприменимо                                             | неприменимо                    | несущественно | неприменимо                                                               | невозможно         |                  | неприменимо, так как на устройстве не имеется съемных ограждений.                                                                                                                                                                                                           | IEC 60601-1:2005 9.2.2.4.3 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям  | IEC 60601-1:2005 / EN 60601-1:2006 | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо             | неприменимо        | невозможно | неприменимо                     |             |
| HA1230                                                      | неприменимо                                             | неприменимо                    | несущественно | неприменимо                                                               | невозможно         |                  | неприменимо, так как элементы управления не предусматривают защитных мер                                                                                                                                                                                                    | IEC 60601-1:2005 9.2.2.4.4 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям  | IEC 60601-1:2005/ EN 60601-1:2006  | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо             | неприменимо        | невозможно | неприменимо                     |             |
| HA1240                                                      | неприменимо                                             | неприменимо                    | несущественно | неприменимо                                                               | невозможно         |                  | Неприменимо, нет постоянной активации применительно к пункту 9.2.2.5                                                                                                                                                                                                        | IEC 60601-1:2005 9.2.2.5 c) [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006  | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо             | неприменимо        | невозможно | неприменимо                     |             |
| HA1250                                                      | неприменимо                                             | неприменимо                    | несущественно | неприменимо                                                               | невозможно         |                  | неприменимо, потому что нет позиционирования устройства и пациента.                                                                                                                                                                                                         | IEC 60601-1:2005 9.2.2.6 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям    | IEC 60601-1:2005/ EN 60601-1:2006  | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо             | неприменимо        | невозможно | неприменимо                     |             |
| HA1260                                                      | неприменимо                                             | неприменимо                    | несущественно | неприменимо                                                               | невозможно         |                  | неприменимо, так как избыточный ход (вынос) устройства                                                                                                                                                                                                                      | IEC 60601-1:2005 9.2.3.2 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям    | IEC 60601-1:2005/ EN 60601-1:2006  | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо             | неприменимо        | невозможно | неприменимо                     |             |
| HA1270                                                      | неприменимо                                             | неприменимо                    | несущественно | неприменимо                                                               | невозможно         |                  | неприменимо, так как освобождение пациента не является необходимым для этого устройства                                                                                                                                                                                     | IEC 60601-1:2005 9.2.5 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям      | IEC 60601-1:2005/ EN 60601-1:2006  | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо             | неприменимо        | невозможно | неприменимо                     |             |
| HA1280                                                      | неприменимо                                             | неприменимо                    | несущественно | неприменимо                                                               | невозможно         |                  | неприменимо, так как устройство не имеет функции аварийной остановки.                                                                                                                                                                                                       | IEC 60601-1:2005 9.2.4 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям      | IEC 60601-1:2005/ EN 60601-1:2006  | неприменимо            | неприменимо | неприменимо             | неприменимо          | неприменимо             | неприменимо        | невозможно | неприменимо                     |             |
| 5.4 Опасности, связанные с поверхностями, углами и кромками |                                                         |                                |               |                                                                           |                    |                  |                                                                                                                                                                                                                                                                             |                                                                                      |                                    |                        |             |                         |                      |                         |                    |            |                                 |             |
| HA1290                                                      | Опасности, связанные с поверхностями, углами и кромками | Общая травма (средней тяжести) | критически    | Недостатки конструкции, связанные с острыми краями, углами, поверхностями | слабо или возможно |                  | При разработке конструкции изделия необходимо избегать острых углов и кромок. Визуальный осмотр внешних компонентов                                                                                                                                                         | IEC 60601-1:2005 9.3 [TRF]<br><br>Директива 93/42/EEC по медицинским изделиям        | IEC 60601-1:2005/ EN 60601-1:2006  | да                     | -           | -                       | да                   | да                      | Чертежи            | KI         | невозможно                      | неприменимо |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| №                                                                   | Анализ рисков                                                           |                                |                       |                                     |                       | Управление рисками                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                       |                                    |                      |              |               |             |                          |                                                                                                                                       |                 |                    |             | Оценка остаточного риска |                                 |  |  |
|---------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------|-----------------------|-------------------------------------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|--------------|---------------|-------------|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|-------------|--------------------------|---------------------------------|--|--|
|                                                                     | №                                                                       | Опасность                      | Мед./технолог. Эффект | S                                   | Причина неисправности | A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Первая оценка                                                                                         | Меры противодействия               | Применимые стандарты | Безопасность |               |             | Осуществление контроля   |                                                                                                                                       |                 |                    |             |                          |                                 |  |  |
|                                                                     |                                                                         |                                |                       |                                     |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                       |                                    |                      | Конструкция  | Защитные меры | Информация  | Эффективность проверена? | Выполнение проверено?                                                                                                                 | Запись (записи) | Ответственное лицо |             |                          |                                 |  |  |
|                                                                     |                                                                         |                                |                       |                                     |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                       |                                    |                      |              |               |             |                          |                                                                                                                                       |                 |                    | A           | Оценка остаточного       | Анализ соотношения рисков/выгод |  |  |
|                                                                     |                                                                         |                                |                       |                                     |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                       |                                    | изделием             |              |               |             |                          |                                                                                                                                       |                 |                    |             |                          |                                 |  |  |
| 5.5 Опасности, связанные с акустической энергией                    |                                                                         |                                |                       |                                     |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                       |                                    |                      |              |               |             |                          |                                                                                                                                       |                 |                    |             |                          |                                 |  |  |
| 5.5.1 Опасности, связанные с энергией ультразвука                   |                                                                         |                                |                       |                                     |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                       |                                    |                      |              |               |             |                          |                                                                                                                                       |                 |                    |             |                          |                                 |  |  |
| HA1300                                                              | неприменимо                                                             | неприменимо                    | несущественно         | неприменимо                         | невозможно            | неприменимо, так как устройство не генерирует акустическое давление                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | IEC 60601-1:2005 12.4.6 [TRF]                                                                         | IEC 60601-1:2005 / EN 60601-1:2006 | неприменимо          | неприменимо  | неприменимо   | неприменимо | неприменимо              | неприменимо                                                                                                                           | неприменимо     | неприменимо        | невозможно  | неприменимо              |                                 |  |  |
| 5.5.2 Опасности, связанные с инфразвуковой энергией                 |                                                                         |                                |                       |                                     |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                       |                                    |                      |              |               |             |                          |                                                                                                                                       |                 |                    |             |                          |                                 |  |  |
| HA1310                                                              | неприменимо                                                             | неприменимо                    | несущественно         | неприменимо                         | невозможно            | неприменимо, так как устройство не генерирует энергию в инфразвуковом и ультразвуковом спектре                                                                                                                                                                                                                                                                                                                                                                                                                                        | IEC 60601-1:2005 9.6.2.2 [TRF]                                                                        | IEC 60601-1:2005 / EN 60601-1:2006 | неприменимо          | неприменимо  | неприменимо   | неприменимо | неприменимо              | неприменимо                                                                                                                           | неприменимо     | неприменимо        | невозможно  | неприменимо              |                                 |  |  |
| 5.5.3 Акустические опасности                                        |                                                                         |                                |                       |                                     |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                       |                                    |                      |              |               |             |                          |                                                                                                                                       |                 |                    |             |                          |                                 |  |  |
| HA1320                                                              | Акустические опасности                                                  | Общая травма (средней тяжести) | критически            | Акустическая энергия слишком высока | едва ли возможно      | Устройство разработано так, чтобы воздействие на человека акустической энергии и вибрации не могло привести к неприемлемому риску. Проверьте спецификации системы охлаждения (с компрессором, вентилятором и насосом). Акустическая энергия < 65 дБ(А) на расстоянии 1 м (спецификации системы охлаждения).                                                                                                                                                                                                                           | IEC 60601-1:2005 9.6.1 [TRF]<br>IEC 60601-1:2005 9.6.2.1                                              | IEC 60601-1:2005 / EN 60601-1:2006 | да                   | -            | -             | да          | да                       | Протокол испытаний согласно IEC 60601-1<br>Спецификация системы охлаждения (компрессор, вентилятор, насос)<br>Устройство для проверки | «ЛГА» (LGA)     | невозможно         | неприменимо |                          |                                 |  |  |
| HA1330                                                              | неприменимо                                                             | неприменимо                    | несущественно         | неприменимо                         | невозможно            | неприменимо, так как система сигнализации не реализована                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | IEC 60601-1:2005 12.3 [TRF]                                                                           | IEC 60601-1:2005 / EN 60601-1:2006 | неприменимо          | неприменимо  | неприменимо   | неприменимо | неприменимо              | неприменимо                                                                                                                           | неприменимо     | неприменимо        | невозможно  | неприменимо              |                                 |  |  |
| 5.6 Опасности, связанные с выбрасываемыми частями                   |                                                                         |                                |                       |                                     |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                       |                                    |                      |              |               |             |                          |                                                                                                                                       |                 |                    |             |                          |                                 |  |  |
| HA1340                                                              | неприменимо                                                             | неприменимо                    | несущественно         | неприменимо                         | невозможно            | неприменимо, так как в устройстве не предусмотрены выбрасываемые части.                                                                                                                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 9.5.1 [TRF]                                                                          | IEC 60601-1:2005 / EN 60601-1:2006 | неприменимо          | неприменимо  | неприменимо   | неприменимо | неприменимо              | неприменимо                                                                                                                           | неприменимо     | неприменимо        | невозможно  | неприменимо              |                                 |  |  |
| 5.7 Опасности, связанные с неконтролируемыми переменными процессами |                                                                         |                                |                       |                                     |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                       |                                    |                      |              |               |             |                          |                                                                                                                                       |                 |                    |             |                          |                                 |  |  |
| HA1350                                                              | контур охлаждения (Сосуды и детали под давлением, номинальное давление) | Общая травма (средней тяжести) | критически            | [SFC] Потеря давления               | невозможно            | неприменимо, потому что<br>Общий объем (л) * давление (кПа) < 200<br>Насос:<br>1 л * 190 кПа = 190 < 200<br>Компрессор:<br>0.1 л * 1700 кПа = 170 < 200                                                                                                                                                                                                                                                                                                                                                                               | IEC 60601-1:2005 9.7.5<br>IEC 60601-1:2005 9.7.6 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005 / EN 60601-1:2006 | неприменимо          | неприменимо  | неприменимо   | неприменимо | неприменимо              | неприменимо                                                                                                                           | неприменимо     | неприменимо        | невозможно  | неприменимо              |                                 |  |  |
| HA1360                                                              | контур охлаждения (устройство для сброса давления)                      | Общая травма (средней тяжести) | критически            | [SFC] Потеря давления               | едва ли возможно      | Применяется устройство для сброса давления (см. LoCC) со следующими спецификациями:<br>- открывается при 17,7 бар ±0,7<br>- испытательное давление 41 бар<br>- давление разрыва 345 бар<br>- предельное количество циклов: минимум 100000<br>Устройство для сброса давления установлено на блоке охлаждения, рядом с элементами, работающими под давлением. Его нельзя регулировать или отключать без использования специальных инструментов и расположен он внутри устройства. Между устройством для сброса давления и компонентами, | IEC 60601-1:2005 9.7.7 [TRF]<br>Директива 93/42/EEC по медицинским изделиям                           | IEC 60601-1:2005 / EN 60601-1:2006 | да                   | -            | -             | да          | да                       | Спецификация системы охлаждения (компрессор, вентилятор, насос)                                                                       | Мпо             | невозможно         | неприменимо |                          |                                 |  |  |



Управление рисками по устройству  
Анализ рисков, оценка и контроль  
На основе анализа характера, последствий и важности отказов

| Анализ рисков                                                                                |                                                                                             |                                                                                       |               |                                                                                                                                  |            | Управление рисками                                                                                                                                                                                                                                                     |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------|----------------------------------------------------------------------------------------------------------------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------------------|--------------|---------------|-------------|------------------------|----------------------|-------------------------------------------------------------------------------------------------|----------------|--------------------------|---------------------------------|
|                                                                                              |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   | Безопасность |               |             | Осуществление контроля |                      |                                                                                                 |                | Оценка остаточного риска |                                 |
|                                                                                              |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   | Конструкция  | Защитные меры | Информация  | Эффективность проверки | Выполнение проверено | Зачисл. (записи)                                                                                | Оценочные меры |                          |                                 |
| №                                                                                            | Опасность                                                                                   | Мед./технолог. Эффект                                                                 | S             | Потенциал серьезности                                                                                                            | A          | Меры противодействия                                                                                                                                                                                                                                                   | Применяемые стандарты                                                                    |                                   |              |               |             |                        |                      |                                                                                                 |                | A                        | Анализ соотношения рисков/выгод |
|                                                                                              |                                                                                             |                                                                                       |               |                                                                                                                                  |            | Меры, которые он защищает, отсечного клапана вет.                                                                                                                                                                                                                      |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
| 6. Биологические и химические опасности                                                      |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
| 6.1 Биологические опасности                                                                  |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
| HA1370                                                                                       | Биологическая несовместимость (выбор материала, совместимость с вещества, тканя, материалы) | Травмы пациента, пользователей или третьих лиц                                        | критически    | Использование материалов, которые не разрешены к применению в частях, контактирующих с пациентом (трубка, аппликатор, подкладка) | часто      | Соответствие ISO 10993-1                                                                                                                                                                                                                                               | IEC 60601-1:2005 11.7<br>ISO 10993-1:2009<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006 | -            | да            | -           | да                     | да                   | Проверка аппликаторов и сканера                                                                 | JE             | невозможно               | неприменимо                     |
| 6.2 Химические опасности                                                                     |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
| 6.2.1 Воздействие на имущество                                                               |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
| HA1380                                                                                       | Опасности, связанные с эксплуатацией устройства                                             | Нежелательные побочные эффекты (умеренные)                                            | несущественно | использование несовместимых веществ                                                                                              | невозможно | Ультразвуковой гель используется между сапфировой пластиной аппликатора и кожей. Описание в руководстве пользователя об использовании с ультразвуковым гелем и очистке аппликатора                                                                                     | IEC 60601-1:2005 11.6.8 [TRF]                                                            | IEC 60601-1:2005/ EN 60601-1:2006 | да           | -             | да          | да                     | да                   | Руководство пользователя<br>Проверка несовместимости                                            | ZI<br>IH       | невозможно               | неприменимо                     |
| 7. Опасности, связанные с эксплуатацией устройства                                           |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
| 7.1 Опасности, связанные с функциональными возможностями устройства                          |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
| HA1390                                                                                       | неприменимо                                                                                 | неприменимо                                                                           | несущественно | неприменимо                                                                                                                      | невозможно | неприменимо, так как в устройстве не используется батарея или дополнительный источник питания согласно IEC 60601-1 пункт 7.9.2.4                                                                                                                                       | IEC 60601-1:2005 7.9.2.4 [TRF]                                                           | IEC 60601-1:2005/ EN 60601-1:2006 | неприменимо  | неприменимо   | неприменимо | неприменимо            | неприменимо          | неприменимо                                                                                     | неприменимо    | невозможно               | неприменимо                     |
| HA1400                                                                                       | неприменимо                                                                                 | неприменимо                                                                           | несущественно | неприменимо                                                                                                                      | невозможно | Отсутствуют световые индикаторы согласно IEC 60601-1 пункт 7.8.1                                                                                                                                                                                                       | IEC 60601-1:2005 7.8.1                                                                   | IEC 60601-1:2005/ EN 60601-1:2006 | неприменимо  | неприменимо   | неприменимо | неприменимо            | неприменимо          | неприменимо                                                                                     | неприменимо    | невозможно               | неприменимо                     |
| HA1430                                                                                       | Сложная и запутанная система управления и эксплуатации (эксплуатационная ошибка)            | Неправильно заданы значения параметров<br>Автоматическая остановка лечебной процедуры | незначительно | Слишком сложная система управления / Пользовательский интерфейс                                                                  | иногда     | Проверка эксплуатационной пригодности (Хорошо различимое изображение на ЖК-дисплее с сенсорным экраном, с очевидным предназначением кнопки аварийного выключения лазера на передней части, звуковой сигнал при изменении параметров, эргономичное расположение кнопок) | IEC 60601-1:2005 15.1 [TRF]<br>EN 62366:2008 4.1, 5.3, 6                                 | EN 60601 1 6: 2010                | да           | -             | -           | да                     | да                   | Файл проектирования эксплуатационной пригодности                                                | ZI             | невозможно               | неприменимо                     |
| 7.2 Опасности, связанные с нежелательными побочными эффектами и недостаточной эффективностью |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
| 7.2.1 Неправильный результат процедуры                                                       |                                                                                             |                                                                                       |               |                                                                                                                                  |            |                                                                                                                                                                                                                                                                        |                                                                                          |                                   |              |               |             |                        |                      |                                                                                                 |                |                          |                                 |
| HA1440                                                                                       | Неправильный результат процедуры                                                            | Общая травма (средней тяжести)                                                        | критически    | Нестандартная задача может потребовать изменения заданных настроек элементов управления.                                         | иногда     | Отображение на дисплее выбранных параметров соответствующей лазерной процедуры:<br>- Плотность энергии<br>- Длительность импульса<br>- Частота повторения импульсов                                                                                                    | IEC 60601-1:2005 15.4.5 [TRF]                                                            | IEC 60601-1:2005/ EN 60601-1:2006 | да           | да            | -           | да                     | да                   | Программное обеспечение для проверки, HA120<br>Файл проектирования эксплуатационной пригодности | MMo<br>ZI      | невозможно               | неприменимо                     |
| HA1450                                                                                       | Ошибочные измерения и другие аспекты измерений                                              | Передозировка процедуры<br>Везикулы и/или рубцы                                       | незначительно | Неправильные параметры лазера из-за неправильного выбора аппликатора                                                             | иногда     | - Данные аппликатора, сохраненные в модуль памяти EEPROM, где указан тип дисплея и/или размер лазерных пятен на дисплее<br>- Защита от опасных начальных значений через отображение плотности энергии на дисплее                                                       | IEC 60601-1:2005 14.6.1 (данные недоступны)                                              | EN 62304: 2006                    | да           | -             | да          | да                     | да                   | Программное обеспечение для проверки, HA120<br>Анализ отскакиваемости                           | RH             | невозможно               | неприменимо                     |

**Управление рисками по устройству**  
**Анализ рисков, оценка и контроль**  
**На основе анализа характера, последствий и важности отказов**

| №      | Анализ рисков                                                                                                                                                                                  |                                                                                                            |               |                                                                                                                                                                     |        |                                                                                                                                                                                                                                                                                                                                           | Управление рисками                                                               |                    |               |                        |                         |                      |                                                                                                                                    |                                                                       |            |            |                                 |             |
|--------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------|---------------|------------------------|-------------------------|----------------------|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|------------|------------|---------------------------------|-------------|
|        |                                                                                                                                                                                                |                                                                                                            |               |                                                                                                                                                                     |        |                                                                                                                                                                                                                                                                                                                                           | Безопасность                                                                     |                    |               | Осуществление контроля |                         |                      |                                                                                                                                    | Оценка остаточного риска                                              |            |            |                                 |             |
|        | Идентификация опасности                                                                                                                                                                        | Мед./технолог. Эффект                                                                                      | S             | Последствия                                                                                                                                                         | A      | План действий                                                                                                                                                                                                                                                                                                                             | Применяемые стандарты                                                            | Конструкция        | Защитные меры | Информация             | Эффективность проверки? | Выполнение проверки? | Запись (данные)                                                                                                                    | Ответственное лицо                                                    | A          | Важность   | Анализ соотношения рисков/выгод |             |
| HA1460 | Ошибочные измерения и другие аспекты измерений                                                                                                                                                 | Передозировка процедуры<br>Везикулы и/или рубцы                                                            | незначительно | неправильное значение параметров лазера вследствие изменения параметров тока из-за неисправности блока управления диодом                                            | иногда | - контроль значений привода и длительности импульса<br>- блокировка импульсов<br>- избыточное измерение тока                                                                                                                                                                                                                              | EN 62304: 2006                                                                   | -                  | да            | -                      | да                      | да                   | Программное обеспечение для проверки, HA120<br>Анализ отслеживаемости                                                              | RH                                                                    | невозможно | -          | неприменимо                     |             |
| HA1470 | Ошибочные измерения и другие аспекты измерений                                                                                                                                                 | Передозировка процедуры<br>Везикулы и/или рубцы                                                            | незначительно | Неверные параметры лазера из-за ошибок индикации (главный процесс)                                                                                                  | иногда | - Отображение сообщений с подтверждением                                                                                                                                                                                                                                                                                                  | IEC 60601-1:2005 14.6.1 (отсутствие достоверности данных)                        | EN 62304: 2006     | -             | да                     | -                       | да                   | да                                                                                                                                 | Программное обеспечение для проверки, HA120<br>Анализ отслеживаемости | RH         | невозможно | -                               | неприменимо |
| HA1480 | Ошибочные измерения и другие аспекты измерений                                                                                                                                                 | Передозировка процедуры<br>Везикулы и/или рубцы<br>Ожоги кожи третьей степени                              | незначительно | Неверные параметры лазера из-за неправильной длительности импульсов                                                                                                 | иногда | - контроль тактовой частоты<br>- блокировка импульсов                                                                                                                                                                                                                                                                                     | IEC 60601-1:2005 14.6.1 (неправильное согласование данных во времени)            | EN 62304: 2006     | -             | да                     | -                       | да                   | да                                                                                                                                 | Программное обеспечение для проверки, HA120<br>Анализ отслеживаемости | RH         | невозможно | -                               | неприменимо |
| HA1481 | Ошибочные измерения и другие аспекты измерений                                                                                                                                                 | Передозировка процедуры<br>Везикулы и/или рубцы                                                            | незначительно | неправильная временная последовательность соединения / главный - подчиненный                                                                                        | иногда | - Отображение сообщений с подтверждением                                                                                                                                                                                                                                                                                                  | IEC 60601-1:2005 14.6.1 (отсутствие достоверности данных)                        | EN 62304: 2006     | -             | да                     | -                       | да                   | да                                                                                                                                 | Программное обеспечение для проверки, HA120<br>Анализ отслеживаемости | RH         | невозможно | -                               | неприменимо |
| HA1482 | Ошибочные измерения и другие аспекты измерений                                                                                                                                                 | Передозировка процедуры<br>Везикулы и/или рубцы                                                            | незначительно | неправильная временная последовательность лазерного импульса и оценки                                                                                               | иногда | - Синхронизированы лазерный импульс с оценкой и контролем переполнения                                                                                                                                                                                                                                                                    | IEC 60601-1:2005 14.6.1 (отсутствие достоверности данных)                        | EN 62304: 2006     | -             | да                     | -                       | да                   | да                                                                                                                                 | Программное обеспечение для проверки, HA120<br>Анализ отслеживаемости | RH         | невозможно | -                               | неприменимо |
| HA1490 | Недостаточная спецификация на проверку перед использованием<br>1. Неправильное значение для процедуры<br>2. Неконтролируемый выброс несфокусированного излучения<br>3. Биологическое заражение | Отсутствует герметический эффект<br>Повреждения глаз<br>Передозировка процедуры<br>Перекрестное заражение  | критически    | Повреждение оптическим излучением<br>Эксплуатация в ненадлежащих внешних условиях<br>Неправильная насадка / ленто<br>Использование неидентифицированного приложения | иногда | Рекомендации в руководстве пользователя:<br>Описание в руководстве пользователя мер безопасности до процедур и во время процедур<br>Определение в руководстве пользователя условий хранения, транспортировки и эксплуатации<br>Спецификация требований для безопасного использования лазерного устройства<br>Четкое описание аппликаторов | EN 62366:2008 4.1, 5.3, 6<br>EN 60601-1-6:2010<br>EN 62366:2008 / IEC 62363:2007 | да                 | да            | да                     | да                      | да                   | Руководство пользователя<br>Контрольный список, руководство пользователя<br>Файл эксплуатационной пригодности<br>Протокол обучения | ZI                                                                    | невозможно | -          | неприменимо                     |             |
| HA1500 | Спорное или неоднозначное отображение на дисплее настроек параметров, результатов измерений и других характеристик (Непреднамеренная настройка параметров или сбой при настройке параметров)   | Отсутствует или слишком незначительный герметический эффект<br>Передозировка процедуры<br>Побочные эффекты | критически    | Вводящая в заблуждение индикация на дисплее                                                                                                                         | иногда | Интуитивно понятный дизайн графического интерфейса.<br>Проверка эксплуатационной пригодности.<br>(Коммуникационный дисплей с подтверждением, изменение параметров только в режиме ожидания и проверка данных во время перехода в режим готовности, понятный без пояснений дисплей)                                                        | 60601-1-6:2004 4.2, 6.1, 6.2.2.3                                                 | EN 60601-1-6: 2010 | да            | -                      | да                      | да                   | да                                                                                                                                 | Файл проектирования эксплуатационной пригодности                      | ZI         | невозможно | -                               | неприменимо |
| HA1510 | Спорное или неоднозначное отображение на дисплее настроек параметров, результатов измерений и других характеристик (Неправильное толкование отображаемых на дисплее значений)                  | Отсутствует или слишком незначительный герметический эффект<br>Передозировка процедуры, Побочные эффекты   | критически    | Вводящая в заблуждение индикация на дисплее                                                                                                                         | иногда | Интуитивно понятный дизайн графического интерфейса.<br>Проверка эксплуатационной пригодности.<br>(Четкое изображение на ЖК дисплее с сенсорным экраном)<br>Идентичные позиции отображаемых значений на всех пользовательских дисплеях)                                                                                                    | 60601-1-6:2004 4.2, 6.1, 6.2.2.3                                                 | EN 60601-1-6: 2010 | да            | -                      | да                      | да                   | да                                                                                                                                 | Файл проектирования эксплуатационной пригодности                      | ZI         | невозможно | -                               | неприменимо |
| HA1520 | Спорное или неоднозначное отображение на дисплее настроек параметров, результатов измерений и других характеристик (Вводящее в заблуждение отображение данных)                                 | Отсутствует или слишком незначительный герметический эффект<br>Передозировка процедуры, Побочные эффекты   | критически    | Вводящая в заблуждение индикация на дисплее                                                                                                                         | иногда | Интуитивно понятный дизайн графического интерфейса.<br>Проверка эксплуатационной пригодности.<br>(Четкое изображение на ЖК дисплее с сенсорным экраном, понятный без пояснений, несуществующие данные отображаются только в подменю, отображение значений в единицах СИ)                                                                  | 60601-1-6:2004 4.2, 6.1, 6.2.2.3                                                 | EN 60601-1-6: 2010 | да            | -                      | да                      | да                   | да                                                                                                                                 | Файл проектирования эксплуатационной пригодности                      | ZI         | невозможно | -                               | неприменимо |



**Управление рисками по устройству**  
**Анализ рисков, оценка и контроль**  
**На основе анализа характера, последствий и важности отказов**

| Анализ рисков          |                                                                                                 |                                                                                                            |               |                                                                                 | Управление рисками |                                                                                                                                                                                                                                                                                                                                                 |                                                                              |                                   |                        |             |                         |                      |                                                                                                  |                    |            |                                 |
|------------------------|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------|---------------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------|------------------------|-------------|-------------------------|----------------------|--------------------------------------------------------------------------------------------------|--------------------|------------|---------------------------------|
|                        |                                                                                                 |                                                                                                            |               |                                                                                 | Безопасность       |                                                                                                                                                                                                                                                                                                                                                 |                                                                              |                                   | Осуществление контроля |             |                         |                      | Оценка остаточного риска                                                                         |                    |            |                                 |
| №                      | Опасность                                                                                       | Мед./технолог. Эффект                                                                                      | S             | Причина неадекватности                                                          | A                  | Последствия                                                                                                                                                                                                                                                                                                                                     | Применимые стандарты                                                         | Конструкция                       | Защитные меры          | Информация  | Эффективность проверки? | Выполнение проверки? | Запись / отчет                                                                                   | Ответственное лицо | А          | Анализ соответствия требованиям |
| HA1530                 | Недостаточная видимость, слышимость и достаточный контакт (Неправильная настройка параметров)   | Отсутствует или слишком незначительный терапевтический эффект<br>Передозировка процедуры, побочные эффекты | критически    | Видимость дисплея при интенсивном освещении или через лазерные защитные очки    | иногда             | Меры противодействия:<br>Интуитивно понятный дизайн графического интерфейса.<br>Проверка эксплуатационной пригодности.<br>(Дисплей с подсветкой, кнопка аварийной остановки лазера, регулируемая яркость дисплея, четкая цветовая гамма дисплея, легко различимая при чтении через защитные очки)                                               | EN 62366:2008 4.1, 5.3                                                       | EN 60601 1:2010                   | да                     | -           | да                      | да                   | Файл проектирования эксплуатационной пригодности                                                 | ZI                 | невозможно | исприменено                     |
| 7.2.2 Побочные эффекты |                                                                                                 |                                                                                                            |               |                                                                                 |                    |                                                                                                                                                                                                                                                                                                                                                 |                                                                              |                                   |                        |             |                         |                      |                                                                                                  |                    |            |                                 |
| HA 1551                | Эксплуатация за пределами требуемых условий окружающей среды                                    | - перегрев устройства<br>- отклонение параметров лазера<br>- передозировка процедуры                       | незначительно | Слишком высокая температура теплоотвода                                         | иногда             | - постоянные проверки температуры воды для дна и температуры охлаждающей жидкости для компрессора<br>- постоянная регулировка скорости вентилятора<br>- рекомендации в инструкции по эксплуатации<br>При слишком высокой температуре устройство переключается в режим STANDBY (ожидание) Без опасности для пациента, пользователя и третьих лиц | EN 62304: 2006                                                               | -                                 | да                     | -           | да                      | да                   | Программное обеспечение для проверки HA120<br>Анализ отслеживаемости                             | RH                 | невозможно | исприменено                     |
| HA1560                 | Сбой устройства или функции из-за неполадки / или функции                                       | - Передозировка процедуры<br>- Везкулы и/или рубцы                                                         | незначительно | отказы датчиков тока                                                            | иногда             | Постоянный контроль за состоянием оборудования и программного обеспечения, устройство сигнализации о неисправностях<br>- избыточное измерение тока<br>- Автоматический перевод устройства в режим ожидания или отключение при неполадках<br>- Кнопка аварийного выключения лазера                                                               | EN 62304: 2006                                                               | -                                 | да                     | -           | да                      | да                   | Программное обеспечение для проверки HA120<br>Анализ отслеживаемости                             | RH                 | невозможно | исприменено                     |
| HA1570                 | Опасности на основе исследования базы данных Управления по контролю за продуктами и лекарствами | - Передозировка процедуры<br>- Везкулы и/или рубцы                                                         | незначительно | слишком высокий выход энергии                                                   | иногда             | - избыточная система измерения тока<br>- блокировка импульсов<br>- ежедневный контроль калибровки выходного излучения лазера                                                                                                                                                                                                                    | EN 62304: 2006                                                               | -                                 | да                     | -           | да                      | да                   | Программное обеспечение для проверки HA120<br>Анализ отслеживаемости<br>Руководство пользователя | RH<br>ZI           | невозможно | исприменено                     |
| HA1580                 | Опасности, связанные с эксплуатацией устройства (неконтролируемое функционирование)             | Неправильный терапевтический эффект вызванный неправильной мощностью неадекватного излучения               | незначительно | Слишком низкое или слишком высокое напряжение                                   | иногда             | - источник питания с входным напряжением 115 В~; 50/60 Гц, 1400 ВА<br>220-240 В~; 50/60 Гц, 1500 ВА (+/- 10%)<br>- Контроль выходных параметров                                                                                                                                                                                                 | Директива 93/42/ЕЕС по медицинским изделиям                                  | да                                | -                      | -           | да                      | да                   | Устройство для проверки<br>Спецификация                                                          | MMo                | невозможно | исприменено                     |
| HA 1590                | Опасности, связанные с эксплуатацией устройства                                                 | Нежелательные побочные эффекты (умеренные)                                                                 | незначительно | Повреждения деталей в принадлежностях из-за многократной очистки и дезинфекция. | иногда             | При более обширной очистке и дезинфекции неприемлемых рисков не ожидается<br>- поверхность устройства может очищаться многократно<br>- контактная часть с биосовместимым материалом (сапфировое стекло)<br>- Руководство пользователя: описание процедур очистки и дезинфекции                                                                  | IEC 60601-1:2005 11.6.6 (TRF)<br>Директива 93/42/ЕЕС по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006 | да                     | -           | да                      | да                   | Проверка аппликаторов и станера<br>Руководство пользователя                                      | ZI                 | невозможно | исприменено                     |
| HA1600                 | исприменено                                                                                     | исприменено                                                                                                | несущественно | исприменено                                                                     | невозможно         | исприменено, так как стерилизация не требуется                                                                                                                                                                                                                                                                                                  | IEC 60601-1:2005 11.6.7 (TRF)<br>Директива 93/42/ЕЕС по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006 | исприменено            | исприменено | исприменено             | исприменено          | исприменено                                                                                      | исприменено        | невозможно | исприменено                     |



**Управление рисками по устройству**  
**Анализ рисков, оценка и контроль**  
**На основе анализа характера, последствий и важности отказов**

| Анализ рисков                                        |                                                                                                              |                                                                                         |               |                                                                                             |            | Управление рисками                                                                                                                                                                                                                                     |                                                                             |                                             |                        |               |              |                         |                      |                                                                                                                                                   |                 |            |                                 |
|------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|---------------|---------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|---------------------------------------------|------------------------|---------------|--------------|-------------------------|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------|---------------------------------|
|                                                      |                                                                                                              |                                                                                         |               |                                                                                             |            | Безопасность                                                                                                                                                                                                                                           |                                                                             |                                             | Осуществление контроля |               |              |                         |                      | Оценка остаточного риска                                                                                                                          |                 |            |                                 |
|                                                      |                                                                                                              |                                                                                         |               |                                                                                             |            |                                                                                                                                                                                                                                                        |                                                                             |                                             | Конструкция            | Защитные меры | Информация   | Эффективность проверки? | Выполнение проверки? | Зачем (зачем)                                                                                                                                     | Отвечающее лицо | А          | Анализ соотношения рисков/выгод |
| HA1610                                               | Опасности, связанные с эксплуатацией устройства                                                              | Нежелательные побочные эффекты (умеренные)                                              | незначительно | Сопроводительные документы отсутствуют или с алаповитными формулировками                    | невозможно | Меры противодействия<br>неприменяемо, потому что документация предоставляется в бумажном виде.<br>Сопроводительные документы для MedioStar включают в себя:<br>- Руководство пользователя<br>- Техническое описание как часть руководства пользователя | IEC 60601-1:2005 7.9.1 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006           | неприменяемо           | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо         | Зачем (зачем)<br><br>неприменяемо                                                                                                                 | неприменяемо    | невозможно | неприменяемо                    |
| HA1620                                               | Хранение и эксплуатация в пределах указанных условий окружающей среды                                        | Нежелательные побочные эффекты (умеренные)                                              | незначительно | Недостаточная упаковка                                                                      | иногда     | Испытание упаковки на соответствие указанным условиям транспортировки, хранения и эксплуатации                                                                                                                                                         |                                                                             | Директива 93/42/EEC по медицинским изделиям | да                     | -             | -            | да                      | да                   | Проверка упаковки                                                                                                                                 | KI              | невозможно | неприменяемо                    |
| HA1630                                               | Обоснованно прогнозируемое исправальное использование (использование не по назначению)                       | Общая травма (средней тяжести)                                                          | критически    | Человеческая ошибка                                                                         | иногда     | Имитационно понятный дизайн устройства MedioStar<br>Проверка эксплуатационной пригодности.<br>(Точное описание предполагаемого использования и обращения с устройством в руководстве пользователя)                                                     | EN 62366:2008 4.1, 5.3, 6                                                   | EN 60601-1-6:2010                           | да                     | -             | да           | да                      | да                   | Файл проектирования эксплуатационной пригодности                                                                                                  | ZI              | невозможно | неприменяемо                    |
| HA1640                                               | Неудовлетворительное предупреждение о побочных эффектах (Ошибочные параметры процедур)                       | Побочные эффекты                                                                        | критически    | Необученный или недостаточно квалифицированный пользователь                                 | иногда     | Описание профиля предполагаемого пользователя<br>Подготовка персонала                                                                                                                                                                                  | EN 62366:2008 4.1, 5.3, 6                                                   | EN 60601-1-6:2010                           | да                     | -             | да           | да                      | да                   | Файл проектирования эксплуатационной пригодности<br>Руководство пользователя<br>Контрольный список, руководство пользователя<br>Протокол обучения | ZI              | невозможно | неприменяемо                    |
| HA1650                                               | Неудовлетворительное предупреждение о противопоказаниях (Неправильное использование устройства)              | Побочные эффекты                                                                        | незначительно | Недостаточное описание предполагаемого использования                                        | иногда     | Описание предполагаемого использования в руководстве пользователя                                                                                                                                                                                      | EN 62366:2008 4.1, 5.3, 6                                                   | EN 60601-1-6:2010                           | да                     | -             | да           | да                      | да                   | Руководство пользователя<br>Контрольный список, руководство пользователя                                                                          | ZI              | невозможно | неприменяемо                    |
| HA1660                                               | Повреждения при транспортировке (Слишком большой вес или неправильное распределение массы; затупленные края) | Повреждения во время транспортировки; Вред, причиненный вследствие перемещения тяжестей | незначительно | Слишком большое, не эргономичное и тяжелое устройство, неудовлетворительная упаковка        | иногда     | Минимизация веса<br>Равномерно распределенный вес<br>Отсутствие несущих элементов<br>Встроенные ручки<br>Надлежащая упаковка, датчики для отгрузки изделий (Испытания упаковки)                                                                        | EN 62366:2008 4.1, 5.3                                                      | EN 60601-1-6:2010                           | да                     | -             | да           | да                      | да                   | Чертеж<br>Проверка упаковки<br>Устройство для проверки                                                                                            | ZI              | невозможно | неприменяемо                    |
| 8. Маркировка                                        |                                                                                                              |                                                                                         |               |                                                                                             |            |                                                                                                                                                                                                                                                        |                                                                             |                                             |                        |               |              |                         |                      |                                                                                                                                                   |                 |            |                                 |
| 8.1 Опасности, связанные с инструкциями по установке |                                                                                                              |                                                                                         |               |                                                                                             |            |                                                                                                                                                                                                                                                        |                                                                             |                                             |                        |               |              |                         |                      |                                                                                                                                                   |                 |            |                                 |
| HA1670                                               | неприменяемо                                                                                                 | неприменяемо                                                                            | неприменяемо  | неприменяемо                                                                                | невозможно | неприменяемо, из-за отсутствия опасности в случае преждевременной распаковки устройства MedioStar.                                                                                                                                                     | IEC 60601-1:2005 7.2.17 [TRF]                                               | IEC 60601-1:2005/ EN 60601-1:2006           | неприменяемо           | неприменяемо  | неприменяемо | неприменяемо            | неприменяемо         | неприменяемо                                                                                                                                      | неприменяемо    | невозможно | неприменяемо                    |
| 8.2 Опасности, связанные с маркировкой устройства    |                                                                                                              |                                                                                         |               |                                                                                             |            |                                                                                                                                                                                                                                                        |                                                                             |                                             |                        |               |              |                         |                      |                                                                                                                                                   |                 |            |                                 |
| HA1680                                               | Опасности, связанные с маркировкой устройства                                                                | Нежелательные побочные эффекты (умеренные)                                              | незначительно | Маркировка неправильная или отсутствует                                                     | иногда     | Маркировка устройства в соответствии с пунктом 7.2.2 - Заводская табличка на устройстве:<br>- Этикетка с номером детали на аппликаторе<br>- Номер редакции программного обеспечения и дата выпуска в ГИП (и в сервисном режиме)                        | IEC 60601-1:2005 7.2.2 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601-1:2005/ EN 60601-1:2006           | да                     | -             | да           | да                      | да                   | Контрольный список, этикетки устройства<br>AA 7331 Техническая документация                                                                       | MMo             | невозможно | неприменяемо                    |
| HA1690                                               | Недостаточная маркировка и спецификация принадлежностей                                                      | Повреждения глаз<br>Передозировка процедуры                                             | критически    | Неконтролируемый выброс ионизирующего излучения<br>Неправильный аппликатор / лазерное пятно | иногда     | Маркировка и спецификация принадлежностей (например, аппликатор, ножной переключатель, индикаторная лампа лазерного излучения и блокировка лазера)                                                                                                     | Директива 93/42/EEC по медицинским изделиям<br>EN 62366:2008 4.1, 5.3, 6    | EN 60601-1-6:2010                           | -                      | да            | -            | да                      | да                   | Схема маркировки<br>Контрольный список, этикетки устройства<br>Схема, EN 980 / EN ISO 15223-1                                                     | MMo             | невозможно | неприменяемо                    |

Управление рисками по устройству  
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| Анализ рисков                                        |                                                                          |                                                          |               |                                                                                                                                                     |            | Управление рисками                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                              |                                   |                         |                           |                  |                    |              |                                                                                                |                          |            |              |
|------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------|-------------------------|---------------------------|------------------|--------------------|--------------|------------------------------------------------------------------------------------------------|--------------------------|------------|--------------|
|                                                      |                                                                          |                                                          |               |                                                                                                                                                     |            | Безопасность                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                              |                                   |                         | Эффективность мониторинга |                  |                    |              | Оценка остаточного риска                                                                       |                          |            |              |
|                                                      |                                                                          |                                                          |               |                                                                                                                                                     |            | Конструкция                                                                                                                                                                                                                                                                                                                                                                                                         | Защитные меры                                                                | Информация                        | Эффективность проверки? | Выполнение проверки?      | Запись (информ.) | Ответственное лицо | А            | Остаточный риск                                                                                | Анализ остаточного риска |            |              |
| №                                                    | Опасность                                                                | Мед./технолог. Эффект                                    | В             | Точность неисправности                                                                                                                              | А          | Меры предотвращения                                                                                                                                                                                                                                                                                                                                                                                                 | Директива 93/42/EEC по медицинским изделиям                                  | Применяемые стандарты             |                         |                           |                  |                    |              |                                                                                                |                          |            |              |
| HA1691                                               | Неудовлетворительная маркировка устройства (несоответствующее излучение) | Повреждения глаз<br>Повреждение кожи<br>Опасность пожара | критически    | Отсутствуют или неверные правила техники безопасности                                                                                               | иногда     | Маркировка устройства о соответствии стандартам<br>Рекомендации-предупреждения в руководстве пользователя:                                                                                                                                                                                                                                                                                                          | Директива 93/42/EEC по медицинским изделиям<br>EN 62366:2008 4.1, 5.3, 6     | EN 60601-1-6:2010                 | -                       | да                        | -                | да                 | да           | Схема маркировки<br>Контрольный список, этикетки устройства<br>Оценка, EN 980 / EN ISO 15223-1 | ММ                       | невозможно | неприменяемо |
| HA1692                                               | Неудовлетворительная маркировка устройства (неправильное применение)     | нарушение процедуры лечения                              | незначительно | Отсутствует или неоднозначная маркировка                                                                                                            | иногда     | Маркировка устройства соответствует стандартам и точна<br>Предполагаемое использование в руководстве пользователя                                                                                                                                                                                                                                                                                                   | Директива 93/42/EEC по медицинским изделиям<br>EN 62366:2008 4.1, 5.3, 6     | EN 60601-1-6:2010                 | -                       | да                        | -                | да                 | да           | Схема маркировки<br>Контрольный список, этикетки устройства<br>Оценка, EN 980 / EN ISO 15223-1 | ММ                       | невозможно | неприменяемо |
| HA 1700                                              | неприменяемо                                                             | неприменяемо                                             | несущественно | неприменяемо                                                                                                                                        | невозможно | неприменяемо, так как отсутствует соединение с внешним источником питания                                                                                                                                                                                                                                                                                                                                           | IEC 60601-1:2005 7.2.5 [TRF]                                                 | IEC 60601-1:2005/ EN 60601-1:2006 | неприменяемо            | неприменяемо              | неприменяемо     | неприменяемо       | неприменяемо | неприменяемо                                                                                   | неприменяемо             | невозможно | неприменяемо |
| HA1710                                               | Опасности, связанные с маркировкой устройства                            | Нежелательные побочные эффекты (умеренные)               | незначительно | Знак безопасности на устройстве отсутствует или размещен в неправильном месте                                                                       | невозможно | неприменяемо, потому что все физиологические последствия очевидны для оператора, предупредительные знаки не требуются - общая информация о технике безопасности в руководстве пользователя, глава 2                                                                                                                                                                                                                 | IEC 60601 1:2005 7.2.13 [TRF]<br>Директива 93/42/EEC по медицинским изделиям | IEC 60601 1:2005/ EN 60601-1:2006 | неприменяемо            | неприменяемо              | неприменяемо     | неприменяемо       | неприменяемо | неприменяемо                                                                                   | неприменяемо             | невозможно | неприменяемо |
| HA1720                                               | Опасности, связанные с маркировкой устройства                            | Нежелательные побочные эффекты (умеренные)               | несущественно | неприменяемо                                                                                                                                        | невозможно | неприменяемо, так как замена местами «земли» и «нейтрала» не создает опасность.<br>- нет зависимых от поляризации компонентов<br>- разделение 2 полюсов<br>- протокол заключительных испытаний: электрические измерения (ток утечки) при смене полярности                                                                                                                                                           | IEC 60601-1:2005 7.3 7 [TRF]                                                 | IEC 60601-1:2005/ EN 60601-1:2006 | неприменяемо            | неприменяемо              | неприменяемо     | неприменяемо       | неприменяемо | неприменяемо                                                                                   | неприменяемо             | невозможно | неприменяемо |
| HA1730                                               | Опасности, связанные с эксплуатацией устройства                          | Нежелательные побочные эффекты (умеренные)               | незначительно | Неправильные настройки элементов управления из-за отсутствующей / неправильной индикации положения либо четко виден статус регулируемой переменной. | иногда     | - главный выключатель<br>- выключатель с ключом<br>- Кнопка останова/лазера отмечена знаком вращения для разблокирования<br>- режимы READY (готовность) и STANDBY (ожидание)<br>Обозначения элементов управления согласно IEC60601-1, таблица D1<br>- № 12 «ON» (Вкл.) (сетевой выключатель)<br>- № 13 «OFF» (Выкл.) (сетевой выключатель)<br>- № 16 «ON» (Вкл.) для компонента оборудования (выключатель с ключом) | IEC 60601-1:2005 7.4.2 [TRF]<br>Директива 93/42/EEC по медицинским изделиям  | IEC 60601-1:2005/ EN 60601-1:2006 | да                      | -                         | да               | да                 | да           | Чертежи                                                                                        | KI                       | невозможно | неприменяемо |
| HA1740                                               | Опасности, связанные с эксплуатацией устройства                          | Общая травма (средней тяжести)                           | незначительно | Неподходящая конструкция индикаторов                                                                                                                | иногда     | Состояния системы отображаются на дисплее. Во время прогрева (тестирования системы) на дисплей выводится соответствующий экран-заставка.<br>Подсоединение аппликатора отображается на рабочем экране и индикаторной лампочкой на аппликаторе.                                                                                                                                                                       | IEC 60601-1:2005 15.4.4 [TRF]                                                | IEC 60601-1:2005/ EN 60601-1:2006 | -                       | да                        | -                | да                 | да           | Программное обеспечение для подтверждения, HA130(s)<br>Анализ отслеживаемости                  | RH                       | невозможно | неприменяемо |
| 8.3 Опасности, связанные с руководством пользователя |                                                                          |                                                          |               |                                                                                                                                                     |            |                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                              |                                   |                         |                           |                  |                    |              |                                                                                                |                          |            |              |
| HA1750                                               | Опасности, связанные с руководством пользователя                         | Общая травма (средней тяжести)                           | критически    | Не приведена информация по остаточным рискам из-за недостаточных сопроводительных сведений                                                          | иногда     | Проверьте руководство пользователя на соответствие всем применимым требованиям стандарта IEC 60601-1                                                                                                                                                                                                                                                                                                                | IEC 60601-1:2005 7.9.2 [TRF]<br>Директива 93/42/EEC по медицинским изделиям  | IEC 60601-1:2005/ EN 60601-1:2006 | да                      | -                         | да               | да                 | да           | Контрольный список, руководство пользователя                                                   | ZI                       | невозможно | неприменяемо |



Управление рисками по устройству  
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| №                                             | Анализ рисков |                                                                                                               |                                                                     |               |                                                                        | Управление рисками |               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                          |                                   |               |            |                          |                       |                 |                                                                              |     |                    |                                 |
|-----------------------------------------------|---------------|---------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|---------------|------------------------------------------------------------------------|--------------------|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-----------------------------------|---------------|------------|--------------------------|-----------------------|-----------------|------------------------------------------------------------------------------|-----|--------------------|---------------------------------|
|                                               |               |                                                                                                               |                                                                     |               |                                                                        | Безопасность       |               |                                                                                                                                                                                                                                                                                                                                                                                                                                                | Осуществление контрмер                                                   |                                   |               |            | Оценка остаточного риска |                       |                 |                                                                              |     |                    |                                 |
|                                               |               |                                                                                                               |                                                                     |               |                                                                        |                    |               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                          |                                   |               |            |                          |                       |                 |                                                                              |     |                    |                                 |
|                                               | №             | Опасность                                                                                                     | Мед./технолог. Эффект                                               | S             | Причина неисправности                                                  | A                  | Первая оценка | Меры противодействия                                                                                                                                                                                                                                                                                                                                                                                                                           | Применимые стандарты                                                     | Конструкция                       | Защитные меры | Информация | Эффективность проверки?  | Выполнение проверено? | Запись (записи) | Ответственное лицо                                                           | A   | Оценки остаточного | Анализ соотношения рисков/выгод |
|                                               | HA1760        | Руководство пользователя слишком сложное (Неправильное обращение и техническое обслуживание)                  | нарушение процедуры лечения                                         | незначительно | Неправильное обращение<br>Неудовлетворительно техническое обслуживание | иногда             |               | Меры противодействия основано на предшествующем устройстве, которое никогда не вызывало никаких проблем<br>Проверка пригодности руководства пользователя                                                                                                                                                                                                                                                                                       | Директива 93/42/EEC по медицинским изделиям<br>EN 62366:2008 4.1, 5.3, 6 | EN 60601-1-6: 2010                | да            | -          | да                       | да                    | да              | Файл проектирования эксплуатационной пригодности                             | ZI  | невозможно         | неприменим                      |
| 9. Изучение рекламаций / рыночной конъюнктуры |               |                                                                                                               |                                                                     |               |                                                                        |                    |               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                          |                                   |               |            |                          |                       |                 |                                                                              |     |                    |                                 |
| 9.1 Ответности, связанные с жалобами          |               |                                                                                                               |                                                                     |               |                                                                        |                    |               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                          |                                   |               |            |                          |                       |                 |                                                                              |     |                    |                                 |
|                                               | HA1770        | Использование устройства неквалифицированным / необученным персоналом (Неправильное использование устройства) | Недостаточный терапевтический эффект<br>Нарушение процедуры лечения | незначительно | Отсутствуют требования по целевому применению                          | иногда             |               | Описание профиля предполагаемого пользователя<br>Подготовка персонала<br>Защита от несанкционированного использования с помощью выключателя с ключом                                                                                                                                                                                                                                                                                           | EN 62366:2008 4.1, 5.3, 6                                                | EN 60601-1-6:2010                 | да            | -          | да                       | да                    | да              | Файл проектирования эксплуатационной пригодности<br>Руководство пользователя | ZI  | невозможно         | неприменим                      |
|                                               | HA1780        | Осложнения / Прекращение процедуры                                                                            | Прекращение процедуры                                               | критически    | [SFC] Неточные значения элементов управления и/или приборов.           | иногда             |               | Фактическое значение излучения в пределах ± 20% от значения на дисплее (плотность энергии).<br>Непрерывный контроль и управление параметрами, предупреждения или сообщения об ошибках при превышении допусков параметров (отклонение > 20%).<br>Непрерывный мониторинг с помощью двух независимых систем измерения (электрические датчики)<br>Отключите устройство в случае превышения более чем на 50%<br>Укажите DIN EN 60601-2-22 раздел 51 | IEC 60601-1:2005 12.1 [TRF]<br>4.7 [TRF]                                 | IEC 60601-1:2005/ EN 60601-1:2006 | -             | да         | -                        | да                    | да              | Акт о проверке лазера                                                        | MMo | невозможно         | неприменим                      |
|                                               | HA1790        | Осложнения / Прекращение процедуры                                                                            | Прекращение процедуры                                               | критически    | [SFC] Неточные значения элементов управления и/или приборов.           | иногда             |               | Используйте сторожевое устройство, на который должны посылаться лусковые сигналы с заданной периодичностью.                                                                                                                                                                                                                                                                                                                                    | IEC 60601-1:2005 12.1 [TRF]<br>4.7 [TRF]                                 | IEC 60601-1:2005/ EN 60601 1:2006 | -             | да         | -                        | да                    | да              | Программное обеспечение для проверки, HA120<br>Анализ отслеживаемости        | RH  | невозможно         | неприменим                      |



Список записей

| Запись                                                       | Название документа                                                              | Файл истории проекта |
|--------------------------------------------------------------|---------------------------------------------------------------------------------|----------------------|
| Концепция управления рисками                                 | FB 7301 RMC MSPRO V02_MM0140519-02                                              | KA ALT 003/14 7.2.1  |
| Отчет об управлении рисками                                  | FB 7301 RMR MSPRO V02 RH141110-02                                               | KA ALT 003/14 7.2.1  |
| Схема изоляции                                               | Isolationsdiagramm MSPRO V02_MM0140708-02                                       | KA ALT 003/14 7.3    |
| Протокол испытаний согласно 60601-1                          | 21215627_001_IEC60601-1 Test report                                             | KA ALT 003/14 7.3    |
| Свидетельство об испытаниях источника питания                | HPC825 CB_Certificate DE2-018029                                                | KA ALT 003/14 7.3    |
| Протокол испытаний согласно 60601-1-2                        | 1430-13-EE-14-PB001                                                             | KA ALT 003/14 7.4    |
| Протокол испытаний согласно 60601-2-22                       | 21215627_001_atm#3_1 EC60601 -2-22                                              | KA ALT 003/14 7.3    |
| Руководство пользователя                                     | 159099001 -V06-2.Сент.2014-GA-MSPRO-DE<br>159099002-V06-2.Сент.2014-GA-MSPRO-EN | KA ALT 003/14 2.2    |
| Файл эксплуатационной пригодности                            | FB 73513 UsabilityFile MSPRO Vs01 ZI 140429-01                                  | KA ALT 003/14 7.6    |
| Техническое задание для программного обеспечения             | FB 73211 SRS MSPRO V01_CaM140205-01                                             | KA ALT 003/14 5.2    |
| Уровень озабоченности                                        | FB 7354 Level of Concern MSPRO V01_RH140204-02                                  | KA ALT 003/14 7.2.1  |
| Управление конфигурацией программного обеспечения            | FB 7332 SKM MSPRO V01 RH140204-01                                               | KA ALT 003/14 4.3    |
| Схема архитектуры                                            | ArchitectureDesignChart MSPRO V01_RH140206-23                                   | KA ALT 003/14 5.4.1  |
| <b>Спецификация на архитектуру программного обеспечения:</b> |                                                                                 |                      |
| ГИП, центральный блок                                        | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| ГИП, диод                                                    | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| ГИП, служба                                                  | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| Аппликатор                                                   | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| Подчиненный, начальная загрузка                              | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| Подчиненный, система охлаждения                              | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| Подчиненный, диод                                            | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| Подчиненный, оборудование                                    | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| Подчиненный, центральный блок                                | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| Программное обеспечение для проверки                         | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| Программное обеспечение для подтверждения                    | см. анализ отслеживаемости                                                      | KA ALT 003/14 5.4    |
| Схема маркировки                                             | 159199020 Labeling MSPRO (BL1+BL2)                                              | KA ALT 003/14 2.3    |
| Список защитных материалов и компонентов                     | FB 7331 LoCC MSPRO V02_MM0140519-01                                             | KA ALT 003/14 2.4    |
| Контрольный список, руководство пользователя                 | CL7356 GA MSPRO V02_Z1141027-01                                                 | KA ALT 003/14 7.9    |

|                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                              |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Контрольный список, этикетки устройства | CL7357 Geräteschilder MSPRO V04_AWi141110-02                                                                                                                                                                                                                                                                                                                                                                                                                                                  | KA ALT 003/14 7.9                                                            |
| Проверка упаковки                       | FB7351 Vali Verpackung MSPRO V02 KL141106-01                                                                                                                                                                                                                                                                                                                                                                                                                                                  | KA ALT 003/14 7.9                                                            |
| Проверка разлива / перелива / утечки    | FB 7351 Veri Spillage_Overflow_Leakage MSPRO V01_MMo140710-03                                                                                                                                                                                                                                                                                                                                                                                                                                 | KA ALT 003/14 7.9                                                            |
| Проверка функции охлаждения             | FB 7351 Veri Kühlung MSPRO V01 MMo140522-01                                                                                                                                                                                                                                                                                                                                                                                                                                                   | KA ALT 003/14 7.15                                                           |
| Проверка аппликаторов и сканера         | FB7351e Veri MSPRO HP V01 IH141111 -03                                                                                                                                                                                                                                                                                                                                                                                                                                                        | KA ALT 003/14 7.12                                                           |
| Акт о проверке лазера                   | FB 7351e Verification Report MDS SE Energy Adjustment rev. 01-110608<br>FB 7351e Verification Stability of Laser output MDS SE ред. 01<br>FB 7351e Verification Stability of Laser output MSNeXT V01_MMo120516-03<br>FB 7351e Veri Energy Adjustment HS ALX V01_MMo140619-04<br>FB 7351e Veri spotsize HP ALX V01_MMo140619-09<br>FB 7351e Veri Stability HS ALX V01_MMo140619-02<br>FB 7351e Veri Stability HS XL V01_MMo140819-02<br>FB 7351e Veri Energy Adjustment HS XL V01_MMo140819-01 | KA ALT 002/10 7.11<br><br><br><br><br><br><br><br><br><br>KA ALT 003/14 7.11 |
| Проверка на биосовместимость            | FB 7336BewertungMatVer Прибор_V01 AWi_141010-01<br>FB7351e Veri Biocom MS PRO HP V01 IH140710-01<br>FB7351e Veri Biocom MS NeXT HP V02 IH140617-01                                                                                                                                                                                                                                                                                                                                            | KA ALT 003/14 7.13                                                           |
| Устройство для проверки                 | FB 7351 Veri Gesamtgerät MSPRO V02 AWi141110-01                                                                                                                                                                                                                                                                                                                                                                                                                                               | KA ALT 003/14 7.9                                                            |
| Оценка, EN 980 / EN ISO 15223-1         | CL 7363 EN 980 EN 15223-1 MSPRO V01_MMo140819-04                                                                                                                                                                                                                                                                                                                                                                                                                                              | KA ALT 003/14 7.9                                                            |
| Оценка риска, датчик охлаждения         | TP 7342 Risikobetrachtung Unterkühlung V01 MMo111111-01                                                                                                                                                                                                                                                                                                                                                                                                                                       | KA ALT 002/10 7.13                                                           |

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|---------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| CL 73523      | Оценка соответствия согласно 62366 и 60 601-1-6                                       | «Асклепион»<br>Лейзер Текнолоджис<br>(Asclepion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 1 из 15<br>CL 73523 Usab MSPRO Vs02_ZI150410-01.doc            |

Протестированное оборудование: MeDioStar

Название и/или модель: 1591,1592 и 15912

Производитель: «Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)

Адрес: Брюсселер Штрассе, 10, 07747 Йена, Германия

Применяемый стандарт: EN 62366: 2008 (IEC 62366: 2007)

Медицинские приборы - применение проектирования эксплуатационной пригодности для медицинских приборов

EN 60 601-1-6: 2010 (IEC 60 601-1-6: 2010)

Медицинское электрическое оборудование - общие требования безопасности - вспомогательный стандарт: Эксплуатационная пригодность

Вложения:

| проверка и выпуск: | отдел                                | дата                | фамилия   | подпись   |
|--------------------|--------------------------------------|---------------------|-----------|-----------|
| проверено          | Отдел усовершенствованной технологии | 16 апреля 2015года  | Циммерман | /Подпись/ |
| выпущено:          | Отдел усовершенствованной технологии | 17 апреля 2015 года | А. Катцер | /Подпись/ |

|                                                         |                              |                 |                                                                 |              |                  |
|---------------------------------------------------------|------------------------------|-----------------|-----------------------------------------------------------------|--------------|------------------|
| Основание для последнего изменения:                     | новая редакция EN 60 601-1-6 |                 |                                                                 |              |                  |
| Форма составлена Отделом научно-исследовательских работ |                              |                 | Форма документа проверена и выпущена Отделом контроля качества: |              |                  |
| 04.06.2013                                              | И. Штрайт                    | Подписал Штрайт | 10.06.2013                                                      | Р. Тиме      | Подписал Р. Тиме |
| Дата                                                    | Имя, фамилия                 | Подпись         | Дата                                                            | Имя, фамилия | Подпись          |



|                 |                                                                                              |                                                                      |
|-----------------|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| CL <b>73523</b> | <b>Оценка соответствия согласно 62366 и 60 601-1-6</b>                                       | «Асклепион»<br>Лазерные Технологии<br>(Asclepion Laser Technologies) |
| Редакция №: В   | <b>Идентификационный номер: ZI/15/04/10-01</b><br>Идентификационный код/год/месяц/день-номер | Стр. 2 из 15<br>CL 73523 Usab MSPRO Vs02_ZI150410-01                 |

## Идентификация

### Подробная информация о лице, ответственном за экспертизу:

Идентификация лица, ответственного за экспертизу и классификацию продукции, подлежащих проверке:

ФИО: Габи Циммерман  
полные имя и фамилия  
(печатными буквами)

Должность: Главный конструктор  
полное название  
должности

Если вышеуказанное лицо не является сотрудником предприятия-производителя продукции, подлежащей экспертизе, укажите сведения о работодателе ответственного за экспертизу лица или организацию:

Организация: неприменимо\_\_\_\_\_

Адрес: неприменимо\_\_\_\_\_

### Медицинское изделие

Подробная информация о продукции, подлежащей проверке:  
см. руководство пользователя

## Изображение устройства MeDioStar 1591/1592:



## MeDioStar 15912:



|                 |                                                                                              |                                                                     |
|-----------------|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| CL <b>73523</b> | <b>Оценка соответствия согласно 62366 и 601-1-6</b>                                          | «Асклепион»<br>Лейзер Текнолоджис<br>(Asclepion Laser Technologies) |
| Редакция №: В   | <b>Идентификационный номер: ZI/15/04/10-01</b><br>Идентификационный код/год/месяц/день-номер | Стр. 3 из 15<br>CL 73523 Usab MSPRO V502_ZI150410-01                |

| Параметр, Описание, Требование | Результаты, комментарии | Соответствие |     |              |
|--------------------------------|-------------------------|--------------|-----|--------------|
|                                |                         | да           | нет | не применимо |

|                                                                                                                                                                                                                                                                     |                                                                                                                                                                          |                                     |                          |                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|
| <b>4 Общие требования</b>                                                                                                                                                                                                                                           |                                                                                                                                                                          |                                     |                          |                          |
| <b>4.1 Общие требования</b>                                                                                                                                                                                                                                         |                                                                                                                                                                          |                                     |                          |                          |
| <b>4.1.1 Процесс проектирования эксплуатационной пригодности</b>                                                                                                                                                                                                    |                                                                                                                                                                          |                                     |                          |                          |
| Смог ли изготовитель создать, задокументировать и обеспечить процесс проектирования эксплуатационной пригодности для безопасности пациентов, пользователей и других лиц в сфере эксплуатационной пригодности продукции?                                             | MeDioStar 1591/1592:<br>Файл эксплуатационной пригодности<br>ZI/14/04/29-01 в КА 7.6<br>MeDioStar 15912:<br>Файл эксплуатационной пригодности<br>ZI/15/04/01-01 в КА 7.6 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Рассмотрено ли в этом процессе обращение пользователя с медицинским прибором в соответствии с сопроводительными документами, включая (но не ограничиваясь) его транспортировку, хранение, установку, эксплуатацию, техобслуживание, ремонт и утилизацию?            | Файл эксплуатационной пригодности<br>ZI/14/04/29-01;<br>Файл эксплуатационной пригодности<br>ZI/14/04/29-01; глава 4.1                                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>4.1.2 Остаточный риск</b>                                                                                                                                                                                                                                        |                                                                                                                                                                          |                                     |                          |                          |
| Считаются ли допустимыми остаточные риски, связанные с эксплуатационной пригодностью медицинского прибора, или имеются задокументированные объективные доказательства противоположного?                                                                             | Файл эксплуатационной пригодности<br>ZI/14/04/29-01;<br>Файл эксплуатационной пригодности<br>ZI/15/04/01-01; глава 3.13, глава 4.3                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>4.1.3 Информация о безопасности</b>                                                                                                                                                                                                                              |                                                                                                                                                                          |                                     |                          |                          |
| Изготовитель предоставляет информацию о безопасности, которая используется для управления рисками в процессе проектирования эксплуатационной пригодности (например, предупреждения или ограничения использования в сопроводительных документах, маркировка и т. д.) | Файл эксплуатационной пригодности<br>ZI/14/04/29-01;<br>Файл эксплуатационной пригодности<br>ZI/15/04/01-01; глава 3.14                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|               |                                                                                       |                                                                      |
|---------------|---------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| CL 73523      | Оценка соответствия согласно 62366 и 60601-1-6                                        | «Асклепион»<br>Лазерные Технологии<br>(Asclepion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 4 из 15<br>CL 73523 Usab MSPRO Vs02_ZII50410-01                 |

| Параметр, Описание, Требование                                                                                                                                                                                            | Результаты, комментарии                                                                                           | Соответствие                        |                                     |                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|--------------------------|
|                                                                                                                                                                                                                           |                                                                                                                   | да                                  | нет                                 | не применимо             |
| Игнорирование такой информации о безопасности рассматривается как выходящее за пределы любых разумных средств по управлению рисками                                                                                       | Файл эксплуатационной пригодности ZI/14/04/29-01;<br>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.13 | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> |
| 4.2 Файл проектирования эксплуатационной пригодности                                                                                                                                                                      |                                                                                                                   |                                     |                                     |                          |
| Результаты процесса проектирования эксплуатационной пригодности зарегистрированы в файле проектирования эксплуатационной пригодности                                                                                      | Файл эксплуатационной пригодности ZI/14/04/29-01;<br>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 4    | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> |
| Записи и другие документы, составляющие файл проектирования эксплуатационной пригодности, являются частью других документов и файлов (например, файл изготовителя по проектированию изделия или файл управления рисками). |                                                                                                                   | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/> |



|               |                                                                                       |                                                             |
|---------------|---------------------------------------------------------------------------------------|-------------------------------------------------------------|
| CL 73523      | Оценка соответствия согласно 62366 и 60 601-1-6                                       | «Асклепион»<br>Технологии<br>(Asclepion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 5 из 15<br>CL 73523 Usab MSPRO Vs02_ZI150410-01        |

| Параметр, Описание, Требование | Результаты, комментарии | Соответствие |     |              |
|--------------------------------|-------------------------|--------------|-----|--------------|
|                                |                         | да           | нет | не применимо |

|                                                                                                                                                                |                                                                                                                                                                                                                            |                                     |                          |                          |
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| <b>4.3 Шкала проектирования эксплуатационной пригодности</b>                                                                                                   | <b>MeDioStar 1591/1592:</b><br>Файл эксплуатационной пригодности ZI/14/04/29-01; глава 1 (примечание)<br><b>MeDioStar 15912:</b><br>Файл эксплуатационной пригодности ZI/15/02/01-12;<br>Предварительное важное примечание | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>Шкала проектирования эксплуатационной пригодности основана на важности любых задокументированных изменений, зависящих от результатов анализа рисков</i>     |                                                                                                                                                                                                                            |                                     |                          |                          |
| <b>5. Процесс проектирования эксплуатационной пригодности</b>                                                                                                  |                                                                                                                                                                                                                            |                                     |                          |                          |
| <b>5.1 Технические условия к применению</b>                                                                                                                    |                                                                                                                                                                                                                            |                                     |                          |                          |
| <i>Позиции по использованию оборудования указаны производителем в файле проектирования эксплуатационной пригодности</i>                                        | Файл эксплуатационной пригодности ZI/14/04/29-01;<br>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.7                                                                                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>Спецификация включает в себя:</i>                                                                                                                           |                                                                                                                                                                                                                            |                                     |                          |                          |
| <i>предполагаемые медицинские показания (например, состояния или заболевания для анализа, наблюдения, лечения, диагностики или профилактики);</i>              | Файл эксплуатационной пригодности ZI/14/04/29-01;<br>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.7.1                                                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>предполагаемые группы пациентов (например, по возрасту, весу, здоровью, состоянию);</i>                                                                     | Файл эксплуатационной пригодности ZI/14/04/29-01;<br>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.7.3                                                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>предполагаемая часть тела или тип ткани как место применения или взаимодействия;</i>                                                                        | Файл эксплуатационной пригодности ZI/14/04/29-01;<br>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.7.4                                                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>предполагаемые условия применения (например, окружающая среда, включая гигиенические требования, частоту использования, местоположение, мобильность); и</i> | Файл эксплуатационной пригодности ZI/14/04/29-01;<br>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.7.6                                                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>принципы эксплуатации</i>                                                                                                                                   | Файл эксплуатационной пригодности ZI/14/04/29-01;                                                                                                                                                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|               |                                                                                       |                                                                      |
|---------------|---------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| CL 73523      | Оценка соответствия согласно 62366 и 60 601-1-6                                       | «Асклепион»<br>Лазерные Технологии<br>(Asclepion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 6 из 15<br>CL 73523 Usab MSPRO V802_ZI150410-01                 |

| Параметр, Описание, Требование                                                                                                                                                                                                                                                                                              | Результаты, комментарии                                                                                                  | Соответствие                        |                          |                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|
|                                                                                                                                                                                                                                                                                                                             |                                                                                                                          | да                                  | нет                      | не применимо             |
|                                                                                                                                                                                                                                                                                                                             | Файл эксплуатационной пригодности<br>ZI/15/04/01-01; глава 3.7.7                                                         |                                     |                          |                          |
| <b>5.2 Часто используемые функции</b>                                                                                                                                                                                                                                                                                       |                                                                                                                          |                                     |                          |                          |
| Были ли часто используемые функции (в которых пользователь применяет медицинский прибор) определены и записаны в файле проектирования эксплуатационной пригодности?                                                                                                                                                         | Файл эксплуатационной пригодности<br>ZI/14/04/29-01;<br>Файл эксплуатационной пригодности<br>ZI/15/04/01-01; глава 3.8   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>5.3 Идентификация опасностей и опасных ситуаций, связанных с эксплуатационной пригодностью</b>                                                                                                                                                                                                                           |                                                                                                                          |                                     |                          |                          |
| <b>5.3.1 Идентификация характеристик безопасности</b><br><br>Идентификация характеристик, связанных с безопасностью (часть анализа рисков), на основе эксплуатационной пригодности в соответствии с ISO 14971:2007, 4.2.<br><br>Во время идентификации характеристик, связанных с безопасностью, рассматривается следующее: | Файл эксплуатационной пригодности<br>ZI/14/04/29-01;<br>Файл эксплуатационной пригодности<br>ZI/15/04/01-01; глава 3.9.1 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|               |                                                                                       |                                                                       |
|---------------|---------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| CL 73523      | Оценка соответствия согласно 62366 и 60 601-1-6                                       | «Асклепион»<br>Лазерные Технологии<br>(Asclepiion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 7 из 15<br>CL 73523 Usab MSPRO Vs02_ZI150410-01                  |

| Параметр, Описание, Требование                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Результаты, комментарии                                                                                                                                                                                                                                                                                                                                                                                            | Соответствие                        |                          |                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                    | да                                  | нет                      | не применимо             |
| <p><i>технические условия к применению, включая профили пользователей; и</i></p> <p><i>часто используемые функции.</i></p> <p><i>Результаты этой идентификации характеристик, связанных с безопасностью, записываются в файл проектирования эксплуатационной пригодности</i></p>                                                                                                                                                                                                                                                                                                                                                              | <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.9.1</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.9.1</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.13</p>                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p><b>5.3.2 Идентификация известных или прогнозируемых опасностей и опасных ситуаций</b></p> <p><i>изготовитель идентифицировал известные или прогнозируемые опасности (часть анализа рисков), связанные с эксплуатационной пригодностью в соответствии с ISO 14971:2007, 4.3.</i></p> <p><i>Идентификация опасностей, которые считаются опасными для пациентов, пользователей и других лиц</i></p> <p><i>Были выявлены возможные последовательности событий (или их сочетаний) с участием пользователя, которые могут привести к опасным ситуациям при использовании медицинского прибора. Была определена степень возможного вреда.</i></p> | <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; главы 3.4 и 3.9.2</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; главы 3.4 и 3.9.2</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; главы 3.4, 3.9.1 и 3.9.2</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |



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| CL 73523      | Оценка соответствия согласно 62366 и 60601-1-6                                        | «Асклепион»<br>Технологии.<br>(Asclepion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 8 из 15<br>CL 73523 Usab MSPRO Vs02_ZI150410-01         |

| Параметр, Описание, Требование | Результаты, комментарии | Соответствие |     |              |
|--------------------------------|-------------------------|--------------|-----|--------------|
|                                |                         | да           | нет | не применимо |

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| <i>Во время идентификации опасностей и опасных ситуаций учитывалось следующее:</i><br><br><i>технические условия к применению, включая профили пользователей;</i><br><br><i>связанные с задачей требования;</i><br><br><i>обстоятельства применения;</i><br><br><i>имеющаяся информация об опасностях и опасных ситуациях при применении существующих медицинских приборов подобного типа, если имеется;</i><br><br><i>предварительные сценарии использования;</i><br><br><i>возможные ошибки при использовании;</i><br><br><i>если неправильная умозрительная модель эксплуатации медицинского прибора может привести к ошибке применения, приведшей к возникновению опасной ситуации; и</i> | Файл эксплуатационной пригодности ZI/14/04/29-01;             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.9.2 | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности ZI/14/04/29-01;             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.9.2 | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности ZI/14/04/29-01;             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.9.2 | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности ZI/14/04/29-01;             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.9.2 | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности ZI/14/04/29-01;             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.9.2 | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> |

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| CL 73523      | Оценка соответствия согласно 62366 и 60 601-1-6                                       | «Асклепион»<br>Лазерные Технологии<br>(Asclepiion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 9 из 15<br>CL 73523 Usab MSPRO V502_ZI150410-01                  |

| Параметр, Описание, Требование                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Результаты, комментарии                                                                                                                                                                                                                           | Соответствие                        |                          |                          |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                   | да                                  | нет                      | не применимо             |
| <p><i>результаты анализа интерфейса пользователя</i></p> <p><i>Результаты идентификации опасностей, опасных ситуаций и степени опасности записываются в файле проектирования эксплуатационной пригодности.</i></p>                                                                                                                                                                                                                                                                           | <p>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.9.2<br/>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.15</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p><b>5.4 Основные рабочие функции</b></p> <p><i>Основные рабочие функции определены заводом-изготовителем и занесены в файл проектирования эксплуатационной пригодности.</i></p> <p><i>К основным рабочим функциям относятся часто используемые функции и функции, связанные с безопасностью медицинского прибора</i></p>                                                                                                                                                                   | <p>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.10<br/>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.10</p>  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p><b>5.5 Спецификации эксплуатационной пригодности</b></p> <p><i>Изготовитель разработал спецификации эксплуатационной пригодности, записанные в файле проектирования эксплуатационной пригодности как части процесса проектирования эксплуатационной пригодности</i></p> <p><i>Спецификации эксплуатационной пригодности, записанные в файле проектирования эксплуатационной пригодности. Спецификации эксплуатационной пригодности могут быть интегрированы в другие спецификации</i></p> | <p>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.11<br/>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.11</p>  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| CL 73523      | Оценка соответствия согласно 62366 и 60 601-1-6                                       | «Асклепион»<br>Лазерные Технологии<br>(Asclepiion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 10 из 15<br>CL 73523 Usab MSPRO V802_ZI150410-01                 |

| Параметр, Описание, Требование | Результаты, комментарии | Соответствие |     |              |
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|                                |                         | да           | нет | не применимо |

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| <p><i>Спецификации эксплуатационной пригодности включают в себя:</i></p> <p><i>технические условия к применению;</i></p> <p><i>основные рабочие функции</i></p> <p><i>опасности и опасные ситуации, связанные с эксплуатационной пригодностью; и</i></p> <p><i>известные или прогнозируемые ошибки применения медицинского прибора</i></p> <p><i>В спецификациях эксплуатационной пригодности, как минимум, указано следующее:</i></p> <p><i>использование сценариев, связанных с основными рабочими функциями оборудования, включая</i></p> <p><i>часто используемые сценарии,</i></p> <p><i>обоснованно прогнозируемые сценарии худших вариантов использования;</i></p> | <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.7</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.10</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; главы 3.4 и 3.15</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; главы 3.4 и 3.15</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.11.3</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; главы 3.11.1 и 3.11.4</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> <p>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.11.2</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                     |                          |                          |



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| CL 73523      | Оценка соответствия согласно 62366 и 60 601-1-6                                       | «Асклепион»<br>Индустриальные Технологии<br>(Asclepion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 11 из 15<br>CL 73523 Usab MSPRO V302_ZI150410-01                      |

| Параметр, Описание, Требование | Результаты, комментарии | Соответствие |     |              |
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| <p><i>Требования к интерфейсу пользователя для оборудования с основными рабочими функциями, включая направленные на уменьшение риска;</i></p> <p><i>Требования к выявлению того, способен ли пользователь идентифицировать основные рабочие функции оборудования.</i></p>                                                                                                                                                                                                                                                                                                                                                                               | <p>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.11.4<br/>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.11.5</p>                                                                                                                                                                                                                                                                                                                                                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p><b>5.6 План подтверждения эксплуатационной пригодности</b></p> <p><i>Изготовитель разработал и осуществляет план подтверждения эксплуатационной пригодности</i></p> <p><i>План проверки включает следующие положения:</i></p> <p><i>метод оценки эксплуатационной пригодности основных рабочих функций;</i></p> <p><i>критерии определения успешного подтверждения эксплуатационной пригодности основных рабочих функций на основе спецификаций эксплуатационной пригодности; и</i></p> <p><i>участие представителя предполагаемых пользователей</i></p> <p><i>подтверждение эксплуатационной пригодности выполнено в лабораторных условиях.</i></p> | <p>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.12</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.12<br/>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.12<br/>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.12<br/>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 3.12</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| CL 73523      | Оценка соответствия согласно 62366 и 60 601-1-6                                       | «Асклепион<br>Laser Technologies»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 12 из 15<br>CL 73523 Usab MSPRO Vs02_ZI150410-01                  |

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| CL 73523      | Оценка соответствия согласно 62366 и 60601-1-6                                        | «Асклепион»<br>Лазерные Технологии<br>(Asclepion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 13 из 15<br>CL 73523 Usab MSPRO V#02_ZI150410-01                |

| Параметр, Описание, Требование                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Результаты, комментарии                                                                                                                                                                                                                                                                                                                                                      | Соответствие                                                                                                                                   |                                                                                                                          |                                                                                                                                                |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                              | да                                                                                                                                             | нет                                                                                                                      | не применимо                                                                                                                                   |
| <b>5.8 Проверка эксплуатационной пригодности</b><br><br><i>Интерфейс «пользователь-оборудование» был проверен согласно спецификации по эксплуатационной пригодности и документально зарегистрирован в файле эксплуатационной пригодности</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Файл эксплуатационной пригодности<br>ZI/14/04/29-01;<br>Файл эксплуатационной пригодности<br>ZI/15/04/01-01; глава 3.13                                                                                                                                                                                                                                                      | <input checked="" type="checkbox"/>                                                                                                            | <input type="checkbox"/>                                                                                                 | <input type="checkbox"/>                                                                                                                       |
| <b>5.9 Подтверждение эксплуатационной пригодности</b><br><br><i>Изготовитель подтвердил правильность проекта интерфейса «оператор-оборудование» в соответствии с планом по подтверждению эксплуатационной пригодности.</i><br><br><i>Результаты записаны в файле проектирования эксплуатационной пригодности</i><br><br><i>Для критериев приемки, которые задокументированы в плане подтверждения эксплуатационной пригодности и не соблюдаются:</i><br><br><i>выполняются дополнительные работы по разработке и воплощению интерфейса пользователя; или</i><br><br><i>если дальнейшее улучшение нереально, то изготовитель собирает и анализирует данные и литературу, чтобы определить, перевешивают ли выгоды от предполагаемого использования возможные проблемы, связанные с рисками эксплуатационной пригодности</i> | Файл эксплуатационной пригодности<br>ZI/14/04/29-01;<br>Файл эксплуатационной пригодности<br>ZI/15/04/01-01; глава 3.13<br>Файл эксплуатационной пригодности<br>ZI/14/04/29-01;<br>Файл эксплуатационной пригодности<br>ZI/15/04/01-01; глава 3.13<br>Файл эксплуатационной пригодности<br>ZI/14/04/29-01;<br>Файл эксплуатационной пригодности<br>ZI/15/04/01-01; глава 4.3 | <input checked="" type="checkbox"/><br><br><input checked="" type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/> | <input type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/> | <input type="checkbox"/><br><br><input type="checkbox"/><br><br><input checked="" type="checkbox"/><br><br><input checked="" type="checkbox"/> |



|               |                                                                                       |                                                                   |
|---------------|---------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| CL 73523      | Оценка соответствия согласно 62366 и 60 601-1-6                                       | «Асклепион»<br>Лазер Технологии<br>(Asclepion Laser Technologies) |
| Редакция №: В | Идентификационный номер: ZI/15/04/10-01<br>Идентификационный код/год/месяц/день-номер | Стр. 14 из 15<br>CL 73523 Usab MSPRO Vs02_ZI150410-01             |

| Параметр, Описание, Требование | Результаты, комментарии | Соответствие |     |              |
|--------------------------------|-------------------------|--------------|-----|--------------|
|                                |                         | да           | нет | не применимо |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                      |                                     |                          |                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|
| <p><b>6. Сопроводительные документы</b></p> <p><i>Сопроводительные документы включают в себя краткое описание технических условий к применению медицинского прибора</i></p> <p><i>Краткое описание медицинского прибора, его принципы работы, основные физические и эксплуатационные характеристики и профиль предполагаемого пользователя, включены в сопроводительные документы</i></p> <p><i>Сопроводительные документы соответствуют предполагаемому профилю оператора.</i></p> <p><i>По выбору заказчика, сопроводительные документы могут предоставляться в электронном виде</i></p> <p><i>если ДА:</i></p> <p><i>Информация на бумажном носителе или в виде бирки на оборудовании доступна в достаточной степени и отвечает требованиям по действиям в аварийной ситуации.</i></p> | <p>Руководство пользователя, глава 2</p> <p>Руководство пользователя, главы 4.3, 4.2 и 2</p> <p>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 4.1</p>                                                                                | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p><b>7. Обучение и материалы для обучения</b></p> <p><i>Необходимо специальное обучение основным функциям оборудования</i></p> <p><i>если ДА:</i></p> <p><i>Изготовитель предоставил необходимые учебные материалы;</i></p> <p><i>завод-изготовитель обеспечивает доступность материала (или);</i></p> <p><i>производитель предлагает проведение процесса обучения.</i></p>                                                                                                                                                                                                                                                                                                                                                                                                              | <p>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 4.2<br/>Файл эксплуатационной пригодности ZI/14/04/29-01;<br/>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 4.2<br/>Файл эксплуатационной пригодности ZI/14/04/29-01;</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|                      |                                                                                              |                                                                        |
|----------------------|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| CL <b>73523</b>      | <b>Оценка соответствия согласно 62366 и 60 601-1-6</b>                                       | «Асклепион»<br>История Технологий®<br>(Asclepiion Laser<br>Technology) |
| Редакция №: <b>В</b> | <b>Идентификационный номер: ZI/15/04/10-01</b><br>Идентификационный код/год/месяц/день-номер | Стр. 15 из 15<br>CL 73523 Usab MSPRO Vso2_ZI150410-01                  |

| Параметр, Описание, Требование                                                                                                                                                                                                                                        | Результаты, комментарии                                            | Соответствие                        |                          |                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|
|                                                                                                                                                                                                                                                                       |                                                                    | да                                  | нет                      | не применимо             |
| <p><i>В сопроводительных документах описываются возможные варианты обучения, и предлагаются продолжительность и частота такого обучения.</i></p> <p><i>Предполагаемое использование и профиль пользователя являются основой для обучения и учебных материалов</i></p> | <b>Файл эксплуатационной пригодности ZI/15/04/01-01; глава 4.2</b> |                                     |                          |                          |
|                                                                                                                                                                                                                                                                       | <b>Руководство пользователя, главы 2 и 7.1</b>                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                                                                                                                                                                                                                                                       |                                                                    | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|               |                                                                                            |                                                                         |
|---------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / Валидации                                                              | «Аскепион<br>Лейзер<br>Технологии»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/04/22-01<br>Код участника/год/месяц/день - порядковый номер | Страница 1 из 8<br>FB 7351e UsabilityValid<br>MSPRO Vs01 ZI40422-01.doc |

|                    |                                                                                                                                                                                                                      |                                                       |                                                                     |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|---------------------------------------------------------------------|
| Проверка           | <input type="checkbox"/>                                                                                                                                                                                             | Валидация                                             | <input checked="" type="checkbox"/> Эксплуатационная<br>пригодность |
| Изделие / деталь:  | MeDioStar                                                                                                                                                                                                            | Код материала:                                        | 1591, 1592                                                          |
| Основание:         | <input type="checkbox"/> Разработка изделия                                                                                                                                                                          | <input checked="" type="checkbox"/> Изменение изделия | <input type="checkbox"/>                                            |
| Исходный документ: | <input checked="" type="checkbox"/> Техническое задание: FB<br>7321_LH-MSPRO- V01_ZI140127-<br>01 в KA5.1<br><input checked="" type="checkbox"/> Анализ рисков:<br>FB 7302 RAaC MSPRO<br>V01_MM0140204-01 в KA 7.2.2 | <input type="checkbox"/> Проектное задание:           | <input type="checkbox"/>                                            |
| Серийный номер:    | 1591 00 726                                                                                                                                                                                                          | <input type="checkbox"/> Заявка на изменение №:       | <input type="checkbox"/>                                            |

#### Краткое описание:

Это подтверждение эксплуатационной пригодности данной новой, модернизированной версии MeDioStar, основано на текущем устройстве MeDioStar, которое для пользователя почти идентично новой версии, и на подтверждении технического задания для этой новой версии MeDioStar, включая испытания на пригодность.

Разница и преимущества для пользователя будет в новом аппликаторе с большими по размеру лазерными пятнами, чтобы сократить время процедур. Этот новый аппликатор будет продаваться в дополнение (по выбору) к существующим аппликаторам. Кроме нового аппликатора, были также выполнены технические изменения внутри основного устройства, но для пользователя они не имеют значения.

Предполагаемое использование, настройка параметров, дисплей, эксплуатация, включая меры безопасности и процедуры лечения, по сравнению с текущим устройством не изменились.

Текущая версия устройства (а также предыдущих устройств) никогда не вызывала никаких проблем кроме побочных эффектов, указанных в руководстве, и процедуры лечения с помощью устройства очень эффективны.

**Выбранное измерительное и испытательное оборудование:** MeDioStar, устройство № 1591 00 726

#### Документы в приложении:

Приложение 1: Технические условия к применению (TP 7342 Usab-App1SpecifAppl MSPRO Vs01\_ZI140422-02)

Приложение 2: Спецификации основных рабочих функций, включая меры безопасности  
(TP 7342 Usab-App2POFs MSPRO Vs01\_ZI140422-03)

Приложение 3: Протокол отчетов о поиске сообщений о событиях устройств, включая результаты  
(TP 7342 Usab-App3-BfArM+FDA-Vs1 -ZI130827-1)

Приложение 4: Протокол оценки пользователя (TP 7342 Usab-App4-AuswertgFragenVs01\_ZI140425-01)

#### Окончательная оценка результатов:

Суммируя, можно сказать, что эксплуатационная пригодность новой модернизированной версии MeDioStar даже лучше, чем у текущего устройства, потому что время процедур стало короче, а безопасность и эффективность остались такими же как у текущего устройства.

☐ Проверка / подтверждение с отрицательным  
результатом

☒ Проверка / подтверждение с положительным результатом

Если результат отрицательный, то какие приняты меры:

План № ZI/14/04/22/-01 составил:

22 апреля 2014 года Циммерман /Подпись/  
Дата Имя, фамилия Подпись

Проверку/валидацию провел:

25 июня 2014 года Циммерман /Подпись/  
Дата Имя, фамилия Подпись

План проверил и выпустил:

23 апреля 2014 года Катцер /Подпись/  
Дата Имя, фамилия Подпись

Проверку/валидацию провел и выпустил:

26 июня 2014 года Катцер /Подпись/  
Дата Имя, фамилия Подпись

|                                                                          |                 |                 |                                                    |                 |            |
|--------------------------------------------------------------------------|-----------------|-----------------|----------------------------------------------------|-----------------|------------|
| Причина последней модификации FB: обзор                                  |                 |                 | FB проверены и выпущены Отделом контроля качества: |                 |            |
| FB сделанные владельцем процесса Отделом научно-исследовательских работ: |                 |                 |                                                    |                 |            |
| 05.07.2012                                                               | И. Штрайт       | Подп.<br>Штрайт | 06.07.2012                                         | Р. Тиме         | Подп. Тиме |
| Дата                                                                     | Имя,<br>фамилия | Подпись         | Дата                                               | Имя,<br>фамилия | Подпись    |



|               |                                                                                            |                                                                           |
|---------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / Валидации                                                              | «Асклепион<br>Лейзер<br>Технологикс»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/04/22-01<br>Код участника/год/месяц/день - порядковый номер | Страница 2 из 8<br>FB 7351e UsabilityValid<br>MSPRO Vs01 ZI40422-01.doc   |

История:

| Ред. | Краткое описание изменений | Дата                | Имя, фамилия | Подпись   |
|------|----------------------------|---------------------|--------------|-----------|
| 01   | Первая редакция            | 22 апреля 2014 года | Циммерман    | /Подпись/ |
|      |                            |                     |              |           |
|      |                            |                     |              |           |
|      |                            |                     |              |           |

Связанные документы:

| документ                                        | сокращение    | название файла                                         |
|-------------------------------------------------|---------------|--------------------------------------------------------|
| Техническое задание                             | ТЗ            | FB 7321_LH-MSPRO-V01_ZI140127-01                       |
| Обзор 2010 для MeDioStar XT/ miXT               | Обзор 2010 г. | FB 73511 Review 2010 MeDioStar XT-miXT ZI-2010-03-12-1 |
| Контрольный список для руководства пользователя | неприменимо   | CL 7356 GA MeDioStar V01_ZI140205-01                   |
| Анализ рисков                                   | неприменимо   | FB 7302 RAaC MSPRO V01_MM0140204-01                    |

|               |                                                                                            |                                                                          |
|---------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / Валидации                                                              | «Асклепион<br>Лейзер<br>Технологии»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/04/22-01<br>Код участника/год/месяц/день - порядковый номер | Страница 3 из 8<br>FB 7351e UsabilityValid<br>MSPRO Vs01 ZI40422-01.doc  |

#### Примечание:

Модернизированная версия MeDioStar разработана с целью сократить время процедур (особенно для больших участков тела, таких как спина мужчины) для заказчиков и пациентов.

Что достигается с помощью больших по размеру лазерных пятен, когда один лазерный импульс одновременно охватывает большую площадь кожи. В настоящее время, по разумной цене, доступна большая мощность лазера, которая требуется для больших лазерных пятен. **Были выполнены необходимые технические изменения: например, увеличено количество диодов в новом аппликаторе, источник питания внутри основного устройства заменен на более мощный.**

В то же время остались без изменений и полный набор функций и предполагаемое использование текущей версии MeDioStar (включая все аппликаторы):

В связи с большим успехом (начиная с 2011 г. продано почти 1 000 устройств разных версий MeDioStar, а с 1999 г. продано больше 2 500 устройств всех версий) и эффективностью и безопасным использованием устройства, которое за все эти годы не вызывало никаких побочных эффектов, кроме указанных в руководстве, был заметный спрос в ТЗ на это устройство, поэтому вносимые изменения необходимо было сделать минимально заметными:

- Предполагаемое использование, включая профиль оператора, принцип действия на ткани, физическая функциональность и обработка и т.д. (см. Приложение 1) идентичны текущей версии MeDioStar как требуется в ТЗ.
- POFs, включая меры безопасности, идентичны существующим в текущей версии MeDioStar, как требуется в ТЗ (см. Приложение 2 и ТЗ).

Основное устройство для заказчика осталось без изменений. Все аппликаторы, которые доступны сегодня, остались без изменений. Единственная разница для заказчика только в новом (по выбору), более крупном аппликаторе, сокращающем время процедур.

### 1. Подтверждение на основе текущего устройства

#### **1.1 Оценка отчетов о событиях на соответствующих устройствах**

Рекомендации от Федерального института по лекарственным препаратам и медицинской продукции Германии и отчеты для этого института о событиях оценивались для данного устройства (и остальных наших устройств) на регулярной основе, раз в год. Институт не давал рекомендаций и не предлагал снять с продажи MeDioStar. Последние оценки см. в Приложении 3. Кроме того, на сайте Управления по контролю за продуктами и лекарствами США) был выполнен поиск предложений о снятии с продажи медицинских приборов. В отношении MeDioStar таких предложений не обнаружено (см. также Приложение 3).

#### **1.2 Оценка устройств MeDioStar на данный момент**

Начиная с 1999 г. не было зафиксировано ни одного несчастного случая или травмы при применении устройств MeDioStar. Другие побочные эффекты, кроме указанных в руководстве пользователя, не выявлены. Для наблюдения за рынком выполнялись ежегодные обзоры. Большая часть наших исследований была заново рассмотрена в 2010 г. для MeDioStar XT/miXT (см. Обзор 2010 г.).

В качестве примера:

Наиболее всеобъемлющее исследование предполагаемого применения устройства было выполнено доктором А. Неметом из Флориды (лекция в Европейской академии дерматовенерологии в 2004 г., Флоренция, Италия).

Он применял устройство для 200 пациентов всех типов кожи с общим числом сеансов - 978. Во всех этих процедурах у него было только 5 случаев временной гиперпигментации (0,5%), не было ни шрамов, ни каких-то других долговременных побочных эффектов.

Количество необходимых процедур составляло от 3 до 11, что нормально для уменьшения роста волос. Полученные результаты: 26% уменьшение роста волос после 1,47% после 2 и 64% после 3 процедуры.

|               |                                                                                            |                                                                          |
|---------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / Валидации                                                              | «Асклепион<br>Лейзер<br>Технологии»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/04/22-01<br>Код участника/год/месяц/день - порядковый номер | Страница 4 из 8<br>FB 7351e UsabilityValid<br>MSPRO Vs01 ZI40422-01.doc  |

1.3 Подтверждение эксплуатационной пригодности врачами из других стран

В дополнение предлагается исследование, проведенное несколькими врачами из других стран, всех наших устройств, включая MeDioStar. Эти врачи оценивали основные рабочие функции устройства (см. Приложение 4). На данный момент это была небольшая группа, состоящая только из 6 врачей, но это исследование будет продолжено.

Приемлемость функций ранжировалась от 1 (очень хорошие / легко понятные) до 5 (очень плохие / сложные для понимания). Средним баллом при оценке функциональных возможностей стали 1,25, что является очень высокой оценкой. В данном исследовании не было высказано никаких предложений по улучшению устройства.

Этот небольшой опрос подтвердил положительные результаты всех предыдущих обзоров рынка.

2. Подтверждение новой версии устройства

Серийный номер устройства: 1591 00 726 (предсерийное устройство), включая новый аппликатор  
Дата: 25 апреля 2014 года  
Участники: Г. Циммерман, главный конструктор

2.1 Подтверждение требований ТЗ, глава 3.1: часто используемые функции

| Часто используемые функции                                       | Требования к обеспечению безопасной эксплуатации                                                                                                                                                                             | Приемлемость |
|------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 1. Включение /выключение прибора при помощи главного выключателя | Главный выключатель должен быть хорошо доступен и легко управляем (клавишный выключатель на задней стенке прибора)                                                                                                           | OK           |
| 2. Включение /выключение прибора при помощи замка-выключателя    | Замок- выключатель должен быть хорошо доступен и легко управляем (спереди на приборе)                                                                                                                                        | OK           |
| 3. Обращение к дисплею лечебных процедур                         | Должно быть возможным без сложностей                                                                                                                                                                                         | OK           |
| 4. Выбор параметра лечения для настройки                         | Должен быть возможным без сложностей и должно быть однозначно видно, какой параметр изменяется                                                                                                                               | OK           |
| 5. Каждое подтверждение измененного параметра лечения            | Измененный параметр может быть применен лишь в том случае, если произошло подтверждение                                                                                                                                      | OK           |
| 6. Подготовка лазера: Переключиться с режима STANDBY на READY    | В состоянии READY (пусковая кнопка эмиттера разблокирована) на дисплее должен появиться желтый предупреждающий знак                                                                                                          | OK           |
| 7. Вынимание / установка аппликатора из/в крепления              | Должно быть возможным без сложностей; у крепления не должно быть острых краев/углов                                                                                                                                          | OK*          |
| 8. Использование ножного переключателя                           | Переключатель должен быть исполнен таким образом, чтобы сделать невозможным непреднамеренное включение                                                                                                                       | OK           |
| 9. Перемещение аппликатора по коже пациента                      | - Должно быть возможным без сложностей,<br>- все позы должны быть доступными и<br>- не должны утомлять<br>- аппликатор держать прямо или с наклоном назад<br>- оптическая площадь контакта: Сапфир, без острых краев и углов | OK           |
| 10. Очистка и дезинфекция поверхности аппликатора                | Поверхности должны быть гладкими, без труднодоступных отверстий и т.д., так как из-за оптики и электроники возможна лишь влажная протирка                                                                                    | OK           |
| 11. Смена аппликаторов                                           | Штекер должен быть хорошо доступным (на задней стенке прибора), легко обслуживаемым и надежным                                                                                                                               | OK           |

\* удержание возможно, но не безупречно → /неразборчиво/ до серии

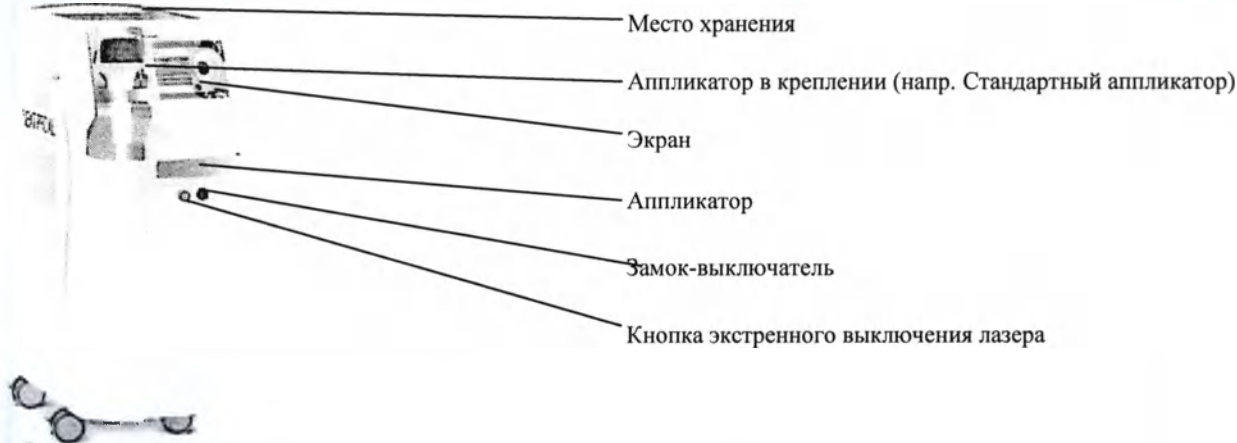


|               |                                                                                            |                                                                          |
|---------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / Валидации                                                              | «Асклепион<br>Лейзер<br>Технологии»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/04/22-01<br>Код участника/год/месяц/день - порядковый номер | Страница 5 из 8<br>FB 7351e UsabilityValid<br>MSPRO Vs01 ZI40422-01.doc  |

## 2.2 Подтверждение требований ТЗ, глава 3.1: функции, связанные с безопасностью

| Функция безопасности                                                                                             | Требования к обеспечению безопасной эксплуатации                                                       | Приемлемость |
|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--------------|
| 12. Кнопка аварийного выключения лазера (использование в экстренных ситуациях)                                   | Спереди на приборе, простая в использовании, легкозаметная                                             | OK           |
| 13. Замок-выключатель (против запрещенного использования прибора неавторизованным персоналом)                    | Съемный замок-выключатель                                                                              | OK           |
| 14. Подтверждение измененного параметра лечения                                                                  | Измененный параметр может быть применен лишь в том случае, если произошло подтверждение                | OK           |
| 15. Сознательная подготовка лазера (Предупреждающая лампа на двери, контроль защитных очков всех присутствующих) | Отдельное нажатие кнопки READY; дополнительный желтый предупреждающий сигнал на дисплее                | OK           |
| 16. Сознательное включение эмитирования                                                                          | Переключатель должен быть исполнен таким образом, чтобы сделать невозможным непреднамеренное включение | OK           |
| 17. Автоматическое запираение дверей                                                                             | Разъем должен располагаться на задней стенке прибора                                                   | OK           |

## 2.3 Подтверждение требований ТЗ, глава 3.2: матрица требований

| №   | Техническое задание для подтверждения *                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Приемлемость |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
|     | * некоторые числа не указаны, потому что выполнение этих требований подтверждается при измерениях                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |              |
| 1   | <p>Конструкция:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | OK           |
| 1.1 | <p>Настольный прибор 365 x 560 x 465мм (ШхГхВ) без рукояток и т.д. Крепление аппликатора; макс. 40 кг, ручки для переноски, более износостойкое лакокрасочное покрытие – белый глянец; поверхность с возможностью дезинфекции</p> <p>Дисплей 8,4"; сенсорный, с легким наклоном назад; легко читаемый при ярком освещении</p> <p>Предусмотреть место для использования с надлежащим местом для хранения</p> <p>Хорошо доступные на задней стенке прибора штекер аппликатора, главный выключатель, сетевой штекер, разъемы ножного переключателя, предупреждающей лампы, дистанционного запираения двери, сервисных интерфейсов</p> |              |
| 1.3 | <p>Не изменять нынешние аппликаторы по внешнему дизайну, в будущем белая или зеркальная наклейка прямо за аппликатором лазера на корпусе аппликатора</p> <p>Эргономичное исполнение новых аппликаторов; без острых краев/углов; с возможностью дезинфекции</p>                                                                                                                                                                                                                                                                                                                                                                     | OK           |
| 1.4 | Новые аппликаторы с охлаждаемым сапфиром в качестве охлаждения кожи; с возможностью дезинфекции                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | OK           |
| 1.5 | Все аппликаторы и наконечники на новом аппликаторе XL должны быть просто и надежно заменяемыми                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | OK**         |
| 1.6 | Хороший дизайн «хранилища» для аппликаторов, должен подходить для всех аппликаторов                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | *            |

\* см. последнюю стр.

\*\* Подсоединение наконечника к основному корпусу аппликатора XL необходимо для оказания большего давления, так как это еще не серийная деталь Проверить /неразборчиво/ серийную деталь.

|               |                                                                                            |                                                                          |
|---------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / Валидации                                                              | «Асклепион<br>Лейзер<br>Технологии»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/04/22-01<br>Код участника/год/месяц/день - порядковый номер | Страница 6 из 8<br>FB 7351e UsabilityValid<br>MSPRO Vs01 ZI40422-01.doc  |

| №   | Требование клиента                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Приемлемость |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 3.  | Программное обеспечение<br>Техническое задание для программного обеспечения / ТЗПО                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | OK           |
| 4.  | Параметры применения<br>- подробности настройки параметров см. в отчете об аттестации FB 7351 e Vali SW MSPRO V01 CaM140520-01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |              |
| 4.2 | <p>Следующие режимы заданы для указанных аппликаторов:</p> <p>BASIC: настраиваются: Плотность энергии, частота следования (скорость),<br/>автом. самая короткая возможная длительность импульса при выбранной плотности энергии, двойной импульс,<br/>возможно с ST, HP, ALX, XLS, XLL</p> <p>PROF: настраиваются: Плотность энергии, длительность импульса, скорость, одиночный или двойной импульс<br/>возможно с ST, HP, ALX, XLS, XLL</p> <p>SmoothPulse: настраиваются: Плотность энергии, скорость<br/>возможно с ST, HP, ALX, XLS, XLL</p> <p>BURST: настраиваются: Плотность энергии, длительность импульса, скорость, количество импульсов в серии (вспышка), пауза</p> <p>Длительность импульса, число импульсов<br/>Настраиваемая плотность энергии делится на число импульсов<br/>Настраиваемая пауза<br/>Когда изменяется длительность импульса, при необходимости менять также паузу и отображать это<br/>совместное изменение аналоговой скорости,<br/>возможно, со всеми аппликаторами</p> <p>VASCU: настраиваются: Плотность энергии, длительность импульса, скорость, всегда только одиночный импульс<br/>Возможно при VAS</p> | OK           |
| 4.3 | Частота следования в зависимости от аппликатора. Режим длительности импульса и средней производительности<br>Режим BASIC, PROFESSIONAL, BURST, VASCULAR<br>Режим «гладкий импульс» (SmoothPulse)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | OK           |
| 4.4 | Плотность энергии и длительность импульса в зависимости от аппликатора и режима, настраиваемого при аппликаторе                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | OK           |
| 4.6 | Охлаждение кожи: Контактное охлаждение с помощью металла и/или Сапфира (аппликаторы ST, ALX, XLS/L)<br>Достижение температуры охлаждения макс. через 15 сек. после смены штекера и/или Прибор был долго в режиме STANDBY (Индикация на дисплее) – 30 сек. охлаждения для обеспечения быстрого возврата из режима Standby в режим Ready. Показывать течение воды с помощью постоянно горящих светодиодов.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | OK           |

#### 2.4 Подтверждение эксплуатационной пригодности для практического применения лицами, участвующими в разработке устройства, и врачами

Эта оценка была получена для нового аппликатора и обоих лазерных пятен: XLL (9 см<sup>2</sup>) и XLS (3 см<sup>2</sup>), так как остальные аппликаторы уже используются с текущим устройством.

Серийный номер устройства: 159100726 (предсерийное устройство) с новым аппликатором XL

Дата: 16 июня 2014

Участники: Г. Циммерман, главный конструктор  
Дж. Эльбрехт, руководитель отдела разработки аксессуаров  
И. Харрасс, отдел разработки аксессуаров

См. протокол на следующей стр. (6а).

Это были первые испытания, и их провела сама главный конструктор. Проверялась эксплуатационная пригодность нового аппликатора с большими по размерам лазерными пятнами.

Аппликатор применялся для нижней части ног в различных режимах (PROFESSIONAL, Smooth- Pulse) с аппликатором XL и лазерными пятнами обоих размеров, без каких-либо проблем.

Испытательные процедуры были оценены как приемлемые. Нежелательные аспекты при применении нового аппликатора отсутствовали.

|               |                                                                                            |                                                                          |
|---------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / валидации                                                              | «Асклепион<br>Лейзер<br>Технологии»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/04/22-01<br>Код участника/год/месяц/день - порядковый номер | Страница 7 из 8<br>FB 7351e UsabilityValid<br>MSPRO Vs01 ZI40422-01.doc  |

## 2.5 Подтверждение эксплуатационной пригодности для практического применения лицами, не участвующими в разработке устройства, но экспертами в применении

Эта оценка была получена для нового аппликатора и обоих лазерных пятен: XLL (9 см<sup>2</sup>) и XLS (3 см<sup>2</sup>), так как остальные аппликаторы уже используются с текущим устройством.

Серийный номер устройства: 159100726 (предсерийное устройство) с новым аппликатором XL

Дата: 24 июня 2014

Участники:

- Г. Циммерман, главный конструктор, участвует в разработке
- Р. Манкарелли, руководитель отдела продаж в Германии, не участвует в разработке (доброволец)
- Т. Бауэр, руководитель отдела продаж в Германии, не участвует в разработке
- Х. Прюфер, отдел зарубежных продаж, не участвует в разработке
- К. Куршайд, отдел продаж в Германии, не участвует в разработке
- Т. Юнгер, отдел маркетинга, не участвует в разработке
- М. Мёллер, отдел разработки, участвует в разработке (доброволец)

См. протоколы на следующих стр. (7a и 7b).

В этой оценке у двух добровольцев выполнялась эпиляция на спине. Для одного добровольца применялись одновременно оба режима: «PROFESSIONAL» и «SmoothPulse», а для другого добровольца применялся только режим «SmoothPulse».

Оба добровольца хорошо переносили процедуры.

Выполнять обработку с помощью нового аппликатора (который больше и тяжелее из-за более высокой мощности диодов) так же удобно и легко как с другими аппликаторами. Большой вес не важен, потому что

1. Аппликатор во время процедуры находится в контакте с кожей - поэтому возросший вес не приходится только на руки
2. Время процедур очень короткое - около 2 минут на всю мужскую спину

Один вопрос пока еще не совсем решен, это аппликатор аппликатора в передней части устройства. На данный момент это аппликатор для текущих аппликаторов, которые меньше по размерам. Требование 1.6 матрицы T3 (см. главу 2.3 выше) пока не соблюдается, и должно быть выполнено до продажи устройств.

Второе замечание связано с изменением лазерного аппликатора нового аппликатора XL, из-за чего требуются некоторые усилия для ее подсоединения к основному корпусу аппликатора, что не соответствует требованию 1.5 матрицы T3, что это соединение должно выполняться без усилий.

Причина состоит в том, что новый аппликатор XL пока еще не является серийной продукцией и понятно, предсерийные детали не безупречны из-за больших допусков. Как и в случае с первым вопросом, необходимо выполнить еще одну проверку, когда это отклонение будет исправлено в серийной продукции.

Все участники - не участвующие в разработке - оценили новый аппликатор как очень хороший инструмент для обработки больших по размерам участков - при условии, что 2 указанных недоработки будут исправлены.

Даже с большим по размерам аппликаторов устройство удобно в применении, а процедура выполняется очень быстро.

## 2.6 Подтверждение руководства пользователя

Новое руководство пользователя основано на руководстве пользователя текущего устройства. Никогда не было никаких проблем из-за руководства пользователя. Добавлено описание нового аппликатора (включая фотографии):

- Технические данные
- Техническое описание аппликатора
- Как поменять лазерный аппликатор
- Очистка и дезинфекция

Руководство было проверено с помощью контрольного списка CL 7356 GA MeDioStar V01\_ZI140205-01 (включая меры, связанные с анализом рисков) чтобы гарантировать безопасное использование прибора.



|               |                                                                                            |                                                                          |
|---------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / валидации                                                              | «Асклепион<br>Лейзер<br>Технологии»<br>(Asclepion Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/04/22-01<br>Код участника/год/месяц/день - порядковый номер | Страница 8 из 8<br>FB 7351e UsabilityValid<br>MSPRO Vs01 ZI40422-01.doc  |

### 3. Оценка эксплуатационной пригодности

Цель данной модернизации MeDioStar заключается в сокращении времени процедур для больших по размерам участков, при сохранении всех функциональных возможностей, предполагаемого использования и безопасности текущего устройства. Эта оценка основана на доказательствах безопасности и эффективности текущего устройства, подтверждении технического задания (кроме 2 незначительных недоработок, которые будут исправлены) и первых испытательных процедурах обработки.

Резюмируя, можно сказать, что эксплуатационная пригодность новой модернизированной версии MeDioStar даже лучше, чем у текущего устройства, потому что время процедур стало короче, а безопасность и эффективность остались такими же как у текущего устройства.

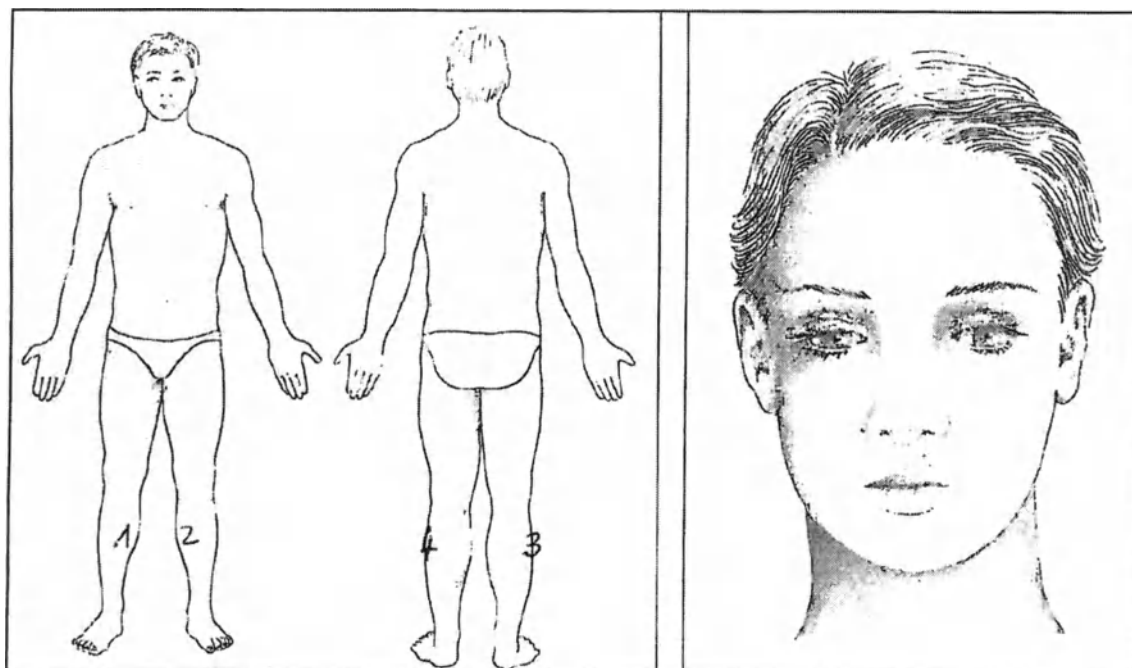
Протокол лечения

Дата: 16.06.2014

Имя пациента: Габи Циммерман

Лечение / очередное лечение: Тест MS-PRO Entw. geraz NeXT text.NT

Индикация: Тест (эпилепсии)



Используемый прибор: 1591 00 726 (Предсердный прибор)

Используемые параметры: Смотри ниже

|                               |           |                                      |                                                                                                    |
|-------------------------------|-----------|--------------------------------------|----------------------------------------------------------------------------------------------------|
| фиг состояние до XLS<br>30x10 | XLS 30x10 | 1 справа внутри<br>«Гладкий импульс» | 2 слева внутри<br>Старт 35 дж/см <sup>2</sup> → слишком болезненно<br>↓<br>30<br>25 /неразборчиво/ |
|-------------------------------|-----------|--------------------------------------|----------------------------------------------------------------------------------------------------|

Примечания:

|           |                                                                                                                                                   |                                                                                                                              |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| XLL 24x38 | 3 справа снаружи<br>«Гладкий импульс»<br>5 дж/см <sup>2</sup> ; 5,3 Гц<br>единственная настройка<br>3. кол-во проходов в порядке 0<br>4. прервано | 4. PROFESSIONAL<br>слева снаружи<br>12 дж/см <sup>2</sup> О 60 мс ОК<br>↓<br>15 слишком болезненно<br>↓<br>13 /неразборчиво/ |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|

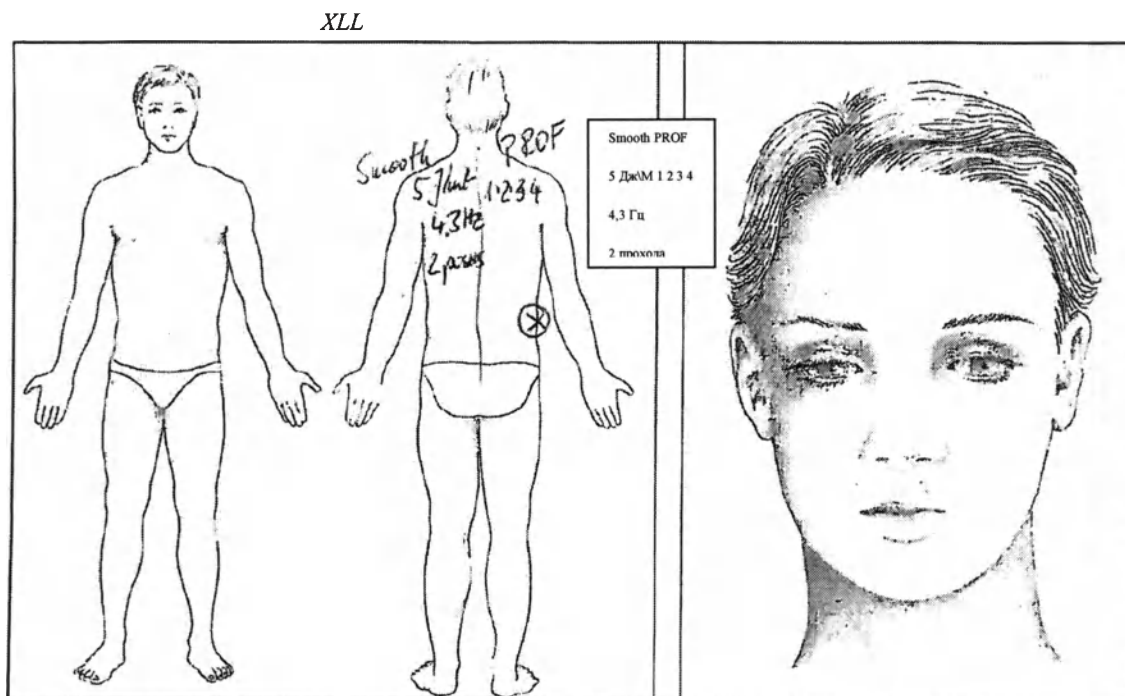
### Протокол лечения

Дата: 24.06.2014

Имя пациента: Роберто Манкарелли

Лечение / очередное лечение: \_\_\_\_\_

Индикация: Тест (эпиляции)



Используемый прибор: MS PRO 1591 00 726 (Венозный прибор)

Используемые параметры: см. сверху / см. снизу Аппликатор XLL

справа PROFESSIONAL 2,1 Гц, самое короткое время

#### Примечания:

- 1) 7 Дж/см<sup>2</sup>
- 2) 8 Дж/см<sup>2</sup>
- 3) 9 Дж/см<sup>2</sup>
- 4) 10 Дж/см<sup>2</sup>

Слегка болезненно с одной стороны -> охлаждено с помощью охлаждающих пакетов  
Сильный /неразборчиво/, но только в одной части пятна (середина?)



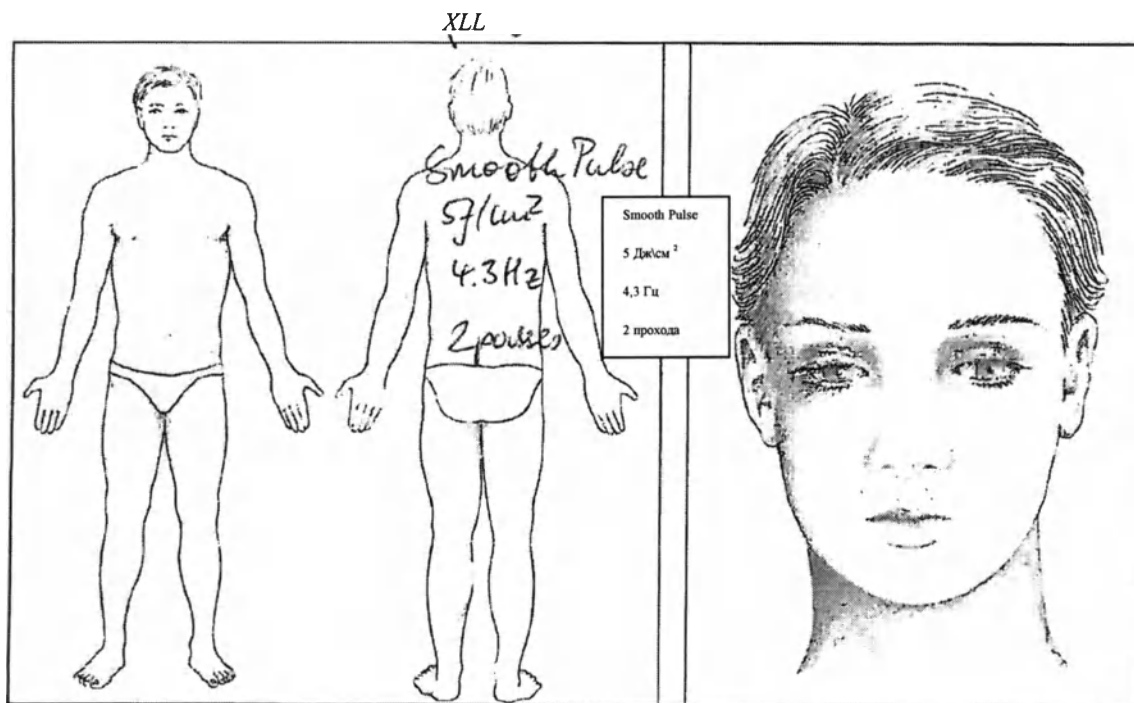
Протокол лечения

Дата: 24.06.2014

Имя пациента: Михаэль Мёллер

Лечение / очередное лечение: 4. Предварительное лечение с помощью MS NEXT 3 года назад

Индикация: Тест (эпиляции)



Используемый прибор: MS PRO 1591 00 726 (Венозный прибор). аппликатор. XLL

Используемые параметры: см. наверху

Примечания: Ничего не отмечено

|               |                                                                                        |                                                                     |
|---------------|----------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| CL 7351       | Основные требования к оценке соответствия согласно Директиве Евросовета 93/42/ЕЕС*     | «Асклепион Лейзер<br>Текнолоджис» (Asclepion<br>Laser Technologies) |
| Редакция №: С | Идентификационный номер: CaM/14/11/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 1 из 30<br>CL7351 93-42-EEC MSPRO<br>V01 CaM141112-01.doc  |

**Протестированные устройства:** *предсерийное устройство*

**Название и/или модель:** *MeDioStar 1591/1592*

**Серийный номер:** *неприменимо*

**Дата изготовления (если известна):** *неприменимо*

**Производитель:** *«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)*

**Адрес:** *Брюсселерштрассе, 10, 07747, Йена, Германия*

**Применяемый стандарт:** Директива 93/42/ЕС от 14 июня 1993 г. по медицинским изделиям\*

**Вложения:** TP7342 Appendix 93-42-EEC MSPRO V01 CaM141112-02

\* RL 93/42/EWG – состояние на 21.03.2010,  
включая изменения  
- Директива 98/79/ЕС  
- Директива 2000/70/ЕС  
- Директива 2001/104/ЕС  
- Постановление (ЕС) 1882/2003  
- Директива 2007/47/ЕС

|                    |                  |                   |                  |
|--------------------|------------------|-------------------|------------------|
| <b>Рассмотрел:</b> | <u>С. Кюлинг</u> | <u>12.11.2014</u> | <u>/Подпись/</u> |
|                    | ФИО              | Дата              | Подпись          |
| <b>Проверил:</b>   | <u>И. Штрайт</u> | <u>12.11.2014</u> | <u>/Подпись/</u> |
|                    | ФИО              | Дата              | Подпись          |

|                                                                                            |           |                 |                                                      |         |               |
|--------------------------------------------------------------------------------------------|-----------|-----------------|------------------------------------------------------|---------|---------------|
| Основание для последнего изменения формы: Введение изменений согласно Директиве 2007/47/ЕС |           |                 |                                                      |         |               |
| Форма по НОКР:                                                                             |           |                 | Форма проверена и утверждена Менеджером по качеству: |         |               |
| 25.09.2009                                                                                 | И. Штрайт | Подписал Штрайт | 25.09.2009                                           | Р. Тиме | Подписал Тиме |
| Дата                                                                                       | ФИО       | Подпись         | Дата                                                 | ФИО     | Подпись       |

|               |                                                                                        |                                                                     |
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| CL 7351       | Основные требования к оценке соответствия согласно Директиве Евросовета 93/42/ЕЕС*     | «Асклепион Лейзер<br>Технолоджис» (Asclepion<br>Laser Technologies) |
| Редакция №: С | Идентификационный номер: CaM/14/11/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 2 из 30<br>CL7351 93-42-EEC MSPRO<br>V01 CaM141112-01.doc  |

## Идентификация

### Подробная информация о лице, ответственном за экспертизу:

Идентификационные данные лица, ответственного за экспертизу подлежащей проверке продукции:

ФИО: Каролин Кюлинг  
полные имя и фамилия  
(печатными буквами)

Должность: Контроль качества НИОКР  
полное название должности

Если вышеуказанное лицо не является сотрудником предприятия-производителя продукции, подлежащей экспертизе, укажите сведения о работодателе ответственного за экспертизу лица или организацию:

Организация: \_\_\_\_\_

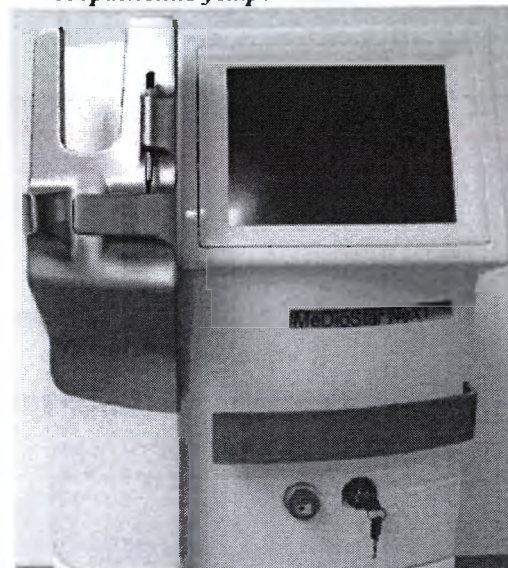
Адрес: \_\_\_\_\_

### Медицинский прибор

Подробная информация о продукции, подлежащей проверке:

См. Руководство пользователя

## Изображение устройства







|               |                                                                                        |                                                                     |
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| Редакция №: С | Идентификационный номер: CaM/14/11/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 4 из 30<br>CL7351 93-42-ЕЕС MSPRO<br>V01 CaM141112-01.doc  |

| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | соответствие                        |                          |                          | согласованный стандарт                                                                      | замечания, отклонения и/или риски                                                                                                                                                                                                                                                  |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | да                                  | нет                      | неприменимо              |                                                                                             |                                                                                                                                                                                                                                                                                    |
|          | Приложение I<br>Основные требования                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                     |                          |                          |                                                                                             |                                                                                                                                                                                                                                                                                    |
| I.       | Общие требования                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                     |                          |                          |                                                                                             |                                                                                                                                                                                                                                                                                    |
| 1.       | Устройства должны быть сконструированы и изготовлены таким образом, чтобы во время использования при условиях и в целях, упомянутых выше, они не ухудшали клиническое состояние или безопасность пациентов, или безопасность и здоровье пользователей, или, если применимо, других лиц при условии, что любые риски, связанные с использованием, представляют собой риски, которым дана оценка в сравнении с положительным эффектом для пациента, и они совместимы с высоким уровнем защиты здоровья и безопасности.<br>Указанное включает: | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Директива 93/42/ЕЕС по медицинским изделиям<br>EN ISO 14971:2009                            | Анализ и контроль рисков<br>Отчет об управлении рисками<br>Анализ просчетов в EN ISO 14971:2012<br>Протокол испытаний согласно EN 60601-1<br>Протокол испытаний согласно EN 60601-1-2<br>Оценка соответствия, эксплуатационная пригодность                                         |
| N        | - максимальное снижение рисков, вызванных сбоями при применении в связи с эргономическими и экологическими характеристиками (проектирование с точки зрения безопасности пациента)                                                                                                                                                                                                                                                                                                                                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1:2006<br>EN 60601-1-2:2007<br>EN 60601-1-2:2010<br>EN 62366:2008<br>EN 62304:2006 | Оценка соответствия, эксплуатационная пригодность                                                                                                                                                                                                                                  |
| N        | - учет знаний, опыта и образования и соответственно физического состояния предполагаемых пользователей (дизайн для пользователей-неспециалистов, медицинских специалистов, инвалидов или других пользователей)                                                                                                                                                                                                                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 62366:2008<br>EN 60601-1-6:2010                                                          | Оценка соответствия, эксплуатационная пригодность<br>Использование только врачом или под ответственность врача. Допускается использование только прошедшими обучение специалистами, обладающими знаниями об устройстве и применении сертифицированной системы управления качеством |

|               |                                                                                        |                                                                    |
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| Редакция №: С | Идентификационный номер: CaM/14/11/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 5 из 30<br>CL7351 93-42-EEC MSPRO<br>V01 CaM141112-01.doc |

| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | соответствие                                                                                                              |                                                                                          |                                                                                          | согласованный стандарт                                                                                                                                                                                                                                                          | замечания, отклонения и/или риски                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | да                                                                                                                        | нет                                                                                      | неприменимо                                                                              |                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2.       | Решения изготовителя по дизайну и конструкции устройства должны соответствовать принципам безопасности с учетом общепринятого уровня развития техники.                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input checked="" type="checkbox"/>                                                                                       | <input type="checkbox"/>                                                                 | <input type="checkbox"/>                                                                 | Основные стандарты:<br>EN ISO 14971:2009<br><br>EN 60601-1:2006<br>EN 60601-1-2:2007<br>EN 60601-1-22:2007<br>EN 60825-1:2007+<br>Поправка 1:2008 +<br>Поправка 2:2009<br>EN 62304:2006<br>EN 60601-1-6:2010<br>EN 62366:2008<br>EN 15223-1:2012<br>EN 980:2008<br>EN 1041:2008 | Анализ и контроль рисков<br>Отчет об управлении рисками<br>Анализ просчетов в EN ISO 14971:2012<br>Протокол испытаний согласно EN 60601-1<br>Протокол испытаний согласно EN 60601-1-2<br>Оценка соответствия, IEC 60601-1-22<br>Оценка соответствия, EN 60825-1<br><br>Оценка соответствия, EN 62304<br>Оценка соответствия, эксплуатационная пригодность<br><br>Оценка соответствия, EN 980 / EN15223-1<br>Оценка соответствия, EN 1041 |
| 2.1      | Для выбора наиболее приемлемых решений изготовитель должен применить следующие принципы в следующем порядке: <ul style="list-style-type: none"> <li>в кратчайшие возможные сроки исключить или уменьшить риски (интеграция концепции безопасности на этапе разработки и изготовления изделия),</li> <li>если необходимо, принять соответствующие защитные меры в отношении рисков, которые не могут быть устранены, по крайней мере посредством аварийной сигнализации.</li> <li>информировать пользователей об остаточных рисках в связи с недостаточностью принятых защитных мер</li> </ul> | <input checked="" type="checkbox"/><br><br><input checked="" type="checkbox"/><br><br><input checked="" type="checkbox"/> | <input type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/> | <input type="checkbox"/><br><br><input type="checkbox"/><br><br><input type="checkbox"/> | EN ISO 14971:2009                                                                                                                                                                                                                                                               | Анализ и контроль рисков<br>Характеристики продукции<br>Отчет об управлении рисками<br>Анализ просчетов в EN ISO 14971:2012<br><br>Контрольный список, руководство пользователя                                                                                                                                                                                                                                                          |



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| Редакция №: С | Идентификационный номер: CaM/14/11/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 6 из 30<br>CL7351 93-42-EEC MSPRO<br>V01 CaM141112-01.doc  |

| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                              | соответствие                        |                          |                          | согласованный стандарт                                                                       | замечания, отклонения и/или риски                                                                                                                                                                                                                                                                                                                                                              |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|          |                                                                                                                                                                                                                                                                                                                                                                       | да                                  | нет                      | неприменимо              |                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                |
| 3.       | Устройства должны функционировать в соответствии с определенными производителем параметрами, быть спроектированы, изготовлены и упакованы так, чтобы выполнять одну или более функций, оговоренные в Статье 1 (2) (а), как это указано производителем.                                                                                                                | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601 -1:2006<br>IEC 60601-2-22:2007<br>EN 980:2008<br><br>EN 1041:2008                   | Основные эксплуатационные характеристики:<br>- энергия лазера и длительность импульса<br>- защита от поражения электрическим током<br><i>Отчет об управлении рисками</i><br><i>Протокол испытаний согласно EN 60601-1</i><br><i>Оценка соответствия, IEC 60601-1-22</i><br><i>Оценка соответствия, EN 980 / EN15223-1</i><br><i>Оценка соответствия, EN 1041</i><br><i>Проверка устройство</i> |
| 4.       | Не допускаются изменения показателей и эксплуатационных характеристик, описанных в Разделах 1, 2, и 3, которые ставят под угрозу клиническое состояние и безопасность пациентов и, где это применимо, других лиц, в течение срока службы, указанного изготовителем, с учетом того, что эти изделия испытывают нагрузки, возможные при нормальных условиях применения. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1:2006<br>IEC 60601-2-22:2007                                                       | <i>Протокол испытаний согласно EN 60601-1</i><br><i>Оценка соответствия, IEC 60601-1-22</i><br><i>Проверка устройства</i><br><i>Проверка аппликатора</i>                                                                                                                                                                                                                                       |
| 5.       | Устройства должны проектироваться, изготавливаться и упаковываться таким образом, чтобы их характеристики и производительность в период их использования по назначению не пострадали при транспортировке и хранении, с учетом инструкций и информации, предоставленных производителем.                                                                                | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1:2006<br>EN 980:2008<br><br>EN 1041:2008                                           | <i>Протокол испытаний согласно EN 60601-1</i><br><i>Оценка соответствия, EN 980 / EN15223-1</i><br><i>Оценка соответствия, EN 1041</i><br><i>Проверка устройства</i><br><i>Проверка аппликатора</i>                                                                                                                                                                                            |
| 6.       | Нежелательные побочные эффекты не создают недопустимых рисков при условии соблюдения заданных эксплуатационных характеристик.                                                                                                                                                                                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>RL 93/42/EEC<br>MEDDEV 2.7.1:2009<br>EN 60601-1-6:2010<br>EN 62366:2008 | <i>Клиническая оценка</i><br><i>Оценка соответствия, эксплуатационная пригодность</i>                                                                                                                                                                                                                                                                                                          |
| 6а.<br>№ | Доказательство соответствия основным требованиям включает клиническую оценку согласно Приложению Х                                                                                                                                                                                                                                                                    | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | MEDDEV 2.7.1:2009                                                                            | <i>Клиническая оценка</i>                                                                                                                                                                                                                                                                                                                                                                      |
| II.      | Требования по дизайну и конструкции                                                                                                                                                                                                                                                                                                                                   |                                     |                          |                          |                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                |

|               |                                                                                        |                                                                     |
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| CL 7351       | Основные требования к оценке соответствия согласно Директиве Евросовета 93/42/ЕЕС*     | «Асклепион Лейзер<br>Технолоджис» (Asclepion<br>Laser Technologies) |
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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | соответствие                        |                          |                                     | согласованный стандарт | замечания, отклонения и/или риски                                      |
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|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | да                                  | нет                      | неприменимо                         |                        |                                                                        |
| 7.       | Химические, физические и биологические свойства                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                     |                          |                                     |                        |                                                                        |
| 7.1      | Устройства должны проектироваться и изготавливаться так, чтобы гарантировать показатели и эксплуатационные характеристики, указанные в Разделе 1 «Общие требования». Особое внимание следует уделить следующим факторам:<br><ul style="list-style-type: none"><li>- выбор используемых материалов, в частности, в том, что касается токсичности и, где это применимо, воспламеняемости,</li><li>- совместимость используемых материалов с биологическими тканями, клетками и жидкостями организма с учетом предполагаемого применения устройства.</li><li>- Результаты исследований на биофизических и других моделях, валидность которых уже доказана</li></ul> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN ISO 10993-1:2009    | Оценка совместимости материалов<br>Оценка соответствия, EN ISO 10993-1 |
| N        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            |                        |                                                                        |
|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                                                        |

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| CL 7351       | Основные требования к оценке соответствия согласно Директиве Евросовета 93/42/ЕЕС*     | «Асклепион Лейзер<br>Технолоджис» (Asclepion<br>Laser Technologies) |
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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                        | соответствие                                                                                                      |                                                                                  |                                                                                  | согласованный стандарт | замечания, отклонения и/или риски                                      |
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|          |                                                                                                                                                                                                                                                                                                                                                                                                                 | да                                                                                                                | нет                                                                              | неприменимо                                                                      |                        |                                                                        |
| 7.2      | Устройства должны проектироваться, изготавливаться и упаковываться так, чтобы свести к минимуму риск, вызванный загрязнениями и остатками, для лиц, занятых в транспортировке, хранении и эксплуатации устройств, а также для пациентов с учетом предполагаемого применения изделия. Особое внимание следует уделять тканям, испытывающим воздействие излучения, а также продолжительности и частоте излучения. | <input type="checkbox"/>                                                                                          | <input type="checkbox"/>                                                         | <input checked="" type="checkbox"/>                                              |                        | загрязнений и отходов нет                                              |
| 7.3 а)   | Изделия должны проектироваться и изготавливаться так, чтобы они могли безопасно применяться с<br>материалами,<br>веществами и<br>газами,<br>с которыми они вступают в контакт в ходе их обычного использования, планового технического обслуживания и ремонта.                                                                                                                                                  | <input checked="" type="checkbox"/><br><input checked="" type="checkbox"/><br><input checked="" type="checkbox"/> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | EN ISO 10993-1:2009    | Оценка совместимости материалов<br>Оценка соответствия, EN ISO 10993-1 |
| б)       | Если изделия предназначены для введения лекарственных препаратов, они должны проектироваться и изготавливаться так, чтобы обеспечить совместимость с указанными лекарственными препаратами в соответствии с положениями и ограничениями, регулирующими эти препараты, и что их эксплуатационные характеристики поддерживаются в соответствии с предполагаемым применением этих изделий.                         | <input type="checkbox"/>                                                                                          | <input type="checkbox"/>                                                         | <input checked="" type="checkbox"/>                                              |                        | не предназначены для введения лекарственных препаратов                 |



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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | соответствие                        |                          |                                     | согласованный стандарт                  | замечания, отклонения и/или риски                                                                                                                                 |
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|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | да                                  | нет                      | неприменимо                         |                                         |                                                                                                                                                                   |
| 7.4      | В случае, если изделие в качестве неотъемлемой своей части включает вещество, которое в случае использования отдельно может рассматриваться лекарственным препаратом согласно определению в Статье 1 Директивы 65/65/ЕЕС, и которое обязано действовать: на организм с эффектом, вспомогательным к действию изделия, безопасность, качество и пригодность данного вещества должны быть подтверждены с учетом предполагаемого использования изделия, по аналогии с соответствующими методами, указанными в Директиве 75/318/ЕЕС. | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                         | изделие не содержит вещества, которые могут считаться лекарственным препаратом                                                                                    |
| 7.5      | Изделия должны проектироваться и изготавливаться так, чтобы сводить к минимуму риски от веществ, протекающих из изделия.                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                         | нет утечки веществ                                                                                                                                                |
| 7.6      | Устройства должны быть спроектированы и изготовлены таким образом, чтобы максимально снизить риски непреднамеренного попадания веществ в устройство, с учетом параметров устройства и характера среды, в которой оно предназначено для использования.                                                                                                                                                                                                                                                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 1041:2008         | Протокол испытаний согласно EN 60601-1<br>Оценка соответствия, EN 1041                                                                                            |
| 8.       | <b>Инфекция и микробное загрязнение</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                     |                          |                                     |                                         |                                                                                                                                                                   |
| 8.1 а)   | Устройства и производственные процессы должны быть спроектированы так, чтобы исключить или максимально снизить возможный риск инфицирования пациента, пользователей и третьих лиц.                                                                                                                                                                                                                                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN ISO 10993-1: 2009 | Протокол испытаний согласно EN 60601-1<br>Оценка совместимости материалов<br>Оценка соответствия, EN ISO 10993-1                                                  |
| б)       | Устройство должно быть простым в использовании и, в случае необходимости, должно минимизировать возможность загрязнения устройства пациентом и наоборот во время использования.                                                                                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN ISO 10993-1: 2009                    | Неинвазивные процедуры: Только насадка аппликатора находится в контакте с пациентом<br><br>Оценка совместимости материалов<br>Оценка соответствия, EN ISO 10993-1 |
| 8.2      | Ткани животного происхождения должны быть получены от животных, которые подверглись ветеринарной проверке и надзору применительно к предполагаемому использованию                                                                                                                                                                                                                                                                                                                                                               | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                         | Ткани животного происхождения не применяются                                                                                                                      |

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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | соответствие             |                          |                                     | согласованный стандарт | замечания, отклонения и/или риски                   |
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|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | да                       | нет                      | неприменимо                         |                        |                                                     |
|          | тканей. В распоряжение уполномоченных органов должны быть предоставлены сведения о географическом происхождении животных. Обработка, консервация, анализы тканей, клеток и веществ животного происхождения и обращение с указанным должны осуществляться таким образом, чтобы обеспечить оптимальную безопасность. В частности, защита от вирусов и других переносчиков и возбудителей заболеваний должны обеспечиваться путем внедрения проверенных методов ликвидации или вирусной инактивации в ходе производственного процесса. |                          |                          |                                     |                        |                                                     |
| 8.3      | Изделия, поставляемые в стерильном состоянии, должны проектироваться, изготавливаться и упаковываться в одноразовую упаковку и/или с применением способов, соответствующих предполагаемому использованию изделий так, чтобы изделия оставались стерильными при поставке в продажу при соблюдении предусмотренных изготовителем условий хранения и транспортировки до момента нарушения целостности или вскрытия стерильной упаковки.                                                                                                | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Изделие не стерильно<br>Принадлежности не стерильны |
| 8.4      | Изделия, поставленные в стерильном состоянии, изготовлены и стерилизованы по утвержденному специальному методу.                                                                                                                                                                                                                                                                                                                                                                                                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Изделие не стерильно<br>Принадлежности не стерильны |
| 8.5      | Изделия, предназначенные для стерилизации, изготовлены в соответствующих контролируемых условиях (например, условиях окружающей среды).                                                                                                                                                                                                                                                                                                                                                                                             | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Изделие не стерильно<br>Принадлежности не стерильны |

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| параграф | требования директивы<br>краткое описание                                                                                                                                | соответствие                        |                          |                                     | согласованный стандарт | замечания, отклонения и/или риски                                            |
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|          |                                                                                                                                                                         | да                                  | нет                      | неприменимо                         |                        |                                                                              |
| 8.6      | Упаковочные системы для нестерильных изделий должны поддерживать уровень чистоты изделия без ухудшения его характеристик и,                                             | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Изделие не стерильно<br>Принадлежности не стерильны                          |
|          | если изделия должны пройти стерилизацию перед использованием, свести к минимуму риск микробного загрязнения;                                                            | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                                                              |
|          | система упаковки должна быть подходящей с учетом метода стерилизации, указанного изготовителем.                                                                         | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                                                              |
| 8.7      | Упаковка и/или маркировка изделия должны позволять отличать изделие от идентичных или схожих изделий, которые продаются как в стерильном, так и нестерильном состоянии. | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Только нестерильные принадлежности                                           |
| 9.       | <b>Свойства конструкции и экологические свойства</b>                                                                                                                    |                                     |                          |                                     |                        |                                                                              |
| 9.1      | Если изделие предназначено для использования в сочетании с другими устройствами или оборудованием,                                                                      |                                     |                          |                                     |                        | Не предназначено для использования вместе с другим медицинским оборудованием |
|          | - все сочетание, включая соединения, должно быть безопасным                                                                                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                                                              |
|          | - не должно ухудшать указанные эксплуатационные характеристики изделия.                                                                                                 | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                                                              |
|          | - Любые ограничения на использование должны быть указаны в маркировке или в инструкциях по применению.                                                                  | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                                                              |



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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | соответствие                        |                          |                                     | согласованный стандарт | замечания, отклонения и/или риски                             |
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|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | да                                  | нет                      | неприменимо                         |                        |                                                               |
| 9.2      | <p>Изделия должны быть разработаны и изготовлены в таком образом, чтобы устранить или свести к минимуму, насколько это возможно:</p> <ul style="list-style-type: none"> <li>риск получения травм, в связи с физическими свойствами изделий, включая соотношение между объемом и давлением, размеры и, при необходимости, эргономические характеристики,</li> <li>риски, связанные с обоснованно предполагаемыми условиями окружающей среды, например, магнитные поля, внешние электрические воздействия, электростатические разряды, давление, температура или колебания давления и ускорение,</li> <li>риски взаимных помех с другими устройствами, обычно используемыми в проведении исследований или лечебных процедур,</li> <li>риски, возникающие в условиях, когда обслуживание или калибровка невозможны (например, в случае с имплантатами), старения используемых материалов или потери точности любого измерительного устройства или элемента управления.</li> </ul> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006        | Протокол испытаний согласно EN 60601-1<br>Проверка устройства |
|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006        | Протокол испытаний согласно EN 60601-1                        |
|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1-2:2007      | Протокол испытаний согласно EN 60601-1-2                      |
|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> | EN 60601-1:2006        | Регулярное ежегодное техническое обслуживание и калибровка    |

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| Редакция №: С | Идентификационный номер: CaM/14/11/12-01<br>Идентификационный код/год/месяц/день-номер | Страница 13 из 30<br>CL7351 93-42-EEC MSPRO<br>V01 CaM141112-01.doc |

| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                     | соответствие                        |                          |                                     | согласованный стандарт | замечания, отклонения и/или риски                                                             |
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|          |                                                                                                                                                                                                                                                                                                              | да                                  | нет                      | неприменимо                         |                        |                                                                                               |
| 9.3      | Изделия должны проектироваться и изготавливаться таким образом, чтобы свести к минимуму риск возникновения пожара или взрыва при нормальной эксплуатации или при первом возникновении дефекта. Особое внимание должно уделяться легко воспламеняющимся веществам или веществ, которые могут вызвать горение. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006        | Протокол испытаний согласно EN 60601-1<br><br>конструкция, безопасная при единичном нарушении |
| 10.      | <b>Изделия с измерительной функцией</b>                                                                                                                                                                                                                                                                      |                                     |                          |                                     |                        |                                                                                               |
| 10.1     | Изделия с измерительной функцией должны быть разработаны и изготовлены в таком образом, чтобы обеспечить достаточную точность и стабильность в соответствующих пределах точности с учетом назначения изделия.<br><br>Пределы точности должны указываться заводом-изготовителем.                              | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Измерительные функции отсутствуют                                                             |
|          |                                                                                                                                                                                                                                                                                                              | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        |                                                                                               |
| 10.2     | Шкала измерения, мониторинга и дисплея должна быть разработана с учетом эргономических принципов и назначения устройства.                                                                                                                                                                                    | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Измерительные функции отсутствуют                                                             |
| 10.3     | Измерения, проводящиеся изделиями с измерительной функцией, должны выражаться в стандартизованных единицах физических величин в соответствии с положениями директивы Евросовета 80/181/ЕЕС (1).                                                                                                              | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                        | Измерительные функции отсутствуют                                                             |

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| параграф       | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                                                                                                   | соответствие                        |                          |                          | согласованный стандарт                                               | замечания, отклонения и/или риски                                                                                                            |
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|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | да                                  | нет                      | неприменимо              |                                                                      |                                                                                                                                              |
| 11.            | Защита от излучения                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                     |                          |                          |                                                                      |                                                                                                                                              |
| 11.1<br>11.1.1 | Общие указания<br>Устройства должны быть спроектированы и изготовлены таким образом, чтобы максимально возможно уменьшить воздействие излучения на пациентов, пользователей и других лиц с учетом назначения изделия, в то же время без ограничения применения соответствующих указанных уровней для терапевтических и диагностических целей.                                                                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1-2:2007<br>IEC 60601-2-22:2007                             | Протокол испытаний согласно EN 60601-1-2<br><br>Оценка соответствия, IEC 60601-1-22                                                          |
| 11.2<br>11.2.1 | Предполагаемое излучение<br>В случае с изделиями, рассчитанными на генерирование опасных уровней излучения, необходимых для конкретной медицинской цели, польза от которого считается значительно большей по сравнению с рисками, связанными с излучением, пользователь должен иметь возможность регулировать излучение.<br>Такие устройства должны разрабатываться и изготавливаться таким образом, чтобы обеспечивать воспроизводимость и допуски соответствующих переменных параметров. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 60601-1:2006<br>IEC 60601-2-22:2007<br><br>EN ISO 14971:2009      | Протокол испытаний согласно EN 60601-1<br>Оценка соответствия, IEC 60601-1-22<br><br>Отчет об управлении рисками<br>Анализ и контроль рисков |
| 11.2.2         | В случае с изделиями, рассчитанными на генерирование потенциально опасного излучения в видимом или невидимом диапазоне, такие изделия должны быть оборудованы (при наличии возможности) средствами визуальной индикации и/или предупреждающей звуковой сигнализацией такого излучения.                                                                                                                                                                                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | IEC 60601-2-22:2007<br>EN 980:2008<br>EN15223-1:2012<br>EN 1041:2008 | Оценка соответствия, IEC 60601-1-22<br>Оценка соответствия, EN 980 / EN15223-1<br>Оценка соответствия, EN 1041                               |



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| параграф       | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                               | соответствие                        |                          |                                     | согласованный стандарт                                                                                                     | замечания, отклонения и/или риски                                                                                                                                                                           |
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|                |                                                                                                                                                                                                                                                                                                                                        | да                                  | нет                      | неприменимо                         |                                                                                                                            |                                                                                                                                                                                                             |
| 11.3<br>11.3.1 | Непреднамеренное излучение<br>Изделия должны разрабатываться и изготавливаться таким образом, чтобы свести к минимуму воздействие на пациентов, пользователей и других лиц непреднамеренного, паразитного или рассеянного излучения.                                                                                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | IEC 60601-2-22:2007<br>EN 60825-1: 2007 +<br>Поправка 1:2008 +<br>Поправка 2:2009                                          | Контактная насадка<br>лазерные защитные очки<br><i>Оценка соответствия, IEC 60601-1-22</i><br><i>Оценка соответствия, EN 60825-1</i>                                                                        |
| 11.4<br>11.4.1 | Инструкции по применению<br>Инструкции по применению изделий, производящих излучение, должны содержать подробную информацию о следующем:<br><br>характер испускаемого излучения<br><br>средства защиты пациента и пользователя, а также способы, позволяющие исключить ненадлежащее использование и устранить риски, присущие изделию. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | IEC 60601-2-22:2007<br>EN 60825-1: 2007+<br>Поправка 1:2008 +<br>Поправка 2:2009<br><br>EN 62366 2008<br>EN 60601-1-6:2010 | <i>Оценка соответствия, IEC 60601-1-22</i><br><i>Оценка соответствия, EN 60825-1</i><br><br><i>Оценка соответствия, эксплуатационная пригодность</i><br><i>Контрольный список, руководство пользователя</i> |
| 11.5<br>11.5.1 | Ионизирующее излучение<br>Изделия, предназначенные для генерирования ионизирующего излучения, должны разрабатываться и изготавливаться таким образом, чтобы обеспечить (где это осуществимо) возможность контролировать и регулировать количество, геометрию и качество излучения с учетом предполагаемого использования изделия.      | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                                                                                            | ионизирующее излучение отсутствует                                                                                                                                                                          |

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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                     | соответствие                        |                          |                                     | согласованный стандарт             | замечания, отклонения и/или риски                                                                      |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|------------------------------------|--------------------------------------------------------------------------------------------------------|
|          |                                                                                                                                                                                                                                                                                                                                                              | да                                  | нет                      | неприменимо                         |                                    |                                                                                                        |
| 11.5.2   | Изделия, вырабатывающие ионизирующее излучение в целях рентгенодиагностики, должны разрабатываться и изготавливаться так, чтобы обеспечивать получение соответствующего изображения и/или выходного качества для предполагаемого использования по назначению в медицинских целях, одновременно минимизируя воздействие излучения на пациента и пользователя. | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                    | ионизирующее излучение отсутствует                                                                     |
| 11.5.3   | Изделия, генерирующие ионизирующее излучение в целях рентгенотерапии, должны разрабатываться и изготавливаться так, чтобы обеспечивать достоверный мониторинг и контроль за дозой излучения, типом луча и энергией и, в применимых случаях, качество излучения.                                                                                              | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                    | ионизирующее излучение отсутствует                                                                     |
| 12.      | <b>Требования по медицинским изделиям, подключенным к источнику питания или оборудованным встроенным источником питания</b>                                                                                                                                                                                                                                  |                                     |                          |                                     |                                    |                                                                                                        |
| 12.1     | Изделия, содержащие электронные программируемые системы, должны разрабатываться так, чтобы обеспечивать                                                                                                                                                                                                                                                      |                                     |                          |                                     |                                    |                                                                                                        |
|          | воспроизводимость                                                                                                                                                                                                                                                                                                                                            | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN ISO 14971:2009<br>EN 62304:2006 | Отчет об управлении рисками<br>Протокол испытаний согласно EN 60601-1<br>Оценка соответствия, EN 62304 |
|          | надежность и                                                                                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            |                                    |                                                                                                        |
|          | эксплуатационные характеристики этих систем в соответствии с их предполагаемым применением.                                                                                                                                                                                                                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | IEC 60601-2-22:2007                | Оценка соответствия, IEC 60601-1-22                                                                    |

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| параграф    | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                               | соответствие                        |                          |                                     | согласованный стандарт           | замечания, отклонения и/или риски                                                                                                       |
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|             |                                                                                                                                                                                                                                                                                                                                                        | да                                  | нет                      | неприменимо                         |                                  |                                                                                                                                         |
|             | В случае состояния единичной неисправности (в системе) должны быть приняты необходимые меры, чтобы устранить или (насколько это возможно) свести к минимуму возможные косвенные риски.                                                                                                                                                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006                  | Протокол испытаний согласно EN 60601-1                                                                                                  |
| 12.1a)<br>N | Изделия, которые содержат программное обеспечение, либо которые представляют собой медицинское программное обеспечение, причем данное программное обеспечение прошло валидацию в соответствии с современным состоянием развития технологии, соблюдены принципы жизненного цикла программного обеспечения, управления рисками, валидации и верификации. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 62304:2006 | Протокол испытаний согласно EN 60601-1<br><br>Оценка соответствия, EN 62304<br>Проверка программного обеспечения и отчеты об аттестации |
| 12.2        | Изделия, в которых безопасность пациентов зависит от внутреннего источника питания, должны быть оборудованы средствами определения уровня зарядки источника питания.                                                                                                                                                                                   | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                  | неприменимо                                                                                                                             |
| 12.3        | Изделия, в которых безопасность пациентов зависит от внешнего источника питания, должны содержать систему сигнализации, которая извещает о прекращении подачи питания.                                                                                                                                                                                 | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                  | неприменимо                                                                                                                             |
| 12.4        | Изделия, которые рассчитаны на отслеживание одного или нескольких клинических параметров пациента, должны быть оборудованы соответствующими системами сигнализации, чтобы информировать пользователя о ситуациях, которые могут вызвать смерть или серьезное ухудшение состояния здоровья пациента.                                                    | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                  | неприменимо                                                                                                                             |



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| параграф       | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                 | соответствие                        |                          |                          | согласованный стандарт                 | замечания, отклонения и/или риски                                                                                        |
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|                |                                                                                                                                                                                                                                                                                                                                                          | да                                  | нет                      | неприменимо              |                                        |                                                                                                                          |
| 12.5           | Изделия должны разрабатываться и изготавливаться так, чтобы они сводили к минимуму риски возникновения электромагнитных полей или оборудования в обычной среде.                                                                                                                                                                                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1-2:2007 | Отчет об управлении рисками<br>Анализ и контроль рисков<br>Протокол испытаний согласно EN 60601-1-2                      |
| 12.6           | Устройства должны разрабатываться и изготавливаться таким образом, чтобы, насколько это возможно, исключать риск случайного поражения электрическим током во время обычного использования либо в условиях единичной неисправности при условии правильной установки этих изделий.                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006   | Отчет об управлении рисками<br>Анализ и контроль рисков<br>Протокол испытаний согласно EN 60601-1                        |
| 12.7<br>12.7.1 | Защита от механических и тепловых рисков<br>Устройства должны разрабатываться и изготавливаться таким образом, чтобы защищать пациента и пользователя от механических рисков, связанных, например, с сопротивлением, устойчивостью или наличием движущихся частей.                                                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006   | Отчет об управлении рисками<br>Характеристики продукции<br>Протокол испытаний согласно EN 60601-1                        |
| 12.7.2         | Устройства должны разрабатываться и изготавливаться таким образом, чтобы сводить к минимуму риски, связанные с вибрацией, производимой этими изделиями, с учетом технического прогресса и имеющихся средств ограничения вибрации, особенно, в месте их возникновения, если только вибрация не является частью указанной эксплуатационной характеристики. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006   | Отчет об управлении рисками<br>Характеристики продукции<br>Протокол испытаний согласно EN 60601-1<br>Проверка устройства |

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| параграф       | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                  | соответствие                        |                          |                          | согласованный стандарт                                                                 | замечания, отклонения и/или риски                                                                                                                                         |
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|                |                                                                                                                                                                                                                                                                                                                                                           | да                                  | нет                      | неприменимо              |                                                                                        |                                                                                                                                                                           |
| 12.7.3         | Устройства должны разрабатываться и изготавливаться таким образом, чтобы сводить к минимум риски, связанные с шумом, производимым этими изделиями, учитывая технический прогресс и имеющиеся средства ограничения шума, особенно в месте его возникновения, если только данный шум не является частью указанной эксплуатационной характеристики.          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006                                                   | Отчет об управлении рисками<br>Характеристики продукции<br>Протокол испытаний согласно EN 60601-1<br>Проверка устройства                                                  |
| 12.7.4         | Оконечные устройства и разъемы линий подачи электричества, газа, гидравлической или пневматической энергии, которые пользователь должен использовать и управлять, должны быть разработаны и изготовлены таким образом, чтобы свести к минимуму все возможные риски.                                                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006<br>EN 980:2008<br>EN 15223-1:2012<br>EN 1041:2008 | Отчет об управлении рисками<br>Протокол испытаний согласно EN 60601-1<br>Оценка соответствия, EN 980 / EN15223-1<br>Оценка соответствия, EN 1041                          |
| 12.7.5         | Доступные части изделий (за исключением частей или участков, предназначенных для подачи тепла или рассчитанных на достижение заданных температур) и их окружение в нормальных условиях эксплуатации не должны достигать потенциально опасных значений температуры.                                                                                        | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006                                                   | Отчет об управлении рисками<br>Характеристики продукции<br>Протокол испытаний согласно EN 60601-1                                                                         |
| 12.8<br>12.8.1 | Защита от рисков, связанных с облучением пациента или введением пациенту веществ<br>Изделия, которые подают энергию или вещества пациенту, должны разрабатываться и изготавливаться таким образом, чтобы имелась возможность достаточно точно задавать и поддерживать скорость подачи, и в результате гарантировать безопасность пациента и пользователя. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>IEC 60601-2-22:2007<br>EN 60601-1:2006<br>EN 62304:2006           | Отчет об управлении рисками<br>Анализ и контроль рисков<br>Оценка соответствия, IEC 60601-1-22<br>Протокол испытаний согласно EN 60601-1<br>Оценка соответствия, EN 62304 |

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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                               | соответствие                        |                          |                          | согласованный стандарт                                                                           | замечания, отклонения и/или риски                                                                                                                                                                                                           |
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|          |                                                                                                                                                                                                                                                                                                                                                                                        | да                                  | нет                      | неприменимо              |                                                                                                  |                                                                                                                                                                                                                                             |
| 12.8.2   | Изделия должны быть оборудованы средствами, которые позволяют предотвращать и/или сообщать о любых несоответствиях в скорости подачи, которые могут представлять опасность.<br><br>Устройства должны включать в свой состав соответствующие средства, которые позволяют предотвратить (насколько это возможно) случайный выброс на опасном уровне энергии и/или вещества из источника. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>IEC 60601-2-22:2007<br>EN 62304:2006                                        | Отчет об управлении рисками<br>Анализ и контроль рисков<br>Оценка соответствия, IEC 60601-1-22<br>Протокол испытаний согласно EN 60601-1<br>Оценка соответствия, EN 62304                                                                   |
| 12.9     | Функции элементов управления и индикаторов должны быть четко указаны на изделии.<br><br>В случаях, если на изделии размещены указания по его применению, или предусмотрена визуальная индикация параметров эксплуатации или регулировки, данные указания и индикация должны быть понятны для пользователя, и, если применимо, для пациента.                                            | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | IEC 60601-2-22:2007<br>EN 980:2008<br>EN 15223-1:2012<br><br>IEC 60601-1-6:2010<br>EN 62366:2008 | Оценка соответствия, IEC 60601-1-22<br>Оценка соответствия, EN 980 / EN15223-1<br><br>Оценка соответствия, эксплуатационная пригодность                                                                                                     |
| 13.      | <b>Информация, представляемая заводом-изготовителем</b>                                                                                                                                                                                                                                                                                                                                |                                     |                          |                          |                                                                                                  |                                                                                                                                                                                                                                             |
| 13.1 а)  | К каждому изделию должна прилагаться информация о заводе-изготовителе, а также о безопасном и надлежащем применении изделия с учетом уровня профессиональной подготовки и знаний потенциальных пользователей. Эта информация включает в себя подробные сведения на этикетке, и данные в инструкциях по применению.                                                                     | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 14971:2009<br>EN 60601-1:2006<br>EN 15223-1:2012<br>EN 980:2008<br>EN 1041:2008           | Отчет об управлении рисками<br>Протокол испытаний согласно EN 60601-1<br>Оценка соответствия, EN 980 / EN15223-1<br>Оценка соответствия, EN 1041<br>Контрольный список, руководство пользователя<br>Контрольный список, этикетки устройства |



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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                     | соответствие                        |                          |                          | согласованный стандарт                                                                     | замечания, отклонения и/или риски                                                                                                                                                                                                                   |
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|          |                                                                                                                                                                                                                                                                                                                                                                                                              | да                                  | нет                      | неприменимо              |                                                                                            |                                                                                                                                                                                                                                                     |
| b)       | Насколько это практически возможно и целесообразно, информация, необходимая для безопасного использования изделия, должна быть указана на самом изделии и/или на индивидуальной упаковке изделия или, при необходимости, на торговой упаковке. Если индивидуальная упаковка не предусмотрена для каждого изделия, информация должна быть указана на листовке, приложенной к одному или несколькими изделиям. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | IEC 60601-2-22:2007<br>EN 980:2008<br>EN 15223-1:2012<br>EN 1041:2008<br>EN 60601-1-6:2010 | Оценка соответствия, IEC 60601-1-22<br>Оценка соответствия, эксплуатационная пригодность                                                                                                                                                            |
| c)       | Инструкции по применению должны быть включены в упаковку для каждого изделия. В порядке исключения, такие инструкции по применению не требуются для изделий класса I или IIa, если такие изделия можно безопасно применять без каких-либо таких инструкций.                                                                                                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 1041:2008<br>EN 60601-1-6:2010<br>EN 62366:2008                                         | Руководство пользователя<br>Оценка соответствия, EN 1041<br>Оценка соответствия, эксплуатационная пригодность<br>Контрольный список, руководство пользователя                                                                                       |
| 13.2     | Там, где уместно, эта информация приводится в виде символов. Любой символ или цветовая идентификация должны соответствовать согласованным стандартам. В областях, для которых стандарты отсутствуют, символы и цветовая идентификация должны быть описаны в документации, поставляемой с изделием.                                                                                                           | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | IEC 60601-2-22:2007<br>EN 980:2008<br>EN 15223-1:2012<br>EN 1041:2008<br>EN 60601-1:2006   | Оценка соответствия, IEC 60601-1-22<br>Оценка соответствия, EN 980 / EN15223-1<br>Оценка соответствия, EN 1041<br>Протокол испытаний согласно EN 60601-1<br>Контрольный список, этикетки устройства<br>Контрольный список, руководство пользователя |
| 13.3     | Этикетка должна содержать следующие сведения:                                                                                                                                                                                                                                                                                                                                                                |                                     |                          |                          |                                                                                            |                                                                                                                                                                                                                                                     |

CL 7351

Основные требования к оценке соответствия согласно Директиве Евросовета 93/42/ЕЕС\*

«Асклепион Лейзер  
Технологис» (Asclepion  
Laser Technologies)

Редакция №: С

Идентификационный номер: CaM/14/11/12-01

Идентификационный код/год/месяц/день-номер

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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                           | соответствие                        |                          |                                     | согласованный стандарт                                   | замечания, отклонения и/или риски                                                                                                        |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
|          |                                                                                                                                                                                                                                                                                                                    | да                                  | нет                      | неприменимо                         |                                                          |                                                                                                                                          |
| k)       | Инструкции по применению должны также включать информацию, которая бы позволила медицинскому персоналу кратко информировать пациентов о противопоказаниях и необходимых мерах. Эта информация должна охватывать, в частности, следующее: меры предосторожности в случае изменения в производительности устройства; | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1-6:2010<br>IEC 60601-2-22:2007<br>EN 1041:2008 | Контрольный список, руководство пользователя<br>Оценка соответствия, IEC 60601-1-22<br>Оценка соответствия, эксплуатационная пригодность |
| l)       | меры предосторожности, необходимые в случае воздействия (в обосновано предсказываемых условиях внешней среды) магнитных полей, внешних электрических воздействий, электростатических разрядов, давления, или колебаний давления, ускорения, тепловых источников возгорания и т.п.;                                 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | EN 60601-1:2006<br>EN 60601-1-2:2007                     | Протокол испытаний согласно EN 60601-1<br>Протокол испытаний согласно EN 60601-1-2<br>Контрольный список, руководство пользователя       |
| m)       | соответствующая информация о лекарственном средстве или средствах, которые рассматриваемое изделие должно подавать, включая любые ограничения в выборе подаваемых веществ;                                                                                                                                         | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                          | Подача веществ не предусмотрена                                                                                                          |
| n)       | меры предосторожности в отношении любых особых, необычных рисков, связанных с утилизацией изделия;                                                                                                                                                                                                                 | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                          | Необычные риски, связанные с утилизацией изделия, отсутствуют                                                                            |
| o)       | лекарственные вещества, включенные в устройство как неотъемлемая его часть в соответствии с разделом 7.4;                                                                                                                                                                                                          | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                          | Лекарственные вещества в соответствии с разделом 7.4 отсутствуют                                                                         |
| p)       | уровень точности, заявленный для изделий с измерительной функцией.                                                                                                                                                                                                                                                 | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |                                                          | Измерительные функции не предусмотрены                                                                                                   |

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| параграф  | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                                                                                                  | соответствие                        |                          |                          | согласованный стандарт | замечания, отклонения и/или риски                                                                                                       |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
|           |                                                                                                                                                                                                                                                                                                                                                                                                                           | да                                  | нет                      | неприменимо              |                        |                                                                                                                                         |
| q)<br>№   | Дата публикации или последнего изменения Руководства пользователя                                                                                                                                                                                                                                                                                                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN 1041:2008           | Оценка соответствия, EN 1041<br>Контрольный список, руководство<br>пользователя                                                         |
| N         | <b>Приложение X</b><br><b>Клиническая оценка</b>                                                                                                                                                                                                                                                                                                                                                                          |                                     |                          |                          |                        |                                                                                                                                         |
| 1.<br>1.1 | <b>Общие требования</b><br>Проверка, выполнены ли требования разделов 1,3 и 6 согласно Приложению I, должна совершаться на основании клинических данных.<br>Оценка этих данных (клиническая оценка) должны проводиться по определенной и методологически правильной процедуре, на основании документа:                                                                                                                    | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | MEDDEV 2.7.1:2009      | по области применения и параметрам<br>изделие схоже со своим предшественником<br>- устройством MedioStar NeXT<br><br>Клиническая оценка |
| 1.1.1     | Критическая оценка соответствующей научной литературы, доступной на текущий момент, по безопасности, производительности, конструктивным характеристикам и предполагаемому использованию базы данных по изделию<br>- действительно ли сходство изделия с устройством имеет место, на что указывают данные документов<br>и<br>- данные представлены надлежащим образом в соответствии с действующими основными требованиями | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | MEDDEV 2.7.1:2009      | Клиническая оценка                                                                                                                      |



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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                       | соответствие                                                                         |                                                                                      |                                                                                                                       | согласованный стандарт                                 | замечания, отклонения и/или риски                                                                                                                           |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
|          |                                                                                                                                                                                                                                | да                                                                                   | нет                                                                                  | неприменимо                                                                                                           |                                                        |                                                                                                                                                             |
| 1.1.2    | Либо критическая оценка результатов всех клинических исследований                                                                                                                                                              | <input type="checkbox"/>                                                             | <input type="checkbox"/>                                                             | <input checked="" type="checkbox"/>                                                                                   |                                                        | неприменимо                                                                                                                                                 |
| 1.1.3    | Либо критическая оценка совокупных клинических данных, представленных в пунктах 1.1.1 и 1.1.2                                                                                                                                  | <input type="checkbox"/>                                                             | <input type="checkbox"/>                                                             | <input checked="" type="checkbox"/>                                                                                   |                                                        | неприменимо                                                                                                                                                 |
| 1.1a     | Имплантируемое изделие либо изделие класса III если ДА:<br><br>• Клиническое исследование проводится либо<br>• Клиническое исследование не проводится, применение имеющихся клинических данных является достаточно оправданным | <input type="checkbox"/><br><br><input type="checkbox"/><br><input type="checkbox"/> | <input type="checkbox"/><br><br><input type="checkbox"/><br><input type="checkbox"/> | <input checked="" type="checkbox"/><br><br><input checked="" type="checkbox"/><br><input checked="" type="checkbox"/> |                                                        | неприменимо                                                                                                                                                 |
| 1.b      | Документально зафиксированы клиническая оценка и ее результаты. Документация (и/или полная ссылка на документацию) включена в техническую документацию на изделие.                                                             | <input checked="" type="checkbox"/>                                                  | <input type="checkbox"/>                                                             | <input type="checkbox"/>                                                                                              | MEDDEV 2.7.1:2009<br>EN 60601-1-6:2010<br>EN 1041:2008 | Клиническая оценка<br>Оценка соответствия, эксплуатационная пригодность<br>Оценка соответствия, EN 1041<br><br>Контрольный список, руководство пользователя |

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| параграф | требования директивы<br>краткое описание                                                                                                                                                                                                                                                                                                      | соответствие                        |                          |                          | согласованный стандарт                              | замечания, отклонения и/или риски                                                                             |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|--------------------------|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
|          |                                                                                                                                                                                                                                                                                                                                               | да                                  | нет                      | неприменимо              |                                                     |                                                                                                               |
| 1.1c     | <p>Клиническая оценка с документацией по ней будет активно поддерживаться и обновляться на основе данных после-продажного мониторинга</p> <p>Клинический после-продажный мониторинг (как часть после-продажного мониторинга) не требуется.<br/>Если ДА</p> <p>Данная необязательность мониторинга обоснована и зафиксирована в документах</p> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | EN ISO 13485:2003<br>+ AC 2009<br>MEDDEV 2.7.1:2009 | <p><i>Клиническая оценка</i></p> <p>QMH:<br/>РА 737 Изменения в проекте<br/>РА851/AA8523 Мониторинг жалоб</p> |
| 1.1d     | <b>Внимание: Данный параграф действителен только в том случае, если доказательство соответствия основным требованиям к обоснованию клинических данных считается необязательным</b>                                                                                                                                                            |                                     |                          |                          |                                                     |                                                                                                               |





|                                |                                                                                             |                                                                                 |
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| ТР 7342                        | Подтверждающие документы<br>Приложение к «CL7351 93-42-EEC MSPRO V01 CaM141112-01»          | «Асклепион Лейзер<br>Технолоджис» (Asclepion<br>Laser Technologies)             |
| Индекс изменений:<br>ПРИМЕНИМО | Идентификационный номер: CaM/14/11/12-02<br>Код участника/год/месяц/день - порядковый номер | Страница 1 из 1<br>ТР 7342 Appendix 93-42-<br>EEC MSPRO V01<br>CaM141112-02.doc |

Подтверждающие документы

| Идентификация                                        | Название документа                                                                                                                                  | Регистрация<br>(KA ALT M 003/14) |
|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Руководство пользователя                             | 159099002-V06-2.Сент.2014-GA-MSPRO-EN                                                                                                               | 2.2                              |
| Табличка устройства                                  | Typenschild MeDioStar (NeXTPRO)                                                                                                                     | 2.3                              |
| Анализ и контроль рисков                             | FB 7302 RAaC MSPRO V03 RH141110-01                                                                                                                  | 7.2.2                            |
| Отчет об управлении рисками                          | FB 7301 RMR MSPRO V02 RH141110-02                                                                                                                   | 7.2.1                            |
| Анализ просчетов в EN ISO 14971:2012                 | FB 7303 14971 Anhang ZA MSPRO V01_MMo140826-03                                                                                                      | 7.2.1                            |
| Характеристики продукции                             | IEC 60601-1 PCF MSPRO                                                                                                                               | 7.2.2                            |
| Протокол испытаний согласно EN 60601-1               | 21215627_001_ IEC60601-1 Test report                                                                                                                | 7.3                              |
| Протокол испытаний согласно EN 60601-1-2             | 1430-13-EE-14-PB001                                                                                                                                 | 7.4                              |
| Оценка соответствия, EMV                             | CL 73532 Bewertung EMV MSPRO V01_MMo140825-01                                                                                                       | 7.4                              |
| Оценка соответствия, IEC 60601-1-22                  | 21215627_001 _attn#3_ IEC60601 -2-22                                                                                                                | 7.3                              |
| Оценка соответствия, EN 60825-1                      | CL 7355 EN 60 825-1 MSPRO VS01 IS140212-02                                                                                                          | 7.8                              |
| Оценка соответствия, EN 62304                        | CL 7365 62304 MSPRO V01 RH140701-01                                                                                                                 | 7.5                              |
| Оценка соответствия,<br>эксплуатационная пригодность | FB 73513 UsabilityFile MSPRO Vs01 ZI 140429-01                                                                                                      | 7.6                              |
|                                                      | CL 73523 Usab MSPRO Vs01_ZI140703-01                                                                                                                | 7.6                              |
| Оценка соответствия, EN 1041                         | CL 7364 EN 1041 MSPRO 159x V01_MMo140704-01                                                                                                         | 7.9                              |
| Оценка соответствия, EN 980 / EN15223-1              | CL 7363 EN 980 EN 15223-1 MSPRO V01_MMo140819-04                                                                                                    | 7.9                              |
| Клиническая оценка                                   | CL73641 ClinEval MSPRO-Vs01_ZI140429-01                                                                                                             | 7.7                              |
|                                                      | FB7351e ClinEval MSPRO V01_ZI140327-01                                                                                                              | 7.7                              |
| Оценка совместимости материалов                      | FB7351e Veri Biocom MS NeXT HP V02 IH140617-01<br>FB7351e Veri Biocom MS PRO HP V01 IH140710-01<br>FB 7336 Bewertung MatVer Gerät_V01 AWi_141010-01 | 7.13                             |
| Оценка соответствия, EN ISO 10993-1                  | CL7372 EN ISO 10993 MSPRO HP IH141111-04                                                                                                            | 7.13                             |
| Контрольный список, руководство пользователя         | CL7356 GA MSPRO V02_ZI141027-01                                                                                                                     | 7.9                              |
| Контрольный список, этикетки устройства              | CL7357 Gerateschilder MSPRO V04_AWi141110-02                                                                                                        | 7.9                              |
| Классификация устройства                             | FB 7320 Klassifizierung MPG_MDR MSPRO V01_MMo140207-01                                                                                              | 3.2.1                            |
| Проверка устройства                                  | FB 7351 Veri Gesamtgerät MSPRO V02 AWi141110-01                                                                                                     | 7.9                              |
| Проверка аппликатора                                 | FB7351e Veri MSPRO HP V01 IH141111-03                                                                                                               | 7.12                             |

Составлено:

| Вер. | Описание изменения | Дата     | Имя, фамилия | Подпись   |
|------|--------------------|----------|--------------|-----------|
| 01   | Первая редакция    | 12.11.14 | С. Кулинг    | /Подпись/ |

|                     |                                                                                   |                                                                           |
|---------------------|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технолоджис»<br>(Asclepion Laser<br>Technologies) |
| Индекс изменений: К | Идентификационный номер: ММо/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 1 из 10<br>CL7321 RNmed MSPRO<br>V02 ММо 140821-01.doc           |

| Для:                                |                               | Файлы: |                                     |          |           |                |
|-------------------------------------|-------------------------------|--------|-------------------------------------|----------|-----------|----------------|
| Опытно-конструкторский проект:      | MeDioStar WE                  | Вер.   | Краткое описание изменения          | Дата     | ФИО       | Подпись        |
| Номер проекта:                      | 4800 93A 73400                | 01     | Первое издание                      | 07.02.14 | И. Штрайт | Подпись Мёллер |
| Название продукта (если присвоено): | MeDioStar NeXT <sup>Pro</sup> | 02     | Контроль используемых директив/норм | 21.08.14 | М. Мёллер | /Подпись/      |
| Артикульный номер (если присвоен):  | 1591, 1592                    |        |                                     |          |           |                |

Примечание: Этот список содержит основные нормы и в случае потребности в соответствующих специфических для прибора нормах должен быть расширен.

Нормы с пометкой «Н» унифицированы согласно директиве 93/42/EWG

Пометка «V» обозначает – обязательная директива Европейской Комиссии

| Проверка и одобрение: | Область                                   | Дата       | Имя, фамилия | Подпись   |
|-----------------------|-------------------------------------------|------------|--------------|-----------|
| Проверено             | Система обеспечения качества, Отдел НИОКР | 13.11.2014 | С. Кюлинг    | /Подпись/ |
| Одобрено              | Отдел контроля качества                   | 13.11.2014 | Тиме         | /Подпись/ |

|                                                                                                                                                                          |           |                 |                                                              |         |                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------------|--------------------------------------------------------------|---------|------------------|
| Причина последнего изменения технического отчета: Дополнение №№.2, 3, 4, 16,32, 42, 43; № обновленного издания 13Н, 19, 22; технический отчет для 22, 25Н и 28Н добавлен |           |                 |                                                              |         |                  |
| Технический отчет (CL) создан собственником процесса (отдел НИОКР):                                                                                                      |           |                 | Технический отчет проверен и одобрен менеджером по качеству: |         |                  |
| 27.01.2014                                                                                                                                                               | С. Мюллер | Подписал Мюллер | 29.01.14                                                     | Р. Тиме | Подписал Р. Тиме |
| Дата                                                                                                                                                                     | ФИО       | Подпись         | Дата                                                         | ФИО     | Подпись          |

|                     |                                                                                   |                                                                           |
|---------------------|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технолоджис»<br>(Asclepion Laser<br>Technologies) |
| Индекс изменений: К | Идентификационный номер: ММо/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 2 из 10<br>CL7321 RNmed MSPRO<br>V02 ММо 140821-01.doc           |

| №    | нужное                              | Директива/ Норма/ Правила                                                                                                                                                                                                                                               | Сопутствующий<br>технический<br>отчет | Имеется                                                         |
|------|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-----------------------------------------------------------------|
| 1. Н | <input checked="" type="checkbox"/> | <b>93/42/EWG</b><br><i>Директива 93/42/ЕС от 14 июня 1993 г. по медицинским изделиям</i><br><i>Официальный журнал европейского сообщества</i>                                                                                                                           | CL 7351                               | <input checked="" type="checkbox"/>                             |
| 2.   | <input checked="" type="checkbox"/> | <b>2011/65/EU (RoHS)</b><br><i>Директива 2011/65/ЕС от 8 июня 2011 года об ограничении использования некоторых опасных веществ в электрическом и электронном оборудовании</i>                                                                                           | CL 7373                               | <input checked="" type="checkbox"/>                             |
| 3.   | <input checked="" type="checkbox"/> | <b>2012/19/EU (WEEE)</b><br><i>Директива 2012/19/ЕС от 4 июля 2012 года об отходах от электрического и электронного оборудования</i>                                                                                                                                    |                                       |                                                                 |
| 4.   | <input type="checkbox"/>            | <b>89/686/EWG + M1 + M2 + M3 + M4</b><br><i>Директива Совета ЕС от 21 декабря 1989 года о сближении законов государств-членов, касающихся индивидуальных средств защиты</i>                                                                                             |                                       |                                                                 |
| 5.   | <input type="checkbox"/>            | <b>2006/42/EG</b><br><i>Директива 2006/42/ЕС Европейского парламента и Совета Европы от 17 мая 2006 года по машинам и оборудованию, отменяющая Директиву 95/16/ЕС.</i>                                                                                                  |                                       |                                                                 |
| 6.   | <input checked="" type="checkbox"/> | <b>Нормативные документы для медицинских приборов (SOR/98-282)</b><br><i>(Закон о пищевых продуктах и медикаментах) Канада</i><br><b>Свод федеральных нормативных актов; Регламент системы контроля качества 21 CFR, часть 820</b><br><i>(Продукты и лекарства) США</i> | CL 7350                               | <input type="checkbox"/><br><input checked="" type="checkbox"/> |



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| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технолоджис»<br>(Asclepion Laser<br>Technologies) |
| Индекс изменений: К | Идентификационный номер: ММо/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 3 из 10<br>CL7321 RNmed MSPRO<br>V02 ММо 140821-01.doc           |

| №     | нужное                              | Директива/ Норма/ Правила                                                                                                                                                                                                                                                               | Сопутствующий<br>технический<br>отчет                                                                                                                                             | Имеется                                                                                    |
|-------|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| 7.    | <input type="checkbox"/>            | <b>EN 60601-1: 1990 + A1:1993 + A2:1995</b><br><i>Медицинское электрическое оборудование - Часть 1: Общие требования к безопасности.</i><br><i>(Не для создания заново, только для изменения/ дополнения)</i>                                                                           | CL 7352                                                                                                                                                                           | <input type="checkbox"/>                                                                   |
| 8. Н  | <input checked="" type="checkbox"/> | <b>EN 60601-1: 2006</b><br><i>Медицинское электрическое оборудование - Часть 1: Общие требования к безопасности.</i>                                                                                                                                                                    | CL 73525<br>Или технические<br>правила по газу и<br>жидкостям<br>внешнего<br>проверяющего<br>органа<br><br>CL 73524<br>или отчет о<br>проверке внешнего<br>проверяющего<br>органа | <input checked="" type="checkbox"/><br><br><br><br><br><input checked="" type="checkbox"/> |
| 9. Н  | <input checked="" type="checkbox"/> | <b>EN 60 601-1-2: 2007</b><br><i>Медицинское электрическое оборудование - Часть 1-2: Общие требования к безопасности и основным эксплуатационным характеристикам - Вспомогательный стандарт: Электромагнитная совместимость - Требования и испытания.</i>                               | CL 73532                                                                                                                                                                          | <input checked="" type="checkbox"/>                                                        |
| 10.   | <input type="checkbox"/>            | <b>EN 60601-1-4: 1996 + A1: 1999</b><br><i>Медицинское электрическое оборудование - Часть 1-4: Общие требования к безопасности - Вспомогательный стандарт: Программируемые электрические медицинские системы</i><br><i>(Применяется в связи с EN 60601-1: 1990 + A1:1993 + A2:1995)</i> | CL 7361                                                                                                                                                                           | <input type="checkbox"/>                                                                   |
| 11. Н | <input checked="" type="checkbox"/> | <b>EN 62304: 2006 / AC:2008</b><br><i>Программное обеспечение медицинского устройства - процессы жизненного цикла программного обеспечения</i>                                                                                                                                          | CL 7365                                                                                                                                                                           | <input checked="" type="checkbox"/>                                                        |

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| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технолджис»<br>(Asclepion Laser<br>Technologies) |
| Индекс изменений: К | Идентификационный номер: ММо/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 4 из 10<br>CL7321 RNmed MSPRO<br>V02 ММо 140821-01.doc          |

| №     | нужное                              | Директива/ Норма/ Правила                                                                                                                                                                                                                                                                                            | Сопутствующий<br>технический<br>отчет                                 | Имеется                             |
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| 12.   | <input type="checkbox"/>            | <b>EN 60601-1-6: 2007</b><br><i>Медицинское электрическое оборудование - Часть 1-6: Общие требования к безопасности - Вспомогательный стандарт: Эксплуатационная пригодность. (Применяется в связи с EN 60601-1: 1990 + A1:1993 + A2:1995)</i>                                                                       |                                                                       |                                     |
| 13. Н | <input checked="" type="checkbox"/> | <b>EN 60601-1-6: 2010</b><br><i>Медицинское электрическое оборудование - Часть 1-6: Общие требования к безопасности - Вспомогательный стандарт: Эксплуатационная пригодность. (Применяется в связи с EN 60601-1: 2006)</i>                                                                                           | CL 73523                                                              | <input checked="" type="checkbox"/> |
| 14. Н | <input checked="" type="checkbox"/> | <b>EN 62 366: 2008</b><br><i>Медицинские приборы - применение проектирования эксплуатационной пригодности для медицинских приборов.</i>                                                                                                                                                                              | CL 73523                                                              | <input checked="" type="checkbox"/> |
| 15. Н | <input type="checkbox"/>            | <b>EN 60 601-2-22: 1996- с исправлением 1:1997 + приложение 1</b><br><i>Медицинское электрическое оборудование - Часть 2: Частные требования к безопасности диагностического и терапевтического лазерного оборудования.</i>                                                                                          | CL 7354                                                               | <input type="checkbox"/>            |
| 16.   | <input checked="" type="checkbox"/> | <b>IEC 60 601-2-22: 2007</b><br><i>Медицинское электрическое оборудование - Часть 2-22: Специальные требования к безопасности и основным эксплуатационным характеристикам лазерного хирургического, терапевтического и диагностического оборудования<br/>(Применять только в связи с IEC 60601-1: 2005)</i>          | CL 7354<br>или отчет о<br>проверке внешнего<br>проверяющего<br>органа | <input checked="" type="checkbox"/> |
| 17.   | <input checked="" type="checkbox"/> | <b>EN 60 825-1: 2007 + Поправка 1: 2008 + Поправка 2: 2009</b><br><i>Безопасность лазерной продукции; часть 1: Классификация оборудования и требования</i>                                                                                                                                                           | CL 7355                                                               | <input checked="" type="checkbox"/> |
| 18.   | <input type="checkbox"/>            | <b>EN 60601-2-57:2011</b><br><i>Медицинское электрическое оборудование - Часть 2-57: Специальные требования к общей безопасности и основным эксплуатационным характеристикам оборудования с не лазерным источником света, предназначенного для терапевтического воздействия, диагностики и контроля, а также для</i> |                                                                       |                                     |

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| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технолоджис»<br>(Asclepion Laser<br>Technologies) |
| Индекс изменений: К | Идентификационный номер: ММо/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 5 из 10<br>CL7321 RNmed MSPRO<br>V02 ММо 140821-01.doc           |

| № | нужное | Директива/ Норма/ Правила                     | Сопутствующий<br>технический<br>отчет | Имеется |
|---|--------|-----------------------------------------------|---------------------------------------|---------|
|   |        | косметического и эстетического использования. |                                       |         |



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| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технолоджис»<br>(Asclepion Laser Technologies) |
| Индекс изменений: К | Идентификационный номер: ММо/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 6 из 10<br>CL7321 RNmed MSPRO<br>V02 ММо 140821-01.doc        |

| №     | нужное                              | Директива/ Норма/ Правила                                                                                                                                                                                                    | Сопутствующий технический отчет | Имеется                               |
|-------|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------------------------|
| 19.   | <input checked="" type="checkbox"/> | <b>MEDDEV 271 2.7.1 ред.3 Клиническая оценка</b><br>Рекомендации по медицинским приборам - оценка клинических данных (ориентир для изготовителей и органов технической экспертизы)                                           | CL 73641                        | <input checked="" type="checkbox"/>   |
| 20. Н | <input type="checkbox"/>            | <b>EN ISO 14155: 2011 + AC:2011</b><br><i>Клинические испытания медицинских приборов для человека.</i>                                                                                                                       |                                 |                                       |
| 21. Н | <input checked="" type="checkbox"/> | <b>EN 1041: 2008</b><br><i>Информация, представляемая заводом-изготовителем медицинских инструментов</i>                                                                                                                     | CL 7364                         | <input checked="" type="checkbox"/>   |
| 22.   | <input checked="" type="checkbox"/> | <b>EN ISO 15223-1: 2012</b><br><i>Медицинские приборы--символы для использования на этикетках медицинских приборов, маркировка и обязательная информация - часть 1: Общие требования</i>                                     | CL 7363                         | <input checked="" type="checkbox"/>   |
| 23. Н | <input checked="" type="checkbox"/> | <b>EN ISO 10993-1:2009 / AC:2010</b><br><i>Биологическая оценка медицинских приборов - часть 1: Оценка и испытания.</i>                                                                                                      | CL 7372                         | <input checked="" type="checkbox"/> * |
| 24. Н | <input type="checkbox"/>            | <b>EN ISO 14937: 2009</b><br><i>Стерилизация медицинских изделий - общие требования к характеристикам стерилизующего вещества и разработка, подтверждение и текущий контроль процесса стерилизации медицинских устройств</i> |                                 |                                       |
| 25. Н | <input type="checkbox"/>            | <b>EN ISO 17664: 2004</b><br><i>Стерилизация медицинских приборов - Информация, предоставляемая изготовителем для обработки повторно стерилизуемых медицинских приборов.</i>                                                 | CL 7376                         | <input type="checkbox"/>              |
| 26. Н | <input type="checkbox"/>            | <b>EN 556-1: 2001 +AC:2006</b><br><i>Стерилизация медицинских приборов - требования к медицинским приборам, обозначенным как «стерильные» - часть 1: Требования к медицинским приборам с финишной стерилизацией.</i>         |                                 |                                       |

\* имеется верификация

|                     |                                                                                   |                                                                           |
|---------------------|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технолоджис»<br>(Asclepion Laser<br>Technologies) |
| Индекс изменений: К | Идентификационный номер: ММо/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 7 из 10<br>CL7321 RNmed MSPRO<br>V02 ММо 140821-01.doc           |

| №     | нужное                              | Директива/ Норма/ Правила                                                                                                                                                                               | Сопутствующий<br>технический<br>отчет | Имеется                  |
|-------|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------|
| 27. Н | <input type="checkbox"/>            | <b>EN ISO 11135-1:2007</b><br><i>Стерилизация медицинских изделий - Окись этилена - Часть 1: Требования к разработке, подтверждению и текущему контролю процессов стерилизации медицинских приборов</i> | CL 7522                               | <input type="checkbox"/> |
| 28. Н | <input type="checkbox"/>            | <b>EN ISO 17665-1: 2006</b><br><i>Стерилизация медицинских изделий -влажный жар</i>                                                                                                                     | CL 7377                               | <input type="checkbox"/> |
| 29. Н | <input type="checkbox"/>            | <b>EN ISO 11607-1 : 2009</b><br><i>Упаковка для медицинских инструментов с финишной стерилизацией - Часть 1: Требования к материалам, системам защиты стерильности и упаковочным системам</i>           | CL 7521                               | <input type="checkbox"/> |
|       |                                     | <b>EN ISO 11607-2 : 2006</b><br><i>Упаковка для медицинских инструментов с финишной стерилизацией - Часть 2: Требования к подтверждению процессов формирования, герметизации и сборки</i>               |                                       |                          |
| 30. Н | <input checked="" type="checkbox"/> | <b>EN ISO 13485: 2012 + AC2012</b><br><i>Системы контроля качества - медицинские приборы - требования для целей регулирования.</i>                                                                      |                                       |                          |

|                     |                                                                                   |                                                                           |
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| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технолоджис»<br>(Asclepion Laser<br>Technologies) |
| Индекс изменений: К | Идентификационный номер: ММо/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 8 из 10<br>CL7321 RNmed MSPRO<br>V02 ММо 140821-01.doc           |

| №     | нужное                              | Директива/ Норма/ Правила                                                                                                                                                                                 | Сопутствующий<br>технический<br>отчет | Имеется                             |
|-------|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-------------------------------------|
| 31. Н | <input type="checkbox"/>            | <b>EN ISO 14971: 2012</b><br><i>Медицинские приборы - применение управления рисками для медицинских приборов.</i>                                                                                         |                                       |                                     |
| 32.   | <input checked="" type="checkbox"/> | <b>EN 50581:2012</b><br><i>Техническая документация для оценки электрических и электронных изделий по ограничению опасных веществ</i>                                                                     | CL 7375                               | <input checked="" type="checkbox"/> |
| 33.   | <input checked="" type="checkbox"/> | <b>DIN EN 60 529: 1991/A1:2000</b><br><i>Степень защиты корпуса (код IP).</i>                                                                                                                             |                                       |                                     |
| 34.   | <input type="checkbox"/>            | <b>DIN EN ISO 14644-1:1999 - 07</b><br><i>Чистые комнаты и соответствующие контролируемые среды--часть 1: Классификация чистоты воздуха</i>                                                               |                                       |                                     |
| 35.   | <input type="checkbox"/>            | <b>DIN EN ISO 14644-2: 2001 - 02</b><br><i>Чистые комнаты и соответствующие контролируемые среды--часть 2: Спецификации для контроля и периодических испытаний, подтверждающих соблюдение ИСО 14644-1</i> |                                       |                                     |
| 36.   | <input checked="" type="checkbox"/> | <b>DIN EN 60721-3-2 : 1998 - 03</b><br><i>Классификация условий окружающей среды - часть 3: Классификация групп параметров окружающей среды и их важности - раздел 2: Транспортировка</i>                 |                                       |                                     |
| 37.   | <input type="checkbox"/>            | <b>CAN/CSA C22.2 № 601.1</b> (Отклонения по государственным стандартам Канады)<br>Медицинское электрическое оборудование, часть 1<br><i>Общие требования к безопасности</i>                               |                                       |                                     |



|                     |                                                                                   |                                                                          |
|---------------------|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технологис»<br>(Asclepion Laser<br>Technologies) |
| Индекс изменений: К | Идентификационный номер: ММо/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 9 из 10<br>CL7321 RNmed MSPRO<br>V02 ММо 140821-01.doc          |

| №     | нужное                              | Директива/ Норма/ Правила                                                                                                                                                                                           | Сопутствующий<br>технический<br>отчет | Имеется                             |
|-------|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-------------------------------------|
| 38.   | <input type="checkbox"/>            | UL 60601-1 (Отклонения по государственным стандартам США)<br>Медицинское электрическое оборудование, часть 1<br><i>Общие требования к безопасности</i>                                                              |                                       |                                     |
| 39.   | <input checked="" type="checkbox"/> | 21 CFR 1040 (04-1-02 редакция) / Уведомление 50, Управление по контролю за продуктами и лекарствами<br><i>Свод федеральных нормативных актов - Продукты и лекарства 21.</i>                                         |                                       |                                     |
| 40.   | <input type="checkbox"/>            | CAN/CSA-ISO 13485:2003<br>Системы управления качеством - требования для целей регулирования Канадской системы оценки качества медицинских приборов<br><i>Канадская система оценки качества медицинских приборов</i> |                                       |                                     |
| 41.   | <input type="checkbox"/>            | ISO 14971: 2007<br><i>Медицинские приборы - применение управления рисками для медицинских приборов</i><br><i>Медицинские приборы - применение управления рисками для медицинских приборов.</i>                      |                                       |                                     |
| 42.   | <input type="checkbox"/>            | EN 207:2009 + AC:2011<br>Индивидуальные средства защиты глаз - фильтры и защитные очки от лазерного излучения                                                                                                       |                                       |                                     |
| 43.   | <input type="checkbox"/>            | DIN 58298:2010<br><i>Медицинские инструменты - материалы, отделка и испытания</i>                                                                                                                                   |                                       |                                     |
| 44.   | <input checked="" type="checkbox"/> | DIN EN 50 419: 2006-06<br><i>Маркировка электрического и электронного оборудования.</i>                                                                                                                             |                                       |                                     |
| 45. Н | <input checked="" type="checkbox"/> | EN 980:2008<br><i>Символы для использования в маркировке медицинских инструментов</i>                                                                                                                               | CL 7363                               | <input checked="" type="checkbox"/> |
| 46.   | <input checked="" type="checkbox"/> | EN ISO 14971: 2009-10<br><i>Медицинские приборы - применение управления рисками для медицинских приборов.</i>                                                                                                       |                                       |                                     |

|                     |                                                                                   |                                                                           |
|---------------------|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| CL 7321             | Список используемых директив и унифицированных сопутствующих норм (MED)           | «Асклепион<br>Лейзер<br>Технолоджис»<br>(Asclepion Laser<br>Technologies) |
| Индекс изменений: К | Идентификационный номер: ММo/14/08/21-01<br>Сокращение / Год / Месяц / День-№ МФД | Страница 10 из 10<br>CL7321 RNmed MSPRO<br>V02 ММo 140821-01.doc          |

#### Приложение 1 «Применение неунифицированных норм»

| №  | Применяемые неунифицированные нормы                                                                                                                               | Обоснование                                                                                                                                                                                                                               |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16 | IEC 60 601-2-22: 2007                                                                                                                                             | Эта норма была применена в связи с IEC 60601 -1: 2005. Согласно введению к EN 60601-1 текст является идентичным с IEC 60601-1.                                                                                                            |
| 17 | EN 60 825-1: 2007 + Поправка 1: 2008 + Поправка 2: 2009                                                                                                           | EN 60 601-1 указывает на эти нормы и поэтому применяется                                                                                                                                                                                  |
| 22 | EN ISO 15223-1: 2012                                                                                                                                              | EN 60 601-1 указывает на эти нормы и поэтому применяется                                                                                                                                                                                  |
| 33 | DIN EN 60 529: 1991/A1:2000                                                                                                                                       | EN 60 601-1 указывает на эти нормы и поэтому применяется                                                                                                                                                                                  |
| 36 | DIN EN 60721-3-2 : 1998-03                                                                                                                                        | Эта норма была использована как вспомогательная для определения условий транспортировки, так как нет сравнимой унифицированной нормы.                                                                                                     |
| 39 | 21 CFR 1040 (04-1-02 редакция) / Уведомление 50, Управление по контролю за продуктами и лекарствами Свод федеральных нормативных актов - Продукты и лекарства 21. | Для получения допусков в США                                                                                                                                                                                                              |
| 42 | EN 207:2009 + AC:2011                                                                                                                                             | Эта норма была использована, чтобы определить степень защиты лазерных очков. Она была использована, так как нет сравнимой унифицированной нормы.                                                                                          |
| 44 | DIN EN 50 419: 2006-06                                                                                                                                            | Норма была использована для корректной маркировки электрических и электронных приборов, так как нет сравнимой унифицированной нормы.                                                                                                      |
| 46 | EN ISO 14971: 2009-10                                                                                                                                             | Унифицированная на данный момент EN ISO14971:2012 соответствует нормативно EN ISO 14971: 2009 и поэтому еще применяется. Изменения по сравнению с EN ISO14971:2012 (приложение ZA) были оценены с помощью метода стратегического анализа. |

|               |                                                                                            |                                                                              |
|---------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / валидации                                                              | «Асклепион<br>Лейзер<br>Текнолоджис»<br>(Asclepion<br>Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/03/27-01<br>Код участника/год/месяц/день - порядковый номер | Стр. 1 из 14<br>FB 7351e ClinEval<br>MSPRO V01_ZI140327-01.doc               |

|                    |                                                                                              |                                                       |                                                 |
|--------------------|----------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------------------------|
| Проверка           | <input type="checkbox"/>                                                                     | Подтверждение                                         | <input checked="" type="checkbox"/> Клиническое |
| Изделие / деталь:  | MeDioStar                                                                                    | Код материала:                                        | 1591, 1592                                      |
| Основание:         | <input type="checkbox"/> Разработка изделия                                                  | <input checked="" type="checkbox"/> Изменение изделия | <input type="checkbox"/>                        |
| Исходный документ: | <input checked="" type="checkbox"/> Техническое задание: FB 7321<br>LH MSPRO V01 ZI140127-01 | <input type="checkbox"/> Проектное задание:           | <input type="checkbox"/>                        |
| Серийный номер:    | <input checked="" type="checkbox"/> Анализ рисков:                                           | <input type="checkbox"/> Заявка на изменение №:       | <input type="checkbox"/>                        |
|                    | неприменимо                                                                                  |                                                       |                                                 |

**КРАТКОЕ ОПИСАНИЕ: Анализ литературы**  
Эта клиническая оценка новой, модернизированной версии MeDioStar основана на текущем утвержденном медицинском приборе MeDioStar (№ 1590) с идентичным предполагаемым использованием. Разница и преимущества для пользователя будет только в новом аппликаторе с большими по размеру лазерными пятнами, чтобы сократить время процедур. Этот новый аппликатор будет добавляться в дополнение (по выбору) к существующим аппликаторам.  
Во всех аспектах, включая процедуры лечения, изменений нет и поэтому он идентичен текущему устройству.  
Устройства семейства MeDioStar, которое продается больше 15 лет, никогда не вызывали никаких проблем кроме побочных эффектов, указанных в руководстве, и процедуры лечения с помощью устройства очень эффективны.

**Выбранное измерительное и испытательное оборудование, неприменимо**

**Документы в приложении: (Протоколы испытаний и т. д.)**  
Приложение A: TP7342 LiteratureMS V01\_ZI140328-01.pdf  
Приложение B: TP 7342 EvalReports BfArM+FDA 2014

**Окончательная оценка результатов: (краткая оценка, итоговые показатели)**  
В ходе этой оценки было продемонстрировано, что процедуры обработки с помощью MS являются эффективными и безопасными. Процентная доля случаев с побочными эффектами очень низкая и, в основном, такие случаи носят временный характер. Что позволяет прийти к выводам о том, что преимущества для пациентов превышают риски. Новая версия MS по своему применению продемонстрирована как эквивалентная текущему устройству.

☐ Проверка / подтверждение с отрицательным результатом

☐ Проверка / подтверждение с положительным результатом

Если результат отрицательный, то какие приняты меры:

№, неприменимо

|      |              |         |
|------|--------------|---------|
| Дата | Имя, фамилия | Подпись |
|------|--------------|---------|

|                    |              |           |
|--------------------|--------------|-----------|
| 22 октября 2014 г. | Г. Циммерман | /Подпись/ |
| Дата               | Имя, фамилия | Подпись   |

**План проверил и выпустил: неприменимо**

**Проверку/валидацию провел и выпустил:**

|      |              |         |
|------|--------------|---------|
| Дата | Имя, фамилия | Подпись |
|------|--------------|---------|

|                    |              |           |
|--------------------|--------------|-----------|
| 28 октября 2014 г. | А. Катцер    | /Подпись/ |
| Дата               | Имя, фамилия | Подпись   |

|                                                                          |              |                 |                                                    |              |         |
|--------------------------------------------------------------------------|--------------|-----------------|----------------------------------------------------|--------------|---------|
| Причина последней модификации FB: обзор                                  |              |                 | FB проверены и выпущены Отделом контроля качества: |              |         |
| FB сделанные владельцем процесса Отделом научно-исследовательских работ: |              |                 | 06.07.2012 Р. Тиме подписал Тиме                   |              |         |
| 05.07.2012                                                               | И. Штрайт    | подписал Штрайт | Дата                                               | Имя, фамилия | Подпись |
| Дата                                                                     | Имя, фамилия | Подпись         |                                                    |              |         |



|               |                                                                                            |                                                                             |
|---------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / валидации                                                              | «Асклепион<br>Лейзер<br>Технологис»<br>(Asclepion<br>Laser<br>Technologies) |
| Редакция №: В | Идентификационный номер: ZI/14/03/27-01<br>Код участника/год/месяц/день - порядковый номер | Стр. 2 из 14<br>FB 7351e ClinEval<br>MSPRO V01_ZI140327-01.doc              |

#### История:

| Ред. | Краткое описание изменений | Дата     | Имя, фамилия | Подпись   |
|------|----------------------------|----------|--------------|-----------|
| 01   | Первая редакция            | 22.10.14 | Циммерман    | /Подпись/ |
|      |                            |          |              |           |
|      |                            |          |              |           |
|      |                            |          |              |           |

#### Связанные документы:

| испытания                                                                                                                                                                                                                             | сокращение                 | название файла                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-------------------------------------------------------------------------------|
| Техническое задание новой версии MS*                                                                                                                                                                                                  | T3                         | FB 7321 LH MSPRO V01 ZI140127-01                                              |
| Протокол отчета о поиске, Федеральный институт по лекарственным препаратам и медицинской продукции Германии и Управление по контролю за продуктами и лекарствами (в КА 7.6; Приложение 3, подтверждение эксплуатационной пригодности) | Приложение 3               | TP 7342 Usab-App3-BfArM+FDA Vs1-ZI130827-1                                    |
| Клиническая оценка MeDioStar SE (торговые наименования: MeDioStar NeXT, The EpiLab, Pronto)                                                                                                                                           | Клиническая оценка 2011 г. | FB 7351e ClinEval MS-SE ZI-2011 -10-05-01 **                                  |
| Клиническая оценка аппликатора ALX (дополнение к CEval 2011)                                                                                                                                                                          | Клиническая оценка 2014 г. | FB 7351 e ClinEval ALX HP V01_ZI140113-01**                                   |
| Проект руководства пользователя для новой версии MS*                                                                                                                                                                                  | Руководство пользователя   | 159099001 -V06-2.Sept2014-GA-MSPRO-DE<br>159099002-V06-2.Sept2014-GA-MSPRO-EN |

\*MS = MeDioStar

\*\*CEval 2011 и 2014 прикреплены в конце pdf версии этого документа (приложения в КА MSPRO ALT-M003\_14/ 7.7/ Anhänge ClinEval 2011+2014)

#### Клиническая оценка MeDioStar

##### Содержание

- 1 Квалификация автора и рецензента
- 2 Основание для анализа литературы
- 3 Анализ литературы
  - 3.1 Просьба исследований с MeDioStar
  - 3.2 Оценка исследований в отношении эффективности
  - 3.3 Оценка исследований в отношении побочных эффектов
  - 3.4 Оценка отчетов Федерального института по лекарственным препаратам и медицинской продукции Германии и Управления по контролю за продуктами и лекарствами
- 4 Окончательная оценка результатов
  - 4.1 Показания к применению устройства
  - 4.2 Противопоказания
  - 4.3 Заключение
  - 4.4 Заключение

Прилагается в pdf-файле этого документа:

Приложение A: TP7342 LiteratureMS V01\_ZI140328-01.pdf

Приложение B: TP 7342 EvalReports BfArM+FDA 2014

Клиническая оценка 2011 и 2014 гг.

Литература Приложения A: указана в КА MSPRO ALT-M003\_14/ 7.7/AnhangClinEval ZI140327-01

|               |                                                                                            |                                                                              |
|---------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| FB 7351e      | Отчет по проверке / валидации                                                              | «Асклепион<br>Лейзер<br>Технолоджис»<br>(Asclepion<br>Laser<br>Technologies) |
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## 1. Квалификация автора и рецензента

Предполагаемое использование этой новой версии MS идентично предполагаемому использованию разрешенного предшествующего устройства (CE 1275; см. также следующую главу). Поэтому вполне возможно, чтобы такая оценка проводилась и анализировалась главными конструкторами «Асклепион» (Asclepion) с многолетним опытом применения лазерного оборудования.

Автор настоящей оценки. Госпожа Г. Циммерманн является главным конструктором и ответственной за медицинское обоснование и применение на фирме «Асклепион Лейзер Технолоджис ГмбХ» (Asclepion Laser Technologies), обладая большим опытом в проведении клинической оценки.

Госпожа Г. Циммерманн имеет диплом физика и более 25 лет опыта в области применения медицинских лазеров, в частности хирургических лазеров в области дерматологии и эстетической медицины, включая лазерную установку MS.

После выпуска из университета госпожа Г. Циммерманн более 10 лет занималась разработкой лазерной техники в качестве инженера-исследователя. Начиная с 1988 года она отвечает за медицинское применение различных лазеров, включая MS, и работает вместе с врачами в различных областях научных исследований. Также она уже 20 лет ведет курсы для врачей по лазерной безопасности, включая медицинское применение, а также занималась подготовкой врачей и сотрудников отдела сбыта по вопросам эксплуатации медицинских лазеров.

На фирме госпожа Г. Циммерманн вела руководство фирменными прикладными исследованиями и анализ научной литературы. Работая в качестве главного конструктора в течении более 20 лет, она также отвечала за определение параметров применения новых лазеров, а также за поддержку разработок в области эргономики, подготовку практической части руководств по эксплуатации и обслуживанию, оценку новых устройств в отношении медицинского применения и эргономики.

Рецензент данной оценки. Госпожа дипломированный физик Антье Катцер — дипломированный специалист по физике с академическим сертификатом. Она имеет многолетний опыт применения медицинского оборудования, особенно дерматологических и лазерных устройств.

В 1986 году она закончила изучение физики по специальности лазерной физики, получив диплом по физике.

Затем она работала в научно-технической области, собирая практический опыт по разработке и проектированию лазерных инструментов.

С 1996 года госпожа Катцер занимает должность руководителя производства медицинских лазерных приборов, особенно оборудования для дерматологии.

Ее обязанности включают тесное сотрудничество с врачами (применение устройств), что позволило ей накапливать медицинский и практический опыт, необходимый для этого вида работ.

В центре внимания ее работ были и продолжают быть клинические исследования по применению и участие в подготовке публикаций и оценки научной литературы.

## 2. Основание для анализа литературы

Модернизированная версия MS разработана с целью сократить время процедур (особенно для больших участков тела, таких как спина и бёдра) для заказчиков и пациентов.

Что достигается с помощью больших по размеру лазерных пятен, когда один лазерный импульс одновременно охватывает большую площадь кожи. Для больших по размерам лазерных пятен с параметрами предполагаемой обработки необходима большая мощность полупроводникового лазера. В настоящее время большая мощность лазера по разумной цене стала доступной.

В то же время остались без изменений и полный набор функций и предполагаемое использование текущей версии MS (включая все аппликаторы).

Почти 1000 устройств разных версий MS были проданы, начиная с 2011 года и свыше 2500 устройств всех версий семейства MS были проданы, начиная с 1999 года.

Такой успех нашей компании стал возможным только потому, что процедуры обработки с MS, с одной стороны, очень эффективны, а другой стороны, обладают очень небольшими побочными эффектами для всех типов кожи, и просты, удобны и безопасны для терапевта. За 15 лет не было зафиксировано каких-либо жалоб и побочных эффектов, кроме обычных для предполагаемого использования (и указанных в руководстве пользователя), несмотря на большое количество проданных лазеров.

И, конечно, нужно сказать, что устройство очень надежно. Некоторые пользователи из Италии и Турции в прошлом году уже перешли рубеж в 10 миллионов импульсов с одним аппликатором, а у одного из заказчиков эта цифра превысила 15 миллионов. При применении полупроводниковых лазеров для эпиляции от других изготовителей, заказчикам приходится заменять аппликаторы после 1 или 2 миллионов импульсов.

Таким образом, основное требование в техническом задании для этого устройства состояло в том, чтобы изменения текущего устройства были, по возможности, незначительными:

### - Предполагаемое использование идентично текущей версии MS

См. также главу 1 технического задания (подробности технических условий к применению) и главы 4.1 (показания к применению) и 4.2 (противопоказания) данного документа.

- POF, включая меры безопасности, идентичны существующим в текущей версии MS, как требуется в ТЗ (см. техническое задание, глава 3.1).

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- Основное устройство осталось без изменений. Все аппликаторы, которые доступны сегодня, остались без изменений.
- Единственная разница для заказчика только в новом (по выбору), более крупном аппликаторе, сокращающем время процедур.

Поэтому эта клиническая оценка может основываться на исследованиях и опыте применения предыдущих версий устройства MS. Клиническая оценка 2011 и 2014 гг. текущего MS остаются в силе.

3. Анализ литературы

3.1. Проект исследований с MeDioStar

Для этой оценки все клинические исследования с MS, опубликованные и неопубликованные, перечислены в Приложении А. Начиная с первого MS в 1999 году и до настоящего момента были одобрены 22 исследования. Так как все исследования выполнялись с MS, нет необходимости в сравнении с другими устройствами, рассмотренными в исследованиях. Сборнике исследований (Приложение А) указаны авторы исследований, названия и источники, а также планы исследований, включая цели исследований, число пациентов, используемые параметры, оценки, результаты и безопасность. Исследования перечислены по времени проведения, у последних по времени исследований будет наибольший номер.

- (А) Среди 22 перечисленных исследований, 18 являются перспективными исследованиями, а 4 - отчетами о применении. Вся литература далее именуется как «исследование». Отчеты о применении включены в эту оценку для полноты обзора опубликованной и неопубликованной на данный момент литературы по применению MS.
- Из 18 перспективных исследований, 6 были сравнительными исследованиями:
- Сравнение размеров лазерных пятен 8, 12, 14 мм при эпиляции на ногах (№1)
  - Сравнение MS и «LightSheer» (№7), который является самым продаваемым полупроводниковым лазером высокой мощности в мире и эквивалентен MS
  - Сравнение версий MS: XT (предшествующая) и miXT (модернизированная на тот момент)
  - Сравнение участка кожи с обработкой MS и необработанного участка для контроля (случайного) эпиляции и изменения свойств кожи (№17)
  - Сравнение участка кожи с обработкой MS (инверсные угри) и необработанного участка для контроля (случайного)
  - Сравнение версии MS: miXT (предшествующая) и NeXT и контроль с помощью плацебо (случайный) при эпиляции (№21)
- (В) Все процедуры применения в этих исследованиях основаны на руководстве пользователя MS, включая предполагаемое использование. Только в №2 (см. Приложение А) обрабатываются вены на ногах, которые больше в диаметре, чем указано в руководстве пользователя. Сосуды больше 3 мм указаны как противопоказания из-за незначительных результатов обработки, что показали и результаты данного отчета о применении.
- (С) Всего в данных исследованиях было 906 пациентов и результаты применения оценивались по эффективности. Исследования различаются по качеству. Подробности перечислены и рассмотрены в главе 3.2.
- (D) В целом, у 780 пациентов изучалось возникновение побочных эффектов. Побочные эффекты не были упомянуты в отрывке из лекции Американской ассоциации лазерной медицины и хирургии (исследование №4) и в отчете о применении №9. Исследования различаются по качеству. Подробности перечислены и рассмотрены в главе 3.3.



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### 3.2 Оценка исследований в отношении эффективности

Всего в данных исследованиях было 906 пациентов, которые прошли обработку MS, и результаты применения оценивались по эффективности.

Результаты лазерных процедур при предполагаемом использовании зависят от индивидуальных особенностей пациента (например, тип кожи и участок для обработки, при эпиляции: цвет и толщина волос, при обработке сосудов: диаметр сосудов), от параметров применения, от числа сеансов и периода врачебного наблюдения. Таким образом, это нормально, что указанная в исследованиях эффективность варьируется.

Подробности исследований, связанные с эффективностью, указаны в Таблице 1 ниже.

Эффективность при эпиляции составила от 50% до 75% после 3 процедур. Это очень хороший результат, потому что среднее число необходимых процедур выше. В исследовании №10 с 200 пациентов среднее число сеансов было около 5. Чем больше процедур (до 12), тем большее уменьшение роста волос может быть достигнуто.

100% эпиляция невозможна, потому что, в зависимости от генетики и гормонов, в течение жизни почти невидимый пушковый волос превращается в «нормальные» пигментированные волосы.

В известной книге Бодендорфа и др.: «Dermatologische Lasertherapie / Laserepilation» (2013 г.), на странице 80 говорится, что после нескольких процедур уменьшение роста волос возможно от 40% до 80%. Это заявление основывается на оценке фактических, всеобъемлющих данных из литературы.

В исследовании №7 2003 г. уже было показано, что процедуры с MS, по крайней мере, столь же эффективны как у «LightSheer» (лидер мирового рынка, также диод высокой мощности как MS) в научном параллельном сравнении.

Кроме того, в исследовании №21 (2013) показано, что последняя версия MS (MS NeXT) по своим характеристикам даже лучше предшественника (MS miXT). В исследовании №18 (2012) было показано, что у 82% пациентов, у которых раньше проводилась эпиляция с помощью других устройств, наблюдалась большая эффективность при применении MS (2013, MS NeXT).

Также важными являются гистологические доказательства в исследованиях №1 (опубликовано в 2002 г.), №4 (2002) и №8 (2003), что фолликулы волос эффективно повреждаются лазерным излучением MS.

Эффективность процедур для избавления от угрей показана в исследованиях №5 (2003 г.) и в исследовании с использованием научного подхода №20 (№19 - это предварительный отчет о применении для 2 пациентов в исследовании №20). В 2013 году результаты этого исследования были опубликованы, несмотря на то, что исследование еще не было завершено. Период врачебного наблюдения спустя 12 месяцев после обработки имеется для 40 пациентов из 68. Однако результаты этих процедур оказались настолько положительными, что уже были опубликованы раньше.

Нужно знать, что инверсные угри\* очень трудно лечить. Инверсные угри - это первая стадия воспаления сальных желез и наружного эпителиального влагалища корня волоса у пигментированных волос. Позднее развиваются гнойники и свищи и полости абсцессов, ведущие к образованию рубцов, несмотря на применение лекарств. Инверсные угри очень болезненны и неприятно пахнут. В конце концов, очень часто гнойники приходится вскрывать снова и снова.

В исследовании №20 показано, что показатель HS\* у 68 пациентов можно сократить примерно на 48% после обработки (эпиляция) и даже на 77% через один год. Это означает, что процесс исцеления продолжается, по крайней мере, один год и улучшает качество жизни этих пациентов. Конечно невозможно вылечить полости абсцессов (поэтому в этих случаях возможны рецидивы, но повторная обработка не является проблемой). Нужно, по возможности, выполнять обработку инверсных угрей на ранних стадиях, чтобы не допустить переход на следующие стадии.

Эффективность обработки сосудов показана в исследованиях №2 (2002), №6 (2003) и №9 (2003).

В исследовании №2 показано, что результаты процедур по обработке судов зависят от диаметра сосудов. Сосуды обрабатывались 3 раза. 70% вен ног диаметром 1-2 мм были полностью исцелены. 70% вен ног диаметром 2-3 мм были полностью исцелены, и 30% 4 мм сосудов были полностью исцелены после применения больше 3 процедур.

В руководстве пользователя ножные вены 3 мм и более исключены из-за низкой эффективности.

В исследовании №6 у 15 пациентов (из 35) произошло полное очищение, а у 20 пациентов наблюдалось 80% улучшение после 1 процедуры. Это очень хороший результат, потому что невозможно исцелить все ножные вены у всех пациентов. В известной книге Бодендорфа и др.: «Dermatologische Lasertherapie/ Gefäßlaser» (2012 г.), на стр. 15 указывается, что полное исцеление ножных вен не всегда возможно.

\* инверсные угри = угри на спине, груди, в подмышечной ямке или лобковой области

= hidradenitis suppurativa = HS (устаревшее и вводящее в заблуждение название, потому что потовые железы не приводят к появлению инверсных угрей)

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Исследование №9 является отчетом о применении процедур для ножных вен до 3 мм. Наблюдалось большое количество пациентов (106). Здесь также подтверждается, что после 3 процедур у 75% наблюдалось полное исцеление, у 20% значительное улучшение, и у 4% среднее, а у 1% только незначительное улучшение.

Эффективность процедур омоложения оценивается в исследованиях №14 (2005 г.), №15 (2006) и №22 (2014).

Так называемое «омоложение» означает, главным образом, исцеление кожи от повреждений, вызванных ультрафиолетовым излучением как части солнечного света. Сюда входят нарушения пигментации, такие как доброкачественный лентигоз, текстура кожи, морщины, дряблость кожи и т. д. В исследовании №14 (2005) выполнялась обработка свыше 120 проявлений лентигоза у 12 пациентов, у каждого пациента проводилась биопсия и оценивались результаты. У всех пациентов наблюдалось больше чем 50% сокращение лентигоза (кроме одного), и это воздействие было показано также по данным гистологии. Пациент с неудовлетворительными результатами был первым пациентом, прошедшим процедуры обработки и для него применялось лазерное пятно размером 12 мм вместо 6 мм.

Исследование №15 (2006) является очень важным, хотя в нем наблюдались только 12 пациентов. Но в этом исследовании использовалась специальная камера, предоставляющая действительно объективные данные о свойствах кожи. Таким образом, было показано, что при данной обработке, улучшение для лентигоза составило 20%, для размера пор - 30%, для морщин - 40%, и для текстуры кожи - 40%. Конечно, нельзя было ожидать сильного эффекта, потому что это очень мягкая процедура и менее агрессивная по сравнению, например, с процедурой лечения, что использовалась в исследовании №14 для лентигоза или по сравнению с лечением дряблости кожи хирургическим путем.

Исследование №22 (2013) посвящено дряблости кожи. В этом исследовании для оценки улучшений также использовался объективный инструмент. У 53% пациентов наблюдалось умеренное улучшение через 1 и 3 месяца после процедур, а через 6 месяцев умеренное улучшение наблюдалось у 67% после процедур, подтверждая известный факт, что на образование нового коллагена требуется время.

**Таблица 1: Подробности результатов процедур в исследованиях:**

| Исследование № | Число пациентов | Наиболее значимые результаты                                                                                                                                                                                                                                                                                | Примечания автора                                                                                                                                                   |
|----------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1              | 20              | Уменьшение роста волос через 3 месяца после 3 процедур:<br>Лазерное пятно 8 мм: 33%, лазерное пятно 12 мм: 46%, лазерное пятно 14 мм: 45%<br><br>Толщина волос уменьшилась на 85%.<br><br>Это уменьшение зависит от цвета волос, через 1 месяц / 8 мм: темные волосы - 89%, каштановые - 74%, светлые - 69% | Хороший результат для 3 процедур.<br><br>Для темных волос результаты потому что большее поглощение меланина приводит к большому теплу.                              |
| 2              | 33              | После трех процедур для ножных вен<br>- 1 - 2 мм диаметр: 70% полностью исцелены<br>- 2 - 3 мм диаметр: 50% полностью исцелены<br>- 4 мм диаметр: 30%, но потребовалось больше 3 процедур                                                                                                                   | В руководстве пользователя исключены сосуды 3 мм и больше                                                                                                           |
| 3              | 20              | После 3 процедур для эпиляции, оценивались:<br>- лазер MS эффективен при обработке каштановых или темных волос с типом кожи I-IV<br>- MS обеспечивает длительное уменьшение роста волос у большинства пациентов после 3 процедур<br>- более толстые волосы лучше поддавались обработке                      | Результаты исследования были представлены для Американской ассоциации лазерной медицины и хирургии, доступен только отрывок. Поэтому информация не очень подробная. |
| 4              | 20              | 6 месяцев, после 3 процедур по уменьшению роста волос: эффективность 75%<br><br>Уничтожение волос доказано с помощью гистологии (5 пациентов).                                                                                                                                                              | Очень хороший результат.<br><br>Важное доказательство!                                                                                                              |
| 5              | 20              | Улучшение с инверсными угрями на основе эпиляции:<br>- новые воспаления: ослабление симптомов в течение нескольких дней<br>- воспаления с рубцами дольше 6 месяцев: исцеление воспалений за 6 недель<br>- полости абсцессов с рубцами: обеззараживающее воздействие                                         | Только отчет о применении, но очень ценный из-за того, что терапия инверсных угрей вообще очень трудна. (как ожидалось, исцеление полостей невозможно)              |

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| Исследование № | Число пациентов | Наиболее значимые результаты                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Примечания автора                                                                                                                                                                                    |
|----------------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6              | 35              | Оценивалось улучшение вен ног после 1 процедуры:<br>- У 15 пациентов наблюдалось полное очищение<br>- У 20 наблюдалось существенное улучшение (> 80%)<br>- стабильная ситуация спустя 6 месяцев                                                                                                                                                                                                                                                                                                               | Очень хороший результат. Необходимо до 3 процедур. У 70% наблюдалась польза для вен ног.                                                                                                             |
| 7              | 29              | через 6 месяцев после 3 процедур, уменьшение роста волос: уменьшение на 49% с MS, на 48% с «LightSheer»                                                                                                                                                                                                                                                                                                                                                                                                       | Доказательство того, что MS так же эффективен как ведущий продукт на рынке.                                                                                                                          |
| 8              | 24              | через 6 месяцев после 3 процедур, уменьшение роста волос: уменьшение на 70%<br><br>Гистология: уменьшение на фазе роста волос: другие обработанные участки, по крайней мере, 1:1 по сравнению с нормальными 8:2                                                                                                                                                                                                                                                                                               | Очень хороший результат.<br><br>Важное доказательство!                                                                                                                                               |
| 9              | 106             | После трех процедур для ножных вен до 3 мм:<br>- полное исцеление: 75% пациентов<br>- значительное улучшение: 20%<br>- умеренное улучшение 4%<br>- незначительное улучшение: 1%                                                                                                                                                                                                                                                                                                                               | Только отчет о применении, но ценный из-за большого числа пациентов                                                                                                                                  |
| 10             | 200 !!!         | Уменьшение роста волос после 3 процедур: 64%<br><br>978 процедур!!!<br>(в среднем, необходимо около 5 процедур на пациента)                                                                                                                                                                                                                                                                                                                                                                                   | Хороший результат, особенно потому, что оценивалось огромное количество пациентов!                                                                                                                   |
| 11             | 17              | После процедур для эпиляции, оценивались:<br>- лучшие результаты для лобковой области и области бороды: > 80% уменьшение роста волос после 5 процедур<br>- руки и ноги: > 50% после 10 - 12 процедур<br>- фолликул волоса родимого пятна: полное удаление после 1 процедуры<br>- эффект длился от 6 до 12 месяцев                                                                                                                                                                                             | Доступен только отрывок. Поэтому информация не очень подробная.<br><br>Небольшое число пациентов.                                                                                                    |
| 12             | 143             | Лучшие результаты при эпиляции наблюдались в подмышечной ямке и на верхней губе, затем - конечности и грудь<br><br>У типа кожи III наблюдался наилучший эффект, у типа кожи V наихудший                                                                                                                                                                                                                                                                                                                       | Очень ценное исследование из-за большого числа пациентов и пациентов с азиатским типом кожи                                                                                                          |
| 13             | 25              | Сравнение уменьшения роста волос - без значимой разницы в эффективности: 58,11% для 810 нм и 60,35% для 940 нм после, в среднем, 3,52 процедур                                                                                                                                                                                                                                                                                                                                                                | У 940 нм преимущество в отношении побочных эффектов (940 нм применяется с MS miXT)                                                                                                                   |
| 14             | 12              | У всех пациентов наблюдалось уменьшение лентиго больше чем на 50% (за исключением 1 пациента, который прошел обработку с 12 мм лазерным пятном в начале исследования)<br><br>Гистология (1 биопсия на пациента) продемонстрировала мелирование ядерного хроматина, расщепление дермо-эпидермального соединения и переменную гомогенизацию тонкого верхнего края у папиллярного кожного коллагена. Воздействие было более выраженным при применении 6 мм лазерного пятна по сравнению с 12 мм лазерным пятном. | Очень ценное исследование из-за включенных данных гистологии. Только 12 пациентов, но, по крайней мере, 10 лентиго на одного пациента (> 120). (Размер лазерного пятна для лентигоза составил 6 мм.) |
| 15             | 12              | После 3 процедур омоложения наблюдалось улучшение: для пятен (лентиго): 20%; для размера пор: 30%; для морщин: 40%; для текстуры: 40%                                                                                                                                                                                                                                                                                                                                                                         | Очень ценное исследование из-за объективного измерения кожи.                                                                                                                                         |



|               |                                                                                            |                                                                              |
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| Исследование № | Число пациентов | Наиболее значимые результаты                                                                                                                                                                                                                                                                                                          | Примечания автора                                                                                                                                              |
|----------------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16             | 5               | На участках для обработки с целью уменьшения роста волос с применением лазера MS XT (предшествующая модель) и MS miXT никаких существенных различий не наблюдалось                                                                                                                                                                    | Небольшое число пациентов, но параллельное сравнение показало одинаковую эффективность для обоих MS                                                            |
| 17             | 31              | После 1 обработки волос (цель заключалась в том, чтобы оценить изменения свойств кожи, а не эффективность обработки):<br>- плотность и толщина волос после обработки статистически заметно уменьшились и в период врачебного наблюдения оставались на том же уровне<br>- 51,85% уменьшение роста волос через 6 недель после процедуры | 1 обработки недостаточно, но цель этого исследования заключалась в том, чтобы оценить изменения кожи - см. побочные эффекты.                                   |
| 18             | 27              | 17 из этих пациентов уже проходили ранее процедуры по уменьшению роста волос с другими устройствами. Эти пациенты оценили обработку с MS NeXT следующим образом:<br>- более эффективна: 82%<br>- более эффективна и меньше побочных эффектов: 65%<br>в среднем, 5,8 процедур на одного пациента (157 процедур)                        | Очень ценный результат для MS NeXT                                                                                                                             |
| 19             | (2)             | См. ниже                                                                                                                                                                                                                                                                                                                              | Отчет о применении №20                                                                                                                                         |
| 20             | 68              | Улучшение инверсных угрей после 6 процедур (на основе эпиляции): уменьшение показателя HS* после обработки: 47,62% уменьшение показателя через 12 месяцев врачебного наблюдения: 77,33% *HS = Hidradenitis suppurativa = инверсные угри)                                                                                              | Очень ценное исследование (см. также примечания к №5). Были достигнуты очень хорошие успехи. На данный момент есть данные о врачебном наблюдении 40 пациентов. |
| 21             | 29              | Уменьшение роста волос с MS NeXT и MS miXT (предшествующая модель) после 3 процедур:<br>- 64,3% и 50,1% для типа кожи I-II<br>- 65,1% и 61.6% для типа кожи III<br>- SmoothPulse («гладкий импульс») NeXT: 67,1 %                                                                                                                     | Исследование очень ценное, показана даже большая эффективность MS NeXT по сравнению с предшествующей моделью MS miXT                                           |
| 22             | 30              | Умеренное улучшение дряблости кожи после 4 процедур для: 53,3% пациентов, 1 и 3 месяца после обработки, 66,7% пациентов, 6 месяцев после обработки                                                                                                                                                                                    | Очень ценное исследование из-за объективного измерения дряблости кожи. Показано, что для этих процедур улучшение наступает через определенное время!           |

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### 3.3. Оценка исследований в отношении побочных эффектов

В целом, у 780 пациентов выполнялась обработка с MS и изучалось возникновение побочных эффектов. Побочные эффекты не были упомянуты в отрывке из лекции Американской ассоциации лазерной медицины и хирургии (исследование №4) и в отчете о применении №9.

Почти для всех процедур необходимо несколько сеансов, обычно 2 - 3 для сосудистой обработки и омоложения, 5 -12 для эпиляции. Таким образом, количество процедур, которые могут вызвать побочные эффекты, потенциально, гораздо выше в исследовании №10, где количество процедур было 978 (!) для 200 пациентов.

Для оценки побочных эффектов нужно знать, что лазерные процедуры действуют через поглощение кожей лазерного излучения.

Поглощение означает, что свет преобразуется в тепло. Чем больше поглощение, тем больше тепла. Тепло необходимо для термического повреждения объекта воздействия (например, волосы, кровь), но не его окружения. Невозможно в каждом случае избежать слишком большого тепла, потому что поглощение зависит не только от параметров лазера, но и от индивидуальных особенностей пациента: например, тип кожи (нежелательное поглощение пигментом), цвет и толщина волос, размеры сосудов.

Поэтому в руководстве пользователя говорится о необходимости выполнить сначала пробную обработку, помогающую настроить нужные параметры. Но даже после пробной обработки толщина и цвет волос все равно остаются различными, так же как размеры и глубина сосудов и т. д.

Побочные эффекты указаны в руководстве пользователя и не менялись для предшествующей модели устройства. В главе 6.4.5 они указаны для эпиляции. Обработка угрей основана на эпиляции, поэтому побочные эффекты будут те же, кроме дискомфорта во время обработки. Большая боль при обработке инверсных угрей вызвана связанным с ними воспалением. Процедура омоложения вызывает еще меньше побочных эффектов, потому что здесь обычно нет волос и поэтому поглощение меньше.

Как указано в руководстве пользователя, все побочные эффекты менее значительны для светлых волос и светлой кожи и становятся тем заметнее, чем темнее, толще и гуще волосы и чем темнее цвет кожи.

Обработка сосудов вызывает больше побочных эффектов, чем процедуры эпиляции, потому что диаметр сосудов (объем крови) у них больше, чем диаметр стержня волоса. Как указано в руководстве пользователя, в главе 6.5.3, все побочные эффекты будут меньше для пациентов со светлой кожей и тонкими сосудами и становятся тем сильнее, тем толще сосуды и темнее кожа.

#### Примечание:

Покраснение кожи и отеки (иногда в сопровождении небольших волдырей) в зоне обработки, а также дискомфорт во время обработки рассматриваются как конечная точка применения процедур и поэтому авторы исследования не считают их побочными эффектами. В большинстве исследований эти «побочные эффекты» не упоминаются и поэтому не рассматриваются ниже, несмотря на то, что они указаны в руководстве пользователя и подробно перечислены в приведенной ниже таблице (здесь они указаны для полноты картины).

Какие побочные эффекты не наблюдались в исследованиях №3 (20 пациентов), №7 (29 пациентов), №8 (24 пациента), №15 (12 пациентов), №16 (5 пациентов), №17 (31 пациент), №18 (27 пациентов), №21 (29 пациентов) и №22 (30 пациентов).

временная гипопигментация наблюдалась только в исследованиях №1 (6 из 20 пациентов) и №2 (1 из 33 пациентов). Временная гиперпигментация наблюдалась в исследованиях №2 (4 из 33 пациентов), №10 (5 из 978 процедур), №12 (7 из 143 пациентов), №13 (1 пациент из 25, прошел обработку только с 810 нм) и №22 (умеренная гиперпигментация у нескольких пациентов из 30). В исследовании №13 (25 пациентов) наблюдался один случай продолжительного покраснения кожи. Небольшие рубцы наблюдались после обработки вен ног в исследованиях №2 (1 из 33 пациентов) и №6 (2 пациента с умеренным образованием рубцов из 35).

Общее число сеансов является примерным, потому что в некоторых исследованиях оно не было указано точно. В целом, по крайней мере, 3285 сеансов оценивались на возникновение побочных эффектов.

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Эти процедуры вызвали:

- 0,21% временной гипопигментации
- 0,67% временной гиперпигментации («несколько» пациентов в исследовании №22, предположительно, - это 5 из 30)
- 0,03% продолжительное покраснение кожи
- 0,09% небольшие рубцы (все после обработки сосудов)
- постоянная гипопигментация отсутствует
- постоянная гиперпигментация отсутствует
- другие серьезные побочные эффекты не наблюдались

Все эти побочные эффекты перечислены и указаны в руководстве пользователя.

Все вместе побочные эффекты составили только 1% от процедур обработки. Эта процентная доля очень мала, учитывая тот факт, что обработку проходили пациенты со всеми типами кожи, включая азиатов. В темной коже и коже азиатов больше меланина и поэтому риск возникновения побочных эффектов выше по сравнению со светлой кожей.

Единственными постоянными побочными эффектами оказались небольшие рубцы, которые появились после обработки вен ног. Нужно заметить, что эти небольшие рубцы по своим размерам не превышают диаметр сосудов и светлее по цвету кожи. Поэтому пациенты почти всегда принимают этот риск, потому что маленький, небольшой рубец выглядит лучше, чем более темный сосуд до этого.

Подробности исследований, связанные с побочными эффектами, указаны в таблице ниже.

**Таблица 2. Подробная информация о побочных эффектах:**

| Исследование № | Число пациентов | Зафиксированные побочные эффекты                                                                                                                                                                                                                                                              | Примечания автора                                                                                                                                      |
|----------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1              | 20              | Околофолликулярное покраснение кожи и отеки после эпиляции наблюдались у 16 пациентов из 20<br>Боль во время процедур: максимум 0,8 по 10 бальной шкале, отсутствуют постоянные пигментные или текстурные изменения, нет образования рубцов при временной гипопигментации у 6 пациентов из 20 | Стандартная конечная точка применения процедур<br><br>Небольшая боль                                                                                   |
| 2              | 33              | у 30% пациентов наблюдалось образование коросты после обработки вен ног, у 4 пациентов была гиперпигментация, у 1 - гипопигментация, у 1 - рубец (на лодыжке)                                                                                                                                 | Все побочные эффекты являются, как правило, преходящими, кроме рубцов. (обработка сосудов вызывает больше побочных эффектов из-за большего поглощения) |
| 3              | 20              | После эпиляции не наблюдалось ни изменений пигментации, ни постоянного покраснения кожи или образования рубцов.<br>Боль во время обработки было сильнее у пациентов с более темными, густыми волосами.                                                                                        | Что объясняется большим поглощением                                                                                                                    |
| 4              | (20)            | Не упоминается                                                                                                                                                                                                                                                                                | Лекция в Американской ассоциации лазерной медицины и хирургии; доступен только отрывок.                                                                |
| 5              | 20              | Речевая информация:<br>Кроме боли, дополнительные побочные эффекты при обработке инверсных угрей по сравнению с эпиляцией отсутствуют.                                                                                                                                                        | Боль усиливается из-за воспаления, вызванного инверсными угрями.                                                                                       |
| 6              | 35              | После лечения вен ног, кроме 2 пациентов с умеренным образованием рубцов, никакие побочные эффекты не наблюдались.                                                                                                                                                                            | Обработка сосудов вызывает больше побочных эффектов из-за большего поглощения.                                                                         |



|               |                                                                                            |                                                                              |
|---------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
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| Исследование № | Число пациентов | Зафиксированные побочные эффекты                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Примечания автора                                                                                                                                                |
|----------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7              | 29              | Сравнение MS и лидера рынка «LightSheer» при эпиляции<br>После обработки отсутствует образование рубцов или изменение пигментации. Степень покраснения кожи и процентная доля сожженных волос меньше у MS.<br>Отеки и боль статистически не отличаются.                                                                                                                                                                                                                                                                           | Доказательство того, что MS вызывает не больше побочных эффектов, чем ведущий продукт на рынке; преходящее покраснение кожи и сожжение волос у него даже меньше. |
| 8              | 24              | Эпиляция не приводила к каким-либо серьезным побочным эффектам.<br><br>Гистология после обработки:<br>кожные сосуды, экзокринные каналы, эластичные волокна и жировая ткань не показали каких-либо изменений после обработки.                                                                                                                                                                                                                                                                                                     | Очень хороший результат.<br>Важное доказательство!                                                                                                               |
| 9              | (106)           | Не упоминается.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Отчет о применении                                                                                                                                               |
| 10             | 200 !!!         | 978 процедур по уменьшению роста волос!<br>- постоянные осложнения или рубцы отсутствуют<br>- только 0,5% временная гиперпигментация                                                                                                                                                                                                                                                                                                                                                                                              | Очень хороший результат, особенно из-за большого числа пациентов всех типов кожи!                                                                                |
| 11             | 17              | После обработки для уменьшения роста волос:<br>- изменения пигментации отсутствуют<br>- чувство жжения, зависящее от применяемой плотности энергии и области обработки<br>- незначительные ожоги у 2 пациентов зажили без изменения пигментации                                                                                                                                                                                                                                                                                   | Небольшое число пациентов.                                                                                                                                       |
| 12             | 143             | После эпиляции:<br>- у 4 пациентов наблюдались волдыри<br>- у 7% временная гиперпигментация сохранялась 2 месяца                                                                                                                                                                                                                                                                                                                                                                                                                  | Очень ценное исследование из-за большого числа пациентов. Очень хорошее доказательство безопасности для пациентов с азиатским типом кожи.                        |
| 13             | 25              | Сравнение уменьшения роста волос при применении 810 нм и 940 нм:<br>- у 1 пациента (IV тип кожи) наблюдалось образование коросты только на стороне с обработкой 810 нм<br>- у 1 пациента (III тип кожи) наблюдалось продолжительное покраснение кожи и гиперпигментация только на стороне с обработкой 810 нм<br>- побочные эффекты на стороне с обработкой 940 нм отсутствуют                                                                                                                                                    | Преимущество 940 нм (940 нм применяются с MS miXT)                                                                                                               |
| 14             | 12              | через 1 месяц после обработки лентигоноза (обработано больше 120 повреждений):<br>- образование рубцов отсутствует<br>- некоторые повреждения показали остаточное покраснение кожи через этот короткий промежуток времени                                                                                                                                                                                                                                                                                                         | Очень хороший результат, потому что обычно покраснение кожи сохраняется иногда дольше, чем 1 месяц                                                               |
| 15             | 12              | После процедур омоложения не наблюдались никакие побочные эффекты, такие как постоянное покраснение кожи, отеки, волдыри, гиперпигментация или образование рубцов.                                                                                                                                                                                                                                                                                                                                                                | Из-за небольшого поглощения в процедурах омоложения риск возникновения побочных эффектов ниже.                                                                   |
| 16             | 5               | На участках для обработки с целью уменьшения роста волос с применением лазера MS XT (предшествующая модель) и MS miXT никаких различий не наблюдалось:<br>- отсутствуют случаи изменения пигментации, образования струпьев или рубцов<br>- незначительное околофолликулярное покраснение кожи и отеки считаются нормальными и рассматривается как конечная точка применения процедур<br>- ни один из пациентов не чувствовал ничего кроме небольшого потепления в зоне обработки; один из пациентов был очень чувствителен к боли | Небольшое число пациентов, но параллельное сравнение показало одинаковую безопасность для обоих MS.                                                              |

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| Исследование № | Число пациентов | Зафиксированные побочные эффекты                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Примечания автора                                                                                                                                       |
|----------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| 17             | 31              | Исследование изменений кожи после эпиляции с помощью объективных измерений и контроля по необработанным участкам:<br>- покраснение кожи может сохраняться до двух недель<br>- никакой разницы в уровне меланина, хотя изменение пигментации является обычным побочным эффектом лазерных процедур<br>- никаких изменений в биофизических свойствах кожи, включая потери влаги испарением через кожу, объем водного баланса рогового слоя, кожное сало и уровень pH                                                                                                                                                                                                                          | Это очень интересное исследование, посвященное, в основном, изменениям кожи и поэтому показавшее безопасность процедур с помощью объективных измерений. |
| 18             | 27              | После процедур эпиляции был замечен следующий аспект:<br>- в сущности, безболезненность, особенно при многократных проходах*<br>- в сущности, незначительные побочные эффекты (т. е. поверхностное покраснение кожи и краткосрочные околофолликулярные отеки) при многократных проходах<br><br>17 из этих пациентов уже проходили ранее процедуры по уменьшению роста волос с другими устройствами.<br>Эти пациенты оценили обработку с MS NeXT следующим образом:<br>- меньше побочных эффектов: 71%<br>- более эффективна и меньше побочных эффектов: 65%<br>- только у 1 пациента отеки сохранялись 3 дня (но ранее, после обработки другим устройством, отеки сохранялись даже 7 дней) | Очень ценный результат для MS NeXT, показывающий безопасность и, в сущности, безболезненность процедур с MS NeXT, особенно в режиме «гладкий импульс».  |
| 19             | (2)             | См. ниже                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Отчет о применении №20                                                                                                                                  |
| 20             | 68              | После обработки инверсных угрей наблюдались:<br>- побочные эффекты как при эпиляции, кроме боли<br>- боль существенно возрастает из-за воспаления, вызванного инверсными угрями                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Очень ценное исследование. Продemonстрирован очень безопасный способ лечения болезни, которая на данный момент очень плохо поддается лечению.           |
| 21             | 29              | Побочные эффекты, зафиксированные после процедур для уменьшения роста волос с применением MS NeXT и MS miXT (предшествующая модель):<br>- Побочные эффекты были небольшими и ограничивались только краткосрочным покраснением кожи.                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Исследование очень ценное, показана безопасность MS NeXT и предшествующей модели MS miXT                                                                |
| 22             | 30              | Побочные эффекты, зафиксированные после процедур омоложения по устранению дряблости кожи:<br><br>- серьезное неблагоприятное воздействие отсутствует<br>- только временная боль и покраснение кожи, которые хорошо переносились при последующих обработках.<br>- у пациентов был тип кожи III – IV (азиатский),<br>- однако большинство пациентов о гиперпигментации не сообщали<br>- было зафиксировано только несколько случаев преходящей и умеренной гиперпигментации, которые не нуждались в каких-либо процедурах                                                                                                                                                                    | Очень ценное исследование, потому что у пациентов азиатский тип кожи, которая склонна приводить к побочным эффектам, особенно гиперпигментации.         |

|               |                                                                                            |                                                                              |
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### 3.4 Оценка отчетов Федерального института по лекарственным препаратам и медицинской продукции Германии\* и Управления по контролю за продуктами и лекарствами

За все время продаж MS не было ни одной рекомендации или предложения о снятии с продажи со стороны Федерального института по лекарственным препаратам и медицинской продукции Германии в отношении MS или аналогичных устройств.

Последнее исследование рекомендаций Федерального института по лекарственным препаратам и медицинской продукции Германии, а также предложений института и Управления по контролю за продуктами и лекарствами о снятии с продажи медицинских приборов, выполнялось 2 сентября 2014 года и снова в отношении MS никаких замечаний не было. См. подробную информацию в Приложении В.

\* Федеральное ведомство Германии по лекарствам и медицинским приборам

## 4. Окончательная оценка

### Показания к применению устройства

Идентично предшествующей модели устройства, применение MS:

- удаление нежелательных волос
- обработка угрей
- обработка сосудов
- омоложение кожи (обработка актинического эластоза)

Во всех указанных процедурах обработки лазер применяется для неповрежденной кожи.

Эти показания изложены в главе 2.1 руководства пользователя.

### 4.2 Противопоказания

В клинической оценке 2011 были подробно процитированы и оценены все исследования и известные книги о противопоказаниях и критериях исключения (глава 3.4). Клиническая оценка 2014 посвящена аппликатору ALX, который был новым на тот момент. В результате этой оценки (главы 3.1. d, 3.2 B, 4-2), пациенты с типом кожи VI были добавлены в список противопоказаний и поэтому исключены из процедур обработки с аппликатором ALX (см. список ниже).

Идентично предшествующей модели устройства, должны соблюдаться следующие противопоказания, изложенные в главе 2.2 руководства пользователя:

- Чувствительность к свету
- Прием внутрь препаратов, которые усиливают чувствительность к свету
- Терапия целлюлита в зоне обработки (подождите несколько недель)
- Раковые и предраковые патологические изменения в зоне обработки
- Покрытые волосами родимые пятна в зоне обработки
- Простой герпес в зоне обработки
- Склонность к чрезмерному образованию рубцов
- Когда применяется аппликатор ALX: Пациенты с типом кожи VI
- Лазер нельзя применять на участках, находящихся близко к глазам
- Применение для детей или беременных и кормящих женщин
- Загорелая кожа на участках для обработки, особенно при использовании аппликатора ALX
- Татуировки на участках для обработки

**Противопоказания, особенно для обработки сосудистой сеточки на ногах:**

- Поверхностное варикозное расширение вен диаметром больше 3 мм
- Ветви вен и второстепенные варикозно расширенные вены
- Язва
- Диабет
- Васкулит
- Гемостатический дерматит
- Отек стоп и лодыжек
- Невропатия ног
- Прием внутрь кортикостероидов в последние три месяца
- Тромбофлебит

### 4.3 Заключение

- (1) Данная новая версия MS полностью идентична по предполагаемому использованию (включая показания к применению и противопоказания) текущей версии MS. Единственная разница для пользователя только в новом, более крупном аппликаторе, сокращающем время процедур. Положительные результаты клинической оценки 2011 и 2014 гг. остаются в силе.



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- (2) Большое число проданных за последние годы устройств MS наглядно показывает клиническую эффективность и безопасность (а также эксплуатационную пригодность и надежность) устройства MS. Иначе этот успех был бы невозможен.
- (3) В обновленном обзоре (2013 г.), а также в предыдущих обзорах с рекомендациями и предложениями о снятии с продажи сопоставимых с MS медицинских лазеров, перечисленных Федеральным институтом по лекарственным препаратам и медицинской продукции Германии и Управлением по контролю за продуктами и лекарствами, нет ничего, что указывало бы на необходимость модернизировать устройство MS.
- (4) В этой оценке исследования и отчеты о применении MS рассматривались в отношении эффективности. В целом, наблюдались 906 пациентов.  
Была продемонстрирована эффективность, включая гистологические доказательства, для всех показаний к применению при предполагаемом использовании.

В этой оценке исследования и отчеты о применении MS рассматривались также в отношении побочных эффектов. По крайней мере, 3285 сеансов\* подлежали оценке.

Только 1% сеансов вызвал побочные эффекты, большинство из них были преходящими. Постоянными оказались только 3 небольших рубца (меньше 0,1%). Но следует принять во внимание, что по своим размерам эти рубцы ограничены размерами сосудов. Это означает, что они небольшие и светлого цвета. Таким образом, данные участки не выглядят идеальными, но светлые линии или пятна не настолько заметны как красные или фиолетовые линии сосудов до обработки.

Очень небольшая процентная доля побочных эффектов обращает на себя внимание, если учесть, что обрабатывались все типы кожи, в том числе азиатская. Темная кожа и азиатская кожа больше склонны к побочным эффектам из-за большего поглощения меланина.

\* Общее число сеансов является оценочным, потому что точные данные в нескольких исследованиях не были заявлены

#### 4.4 Заключение:

В ходе этой оценки было продемонстрировано, что процедуры обработки с помощью MS являются эффективными и безопасными. Процентная доля случаев с побочными эффектами очень низкая и, в основном, такие случаи носят временный характер. Что позволяет прийти к выводам о том, что преимущества для пациентов превышают риски. Новая версия MS по своему применению продемонстрирована как эквивалентная текущему устройству.

12 октября 2014 г.

Г. Циммерман

Свидетельство ЕС  
Директивой 93/42/ЕЕС, Приложение II за главы 4  
Полную систему контроля качества  
Медицинское оборудование

Регистрационный №: HD 60105768 0001

Отчет №: 21232818 001

Производитель:

«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)  
Брюсселер Штрассе 10  
07747 Йена  
Германия

Продукция:

см. вложение о перечисленной продукции

Срок годности:

02.12.2020

Уполномоченный орган настоящим заявляет, что требования, перечисленные в Приложении II, за исключением раздела 4 Директивы № 93/42/ЕЕС, выполнены для перечисленной продукции. Вышеназванный производитель создал и применяет систему обеспечения качества, которая является объектом периодического наблюдения, определенного в Приложении II, раздел 5 вышеупомянутой директивы. Для размещения на рынке устройств класса III, охватываемых данным сертификатом, согласно Приложению II, раздел 4, необходим ЕС сертификат дизайн-экспертизы.

Орган технической экспертизы

Дата вступления в силу: 03.12.2015

Дата: 01.12.2015

/Подпись/  
Дипломированный инженер Д.  
Майер

Печать: «ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH), орган по сертификации,  
«ТЮФ Рейнланд» (TÜV Rheinland)

«ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH) Тиллиштрассе, 2, 90431,  
Нюрнберг

«ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH) является уполномоченным  
органом согласно директиве 93/42/ЕЕС, касающейся медицинских приборов с идентификационным номером  
0197.



«ТЮФ  
Рейнланд»  
(TÜV  
Rheinland)

Док. 1/1, Ред. 0

ОТН Рейнской области  
«ЛГА Продактс ГмбХ» (LGA Products GmbH)  
Тиллиштрассе, 2, 90431, Нюрнберг

Приложение к  
Свидетельство  
Регистрационный №:  
Отчет №:

HD 60105768 0001  
21232818 001

Производитель:

«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)  
Брюсселер Штрассе 10  
07747 Йена  
Германия

Ассортимент:

- хирургические, дерматологические и стоматологические лазеры
- электротерапевтические медицинские приборы
- стерильное лазерное волокно
- лазерные источники питания, лазерные волокна

Орган технической экспертизы

Дата: 01.12.2015

/Подпись/

Дипломированный инженер Д.  
Майер

Печать: «ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH) – Орган сертификации  
«ТЮФ Рейнланд» (TÜVRheinland)





«ТЮФ  
Рейнланд»  
(TÜV Rheinland)

## С в и д е т е л ь с т в о

Орган сертификации «ТЮФ  
Рейнланд ЛГА Продактс ГмбХ»  
(TÜV Rheinland LGA Products  
GmbH)

настоящим подтверждает, что организация  
«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies GmbH)

Брюсселер Штрассе 10

07747 Йена

Германия

создала и применяет систему управления качеством медицинских  
приборов для следующей области применения:

См. приложение

Было доказано, что требования, указанные в

EN ISO 13485:2012  
EN ISO 13485:2012 / AC:2012

выполнены. Система управления качеством является объектом ежегодного  
наблюдения.

Дата вступления в силу: 03.12.2015

Регистрационный номер свидетельства: SX 60105769 0001

Ревизия была проведена. Отчет №: 21232818 001

Настоящее свидетельство действительно до 02.12.2018

Орган по сертификации

«ДАККС» (DAkkS)

Германский центр сертификации  
D-ZM-14169-01-02

Печать: «ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH) – Орган  
сертификации

«ТЮФ Рейнланд» (TÜV Rheinland)

Дата: 30.12.2014

/Подпись/

Дипломированный инженер Д.  
Майер

«ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH) Тиллиштрассе, 2, 90431,  
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«ТЮФ  
Рейнланд»  
(TÜVRhein  
land)

Док. 1/1, Ред. 0

ОТН Рейнской области  
«ЛГА Продактс ГмбХ» (LGA Products GmbH)  
Тиллиштрассе, 2, 90431, Нюрнберг

Приложение к  
Регистрационный №:  
Отчет №:

SX 60105769 0001  
21232818 001

Организация:  
GmbH)

«Асклепион Лейзер Текнолоджис ГмбХ» (Asclepion Laser Technologies

Брюсселер Штрассе 10  
07747 Йена  
Германия

Сфера применения:

Проектирование и разработка, производство, монтаж и обслуживание хирургических и дерматологических лазеров, электротерапевтического медицинского оборудования, местных систем охлаждения кожи, стерильных и рестерилизуемых лазерных волокон, транскутанных канюль, применяющихся в области отоларингологии, гинекологии, урологии, дерматологии, пластической и эндоваскулярной хирургии, лазерных источников питания и оптических волокон.

Орган по сертификации

«ДАККС» (DAkkS)

Германский центр сертификации  
D-ZM-14169-01-02

Печать: «ТЮФ Рейнланд ЛГА Продактс ГмбХ» (TÜV Rheinland LGA Products GmbH) – Орган сертификации  
«ТЮФ Рейнланд» (TÜVRheinland)

Дата: 01.12.2015

/Подпись/

Дипломированный инженер Д.  
Майер

*Перевод данного текста сделан мной, переводчиком Мамедовым Тимуром Джаваншировичем*

*ТД*

*[Large handwritten signature in blue ink]*



*Перевод данного текста сделан мной, переводчиком Мамедовым Тимуром Джаванишировичем*

*ТД*

*[Large handwritten signature in blue ink]*

**Российская Федерация**

**Город Москва**

**Седьмого февраля две тысячи семнадцатого года**

Я, Акимов Глеб Борисович, нотариус города Москвы, свидетельствую подлинность подписи переводчика Мамедова Тимура Джаваниировича.

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