«УТВЕРЖДАЮ»

Менеджер по регистрации медицинских изделий Бизнес-юнита «Радиология»

АО «БАЙЕР» Тихонова М.А.

«__» _____ 2019 г.

АО «БАЙЕР»
АО BAYER

АО «БАЙЕР»

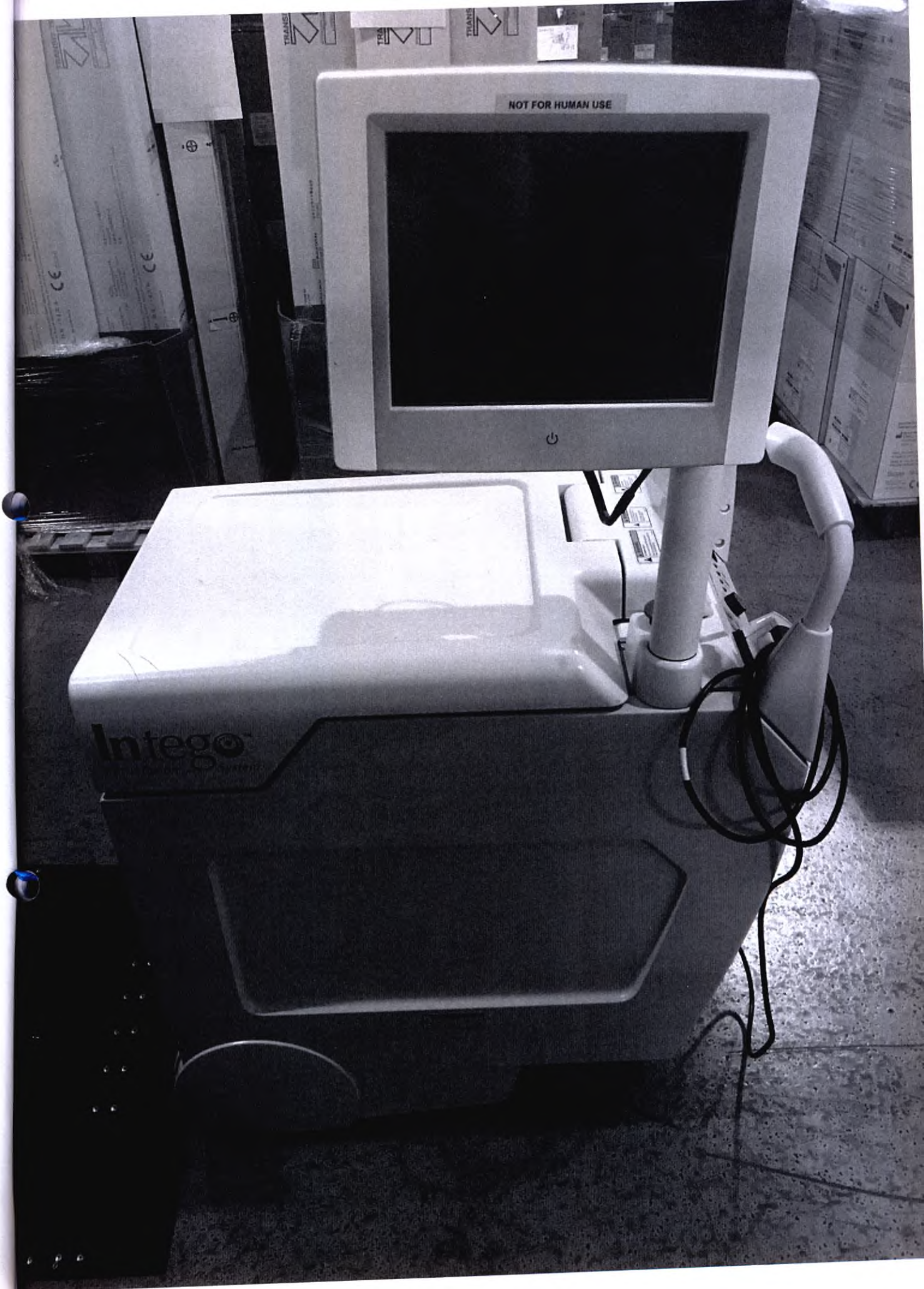
107113, Россия, Москва
ул. 3-я Рыбинская д.18, стр.2

Тел.: (495) 234 20 00

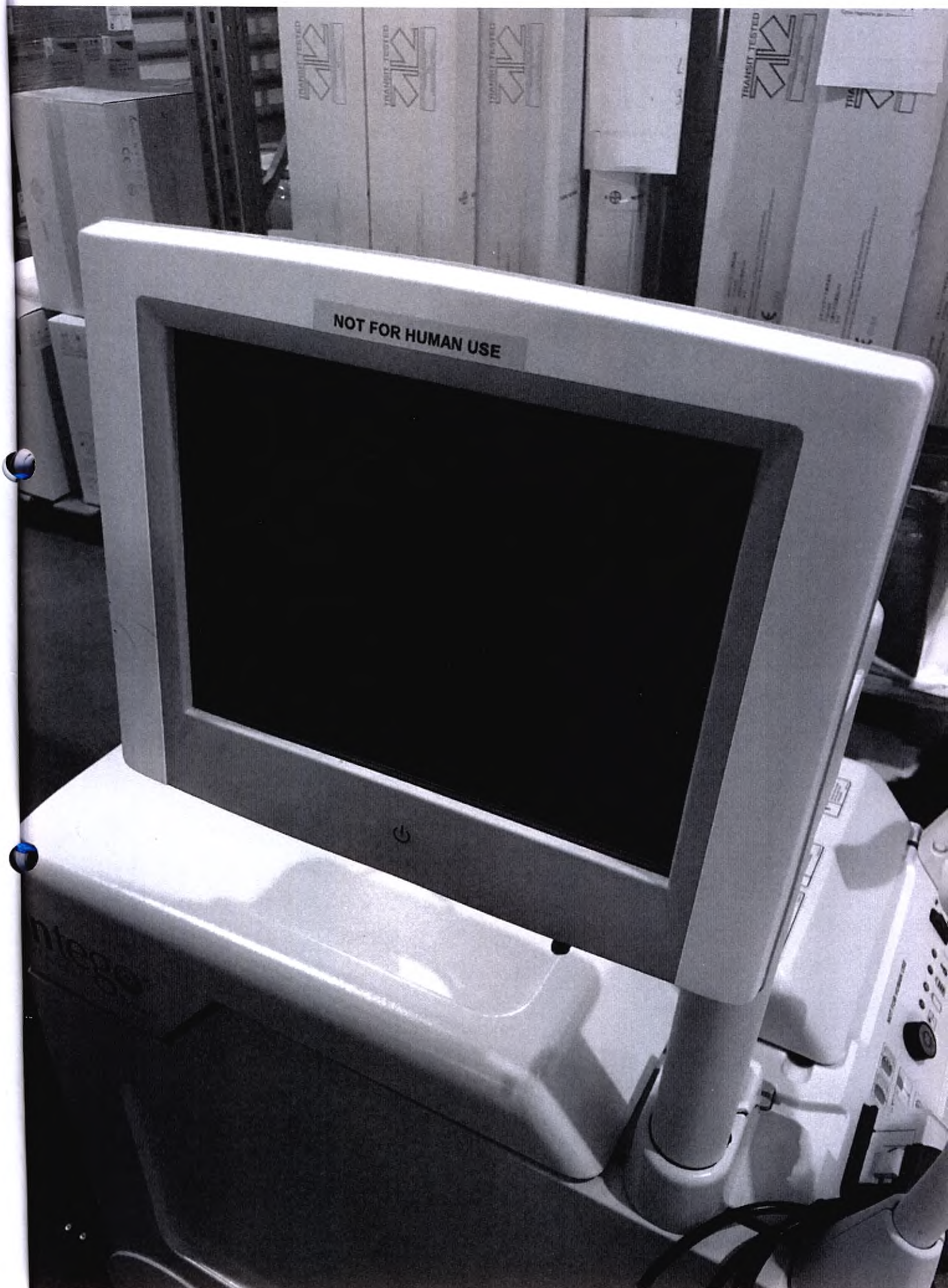
www.bayer.ru

ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

Система инфузионная для позитронно-эмиссионной томографии MEDRAD Intego с принадлежностями

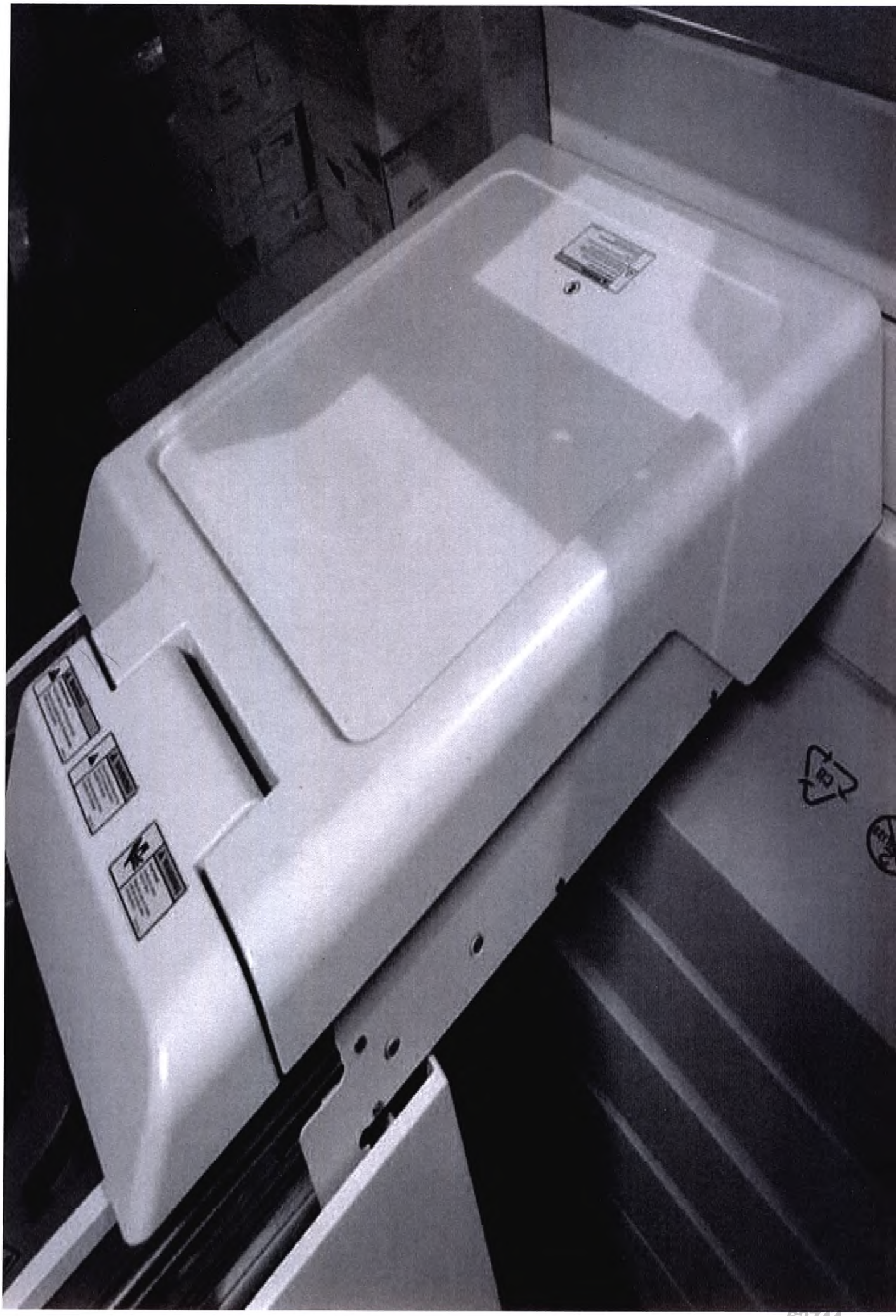


Общий вид системы



1. Дисплей

2. Экранированная камера.



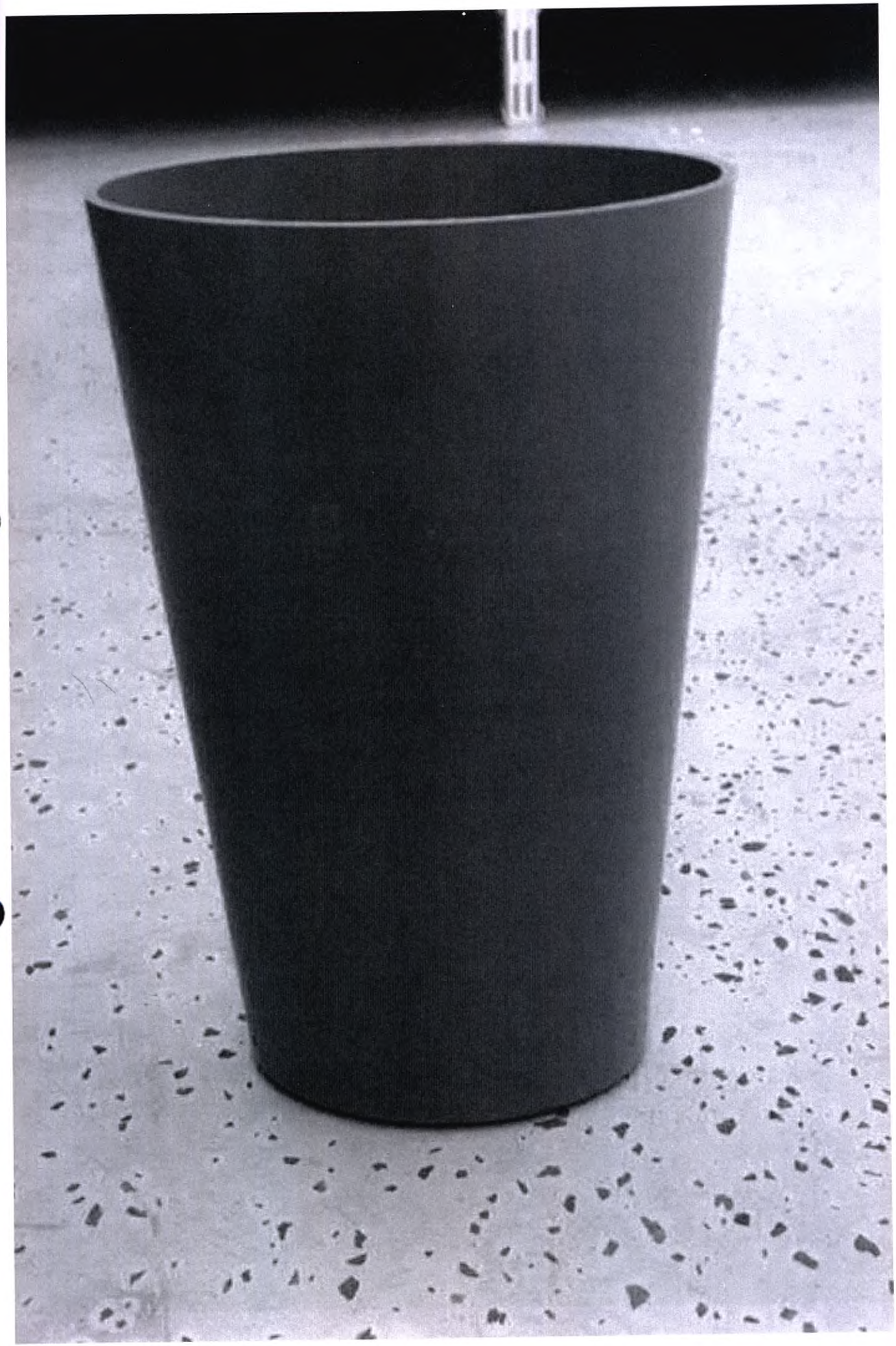
Крышка экранированной камеры

печати индивидуальных данных инфузии пациента.

2. **Калибровщик дозы.**

3. **Вставка калибровщика дозы.**

4. **Крышка калибровщика дозы.**



Вставка хранилища для отходов

6. **Защитный экран емкостей**

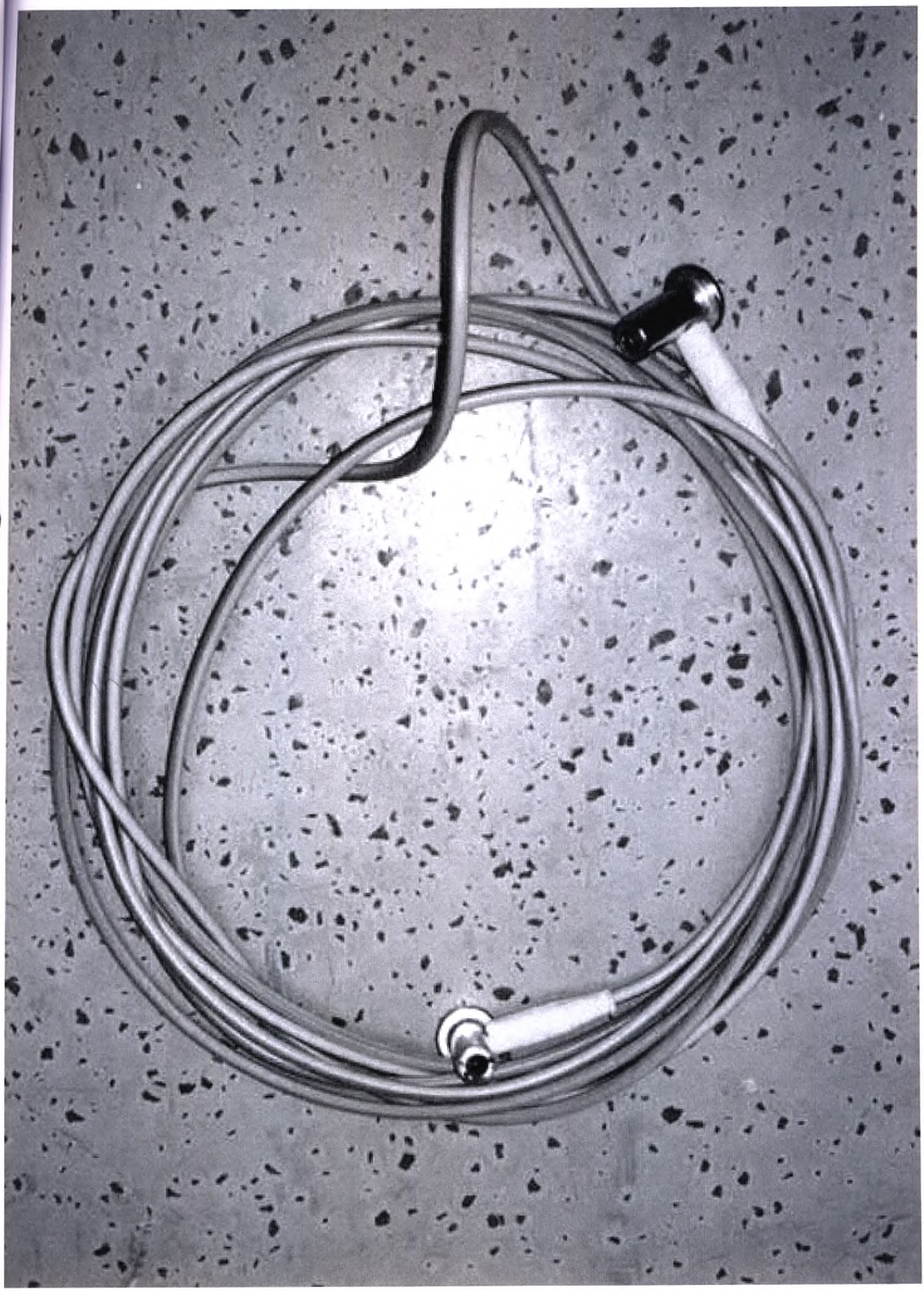
7. **Держатель калибровочного источника.**

8. **Рулон - наклейки, термические для печати индивидуальных данных**

9. **Насос для подачи физиологического раствора.**

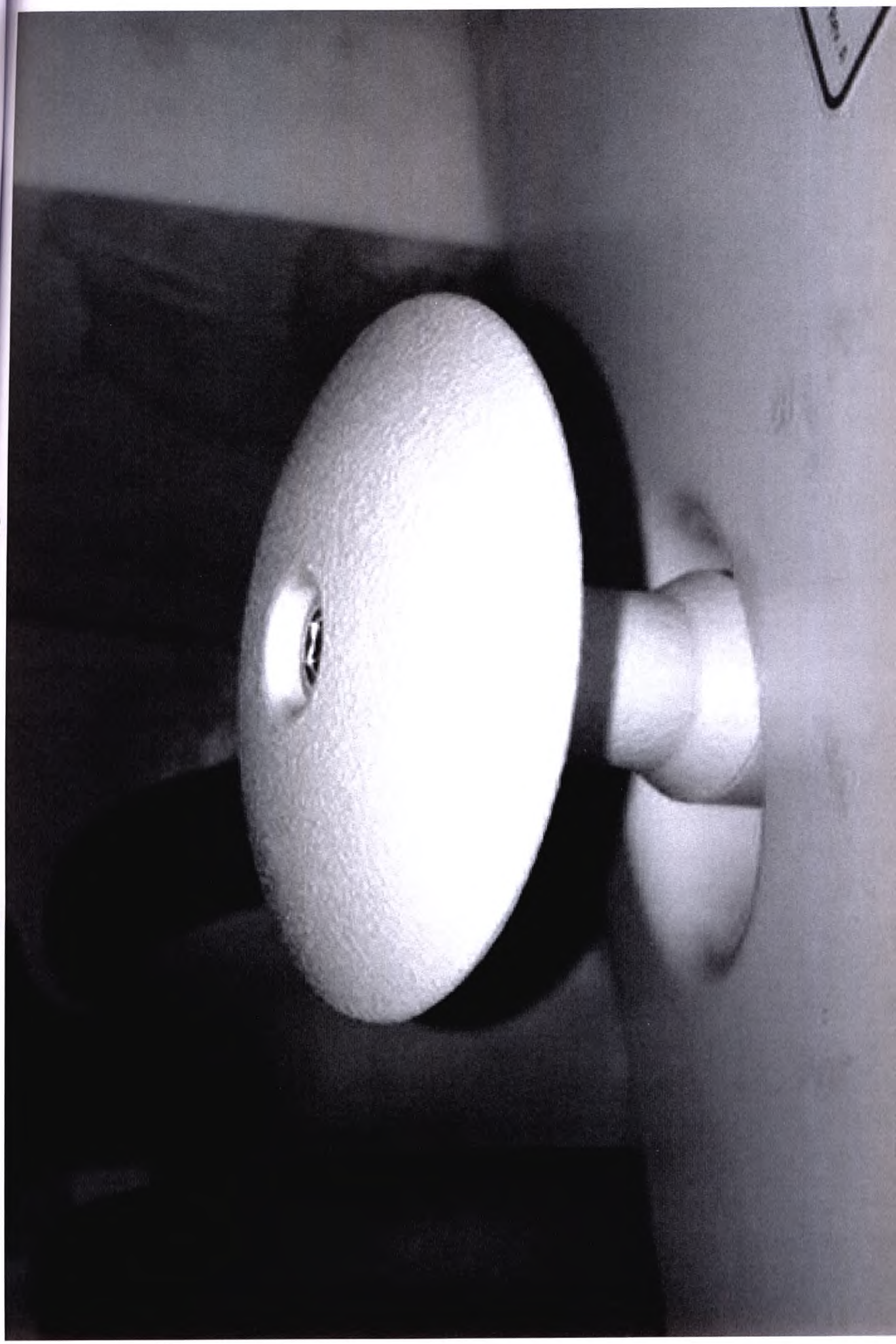
10. **Насос для подачи RP.**

11. Детектор воздуха

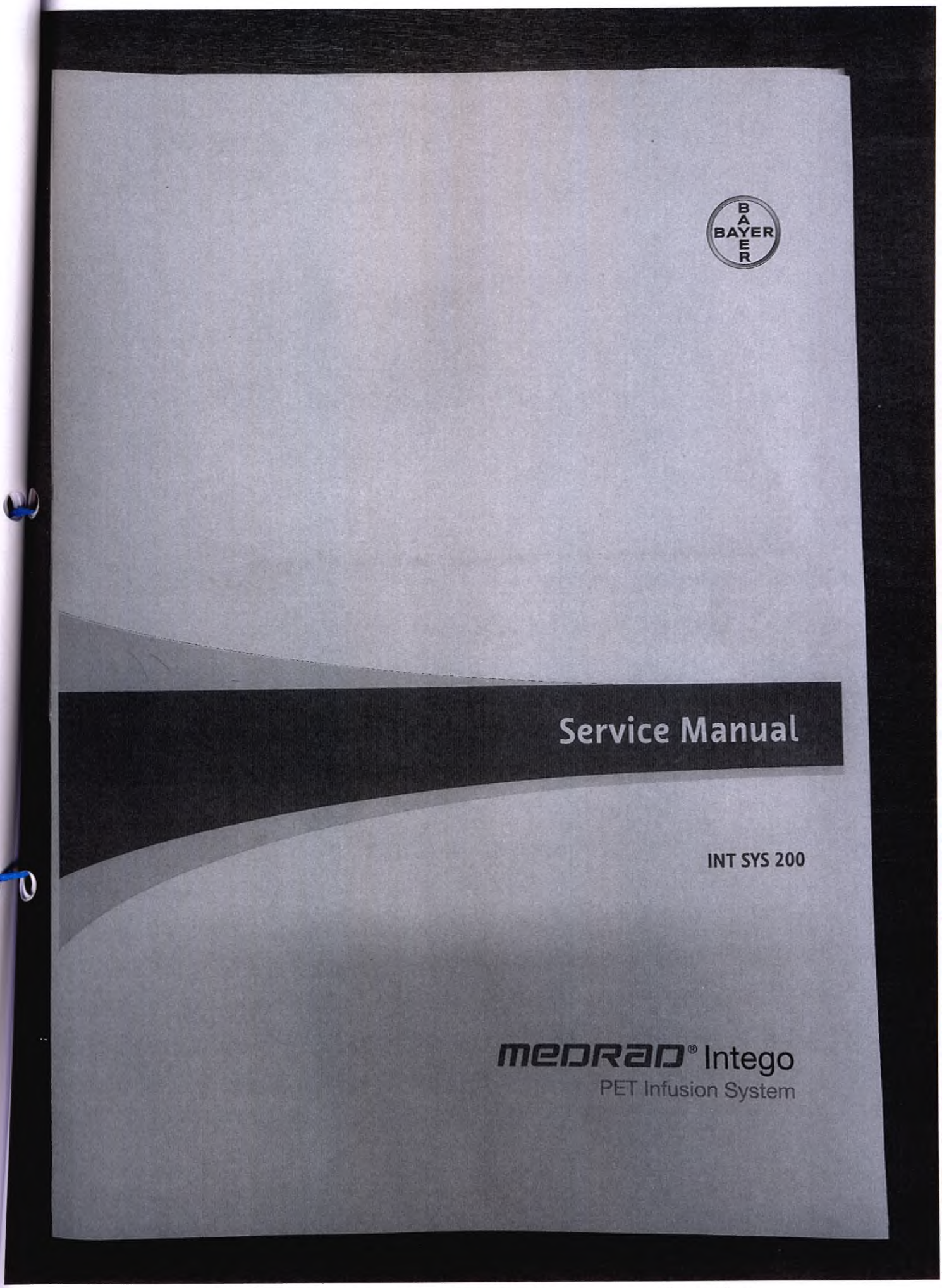


12. **Эквипотенциальный кабель**

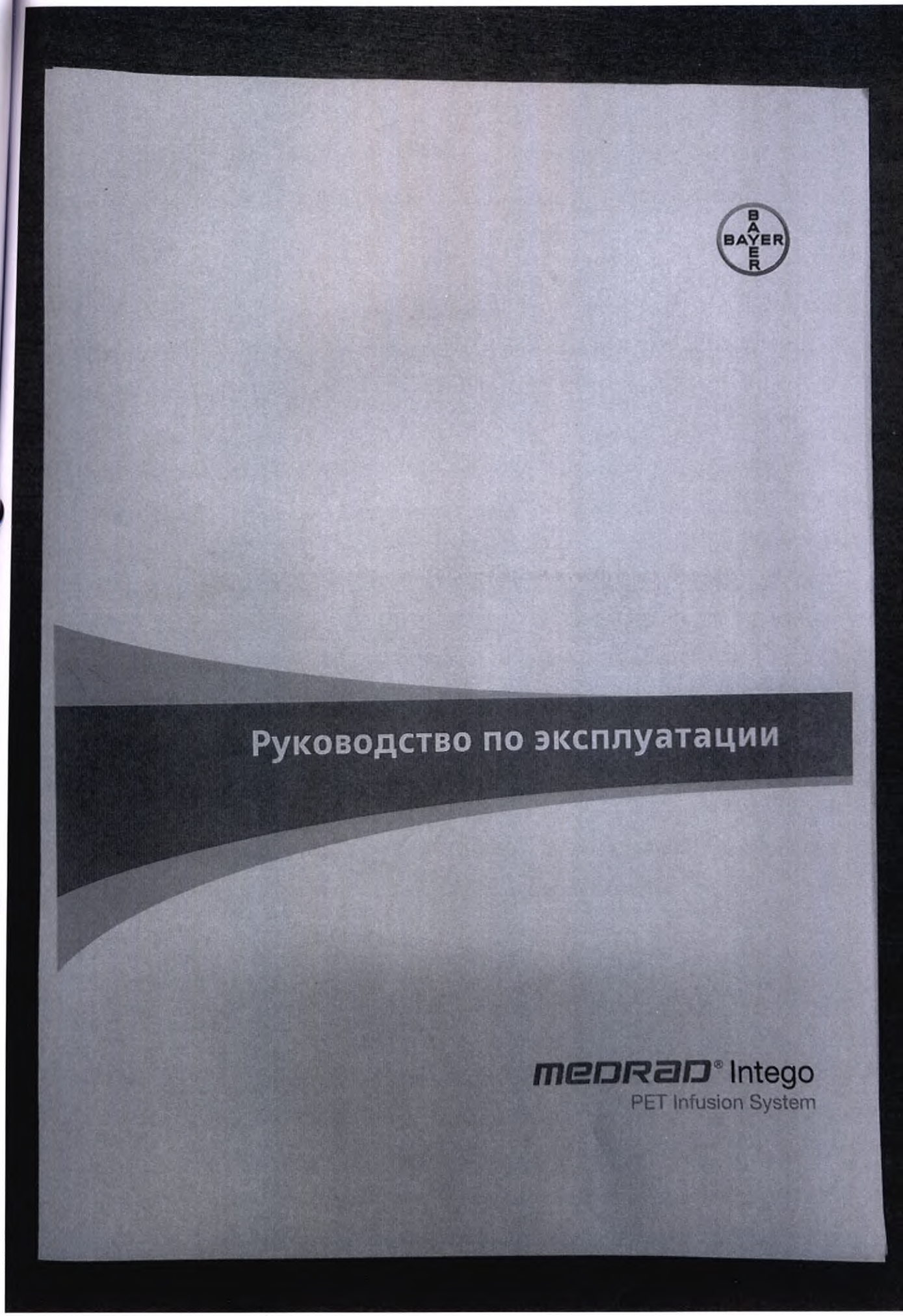
13. **Кабель электропитания**



14. **Держатель кабеля**



15. **Руководство по техническому обслуживанию, не более 4 шт.**



16. **Руководство по эксплуатации, не более 4 шт**

MEDRAD® Intego
PET Infusion System

INT SYS 200
Installation Instructions CE 0086
60722319 Rev. C

Introduction

These instructions provide information for the installation of the MEDRAD® Intego PET Infusion System only and do not provide operation or safety related use information. Read all Warnings and Cautions thoroughly as provided in the MEDRAD® Intego Operation Manual before installing this device.

Installation shall be performed by a qualified Bayer HealthCare Services representative or authorized dealer.

UNITED STATES
Bayer Medical Care Inc.
1 Bayer Drive
Indianola, PA 15051-0780
U.S.A.
Phone: +1.412.767.2400
+1.800.633.7231
Fax: +1.412.767.4320

EUROPE
Bayer Medical Care B.V.
Horsterweg 24
6199 AC Maastricht Airport
The Netherlands
Phone: +31 (0) 43-3585601
Fax: +31 (0) 43-3658598

JAPAN
バイエル薬品株式会社
〒530-0001
大阪市北区梅田2-4-9
日本
電話: +81(0)6-6133-6250
Fax: +81(0)6-6344-2395

Definitions

The following are definitions of the terms WARNING, CAUTION and NOTE found throughout this document:

⚠ **WARNING:** Indicates that the information is a warning. Warnings advise of circumstances that could result in injury or death to the patient or operator. Read and understand the warnings before operating the system.

⚠ **CAUTION:** Indicates that the information is a caution. Cautions advise of circumstances that could result in damage to the device or improper functioning of the device. Read and understand the cautions before operating the system.

NOTE: Indicates that the information that follows is additional important information or a tip.

Warnings, cautions and notes are located throughout this document, where applicable, and in the MEDRAD® Intego Operation Manual.

Installing the System

The following is a list of tools required for the uncrating and set-up of the system:

- Utility Knife
- 10 mm & 19 mm sockets and ratchet
- 4 mm & 5 mm Allen wrench
- Phillips Screwdriver
- Pliers or Vice Grips
- Electrical tape
- Cesium calibration source to be supplied and used by hospital
- Cobalt calibration source to be supplied and used by hospital
- FDG Linearity Check source to be supplied and used by hospital

Uncrating the System

NOTE: Uncrate the system at the loading dock.

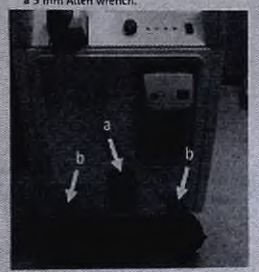
1. Cut the straps holding the cardboard sleeve with a utility knife.
2. Remove the ramp from the top of the cardboard sleeve and set it aside.
3. Remove the top foam and the boxes (accessories box and Ionization chamber) that are underneath the foam on top of the system. Remove both boxes and set aside.
4. Remove the cardboard sleeve from around the system.

5. Place the ramp next to the bottom of crate as shown.

6. On the floor of the crate next to the system is a covered compartment holding the ramp screws. Remove this cover and remove the two screws from inside the compartment. Install these screws into each side of the ramp where it overlaps the bottom of the crate.

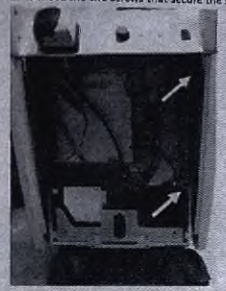
NOTE: The screws only need to be installed deep enough to prevent the ramp from moving.

7. Remove the rear cover to expose the brackets that secure the system to the shipping pallet.
   a. Unscrew the manual override knob.
   b. Remove the screws that secure the cable storage posts to the system using a 5 mm Allen wrench.



8. Remove the printer.
   a. Disconnect the printer cables.
   b. Remove the screws at the bottom of the mounting plate.
   c. Lift the printer off of the top mounting flange.

9. Remove panel on the right side of the system.
   a. Remove the two screws that secure the side panel to the rear of the system.

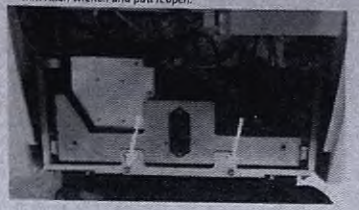


   b. Remove the two screws that secure the side panel to the front of the system.

10. Remove the mounting hardware from the front and rear of the system.
    a. Using a 19 mm socket and ratchet, remove the two mounting bolts from the front of the system.

    b. Using a 19 mm socket and ratchet, remove the mounting bolts that secure the rear mounting brackets to the pallet at the rear of the system.
    c. Using a 10 mm socket and ratchet, remove the bolts that secure the mounting brackets to the rear of the system.

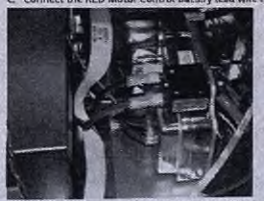
11. Open the Service Tray and setup the batteries.
    a. Remove the 2 bottom screws from the bracket on the service tray using a 4 mm Allen wrench and pull it open.



    b. Install the fuses in the UPS Battery. The two fuses are in a plastic bag attached to the battery.

⚠ **WARNING: Fire hazard: Patient injury could result from using incorrect fuses.** To avoid an electrical fire, ensure that the correct type of fuse is used for replacement. The fuse must be replaced with a Type F 250 V, 5 A fuse by qualified personnel only.

    c. Connect the RED Motor Control Battery lead wire into the circuit breaker.



    d. Leaving the service tray open at this time will help in the installation of the Ion chamber.

⚠ **CAUTION:** Component damage may occur if not installed properly. Ensure all connections are secure and do not get pinched when closing the service tray; DO NOT over tighten.

18. Краткое руководство по установке аппарата для введения раствора от источника, не более ш

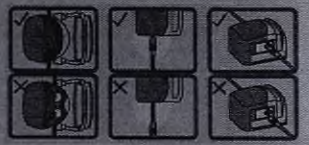
Quick SAS Installation Guide

Pressing the red stop button will stop all fluid movements during any portion of the procedure.
E.g. When infusing a patient, pressing the red stop button will pause the infusion. It will not discontinue the procedure.

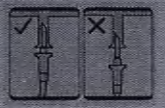
WARNING: Air embolism hazard. Injury or death can result from infusing air.
Ensure air is expelled from the disposable sets before beginning infusion.

✓ **Verify tubing is lying flat prior to closing shielded vault lid.**

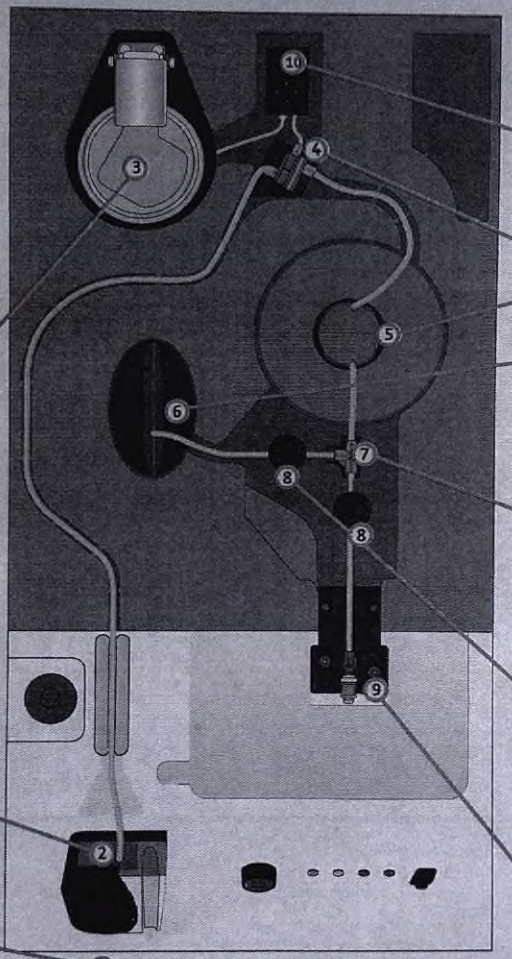
3. **Insert needle cartridge clip properly.**
Tube side of clip should face toward black RP pump.



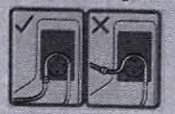
2. **Install tubing through saline pump.**
Center tubing on rollers. Place luer against pump. Center tubing in door.



1. **Fully spike saline bag.**



After installing RP vial:

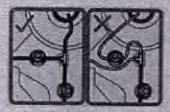


10. **Place collar properly.**
Ensure that the collar rests immediately outside the pump, opposite the hinge.

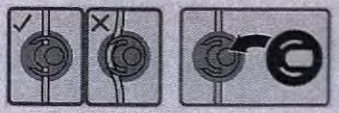
4. **Place confluence into the holder.**

5. **Verify that the dose calibrator is empty before installing the coil.**

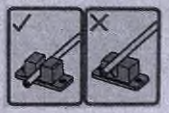
6. **Insert waste container into the shielded waste storage.**



7. **Place tubing T-Connector into the holder.**
Note the orientation of the triangle in one corner.



8. **Insert tubing into pinch valves.**
Depress pinch valve button, insert tubing fully, release button. Ensure tubing is straight. **Install pinch valve covers onto pinch valves, if available.**



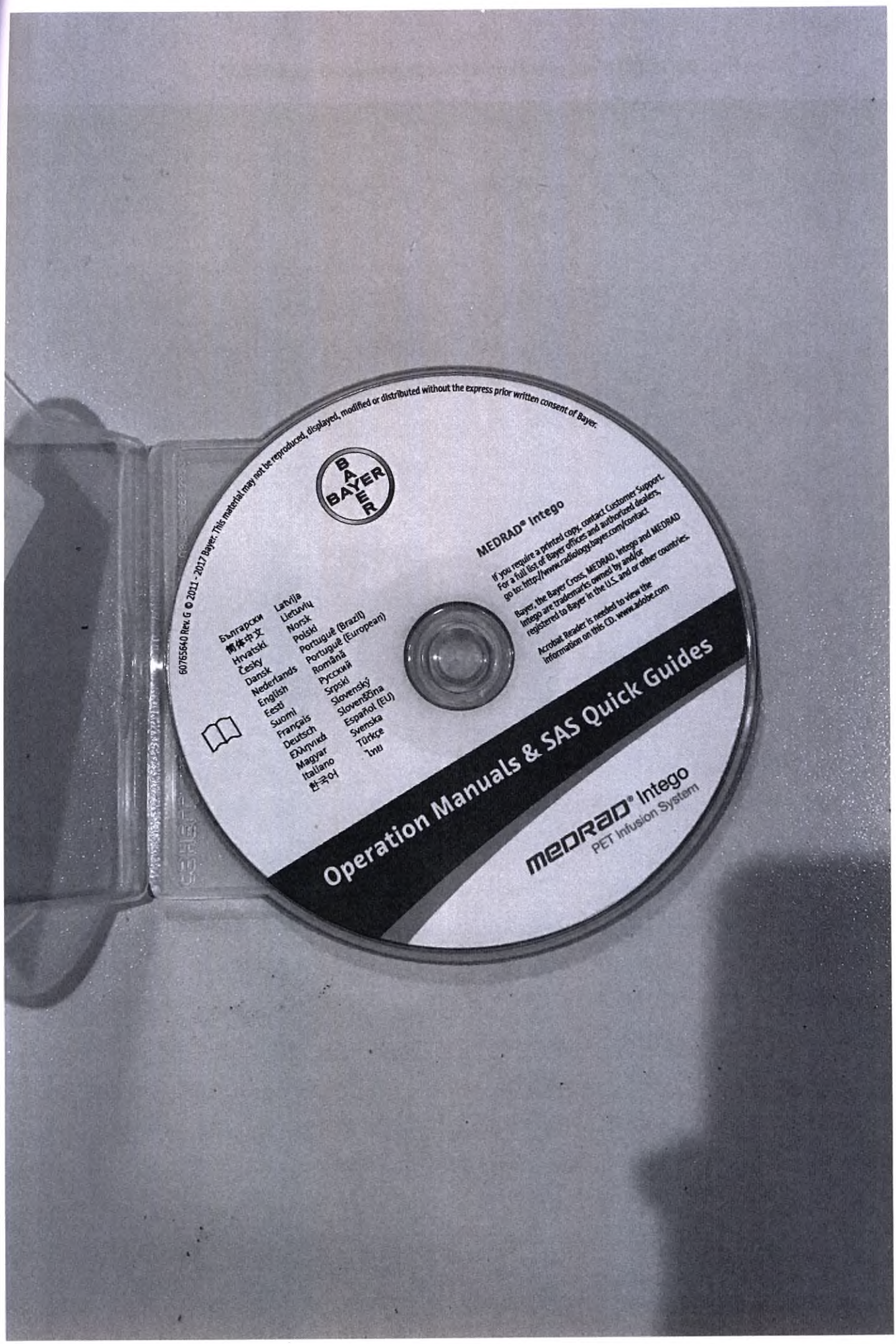
9. **Fully seat tubing into air detector.**

BAYER

MEDRAD® Intego
PET Infusion System

CE 0086 April 8, 2015 60765535 Rev. C

63744
04.10.2019



19. **Многоязычная эксплуатационная документация на диске, не более 2 шт**

Addendum: UL, ISO 7000 Symbol 1641, ISO Safety Sign 7010-M002, and ISO 7000 Symbol 1321B

BAYER

	English	日本語	Deutsch	Français	Italiano
	Description	説明	Beschreibung	Description	Descrizione
CLASSIFIED c UL US	Medical - General Medical Equipment As to Electrical Shock, Fire and Mechanical Hazards Only In Accordance with ANSI/AAMI ES60601-1 (2005, 3rd Ed.) CAN/CSA-C22.2 No. 60601 (2008), IEC 60601-1 3rd Ed.	医療 - 一般的な医療用装置 感電、火災、機械的な危険のおそれあり ANSI/AAMI ES60601-1（2005、第3版）CAN/CSA-C22.2 第60601（2008）、IEC 60601-1 第3版に準拠	Medizinisch - Allgemeine Medizinprodukte in Bezug auf Stromschlag, Brand und mechanische Gefahren nur gemäß ANSI/AAMI ES60601-1 (2005, 3. Fassung) CAN/CSA-C22.2 Nr. 60601 (2008), IEC 60601-1:3. Fassung	Médical - Équipement médical général Concernant les risques mécaniques, d'électrocution et d'incendie seulement Conformément à la norme ANSI/AAMI ES60601-1 (2005, 3e édition) CAN/CSA-C22.2 n° 60601 (2008), CEI 60601-1:3e édition	[illegible] medici - Apparecchiature mediche generali Solo per scosse elettriche, incendio e rischi meccanici In conformità con ANSI/AAMI ES60601-1 (2005, 3a ed.) CAN/CSA-C22.2 N. 60601 (2008), IEC 60601-1:3a ed.
CLASSIFIED c UL US	Medical Equipment As To Electrical Shock, Fire And Mechanical Hazards Only In Accordance With UL 60601-1, CAN/CSA-C22.2 No. 601.1, IEC 60601-1	医療用装置 感電、火災、機械的な危険のおそれあり UL 60601-1、CAN/CSA-C22.2 第601.1、IEC 60601-1に準拠	Medizinprodukte In Bezug auf Stromschlag, Brand und mechanische Gefahren nur gemäß UL 60601-1, CAN/CSA-C22.2 No. 601.1, IEC 60601-1	Équipement médical Concernant les risques mécaniques, d'électrocution et d'incendie seulement Conformément aux normes UL 60601-1, CAN/CSA-C22.2 n° 601.1, CEI 60601-1	Apparecchiature mediche Solo per scosse elettriche, incendio e rischi meccanici In conformità con UL 60601-1, CAN/CSA-C22.2 N. 601.1, IEC 60601-1
	Consult instructions for use	取扱説明書参照	Gebrauchsanleitung lesen	Consultez le mode d'emploi	Consultare le istruzioni per l'uso
	See accompanying documentation. This symbol indicates the user shall refer to the instructions-for-use to ensure safe operation.	付属の資料をご参照ください。この標識が示されている場合は、安全にお使いいただくために取扱説明書を参照してください。	Siehe beiliegende Dokumentation. Dieses Symbol weist den Benutzer darauf hin, dass für den sicheren Betrieb die Gebrauchsanweisung beachtet werden muss.	Consultez la documentation jointe. Ce symbole indique que l'utilisateur doit se référer au mode d'emploi pour utiliser le système en toute sécurité.	Vedere la documentazione di accompagnamento. Questo simbolo indica che l'utente deve fare riferimento alle istruzioni per l'uso per garantire un funzionamento sicuro.
	The maximum weight ("XX") of the injector system and accessories during normal use. (Applicable for systems certified to IEC 60601-1 3rd Edition Amendment 1.)	通常使用でのインジェクターシステムと付属品の総重量("XX")。(IEC 60601-1 3rd Edition Amendment 1に認定されたシステムに適用します)	Maximalgewicht ("XX") des Injektorsystems und Zubehörs während der normalen Verwendung. (Gilt für die nach IEC 60601-1, 3. Fassung, Änderung 1, zertifizierten Systeme)	Poids maximum (« XX ») du système d'injection et des accessoires dans le cadre d'une utilisation normale. (Applicable aux systèmes certifiés conformes à IEC 60601-1, 3e édition, amendement 1.)	Peso massimo ("XX") del sistema di iniezione e degli accessori durante il normale utilizzo (per i sistemi certificati secondo la norma IEC 60601-1 3a edizione, emendamento 1)

	Ελληνικά	Svenska	Nederlands	Dansk	Suomi
	Περιγραφή	Beskrivning	Beschrijving	Beskrivelse	Kuvaus
CLASSIFIED c UL US	Ιατρικός - Γενικός ιατρικός εξοπλισμός Όσον αφορά τους κινδύνους ηλεκτροπληξίας και πυρκαγιάς, καθώς και τους μηχανικούς κινδύνους μόνο σύμφωνα με το πρότυπο ANSI/AAMI ES60601-1 (2005, 3η έκδ.) CAN/CSA-C22.2 αρ. 60601 (2008), IEC 60601-1:3η έκδ.	Medicin - Allmän medicinteknisk utrustning Gällande elstötar, brand och mekaniska risker, endast i enlighet med ANSI/AAMI ES60601-1 (2005, 3:e utg.) CAN/CSA-C22.2 No. 60601 (2008), IEC 60601-1:3:e utg.	Medisch - Algemene medische apparatuur Alleen met betrekking tot elektrische schokken, brand en mechanische gevaren in overeenstemming met ANSI/AAMI ES60601-1 (2005, 3rd Ed.) CAN/CSA-C22.2 nr. 60601 (2008), IEC 60601-1:3rd Ed.	Medicinsk - Generelt medicinsk udstyr. Kun med hensyn til elektrisk stød, brand og mekaniske farer i overensstemmelse med ANSI/AAMI ES60601-1 (2005, 3. udg.) CAN/CSA-C22.2 Nr. 60601 (2008), IEC 60601-1:3. udg.	Lääketieteellinen – yleiset lääkinnälliset laitteet Sähköisku-, tulipalo- ja mekaanisten vaaratekijöiden suhteen vain standardin ANSI/AAMI ES60601-1 mukaisesti (2005, 3. painos) CAN/CSA-C22.2 nro 60601 (2008), IEC 60601-1:3. painos
CLASSIFIED c UL US	Ιατρικός εξοπλισμός Όσον αφορά τους κινδύνους ηλεκτροπληξίας και πυρκαγιάς, καθώς και τους μηχανικούς κινδύνους μόνο σύμφωνα με τα πρότυπα UL 60601-1, CAN/CSA-C22.2 αρ. 601.1, IEC 60601-1	Medicinsk utrustning Endast gällande elektrisk stöt, brand och mekaniska faror I enlighet med UL 60601-1, CAN/CSA-C22.2 nr 601.1, IEC 60601-1	Medische apparatuur Alleen met betrekking tot elektrische schokken, brandgevaar en mechanische risico's Conform UL 60601-1, CAN/CSA-C22.2 nr. 601.1, IEC 60601-1	Medicinsk udstyr Kun vedrørende elektrisk stød, brand og mekaniske farer I overensstemmelse med UL 60601-1, CAN/CSA-C22.2 nr. 601.1, IEC 60601-1	Lääkinnälliset laitteet Sähköisku-, palo- ja mekaanisten vaaratekijöiden osalta standardien UL 60601-1, CAN/CSA-C22.2 No. 601.1, IEC 60601-1 mukaan
	Συμβουλευτείτε τις οδηγίες χρήσεως	Se bruksanvisningen	Raadpleeg de gebruiksaanwijzing	Læs brugsanvisningen	Lue käyttöohjeet
	Ανατρέξτε στο συνοδευτικό υλικό τεκμηρίωσης. Το σύμβολο αυτό υποδηλώνει ότι ο χρήστης θα πρέπει να ανατρέξει στις οδηγίες χρήσης, ώστε να διασφαλιστεί η ασφαλής λειτουργία.	Se den medföljande dokumentationen. Denna symbol anger att användaren ska läsa bruksanvisningen för säker användning av utrustningen.	Raadpleeg de bijbehorende documentatie. Dit symbool geeft aan dat de gebruiker de gebruiksaanwijzing moet raadplegen om een veilige werking te garanderen.	Se den medfølgende dokumentation. Dette symbol angiver, at brugeren skal se brugsanvisningen for at sikre en sikker anvendelse.	Katso mukana tulevia asiakirjoja. Tämä symboli ilmaisee, että käyttäjän on luettava käyttöohjeet turvallisen käytön varmistamiseksi.
	Μέγιστο βάρος («XX») του συστήματος εγχυτήρα και των βοηθητικών εξαρτημάτων κατά τη φυσιολογική χρήση. (Ισχύει για τα συστήματα που είναι πιστοποιημένα κατά το πρότυπο IEC 60601-1, 3η έκδοση, τροποποίηση 1.)	Maximal vikt ("XX") för injektorsystemet och tillbehör under normalt bruk. (Gäller alla system som certifierats enligt IEC 60601-1, 3:e utgåvan, ändring 1.)	Het maximumgewicht ("XX") van het injectorsysteem en accessoires tijdens normaal gebruik. (Van toepassing op systemen met certificatie conform IEC 60601-1, 3e editie, amendement 1.)	Maks. vægt ("XX") af injektionssystemet og tilbehør under normal brug. (Relevant for systemer, der er certificeret til IEC 60601-1 3. udgave, ændring 1).	Injektorijärjestelmän ja lisälaitteiden maksimipaino ("XX") normaalin käytön aikana. (Koskee järjestelmiä, jotka on sertifioitu standardin IEC 60601-1 3. painos, lisäys 1 mukaisesti.)

	Português	Norsk	繁體中文	简体中文	Русский
	Descrição	Beskrivelse	說明	说明	ОПИСАНИЕ
CLASSIFIED c UL US	Equipamento médico geral Apenas sobre risco de choque elétrico e de incêndio. De acordo com ANSI/AAMI ES60601-1 (2005, 3ª Ed.) CAN/CSA-C22.2 nº 60601 (2008), IEC 60601-1:3ª Ed.	Medisinsk - Generelt medisinsk utstyr Vedrørende elektrisk støt, brann og mekaniske farer bare i henhold til ANSI/AAMI ES60601-1 (2005, 3. utg.) CAN/CSA-C22.2 Nr. 60601 (2008), IEC 60601-1, 3. utg.	醫療 - 一般醫療設備 僅有關電擊、火災和機械危害方面 符合 ANSI/AAMI ES60601-1 (2005 第 3 版)、CAN/CSA-C22.2 No. 60601 (2008)、IEC 60601-1 第 3 版的標準	医疗 - 一般医疗设备 仅针对电击、火灾和机械危险 符合 ANSI/AAMI ES60601-1（2005 第 3 版）、CAN/CSA-C22.2 No. 60601 (2008)、IEC 60601-1 第 3 版的标准	Медицинское — общемедицинское оборудование Только относительно риска поражения электрическим током, возгорания и механического воздействия В соответствии с ANSI/AAMI ES60601-1 (2005 г., 3-е издание) CAN/CSA-C22.2 № 60601 (2008 г.), МЭК 60601-1:3-е изд.
CLASSIFIED c UL US	Equipamento médico Somente em relação a perigo de descarga elétrica, de incêndio e mecânico Em conformidade com UL 60601-1, CAN/CSA-C22.2 nº 601.1, IEC 60601-1	Medisinsk utstyr Kun når det gjelder elektrisk støt, brann og mekanisk fare I samsvar med UL 60601-1, CAN/CSA-C22.2 No. 601.1, IEC 60601-1	醫療設備 僅有關電擊、火災和機械危害方面 符合 UL 60601-1、CAN/CSA-C22.2 No. 601.1、IEC 60601-1 的標準	医疗设备 仅针对电击、火灾和机械危险 符合 UL 60601-1、CAN/CSA-C22.2 No. 601.1、IEC 60601-1 的标准	Медицинское оборудование Только относительно риска поражения электрическим током, возгорания и механического воздействия В соответствии с UL 60601-1, CAN/CSA-C22.2 № 601.1, IEC 60601-1
	Ver as instruções de uso	Se bruksanvisningen	請參閱使用說明	请参阅使用说明	Обратитесь к инструкции по эксплуатации
	Consulte a documentação em anexo. Este símbolo indica que o usuário deve consultar as instruções de uso para garantir uma operação segura.	Se vedlagte dokumentasjon. Dette symbolet viser at brukeren skal se på bruksanvisningene for å sikre trygg bruk.	請參閱隨附文件。此符號表示使用者應參閱操作指示以確保操作安全。	请参阅随附文档。此符号表示用户应参阅使用说明以确保安全操作。	См. сопроводительную документацию. Этот символ указывает пользователю на необходимость обращения к инструкции по эксплуатации для обеспечения безопасного выполнения работ.
	O peso máximo do sistema injetor e seus acessórios durante o uso normal é de ("XX"). (Aplicável para sistemas certificados conforme a norma IEC 60601-1 3ª Edição ou Adendo 1.)	Maksimal vekt ("XX") av injeksjonssystemet og tilbehør under normal bruk. (Gjelder for systemer som er sertifisert til IEC 60601-1, 3. utgave, endring 1.)	正常使用時注射系統和配件的最大重量（「XX」）。(適用於通過 IEC 60601-1 第三版修訂版 1 認證的系統。)	正常使用时注射系统和附件的最大重量（"XX"）。(适用于通过 IEC 60601-1 第 3 版修正案 1 认证的系统。)	Максимальный вес («XX») инъекционной системы и принадлежностей при обычном использовании. (Применимо к системам, сертифицированным по стандарту IEC 60601-1, 3-е изд. с поправкой 1.)

304393 / Rev. F

21. **Функция «Рабочий список пациентов» (WLIST)**

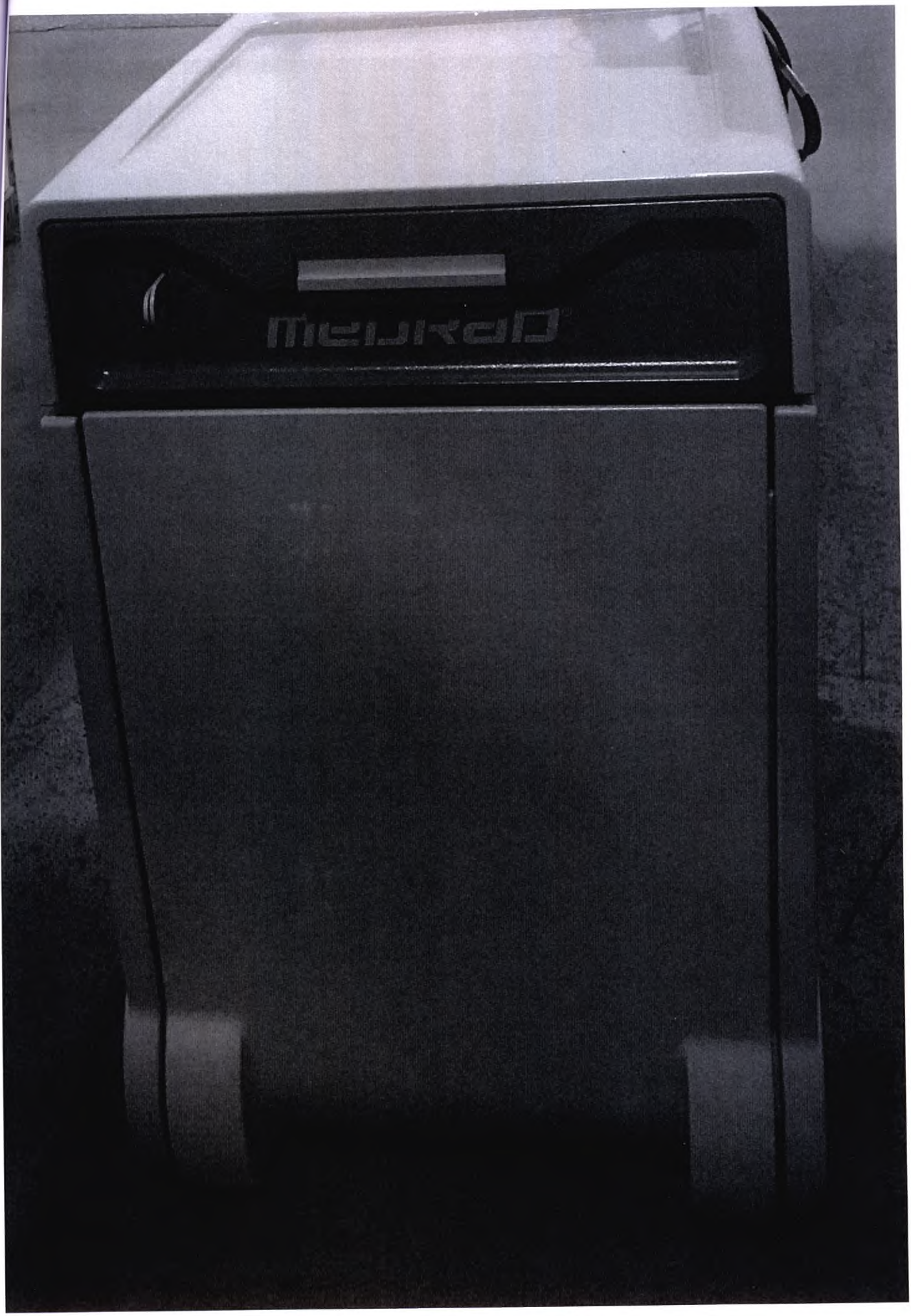
N/A

22. **Функция «Отчет о результатах инфузии, отправка на PACS-сервер» (IRPACS)**

N/A

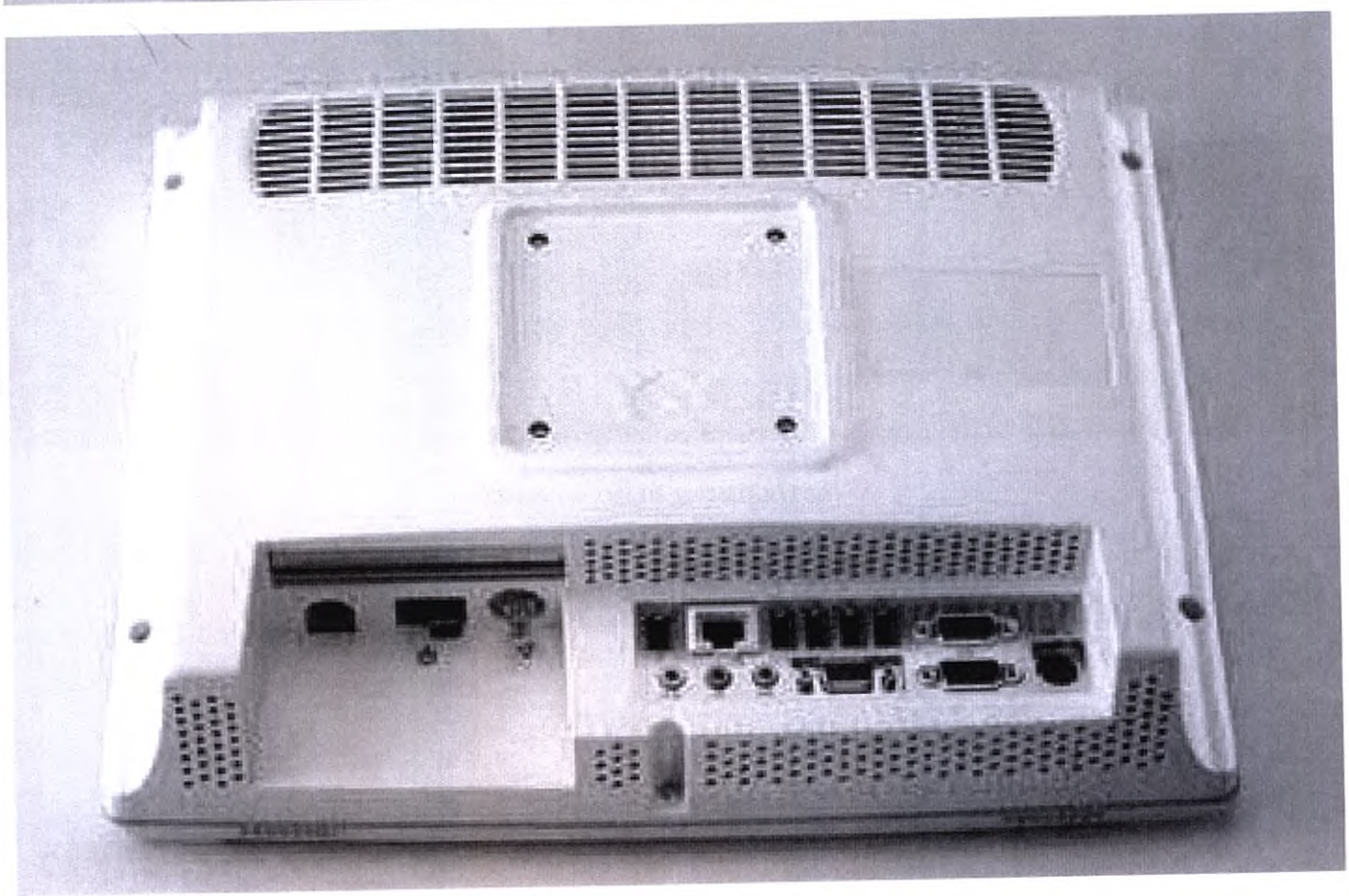
23. **Функция «Отчет о дозе облучения, отправка на PACS-сервер» (RDPACS)**

N/A

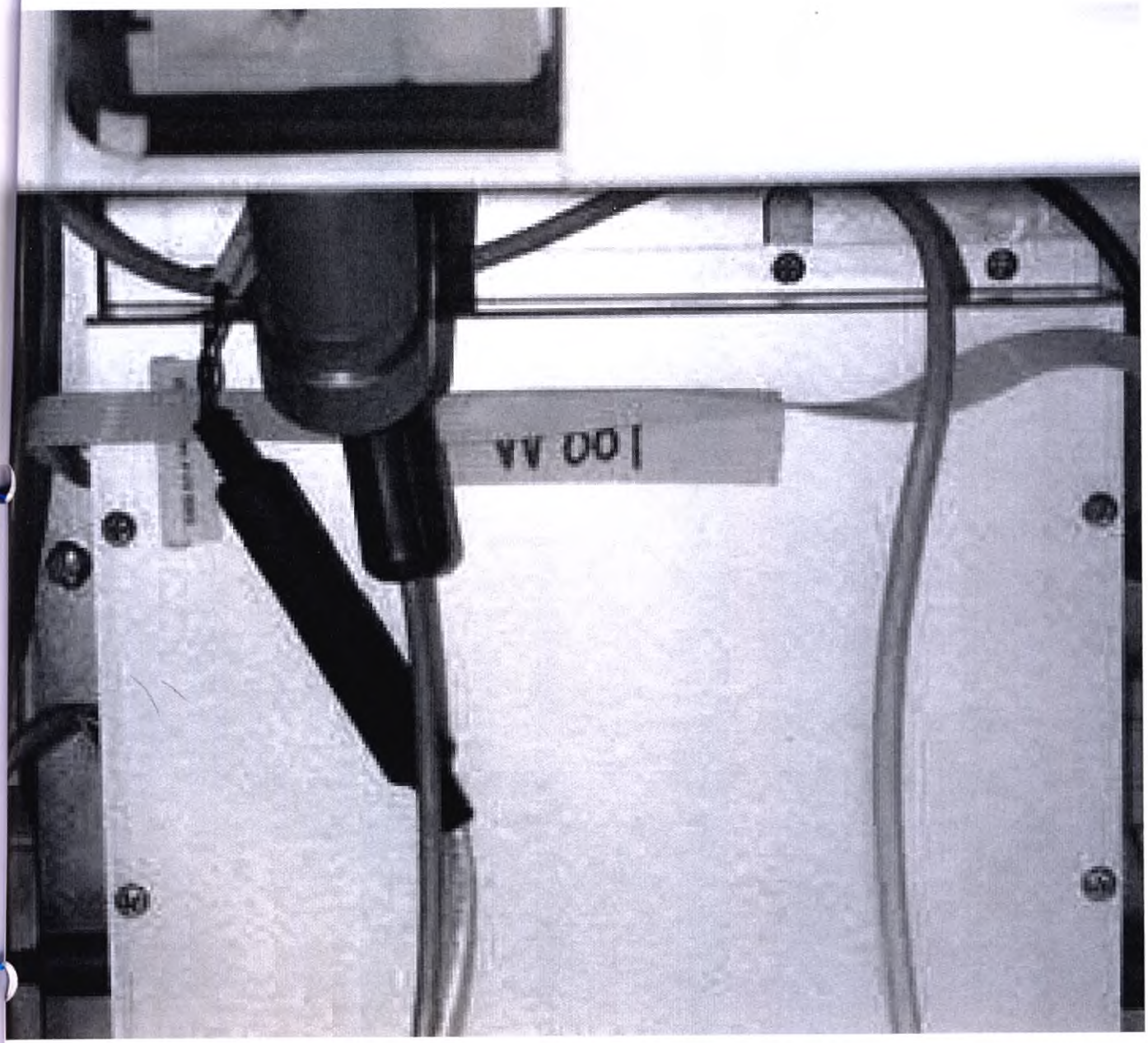


24. **Съёмная крышка передней панели**

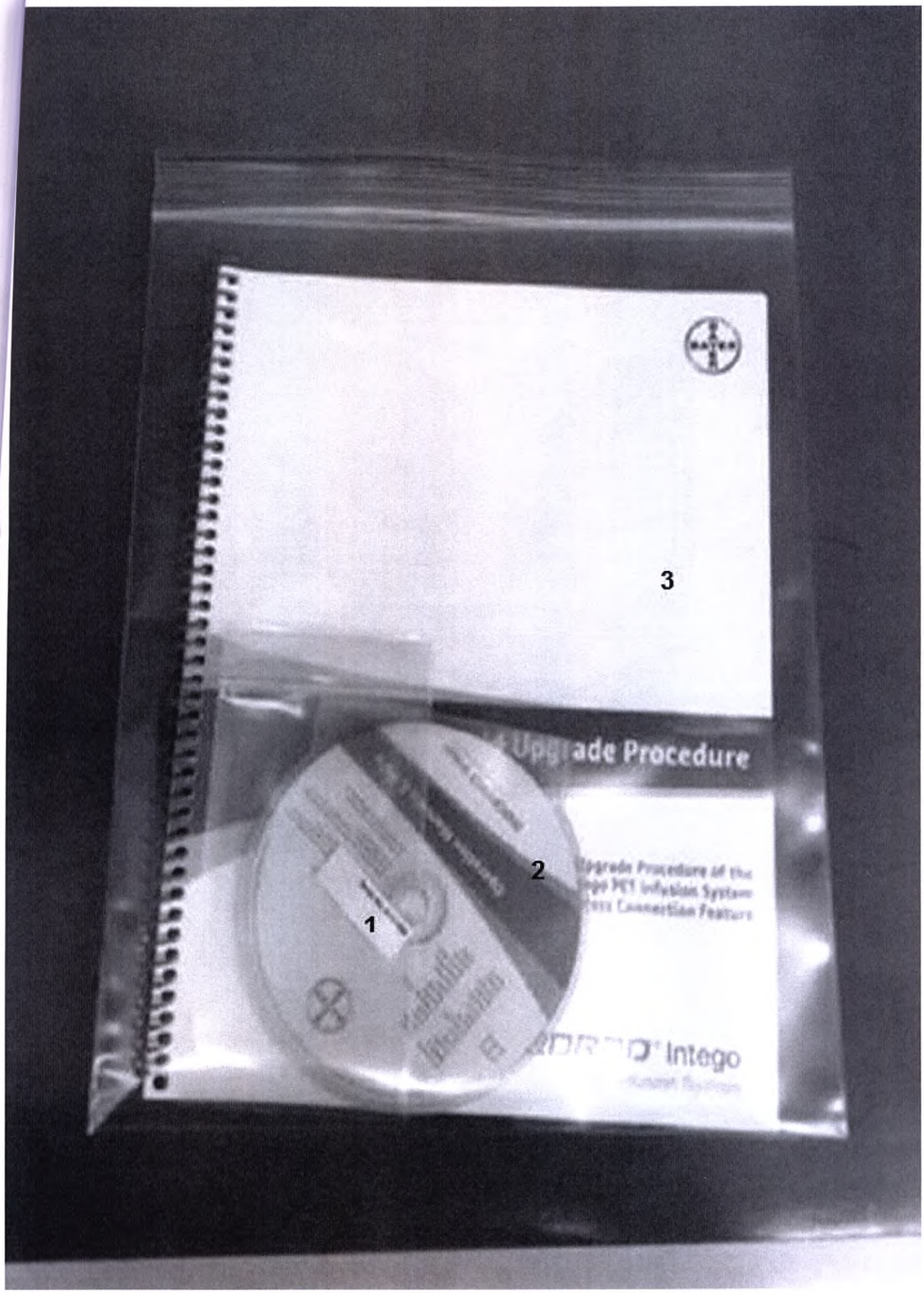
25. **Набор для модернизации системы.**



Дисплей



Одноплатный компьютер



1- Этикетка с номером обновленной детали. 2 – Руководство по обновлению функции беспроводного соединения. 3 - Руководство по установке модуля беспроводной связи MEDRAD Intego

Упаковка комплектующих и принадлежностей системы

Транспортная упаковка системы

Производитель
Байер Медикал Кэа Инк., США

Импортер на территорию России:
АО «БАЙЕР» Бизнес-юнит
«Радиология», 107113,
3-я Рыбинская ул., д.18, стр.2,
Москва, Россия
тел.: +7 495 231 1200
www.bayer.ru

РУ № ФСЗ 2012/13542
от

Собрано в США

86823063 Rev.A

Примечание: Каждый стикер на русском языке, помимо информации, представленной на макете, будет содержать наименование МИ в соответствии с РУ.

Макет маркировки транспортной упаковки и системы на русском языке