Фотографии медицинского изделия:

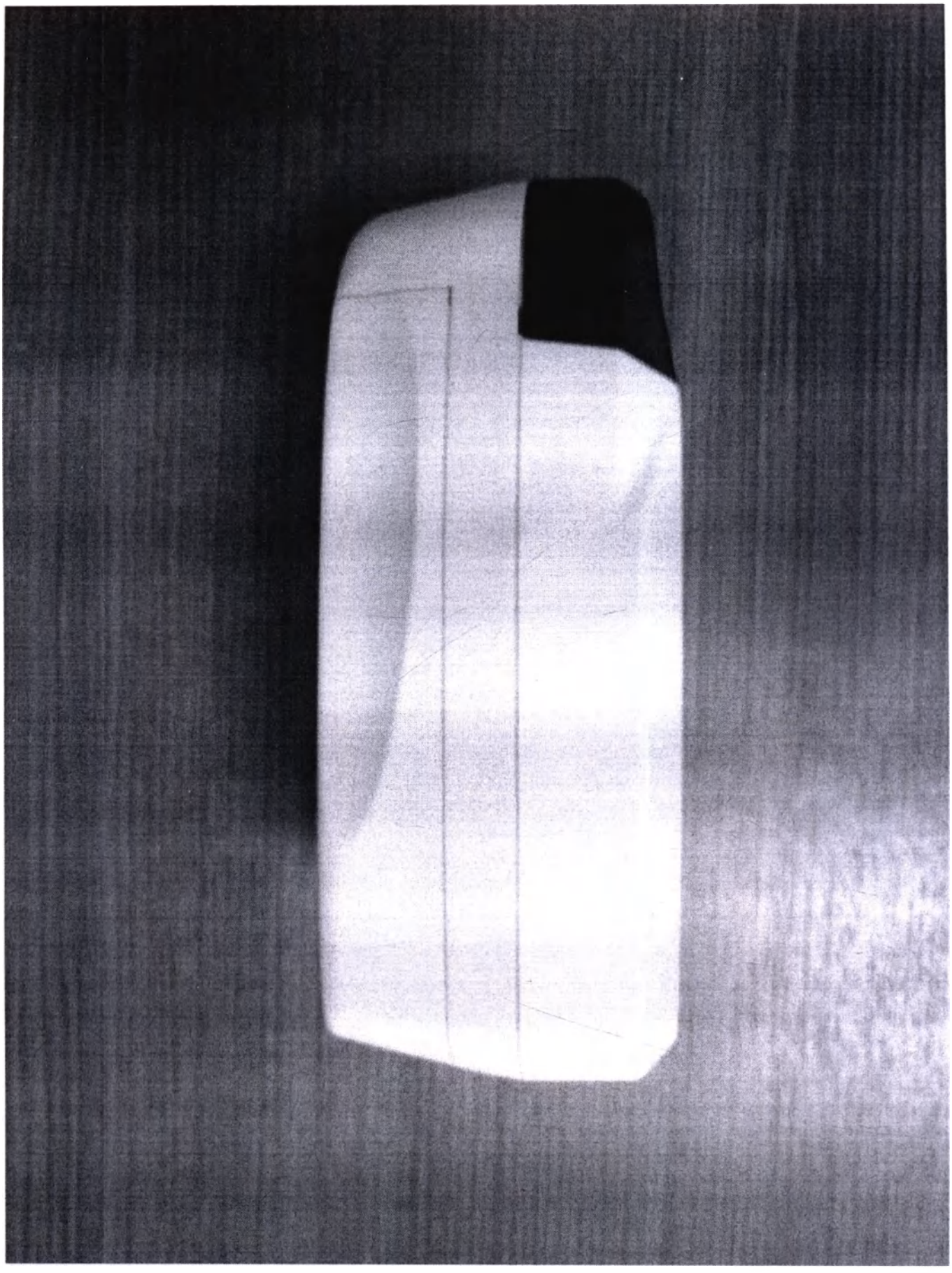
«Портативный ручной монитор окиси азота NObreath в выдыхаемом воздухе, модель NOBreath V2 с принадлежностями»

производства «Бедфонт Сайентифик Лимитед», Великобритания / «Bedfont Scientific Limited», United Kingdom

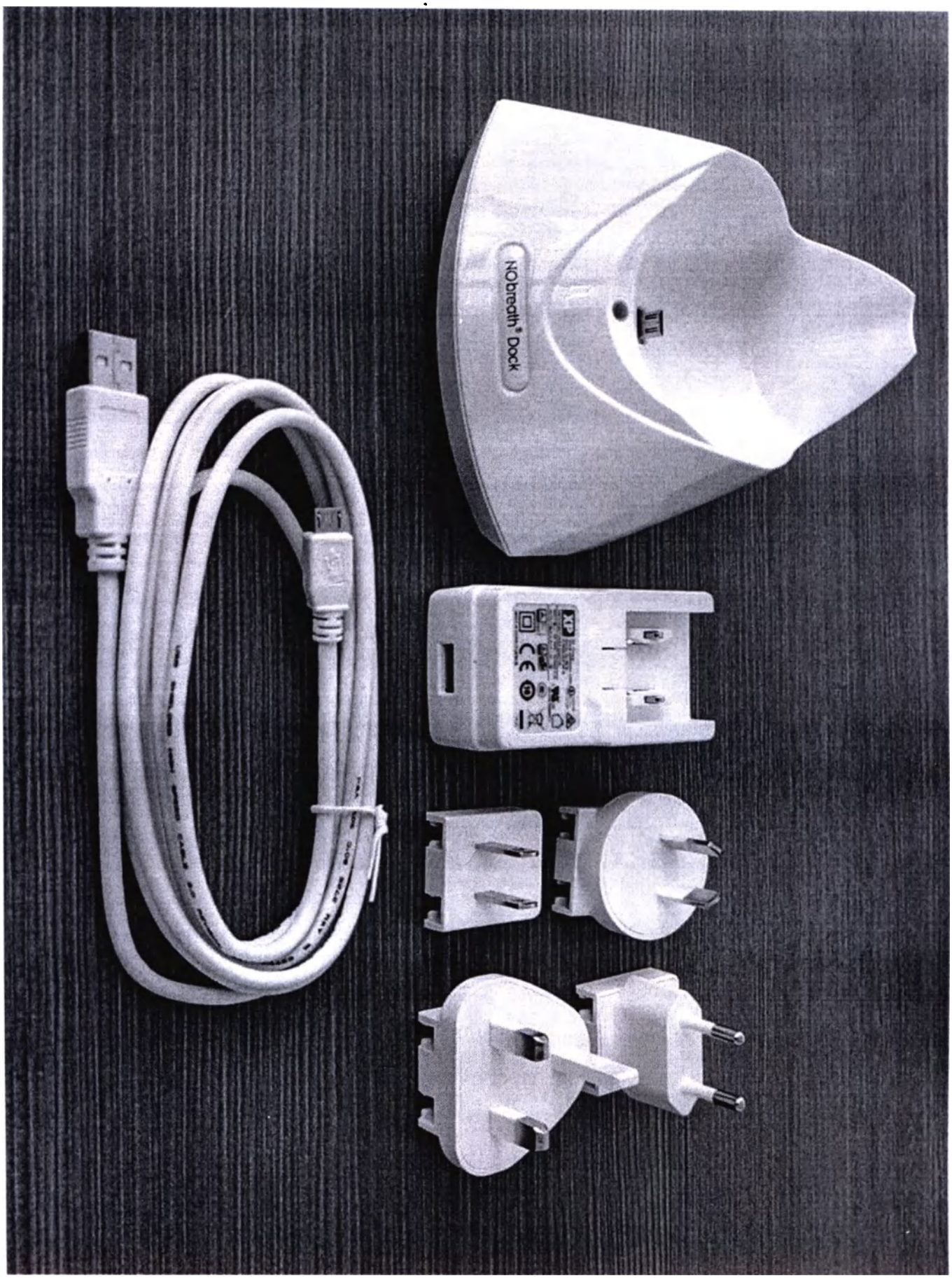
Генеральный директор
ООО «ИНФОМЕД» _____ / О.Н. Вязьмин /

"27" декабря 2021 г. М.П.

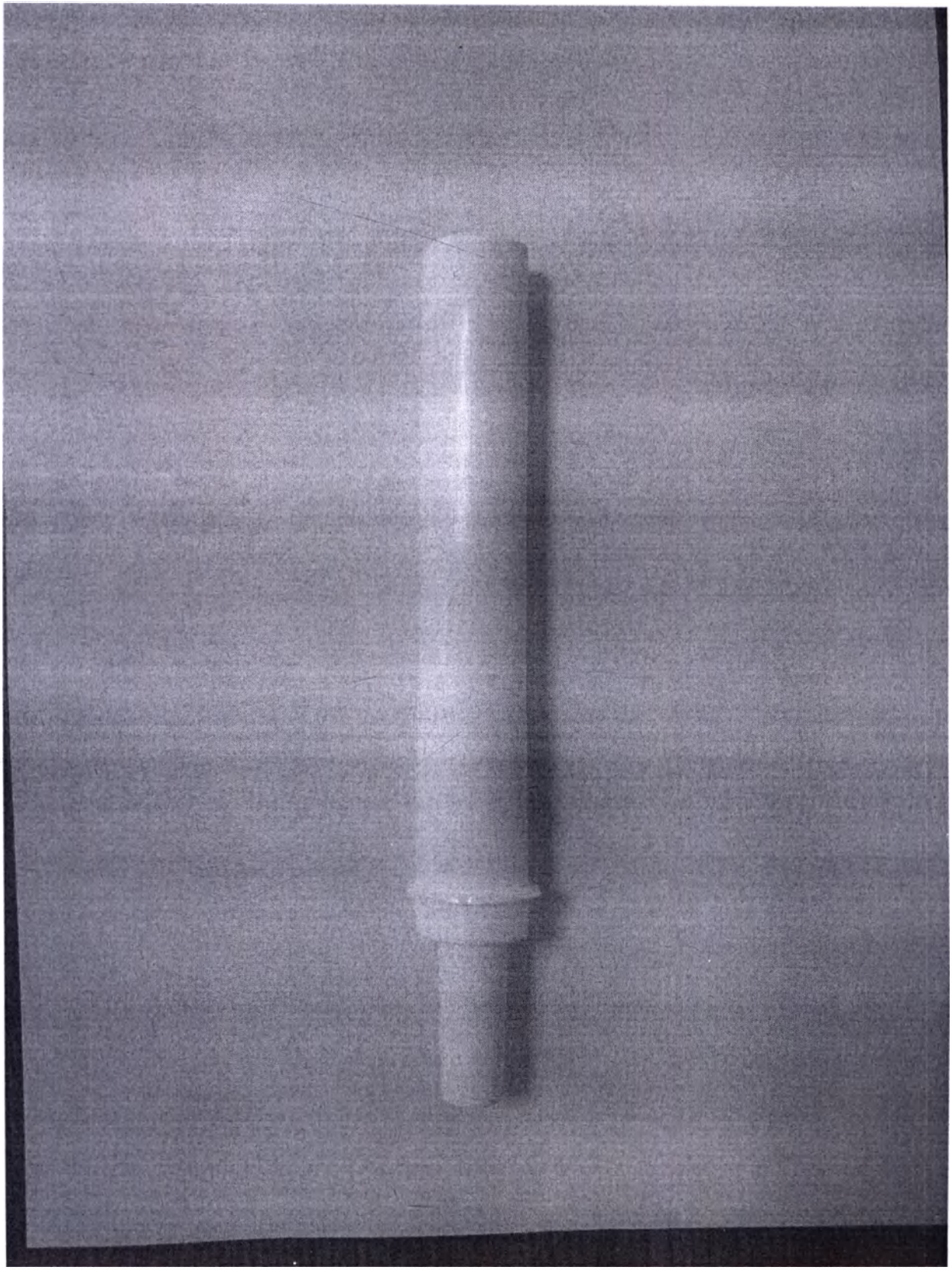
1. Портативный ручной монитор окиси азота NObreath модель NOBreath V2

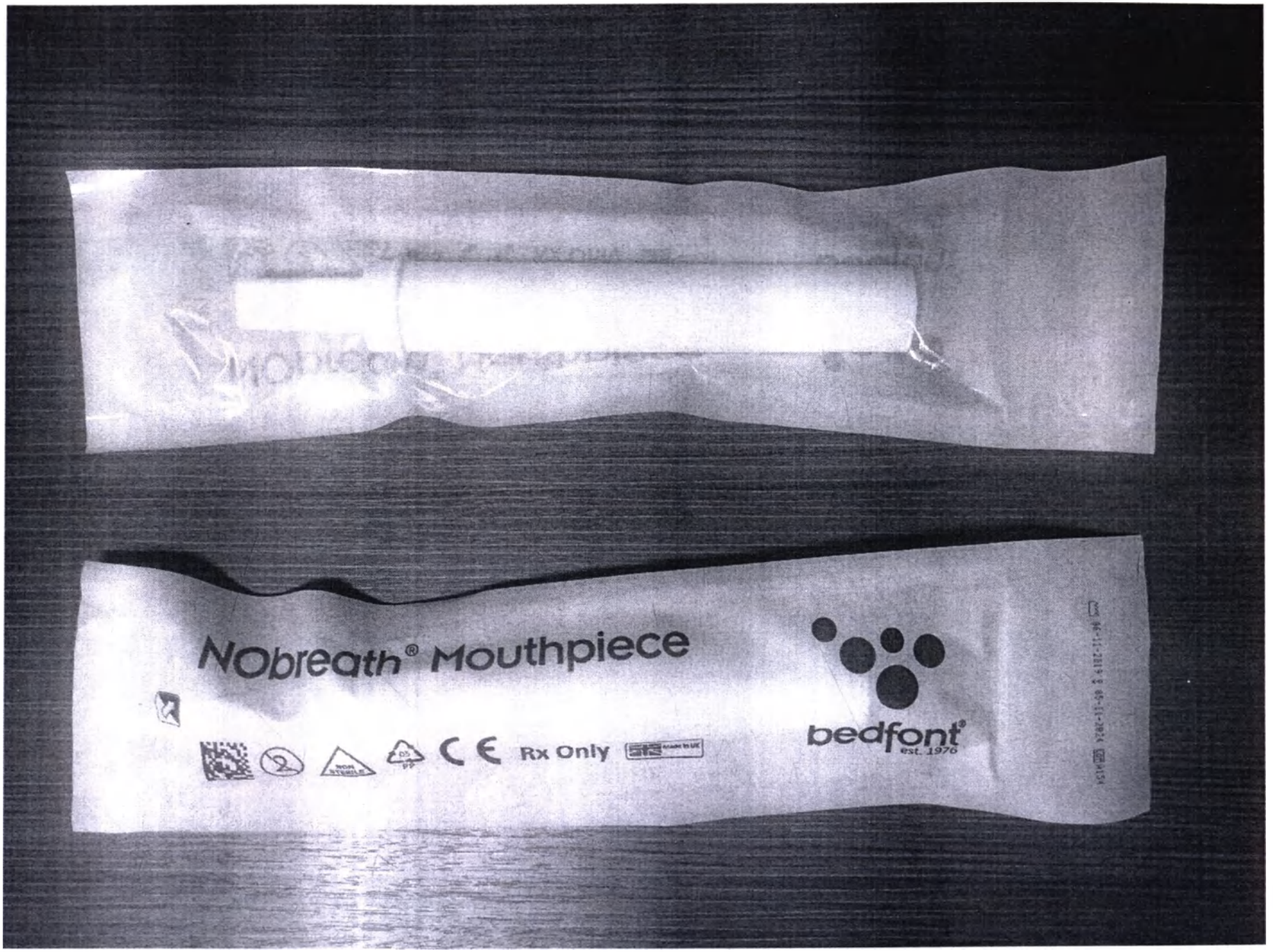


2. ДОК станция, включая адаптер питания со сменными вилками и кабель USB-microUSB.



3. Мунштуки V2.





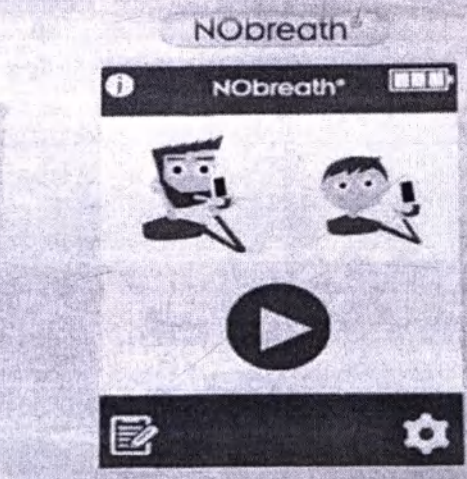
4. Руководство по быстрому запуску.

5. Руководство пользователя.

NObreath®

Монитор окиси азота (FeNO) в выдыхаемом воздухе

Руководство пользователя



CE 0086

Помогает в диагностике и лечении астмы, вдох за вдохом.

6. Инструкция по подготовке пациента

Patient preparation for FeNO breath testing with the NObreath®

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This is a suggested protocol, other protocols may be available.

24 hours prior to test

It is recommended to avoid alcohol consumption for 24 hours before the test.[1*]

12 hours prior to test

It is recommended to avoid smoking for 12 hours before the test.[1*]

It is recommended to avoid eating foods high in nitrates, this includes but is not limited to[2]:

- Rocket
- Spinach
- Lettuce
- Radish
- Beetroot
- Chinese cabbage
- Turnips
- Cabbage
- Green beans
- Leek
- Spring onion
- Cucumber
- Carrot
- Potato
- Garlic
- Sweet pepper
- Green pepper

Day of the test

On the day of the test, it is recommended to avoid any of the following 1 hour before the test[2]:

- Eating
- Drinking
- Smoking
- Exercise

NOTE: It is recommended to perform a FeNO test before spirometry[1].

Tips

- Do not inhale though the nose before exhaling through the mouthpieces
- Be seated and relaxed when taking the test

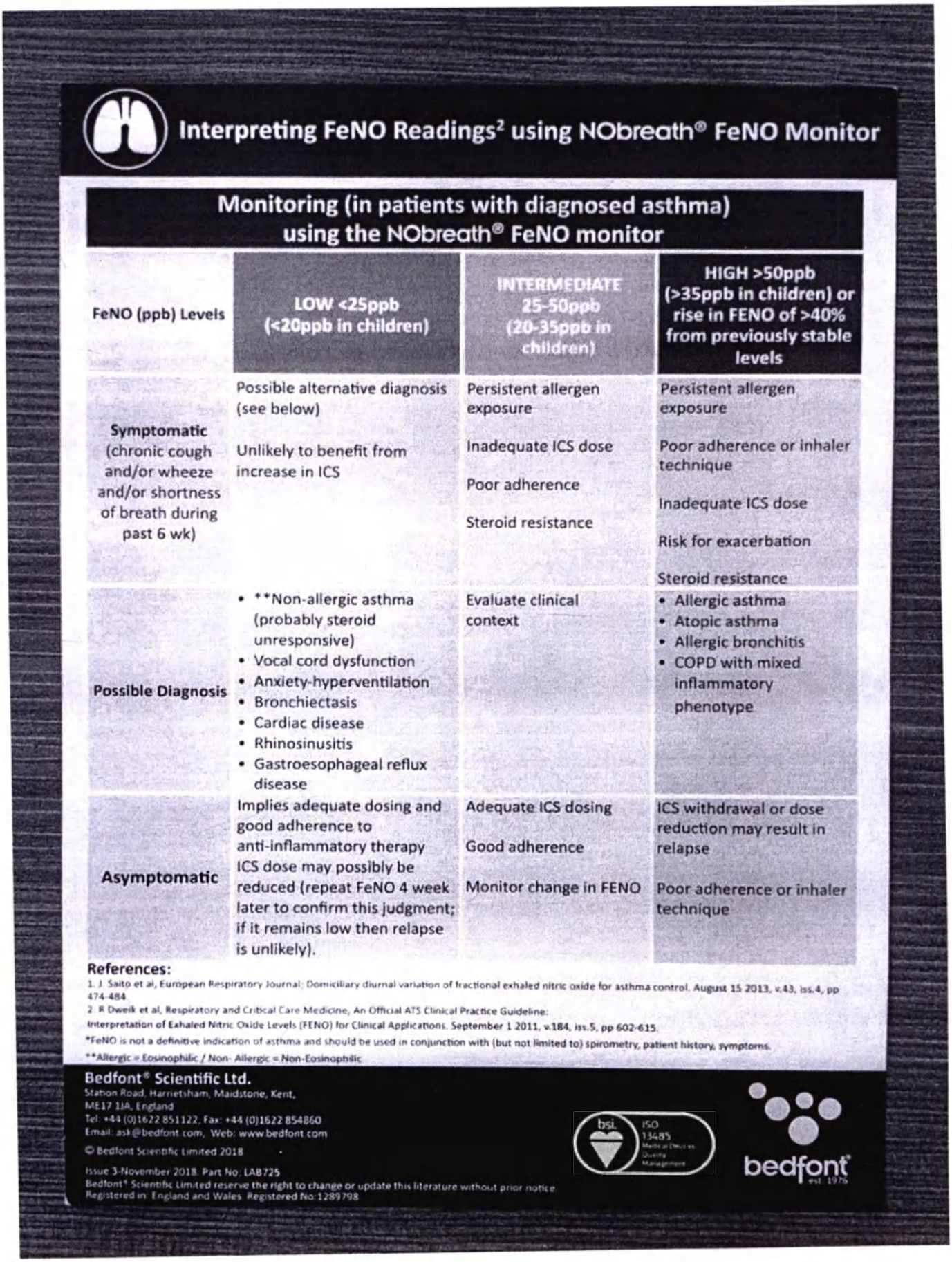
*The ATS/ERS Guidelines referenced below, state that the aforesaid activities can affect FeNO readings and therefore Bedfont® has only recommended a time frame to abstain for.

References

1. ATS/ERS Recommendations for Standardized Procedures for the Online and Offline Measurement of Exhaled Lower Respiratory Nitric Oxide and Nasal Nitric Oxide, 2005. American Journal of Respiratory and Critical Care Medicine. 2005;171(8):912-930.
2. Lidder S, Webb A. Vascular effects of dietary nitrate (as found in green leafy vegetables and beetroot) via the nitrate-nitrite-nitric oxide pathway. British Journal of Clinical Pharmacology. 2013;75(3):677-696.

Bedfont® Scientific Ltd.
Station Road, Harrietsham, Maidstone, Kent, ME17 1JA, England

7. Таблица интерпретации результатов.



Interpreting FeNO Readings[2] using NObreath® FeNO Monitor

Monitoring (in patients with diagnosed asthma) using the NObreath® FeNO monitor

FeNO (ppb) Levels	LOW <25ppb (<20ppb in children)	INTERMEDIATE 25-50ppb (20-35ppb in children)	HIGH >50ppb (>35ppb in children) or rise in FENO of >40% from previously stable levels
Symptomatic (chronic cough and/or wheeze and/or shortness of breath during past 6 wk)	Possible alternative diagnosis (see below) Unlikely to benefit from increase in ICS	Persistent allergen exposure Inadequate ICS dose Poor adherence Steroid resistance	Persistent allergen exposure Poor adherence or inhaler technique Inadequate ICS dose Risk for exacerbation Steroid resistance
Possible Diagnosis	• **Non-allergic asthma (probably steroid unresponsive) • Vocal cord dysfunction • Anxiety-hyperventilation • Bronchiectasis • Cardiac disease • Rhinosinusitis • Gastroesophageal reflux disease	Evaluate clinical context	• Allergic asthma • Atopic asthma • Allergic bronchitis • COPD with mixed inflammatory phenotype
Asymptomatic	Implies adequate dosing and good adherence to anti-inflammatory therapy ICS dose may possibly be reduced (repeat FeNO 4 week later to confirm this judgment; if it remains low then relapse is unlikely).	Adequate ICS dosing Good adherence Monitor change in FENO	ICS withdrawal or dose reduction may result in relapse Poor adherence or inhaler technique

References:

1. J. Saito et al, European Respiratory Journal: Domiciliary diurnal variation of fractional exhaled nitric oxide for asthma control. August 15 2013, v.43, iss.4, pp 474-484
2. R Dweik et al, Respiratory and Critical Care Medicine, An Official ATS Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (FENO) for Clinical Applications. September 1 2011, v.184, iss.5, pp 602-615.

*FeNO is not a definitive indication of asthma and should be used in conjunction with (but not limited to) spirometry, patient history, symptoms.

**Allergic = Eosinophilic / Non- Allergic = Non-Eosinophilic

Bedfont® Scientific Ltd.
Station Road, Harrietsham, Maidstone, Kent,
ME17 1JA, England
Tel: +44 (0)1622 851122, Fax: +44 (0)1622 854860
Email: ask@bedfont.com, Web: www.bedfont.com

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8. Руководство по инфекционной безопасности.

Infection control and maintenance guidelines

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For the Bedfont® NObreath® monitor and NObreath® Dock

Before using any of the above equipment, the operating manual should be read and fully understood.

Infection control

Washing hands before and after testing is highly recommended for both operator and user as part of a sensible infection control regime.

The NObreath® FeNO monitor is integrated with SteriTouch® antimicrobial technology for improved infection control.

The NObreath® uses a single-patient use mouthpiece that can be used up to 3 times by a single patient. Re-use of the mouthpiece between patients can increase the risk of cross-infections.

The NObreath® mouthpiece contains an integrated infection control filter that removes and traps >99% of airborne bacteria and >98% of viruses[1].

Take advice from your infection control expert before use on patients with known communicable diseases/conditions.

It is preferable that the user attaches their own mouthpiece to the monitor before the breath test, and detaches and disposes of it once the test is complete.

Whilst the user is exhaling, the operator should avoid positioning themselves in front of the exhaust port of the instrument.

Routine maintenance

See the operating manual for full maintenance instructions.

- The NObreath® should be calibrated at least annually or the NO sensor should be replaced
- NO sensor should be replaced every 5 years
- The NO scrubber should be replaced annually
- The breath drying cartridge should be replaced every 5 years
- It is best practice to not let the battery run flat

Bedfont® Scientific Ltd.
Station Yard, Station Road, Harrietsham, Kent, ME17 1JA, England
Tel: +44(0)1622 851122 Fax: +44(0)1622 854860 Email: ask@bedfont.com

EC REP

Bedfont® GmbH
Mitterbachweg 18, 5081, Anif, Austria
Tel: +43 662 635050 Fax: +43 662 635050-50
Email: bedfont-gmbh@bedfont.com

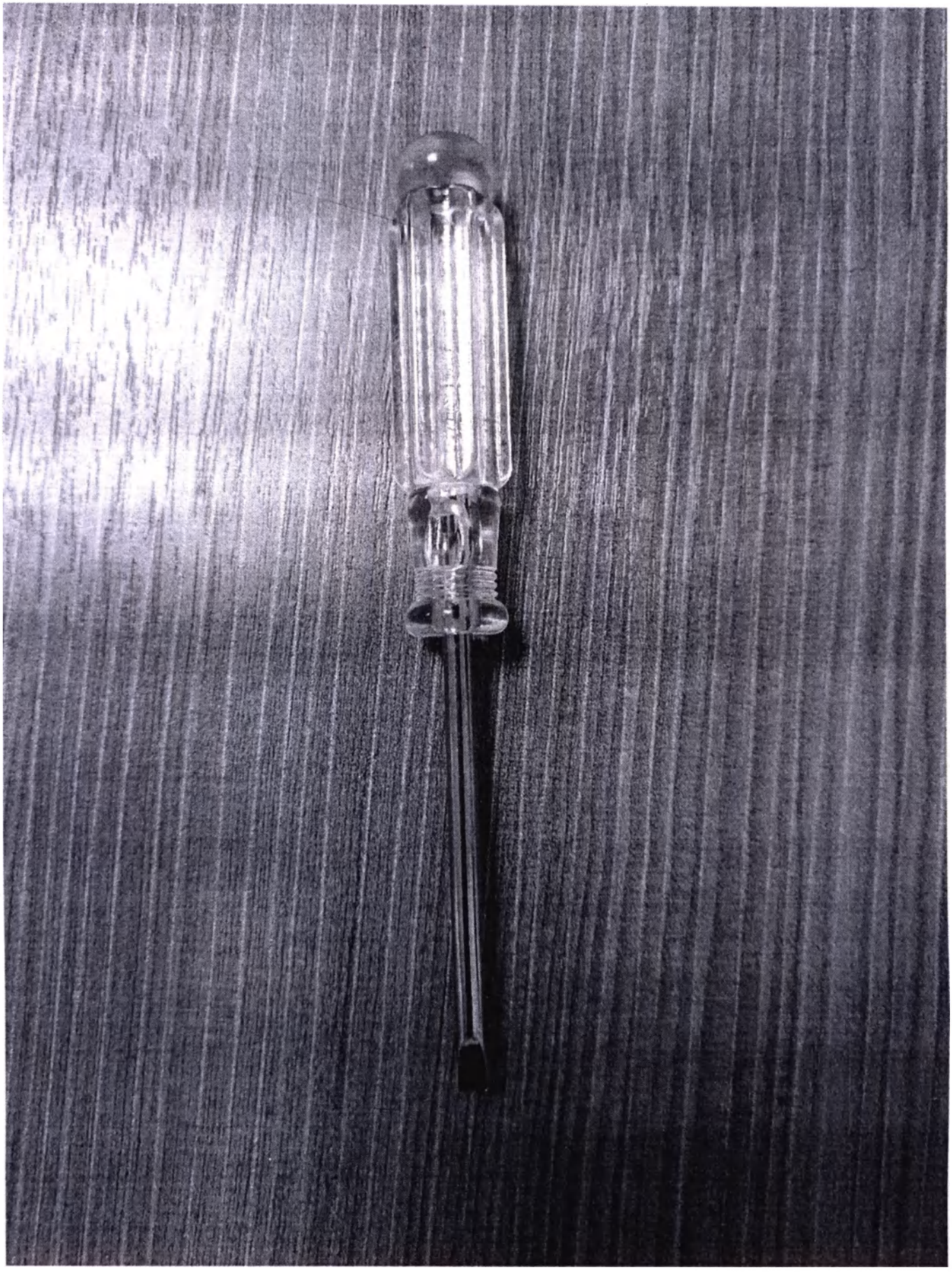
Issue 5 – May 2021. Part No: LAB766

9. Очищающие салфетки.

II. Принадлежности:

1. Чистящая ткань

2. Отвертка - 1 шт.



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