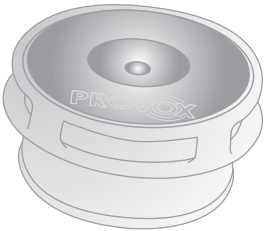
PROVOX XtraHME

热湿交换器

IFU



MD

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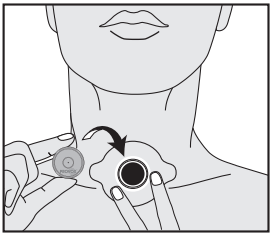

Figure 1 / 图1

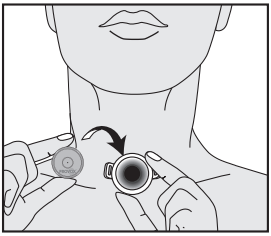

Figure 2 / 图2

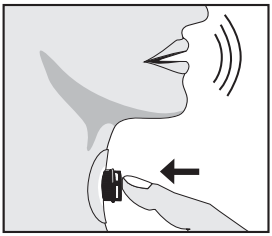

Figure 3 / 图3

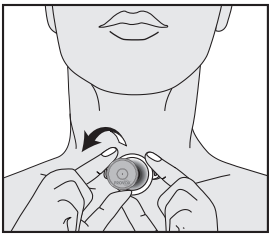

Figure 4 / 图4

Disclaimer

Atos Medical offers no warranty–neither expressed nor implied–to the purchaser hereunder as to the lifetime of the product delivered, which may vary with individual use and biological conditions. Furthermore, Atos Medical offers no warranty of merchantability or fitness of the product for any particular purpose.

Due to local Chinese requirements, the text in the Intended use paragraph and the Overall description and product composition paragraph are not translated verbatim.

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Contents

1. Descriptive information

1.1 Intended use

The Provox XtraHME Cassette is a single use, specialized device intended for patients breathing through a tracheostoma. It is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and moister from exhaled air in the device. It partially restores lost breathing resistance.

1.2 Overall description and product composition

Provox XtraMoist HME and Provox XtraFlow HME are composed of a housing (Polypropylene (PP) and White PP masterbatch), Lid (PP and Beige Polyethylene (LLDPE) masterbatch) and media (Polyurethane foam polyester base with $CaCl_2$). Provox XtraHME Cassettes are single use devices.

1.3 CONTRAINDICATIONS

The devices should only be used in accordance with the Instructions for Use. Patients without the physical, cognitive, or mental ability required to attach, remove or operate the devices themselves, should not use the devices independently and should only use them if they are under sufficient supervision of a clinician or a trained caregiver.

Do not use the Provox XtraHME Cassette in combination with cuffed tracheal cannula; breathing may be restricted and suffocation may occur.

The devices should not be used by patients with a low tidal volume, as the added dead space may cause CO_2 (Carbon dioxide) retention, see 1.5 Technical data.

1.4 Description of the device

The Provox XtraHME Cassettes are single use devices for pulmonary rehabilitation. They are a part of the Provox HME System, which consists of HME cassettes, attachment devices and accessories.
The Provox XtraHME Cassettes have a calcium chloride treated foam in a plastic housing.

The Provox XtraHME Cassettes are available in two versions:

- Provox XtraMoist HME is intended for use during normal everyday activity.

- Provox XtraFlow HME is intended for use during physical activities since it has a lower breathing resistance. It can also be used in a two-step approach to get adapted to the higher breathing resistance of the Provox XtraMoist HME.

1.5 Technical data

Height	14.2 mm
Diameter	27.8 mm
Weight	1.5 g
Compressible Volume	5 ml (dead space)

	Provox XtraMoist	Provox XtraFlow
Pressure Drop at 30 l/min*	0.7 hPa	0.4 hPa
Pressure Drop at 60 l/min*	2.4 hPa	1.3 hPa
Pressure Drop at 90 l/min*	4.8 hPa	2.9 hPa
Moisture loss at VT=1000 ml**	21.5 mg/l	24 mg/l

* Pressure drop after 1 h according to ISO 9360.

** According to ISO 9360.

It is recommended to use the Provox XtraHME continuously. When continuously using an HME the pulmonary function is likely to improve in a majority of patients, and respiratory problems, e.g. coughing and mucus production subsequently decrease.

If you have not used HMEs previously you should be aware that the device increases breathing resistance to some extent. Especially in the beginning this may be experienced as discomfort. Starting with Provox XtraFlow Cassettes may therefore be advisable.
During the first days or weeks of use the mucus production may also appear to increase due to thinning of the mucus by retained water.

1.6 WARNINGS

- Be careful not to exert pressure on the lid of the HME unintentionally. Unintentional or accidental closing of the top lid may cause difficulty in breathing.
- Always inform the patient, caretakers and others about the closing feature of the HME cassette to ensure that they understand its function. Closing the

airway to allow voicing is a well-known feature for the laryngectomized patient with a voice prosthesis. For patients without a voice prosthesis or tracheostomized patients this feature might be unknown.

1.7 PRECAUTIONS

- Always test the function of the Provox XtraHME Cassette prior to use. The top lid should immediately return to its open position after releasing the finger.
- Do not disassemble the Provox XtraHME Cassette since this will interfere with its proper function.
- Do not reuse the Provox XtraHME Cassette or attempt to rinse it with water or any other substance. This will substantially reduce the function of the HME. Additionally the risk of potential infections may increase due to bacterial colonization of the foam.
- Do not use the Provox XtraHME Cassette longer than 24 hours. The risk of potential infections may increase with the time of use due to bacterial colonization of the foam.
- Do not administer medicated nebulizer treatment over the device since the medication can become deposited in the device.
- Do not use humidifiers or heated humidified oxygen via a mask over the tracheostoma while using the device. The HME will become too wet. If oxygen therapy is required, use only non-heated humidified oxygen.

2. Instructions for use

2.1 Operating instruction

Insert the Provox XtraHME Cassette into the connector of the attachment device (Fig. 1 or 2). Breathe normally.
To speak, press the top lid of the Provox XtraHME Cassette down with a finger (Fig. 3).
Note: Always release the lid completely at inhalation to avoid increased breathing resistance.
To remove the Provox XtraHME Cassette, hold the attachment device in place with two fingers and remove the HME Cassette from the holder (Fig. 4).

2.2 Device lifetime and disposal

The HME is for single use and must be replaced at least every 24 hours, or more often if needed.
Always follow medical practice and national requirements regarding biohazard when disposing of a used medical device.

2.3 Accessories

Provox XtraHME Cassettes are mainly intended to be used with the other components of the Provox HME System: the Provox Adhesives, the Provox LaryTubes and the Provox LaryButtons.
The Provox XtraHME Cassette can also be used with tracheostomy tubes that have a 22 mm connector, or with a 15 mm connector together with the Provox HME Cassette Adaptor.
For more detailed information read the Instructions for Use accompanying each product.

3. Product model

Model	Specification
7272-18	Provox XtraFlow HME (20 pcs)
7291-18	Provox XtraFlow HME (30 pcs)
8229-18	Provox XtraFlow & XtraMoist HME (5+5 pcs)
7273-18	Provox XtraMoist HME (20 pcs)
7290-18	Provox XtraMoist HME (30 pcs)

4. Additional information

4.1 Compatibility with MRI Examination

MR-Safe: This device does not contain any metallic elements and has no potential for interaction with the MRI field.

5. Storage conditions

Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C

6. Reporting

Please note that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the national authority of the country in which the user and/or patient resides.

7. Registration and Manufacturer company

Atos Medical AB
Registration & Manufacturer location: Kraftgatan 8, SE-242 35 Hörby, Sweden
Registration & Manufacturer contact: +46 (0)415 198 00 • info@atosmedical.com
Production location: Kraftgatan 8, SE-242 35 Hörby, Sweden
Country of origin: Sweden

8. Legal Agent and After-sales service information

Coloplast (China) Medical Devices Ltd.
Address: Unit1301-1306, 13th Floor, Building 1, No.5
Lido Huayuan Road, Chaoyang District,
Beijing
Agent contact information:
Tel: 010-5920 1888
Fax: 010-5920 1898
Coloplast Customer Service Hotline
Hotline: 400 700 7668
Website: www.coloplast.com.cn

9. Production date and validity

Please see the label for the production date; the shelf life of product is 3 years.

10. Registration certificate number of medical devices

Certificate number of medical devices: 国械注进 20222080154

11. Technical requirements for medical devices

Technical requirement number for medical devices: 国械注进 20222080154

12. Edition of Instruction for Use

Article number: 11614, Edition date: 2024-03-25.

1. 描述性信息

1.1 适用范围

本产品适用于建立人工气道的患者，对经其呼吸的气体进行热湿交换。

1.2 结构及组成

本产品由外壳、盖子、加湿材质等组成。其中外壳材质为聚丙烯（PP）和白色聚丙烯色母（PP）、盖子材质为米黄色聚乙烯（LLDPE）色母粒和聚丙烯（PP）、加湿材料材质为 CaCl2 和聚氨酯泡沫。产品为一次性使用。

1.3 禁忌症

使用此设备必须遵守使用说明书。如患者无法同时满足连接、移动、操作此设备所要求的生理、认知或心理能力要求，则不应独立使用设备，必须在医生或受过训练的护理人员的合理监督下使用。

Provox XtraHME 热湿交换器不得与气囊式气管插管结合使用；否则呼吸将会受限并导致窒息。

潮气量低的患者禁用，因为潮气量过低可增大死腔，从而导致 CO2（二氧化碳）蓄积，详见 1.5 技术数据。

1.4 器械说明

Provox XtraHME 热湿交换器是一款用于肺康复的一次性设备。它们是 Provox HME System（Provox HME 热湿交换器系统）的一部分，该系统包括 HME 热湿交换器、附属设备和配件。
Provox XtraHME 热湿交换器的塑料罩内包含一块经氯化钙处理的泡沫。

Provox XtraHME 热湿交换器有两种型号：

- Provox XtraMoist HME（高湿度热湿交换器）适于在普通日常活动期间使用。
- Provox XtraFlow HME（高通量热湿交换器）适于在体育活动期间使用，因为该型号的呼吸阻力较低。为了适应高湿度热湿交换器的较高呼吸阻力，使用者可先使用并适应高通量热湿交换器而后尝试高湿度热湿交换器。

1.5 技术数据

高度	14.2 mm
直径	27.8 mm
重量	1.5 g
可压缩体积	5 mL（死腔）

	Provox XtraMoist	Provox XtraFlow
30 L/min 时的压降 *	0.7 hPa	0.4 hPa
60 L/min 时的压降 *	2.4 hPa	1.3 hPa
90 L/min 时的压降 *	4.8 hPa	2.9 hPa
VT=1,000 mL 时的水分损失 **	21.5 mg/L	24 mg/L

* 1 小时后的压降，依据 ISO 9360。

** 依据 ISO 9360。

建议持续使用 Provox XtraHME 热湿交换器。当持续使用 HME（热湿交换器）时，大部分患者的肺功能有可能改善，且呼吸道问题（例如咳嗽和粘液形成）随之减轻。

如果您之前没用过 HME（热湿交换器），应注意本设备会在一定程度上增加呼吸阻力。尤其是在开始时，您可能因此感到不适。因而建议在开始时使用 Provox XtraFlow 高通量热湿交换器。
在开始使用的最初几天或几周，粘液形成似乎也会增加，这是因为保留的水分使粘液变稀。

1.6 警告

- 注意不要无意中按到 HME（热湿交换器）顶盖。无意中或意外关闭顶盖可引起呼吸困难。
- 务必向患者、护理人员和其他人讲解 HME（热湿交换器）的关闭功能，确保他们理解其功用。对于装有辅助发音管的喉切除术患者，关闭气道以实现发音是一项熟知的功能。但无辅助发音管或气管切开的患者可能不知道该功能。

1.7 注意事项

- 每次使用前必须测试 Provox XtraHME 热湿交换器的功能。放开手指后，顶盖应立即返回打开位置。

- 请勿拆开 Provox XtraHME 热湿交换器，因为这样会干扰其正常运作。
- 请勿重复使用 Provox XtraHME 热湿交换器，或者尝试使用清水或其他液体冲洗。这样会大幅度减弱 HME（热湿交换器）的功能，泡沫细菌定植引起感染的风险也会增加。
- 请勿使用 Provox XtraHME 热湿交换器超过 24 小时。随着使用时间的增加，泡沫细菌定植引起感染的风险也可能增加。
- 请勿在设备上进行含药雾化治疗，因为药物可能会在设备中沉积。
- 使用设备时，不要在气管造口上通过面罩使用增湿器或加热增湿氧气。否则，HME 将会变得过于潮湿。如果需要进行氧气治疗，请仅使用非加热的增湿氧气。

2. 使用说明

2.1 操作说明

将 Provox XtraHME 热湿交换器插入附属设备的接口（图 1 或图 2）。正常呼吸。
要说话时，用一根手指按下 Provox XtraHME 热湿交换器的顶盖（图 3）。
注：每次吸气都要完全放开顶盖，以免呼吸阻力增加。
要移除 Provox XtraHME 热湿交换器，使用两根手指固定附属设备，并从接口中取出 HME（热湿交换器）（图 4）。

2.2 设备寿命和弃置

HME（热湿交换器）供一次性使用，每 24 小时必须替换，必要时也可更频繁地替换。
弃置使用过的医疗设备时，请务必遵循生物危害相关的医疗惯例和国家要求。

2.3 配件（不包含在此说明书中体现的注册证号的组成内）

Provox XtraHME 热湿交换器主要与 Provox HME System（Provox HME 热湿交换器系统）的其他组件配套使用：Provox Adhesive（Provox 颈部造口底盘）、Provox LaryTube（气管套管）和 Provox LaryButton（纽式气管套管）（见订购信息）Provox XtraHME 热湿交换器也可与带 22 mm 接口的气管造口管配套用，或者与带 15 mm 接口及 Provox HME Cassette Adaptor（Provox HME 热湿交换器适配器）的气管造口管配套使用。更多详细信息请参阅每个产品随附的使用说明。

3. 产品型号

型号	规格
7272-18	Provox XtraFlow HME (20 pcs)（高通量热湿交换器）(20 片装)
7291-18	Provox XtraFlow HME (30 pcs)（高通量热湿交换器）(30 片装)
8229-18	Provox XtraFlow & XtraMoist HME （5+5 pcs）（高通量 & 高湿度热湿交换器）（5 + 5 片装）
7273-18	Provox XtraMoist HME (20 pcs)（高湿度热湿交换器）(20 片装)
7290-18	Provox XtraMoist HME (30 pcs)（高湿度热湿交换器）(30 片装)

4. 其他信息

4.1 与 MRI 检查的兼容性

MR 安全：本设备不包含任何金属元件，不可能与 MRI 场产生相互作用。

5. 储存条件

在室温下储存产品，且存放于阴凉干燥处。温度偏差介于 2°C 至 42°C 之间。

6. 报告

请注意，发生任何与设备有关的严重事故时，应向制造商以及用户和 / 或患者所在国家 / 地区的主管部门报告。

7. 生产企业和注册人

注册人名称 / 生产企业名称：Atos Medical AB 欧拓适医疗有限责任公司
注册人住所 / 生产企业住所：Kraftgatan 8, SE-242 35 Hörby, Sweden
注册人联系方式 / 生产企业联系方式 : +46 (0)415 198 00 • info@atosmedical.com
生产地址 : Kraftgatan 8, SE-242 35 Hörby, Sweden
原产地：瑞典

8. 中国大陆地区代理人及售后服务机构

代理人名称 / 售后服务单位：康乐保（中国）医疗用品有限公司
代理人住所：北京市朝阳区丽都花园路 5 号院 1 号楼 13 层 1301-1306 单元
代理人联系方式：
电话：010-5920 1888
传真：010-5920 1898
康乐保客户服务热线
热线电话：400 700 7668
网址：www.coloplast.com.cn

9. 生产日期和使用期限

请参阅标签了解生产日期；产品的有效期为 3 年。

10. 医疗器械注册证编号

注册证编号：国械注进 20222080154

11. 医疗器械技术要求编号

产品技术要求编号：国械注进 20222080154

12. 说明书版本号

说明书版本编号：11614，说明书修订日期：2024-03-25.

符号的解释

Manufacturer; 制造商

Date of manufacture; 生产日期

Use-by date; 使用期限

Batch code; 批次代码

Product reference number; 产品编号

Do not re-use; 不得二次使用

Keep away from sunlight and keep dry; 怕雨，怕晒

Storage temperature limit; 储存温度限制

Store at room temperature. Temporary deviations within the temperature range (max-min) are allowed;
室温下存放。允许温度范围内（最高-最低）的暂时偏差。

Caution, consult instructions for use; 警告，参阅使用说明书

Instructions for use; 使用说明书

Medical Device; 医疗器械

Indicates that the product is in compliance with European legislation for medical devices; 表示本产品符合欧洲医疗器械法规

Recycling guidelines; 回收指南

XXXXX, NN
YYYY-MM-DD

XXXXX, NN = Reference number, 参考编号, 版本号

YYYY-MM-DD = Date of issue; 发布日期

11614, 03
2024-03-25

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