PROVOX® XtraHME™

Instructions for Use

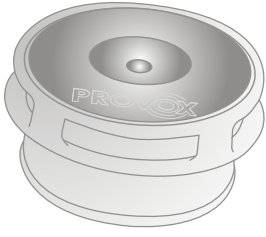

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Figure 1

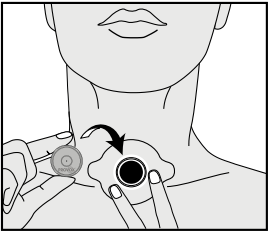


Figure 2

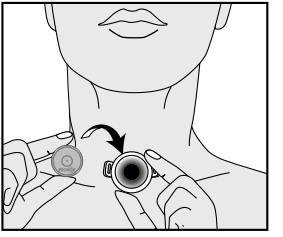


Figure 3

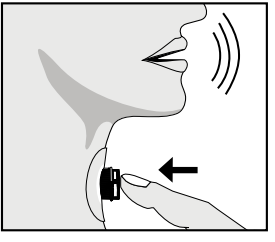
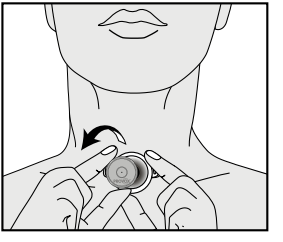


Figure 4



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.

Patents and trademarks

The Instructions for Use, which accompanies this product, may be revised from time to time and must therefore be reviewed prior to each procedure in which the product is used.

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. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

1.2 CONTRAINDICATIONS

The Provox XtraHME Cassette is not intended to be used by patients unable to remove or operate the device, unless the patient is under constant supervision of a clinician or a trained caregiver. For example, patients who are unable to move their arms, patients with decreased levels of consciousness, or patients with diseases that put them at risk for unpredictable periodic loss of consciousness.

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

Do not use on patients with a low tidal volume, as the added dead space (5 ml) may cause CO_2 (carbon dioxide) retention at too low tidal volume.

1.3 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 top lid can be pushed down with a finger to close the cassette and redirect air through the voice prosthesis to enable speech. After releasing the finger, the top lid returns to its rest position.

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.

1.4 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
Moisture output**	22.5 mg/l	20 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 HME's 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.

1.5 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.

1.6 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

The 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 (See Ordering information).

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 (not for sale in the USA).

For more detailed information read the Instructions for Use accompanying each product.

3. Additional information

3.1 Compatibility with MRI Examination

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

3.2 Ordering information

See end of the Instructions for Use.

3.3 Travel or international use

Make sure to have products available for your travel, please contact Atos medical for information if your product is available in the countries you plan to visit.

3.4 User assistance information

For additional help or information, please see back cover of the Instructions for Use for contact information.