Instruction for Use

HME FILTER

Variant : Adult and Peadtrics
Product Class as REGULATION (EU) 2017/745 : IIa
Product Class as per Medical Device Rule 2017 : IIa
Duration of use : Short Term

DESCRIPTION

- To provide sufficient heat and humidity to patients receiving mechanical ventilation without the use of heated humidifiers

The device does not contain;

- DEHP
- medicinal substance, including a human blood or plasma derivative,
- tissues or cells of human origin or their derivatives,
- Tissues or cells of animal origin or their derivatives.

Patient Target Group: All Age groups.

Product Packaging

- The product is available in non-toxic, medical-grade, sterile packing,
- The product is a single-use device.

INTENDED USE

- This device is use to filter anesthetic gas/ air to keep the patient safe from contamination.

MODE OF ACTION

- contains a layer of foam or paper embedded with a hygroscopic salt such as calcium chloride
- expired gas cools as it crosses the membrane, resulting in condensation and release of the mass enthalpy of vaporization to the HME layer
- on inspiration absorbed heat evaporates the condensate and warms the gas, the hygroscopic salt releases water molecules when the vapor pressure is low

INDICATION FOR USE

Pre-application

- Check that the Filter are undamaged before installing them in the respiratory circuit. During use constantly check for any signs of wear, cracks, leaks or air intake and take the appropriate action.
- Adjust tube occlusion prior to each procedure in accordance with the manufacturer's instructions for use. Improper occlusion may cause deterioration of the under-tubes, excessive wear, breathing flow reading.

Application

- contains a layer of foam or paper embedded with a hygroscopic salt such as calcium chloride
- expired gas cools as it crosses the membrane, resulting in condensation and release of the mass enthalpy of vaporisation to the HME layer
- on inspiration absorbed heat evaporates the condensate and warms the gas, the hygroscopic salt releases water molecules when the vapor pressure is low
- warming and humidification is thus regulated by the moisture content of the expired gas and patient's core temperature
- a filter layer is also present, either an electrostatically charged or a pleated hydrophobic layer, the latter helps return moisture to the gas as condensation and evaporation occurs between the pleats

INTENDED USERS:

Any registered medical doctor, nurse, enrolled nurse, anesthetics technician, or a student in any of those fields. Medical professionals use Respiratory circuit in the Emergency room

CONTRAINDICATION

The Doctor's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Patients who produce large volume of secretions or froth may be adversely affected due to increased resistance or HME occlusion. HME's should not be used on patients with copious or frothy secretions.
- Heated humidity systems (rather than HME) will be used on any patient with prevalent infiltrates on Chest X-Ray or with evidence or suspicion of retained secretions.
- HME is contraindicated in patients with a large air leak distal to the HME (such as a large bronchopleural fistula).
- HME is contraindicated in patients with a minute volume > 10 L/min
- Difficult to wean patients may require removal of HME. (Replace with heated humidity system).
- Due to the inherent nature of burn injuries to produce large amounts of secretions and pulmonary fluids, HME shall not be used on burn patients.
- At this time, HME will not be used on PICU patients.
- HME must be removed during medicated aerosol therapy.
- HME products are single patient use items and will be replaced every 24 hours

CLINICAL BENEFITS

- It converts continuous gas flow from the anesthesia machine to the intermittent flow of breathing, facilitates controlled or assisted respiration, and provides other functions such as gas sampling and pressure and Spiro metric measurements.

CAUTION/WARNING

- Read instruction for use before using the device.
- This product is sterilized for single use only, discard after single use. Please do not repeat sterilization, do not clean, do not use it once again.
- Should be used the product immediately after opening the individual package, please destroy when it was used.
- Do not uses it if the inner package has been previously opened or damaged, or package be affected with damp, or the product went moldy.
- Do not use after expiry date. If over the expiry date, please discard it.

Prepared by:	Approved By:

RISKS OF RE-USE

- A device designated, as 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.
- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has legal implications:
  - anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness;
  - Anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
- Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and, therefore, the performance may be compromised.
- If re-used it may lead, but not limited to cross-infection.
- Troubleshooting: User Paramedic staff should be aware & able to troubleshoot the certain complications may occur during the application of the product such as;

STORAGE

Based on the stability study report as per ICH guidelines the recommended storage condition in between Temp 15°C to 40°C and maintaining the relative humidity condition 50 to 75%. In case of any tempering in the packaging, the product condition may be affected even incase store at above defined condition.

DISCLAIMER

The condition of the device must be verified prior to use. Prymax is not responsible for any damage to person, property, etc. from any inappropriate or recommended use of the device, including reuse. Reuse could cause infection or serious health issues.

DISPOSITION

Dispose off/Discard the used Device, in accordance with your country's health care and safety regulations.

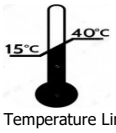
GOODS RETURN POLICY

Refer to the company's return goods policy.
Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818

Company Website Link to product IFU:

https://www.prymaxhealthcare.com

SYMBOLS USED ON PRODUCT LABEL

Symbol			
Meaning	Caution	Medical Device	Manufacturer
Symbol			
Meaning	Do not re-use	Use-by date	Date of Manufacture
Symbol			
Meaning	Batch/Lot Number	Authorized representative in the European Community	Sterilized using ethylene oxide Single sterile barrier system
Symbol			
Meaning	Do not re-sterilize	Consult Instruction for use	Non-pyrogenic
Symbol			
Meaning	Do not use if package is damaged	Catalogue number	Temperature Limit

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Symbol					
Meaning	Fragile, handle with care	Keep dry		This way Up	
Symbol					
Meaning	Keep away from sunlight	Stacking limit by number	Unique Device Identifier	Conformity of European Number	

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