REF HMEF

INSTRUCTIONS FOR USE

GMI HMEF FILTER

PRODUCT SPECIFICATIONS TABLE:

Code	Model	Intended use	Connection tube
HMEF-FT15T-RA	Straight	Adult	Yes

INSTRUCTIONS FOR USE

The GMI HMEF Filter is recommended for use in heating and humidifying airflow originating from a ventilator. It is designed to be used in conjunction with other respiratory apparatuses. The filter may be used as an alternative to an active humidifier provided that this measure is carried out under orientations from a medical professional. The GMI HMEF Filter also acts as a filter against bacteria and viruses.

GMI's HMEF Filter (filter + heat and humidity exchanger) helps to prevent cross infections from ventilators in patients with pulmonary infections, as well as maintains the temperature and humidity of gas at its entrance.

The 115 mm flexible corrugated respiratory connection tube attaches to rigid 22F / 15F proximal and distal connections, allowing the filter to be connected to the wide range of conical connections available on the market that are used in therapies involving mechanical ventilation. The connection on the end closest to the patient is sealed with a cover for protection and disposal.

OPERATING MODE

Ventilation is carried out through the use of devices that intermittently inflate respiratory airways with volumes of air that are sufficient enough to maintain the patient in a condition of stability. The movement of gas into the lungs occurs due to a pressure gradient between the upper airways which may be created by equipment that reduces alveolar pressure or increases proximal airway pressure. The concentration of oxygen that is necessary for maintaining saturation above 90% can also be controlled, which acts to the control the action of bacteria and viruses in present in the exchange of gases and thereby reduces the capacity for cross contamination.
The velocity at which air is administered and the wave form for this flow are also monitored using the humidifying filter.

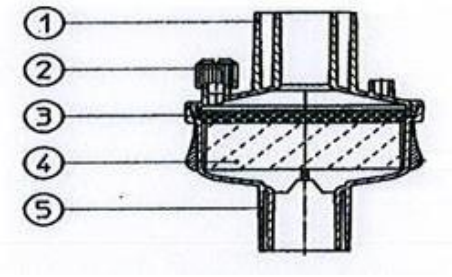
INSTRUCTIONS FOR USE:

1. The GMI HMEF Filter must be directly connected to the endotracheal tube or a catheter (trachea) and attached to "Y" connection in the respiratory circuit.
2. Ensure that the respiratory circuit is not leaking before use.
3. The maximum period for which the GMI HMEF Filter may be used is 24 hours, after which it must be replaced with a new filter.

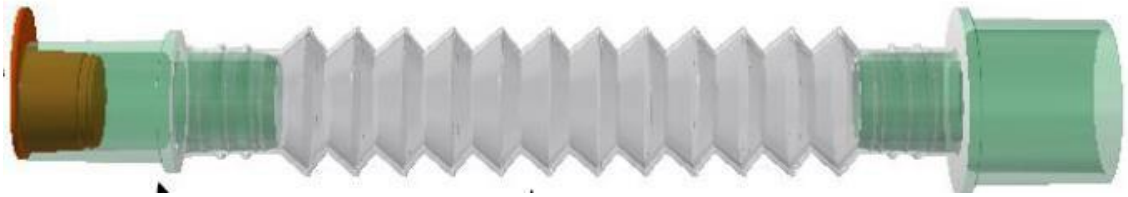
SPECIFICATIONS

- ***GMI HMEF FILTER***

1. Connector - machine end
2. Luer-Lock protective cover
3. Filter membrane
4. Corrugated cellulose paper
5. Connector - patient end



- ***FLEXIBLE RESPIRATORY CONNECTION TUBE WITH RIGID CONNECTORS + PROTECTIVE COVER***



Flexible Respiratory Connection Tube	
1. Composition	Polypropylene
2. Maximum length	115 mm (variation +/- 13mm)
3. Minimum length	62 mm (variation +/- 8mm)
4. Internal diameter	15 mm

Rigid connection MACHINE END	
1. Composition	Polypropylene
2. 15 mm Female connection	15 mm
3. Maximum length	39 mm (variation +/- 3 mm)
4. Diameter - machine end	15.47 mm (variation +/- 0.04 mm)

Rigid connection PATIENT END	
1. Composition	Polypropylene
2. 22 mm Female connection	22 mm
3. Maximum length	39 mm (variation +/- 3 mm)
4. Diameter - patient end	22.37 mm (variation +/- 0.04 mm)

Protective Cover	
1. Composition	Polypropylene
2. 16M Diameter	16 mm (variation +/- 2mm)

- ***PRODUCT SPECIFICATIONS***

ADULT	STRAIGHT
1. Duration of use	No longer than 24 hours
2. Viral and bacterial retention	99.99 %
3. Filtration model	Electrostatic
4. Humidity Inspired in 50 mL	33mg H_2O
5. Connection - patient end	22M/15F
6. Connection - machine end	22F/15M
7. Protecting sample cover	Luer-Lock
8. Weight	34.0 gr
9. Tidal Volume	150 - 1500 mL
10. Internal Volume	55 mL
11. Corrugated cellulose paper	Hygroscopic
12. Polypropylene filter membrane	Hydrophobic
13. Patient weight	Starting at 30 kg

WARNINGS

1. The HMEF Humidifying Filter is completely free of latex and its derivatives.
2. Sterilized using ethylene oxide; resterilization is not permitted;
3. The device has a validity of 5 years after sterilization; once the packaging has been open, it must be used immediately;
4. Always ensure that you have read the HMEF Humidifying Filter's instructions for use before using the device;
5. Do not use the HMEF Humidifying Filter if its packaging has been damaged;
6. HMEF Humidifying Filter must be immediately replaced whenever contamination occurs due to secretion or hemoptysis that significantly contributes to increasing resistance;
7. Do not use the device in conjunction with an active humidifier unless the active device's instructions for use include such usage;
8. The HMEF Humidying Filter must not be used with explosive anesthetic gases,
9. Do not dampen the filter before use; this should be done by the patient themselves during use;
10. Monitor drops in pressure through the filter if it is being used in conjunction with nebulizers for medication;
11. It is extremely important that normal breathing is maintained since this prevents the passage of condensation through the filter;
12. Leakage around the endotracheal tube reduces humidification;
13. The HMEF Humidifying Filter must only be used in patients needing humidification in respiration.
14. Do not use lubricants or other fluids to prepare the HMEF Humidifying Filter for use.
15. The filter is intended for single use only; it must not be reused, reprocessed, or resterilized;
16. If the device is resterilized or reprocessed, its integrity will be compromised, which may result in malfunctions causing serious injury to the patient;
17. Reusing the HMEF Humidifying Filter may compromise the integrity of the product and/or cause cross infections that affect the patient.

PRECAUTIONS

1. Open the device's packaging as close as possible to the moment at which it will be used;
2. Always confirm the product's expiration date and conditions of the packaging before use;
3. Single use device that must only be used on a single patient;
4. After use, the filter must be disposed of in an appropriate location in accordance with hospital standards and protocols.

CONTRAINDICATIONS

1. The product must not be used continuously for more than 24 hours.
2. The filter must be replaced if the humidity inside is clear.
3. It is recommended that the product not be used in patients with excessive pulmonary secretions.
4. Do not use with a humidifier.
5. Do not use with patients requiring a lower tidal volume, such as babies and newborns.
6. This product must not be used without medical supervision.
7. Do not use if the packaging is open or damaged.
8. Do not use after the expiration date.
9. Precautions must be taken when discarding the device and its disposal must adhere to applicable national regulations for hazardous biological waste.

ADVERSE EFFECTS

There is no risk of adverse effects provided that the device is used in accordance with the manufacturer's instructions. The manufacturer is not responsible for inappropriate use of the product.

STORAGE AND TRANSPORT

The device must be stored in a well-ventilated, dry, clean area away from light and excess humidity.
It must be transported in the same conditions in which it is stored, thereby guaranteeing its quality, safety, and effectiveness.

STERILE EO

Sterilized using ethylene oxide

Reprocessing is prohibited

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