 Please read the instruction before use.
The maximum recommended time of use for HMEF is 24 hours.

Product Name: Heat and Moisture Exchange Filter (HMEF)

Model: 504-011



HMEF 1000 Straight



HMEF 1000 Angled



HMEF MIDI Straight



HMEF MIDI Angled

Performance

Item	Pressure drop upper limit, kPa@30L/min	Bacterial filtration efficiency lower limit, %	Viral filtration efficiency lower limit, %	Moisture loss upper limit, mgH ₂ O/l	Leakage upper limit, L/H@(7±0.35)kPa	Compliance upper limit, ml/kPa	Internal volume, ml
HMEF 1000 Straight	0.35	99.9984	99.9797	9.5@V _i =1000ml	0.5	3	35
HMEF 1000 Angled							44
HMEF MIDI Straight	0.35	99.975	99.90	12@V _i =500ml	0.5	3	22
HMEF MIDI Angled							25

Note: The subject HMEF has not been evaluated for viral particle sizes consistent with Coronavirus.

Filtration performance was tested according to Nelson Laboratories.

Conditions	BFE	VFE
Organism	Staphylococcus aureus	Bacteriophage OX174
Challenge level	>1 x 10 ⁶ CFU	>1 x 10 ⁶ PFU
Mean Particle Size	2.7-3.2 micron	2.7-2.9 micron

Indications for Use

For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired and to maintain moisture levels in the patient's respiratory tract during anesthesia, artificial respiration, and other types of assisted ventilation. Use up to 24 hours. For adults with Tidal Volumes > 300 ml.

Precaution

1. This product should be used by trained and qualified medical workers.
2. Check the integrity of product packaging before use. DO NOT use if package is damaged.
3. Do NOT use the HMEF with a heated humidifier or nebulizer.
4. DO NOT place the HMEF between patient and heated humidifier or nebulizer.

Directions for Use

1. Open the package by tearing off from the bottom edge V-shape opening, DO NOT use scissors or cutter to open the package to avoid product damage.
2. Securely connect the product to the patient end of the circuit by using a twisting action to ensure a leak free and tight fit.
3. Test the product following air supply equipment's instruction to make sure the product is compatible with the equipment used and confirms that the product has no leakage and occlusion.
4. If using the sampling port, connect the gas sampling line securely, otherwise make sure the monitoring port for CO₂ is closed when it's not used.
5. Patients should be monitored constantly whenever they are using the product.
6. Check the product periodically; it must always be replaced when it becomes unfit for its intended use.

Warning

1. DO NOT REUSE! This product is FOR SINGLE PATIENT USE ONLY; reuse of this product can result in cross-infection.
2. DO NOT soak, wash or sterilize this product. Avoid contact with chemicals, cleaning agents, or hand sanitizers.
3. Discard after use in accordance with applicable hospital requirement or local laws and regulations.

Product Information: Principle method of filtration is electrostatic.















For further information, please consult the manufacturer or your local sales company.

Storage Condition: Store in clean, cool and dry indoor.

Expiration Date

The device shall be valid for 3 years; date of manufacture and use by date, please see product label.

Symbols

													
Caution	Consult instructions for use	Manufacturer	Date of manufacture	Use-by date	Catalogue number	Batch code	Non-sterile	Do not re-use	Do not use if package is damaged	Fragile, handle with care	This way up	Keep away from sunlight	Keep dry

Rx ONLY Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Customer Service Contact Information

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Noted specific to this Emergency Use Authorization (EUA)

Made in China

- For use during the COVID pandemic only.
- Under the EUA authorization the subject device was tested for biocompatibility per ISO 10993 - Cytotoxicity, Sensitization and Irritation. However, it has not been evaluated for systemic toxicity and genotoxicity risks based upon short-term and repeated/continuous use of the filters and was not tested per ISO 18562 for emission of VOCs and Particle Material 2.5 micron.