

HME Breathing Filters

Product Data Sheet

PRODUCT: HME Breathing Filters**DESCRIPTION / FUNCTION**

Flexicare's HME Breathing Filters consist of a Heat & Moisture Exchange medium together with an electrostatic filter medium, held within a plastic casing. Heat and Moisture Exchange Filters (HMEFs) are used to protect patients and ventilators from cross infection and to warm and humidify the inspired gases.

Breathing filters protect patients from bacterial and viral contamination. Flexicare's HME Filters use an electrostatic medium constructed of permanently charged bipolar rectangular split fibres which are able to capture airborne particles.

HMEFs are intended to help prevent the transmission of bacteria and viruses and prevent cross infection to and from the patient during anaesthesia, artificial respiration and other types of assisted ventilation such as in the critical care environment. Additionally, an HMEF provides a degree of heat and moisture retained from the patient's expired gases, which is then returned to the patient in the next inspired breath. In anaesthesia applications, an HMEF is normally positioned at the patient end of the breathing system between the circuit Y-piece and the patient's airway.

Flexicare's HME Filters are designed to be used in pre-hospital and hospital environments by trained personnel.

WARNINGS / PRECAUTIONS

- Do not use if packaging is open, or packaging or contents are damaged.
- Do not use after the expiry date on the packaging.
- Before use, visually inspect all connections to confirm they are secure. Immediately before each procedure carry out a functional test of the breathing system to ensure there is no occlusion or leakage.
- Always familiarise yourself with the Instructions For Use provided by the manufacturers and suppliers of associated equipment.
- Do not use between the patient and a humidification device (e.g Active Humidifier) or nebuliser device.
- Consider the total system dead space before use.
- Change the filter after a maximum period of use of 24 hours.
- Replace the HME filter immediately if it becomes soiled, ventilation is compromised, or significant pressure change is observed.
- Do not attempt to 'dry out' a breathing system or a breathing system filter.
- Do not use with inflammable anaesthetic gases.
- Do not attempt to decontaminate this product in any way. This includes rinsing, washing or decontamination using gas, heat, steam or boiling water.
- The HME filter should be replaced immediately if contaminated by secretions or haemoptysis, this can result in significantly increased resistance.
- Do not moisten the HME filter prior to use – this must be done by the patient.

- Monitor the pressure-drop across the HME filter if it is being used in combination with medicine nebulisers.
- Maintenance of normal breathing pressure is important. This will prevent any condensation from being forced through the HME filter.
- Leakage around the endotracheal tube can cut down the effective humidification.
- The HME filter should only be used with patients who require humidification.
- Mount the HME filter without the use of lubricants or other fluids.
- Do not reuse, reprocess or resterilise. Reuse, reprocessing or resterilisation may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilisation may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

SPECIFICATION / KEY FEATURES

- Combines electrostatic filtration and HME media.
- Electrostatic filter media provides a high degree of efficiency.
- HME media provides high moisture output to each inspired breath.
- 22M/15F connectors complying with ISO 5356 providing universal connections.
- The design of the filter conical connectors provides unidirectional fitting of the filter and prevents errors in connection.
- Patient side clearly marked on device housing for correct fitting.
- Lightweight design of the HME filters reduces drag on the breathing system.
- Rounded ergonomic shape with no sharp edges reduces the risk of pressure marking.
- Optional Luer port allows easy ETCO2 sampling.

PERFORMANCE CHARACTERISTICS

ThermoShield™

	038-41-350	038-41-330	038-41-355 038-41-355LS	038-41-335 038-41-335LS	038-41-356	038-41-357	038-41-359	038-42-350	038-42-355 038-42-355LS	038-42-356 038-42-356LS	038-42-357
Efficiency (%)	99.999	99.999	99.999	99.999	99.999	99.999	99.999	99.99	99.99	99.99	99.99
Humidification (mg H ₂ O/l air)	33.6	33.6	33.6	33.6	33.6	33.6	33.6	30.3	30.3	30.3	30.3
Resistance 30l/min (cm H ₂ O)	1.4	1.7	1.4	1.7	2.0	2.0	3.1	2.9	2.9	3.1	4.0
Dead Space (ml)	66	52	66	52	76	96	87-105	25	25	35	46-64
Min VT (ml)	198	156	198	156	228	288	261	75	75	105	138
Weight (g)	39	38	41	40	45	55	59	22	25	32	45

Hygrovent

	300-100-000 301-100-000	300-200-000 301-200-000	300-210-000 301-210-000	300-510-000 301-510-000	300-520-000 301-520-000
Efficiency (%)	99.999	99.99	99.99	99.99	99.99
Humidification (mg H ₂ O/l air)	33	33	33	32	32
Resistance 30l/min (cm H ₂ O)	1.1	1.3	1.3	2.0	2.0
Dead Space (ml)	95	55	61	15	12
Min VT (ml)	150	150	150	50	50
Weight (g)	45	34	35	10	9

PRODUCT RANGE & PART NUMBERS

Product Codes	Product Description	Quantity
ThermoShield		
038-41-330	ThermoShield Adult Angled Bacterial Viral HMEF	50
038-41-335	ThermoShield Adult Angled Bacterial Viral HMEF with Luer Port	50
038-41-335LS	LuerSafe Adult Angled ThermoShield Bacterial Viral HMEF with Self-Sealing Luer Port	50
038-41-350	ThermoShield Adult Bacterial Viral HMEF	50
038-41-355	ThermoShield Adult Bacterial Viral HMEF with Luer Port	50
038-41-355LS	LuerSafe Adult Bacterial Viral HMEF with Self-Sealing Luer Port	50
038-41-356	ThermoShield Adult Bacterial Viral HMEF with Luer Port and Elbow 22M/15F	50
038-41-357	ThermoShield Adult Bacterial Viral HMEF with Luer Port and Low Profile Elbow Catheter Mount	50
038-41-359	ThermoShield Adult Bacterial Viral HMEF with Luer Port Swivel Elbow W/Cap Flexi-Lock Catheter Mount	50
Hygrovent		
301-100-000	Hygrovent Bacterial Viral HMEF	50
ThermoShield Mini		
038-42-350	ThermoShield Mini Bacterial Viral HMEF	50
038-42-355	ThermoShield Mini Bacterial Viral HMEF with Luer Port	50
038-42-355LS	LuerSafe Mini Bacterial Viral HMEF with Self-Sealing Luer Port	50
038-42-356	ThermoShield Mini Bacterial Viral HMEF with Luer Port and Low Profile Elbow 22M/15F	50
038-42-356LS	LuerSafe Paediatric Bacterial Viral HMEF with Self-Sealing Luer Port and Low Profile Elbow 22M/15F	50
038-42-357	ThermoShield Mini Bacterial Viral HMEF with Luer Port Swivel Elbow W/Cap F-L Catheter Mount	50
Hygrovent Small/Child		
301-200-000	Hygrovent S Bacterial Viral HMEF Small	50
301-210-000	Hygrovent S Angled Bacterial Viral HMEF Small	50
301-510-000	Hygrovent Child Angled Bacterial Viral HMEF	50
301-520-000	Hygrovent Child Straight Bacterial Viral HMEF	50
ThermoShield Neonatal		
038-43-355	ThermoShield Neonatal Bacterial Viral HMEF with Luer Port	50
ThermoShield Sterile		
038-41-350STR	ThermoShield Adult Bacterial Viral HMEF	50
038-41-330STR	ThermoShield Adult Angled Bacterial Viral HMEF	50
038-41-355STR	ThermoShield Adult Bacterial Viral HMEF with Luer Port	50
038-41-335STR	ThermoShield Adult Angled Bacterial Viral HMEF with Luer Port	50
038-41-355LSSTR	LuerSafe Adult Bacterial Viral HMEF with Self-Sealing Luer Port	50
038-41-335LSSTR	LuerSafe Adult Angled ThermoShield Bacterial Viral HMEF with Self-Sealing Luer Port	50
038-41-357STR	ThermoShield Adult Bacterial Viral HMEF with Luer Port and Low Profile Elbow Catheter Mount	50
038-41-359STR	ThermoShield Adult Bacterial Viral HMEF with Luer Port Swivel Elbow W/Cap Flexi-Lock Catheter Mount	50
Hygrovent Sterile		
300-100-000	Hygrovent Bacterial Viral HMEF	50
ThermoShield Sterile Mini		
038-42-355STR	ThermoShield Mini Bacterial Viral HMEF with Luer Port	50
ThermoShield Sterile Neonatal		
038-43-355STR	ThermoShield Neonatal Bacterial Viral Filter and HME with Luer Port	50

Hygrovent Sterile Small/Child		
300-200-000	Hygrovent S Bacterial Viral HMEF Small	50
300-210-000	Hygrovent S Angled Bacterial Viral HMEF Small	50
300-510-000	Hygrovent Child Angled Bacterial Viral HMEF	50
300-520-000	Hygrovent Child Straight Bacterial Viral HMEF	50

MATERIALS

Component	Material
ThermoShield Filter Housing	Polypropylene (PP)
Hygrovent Filter Housing	Styrene Butadiene Copolymer (SBC)
Luer Port Tethered Cap (ThermoShield)	Polyvinyl Chloride (PVC)
HME Media	Paper HME
Filter Media	Polypropylene (PP)
LuerSafe Port	Polypropylene (PP), Silicone
Male Luer Lock Cap (Hygrovent)	Polyethylene (PE)

LATEX CONTENT

Flexicare's HME Filters do not contain natural rubber latex.

DEHP CONTENT

Flexicare's HME Filters do not contain phthalate DEHP.

PRODUCT USE

Flexicare's HME Filters are single use devices.

STERILITY

Flexicare's HME Filters are available in sterile and non-sterile variants. Contact your local sales representative for information on which HME Filters are available sterile in different regions. Sterilisation method is ethylene oxide (EO).

STORAGE

Store in a cool, dry place out of direct sunlight.

SHELF LIFE

Flexicare declares a shelf life of five years from the date of manufacture. This is based on the stability of the devices' components and raw materials sourced. Expiry date is clearly marked on individual product pouch.

DISPOSAL CONSIDERATIONS

Dispose as clinical waste, in accordance with hospital policy, local guidelines and regulations.

PACKAGING MATERIALS

Non-Sterile

Primary – Polybag – Low Density Polyethylene (LDPE)

Sterile

Primary – Top Web – EO Permeable Paper

Blister Pack – Polyvinyl Chloride (PVC)

All variants

Secondary – Carton / Box - Cardboard