

Breathing System Filters, Single Use, Disposable

Medical device Class; 2A

Intended use

- For airway management / oxygen delivery the filter is used between the patient and the source of the gas / air with the objective of protecting the patient
- HME only used to provide heat and moisture exchange for the patient to prevent their airway drying out.

Connections

Patient = 15mm female / 22mm male connection to BS EN ISO 5356-1

Machine = 15mm male / 22mm female connection to BS EN ISO 5356-1

Gas sampling port (where fitted) = 7mm female Luer

Intended user

Airway filters are primarily used in hospitals under the direction of staff qualified for airway management procedures.

Recommended flow rates

Adult = 30 lt/min

Pediatric = 15 lt/min

Instructions for use

1. This product may only be used by, or under the supervision of, healthcare professionals
2. All connections should be securely attached, by using a twisting action, to ensure a leak free fit.
3. All patient breathing systems must be leak tested prior to patient connection.
4. The in-use life of the filter is: -
 - a. Inspiratory use in normal conditions Electrostatic = 72 hours , HEPA = Max 24 hours
 - b. Expiratory and inspiratory in damp or humid conditions Electrostatic = 48 hours , HEPA = Max 12 Hours
 - c. Use with active humidification Electrostatic = 24 hours
 - d. **HEPA filters should not be used with active humidification!**
5. The Luer lock connection is for gas sampling only
6. When the Luer lock connection is not being used ensure that the cap is securely fitted to prevent leakage from the filter.

Warnings

- This product should not be used if the integrity of the packaging has been compromised.
- Do not use if the packaging is contaminated or wet.
- Do not use if the product has exceeded the shelf life as printed on the product label
- This product is for **single use only**.
- The product must not be reprocessed.
- The product must not be altered or dismantled.

Cleaning

DISPOSABLE FOR SINGLE PATIENT USE NOT INTENDED FOR CLEANING OR REPROCESSING

There is a risk of cross contamination if these devices are reused. They have not been validated for reprocessing or reuse.

Sterilization

Supplied non sterile

Disposal

The devices may be disposed of using local procedures for contaminated medical waste.

The materials are capable of being recycled if a safe process for recycling medical waste is available.

Ordering information:

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Explanation of symbols;

	= Single Use. The definition of single use is for use on a single patient for a single procedure.		= Manufacturer
	= Do not reprocess / re-sterilise		= Temperature range
	= Use by date		= Consult instructions for use
	= Lot or batch number.		= Keep away from sunlight
	= Date of manufacture.		= Keep dry
	= Device catalogue number / product code / stock		= Contains latex
	= Caution		= Do not use if packaging is wet or damaged.
			= Contains or Presence of Phthalates.



1639 =CE mark and notified body number

This is an explanation of the symbols that may be found on Meditech Systems Ltd's products.

ADVERSE INCIDENT REPORTING

Adverse incidents may be reported to the Competent Authority in the country / region where the incident occurred.