


4. If the filter is to be located at the patient / breathing system interface (patient Y piece), then it must be replaced after each patient.
5. If the filter is to be used at the patient/ breathing system interface then the clinician may have the option to use certain Flexicare breathing systems on multiple patients in accordance with the information provided with the breathing system and the warnings below.
- a. Not all Flexicare breathing systems have the option of multiple use (consult breathing system packaging).
- b. If multiple use of the breathing system is permitted, then the filter and any items between it and the patient must be replaced before subsequent use of the breathing system can be allowed.
- c. The maximum permitted use of a Flexicare breathing system with the option of multiple use is seven days, ten operating lists or in accordance with your hospital policy – whichever is shorter.
- d. In addition to this information and that contained on the breathing system packaging, always consult the infection control guidelines for your hospital before reusing breathing systems on multiple patients.

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## ELECTOSTATIC FILTERS

Flexicare electrostatic filters use a bipolar, permanently charged filter media. Electrostatic filters are recommended for applications where high efficiency and low pressure drop are required. The ThermoShield and VentiShield filters offer excellent efficiency, together with a compact, light weight rounded design ideal for use with an endotracheal tube or laryngeal mask airway.

The ThermoShield range of filters incorporate a HME (Heat Moisture Exchange) medium which uses the patients passive humidification to humidify the patients inspired gases as dry gases can cause adverse effects to the intubated patient. ThermoShield Filter HME's counter act the risks of atelectasis, epithelial damage and reduction of mucociliary transport by acting as the humidifier in lieu of the patients upper airways.

Not all HME's are filters, some HME's are designed to offer humidification only with no filtration.

## CLINICALLY CLEAN / STERILE FILTERS

Flexicare Breathing System Filters are manufactured by Flexicare Medical within purpose built clean rooms and are supplied clinically clean.


The clean rooms conform to BS EN ISO 14644 "Clean rooms and associated controlled environments".

Flexicare can also provide a number of sterile filters.

Flexicare sterile filters (and catheter mounts) are supplied by sterilizing our standard product.

As such, product specifications will remain unaltered. Flexicare sterile filters can be identified with the part number suffix 'STR'. For specifications please refer the part number (without STR suffix) to the tables overleaf.

**EXPLANATION OF SYMBOLS:**

			
Caution	Do Not Use	Sterilized	Ethylene Oxide
Product not made with natural rubber latex	If Package is Damaged	Restricts this device to safe order of, a physician.	Product not made with natural rubber latex
Product not made with natural rubber latex	Product not made with natural rubber latex	Product not made with natural rubber latex	Product not made with natural rubber latex

## FILTERS



## FLEXICARE BREATHING SYSTEM FILTERS

Performance data is supported by internal and external testing reports.

Independant Bacterial/Viral Efficiency testing performed by the Health Protection Agency (HPA) at Porton Down, Salisbury, United Kingdom.

Independant moisture output and resistance to flow testing performed by Medical Device Evaluation Unit / Wales Anaesthesia Innovation, Cardiff University, Wales College of Medicine.

## INSTRUCTIONS FOR USE

1. This device is single patient use. The use of this device may permit the multiple use of certain types of anaesthetic breathing system. Consult the packaging of the specific breathing system for further information.
2. Securely attach all connections using a 'push and twist' action to ensure a secure leak free connection.
3. Leak test the breathing system with all accessories attached prior to connecting to patient.

## INTENDED USE

This device provides a medium through which gases may pass between a patient and equipment used in anaesthesia and critical care. This disposable, single patient use device is intended to be replaced with each patient when used at the patient / breathing system interface. It is to be used by medically trained professionals only.

## CAUTIONS

1. **DO NOT** use if the packaging integrity has been compromised.
2. **BEFORE** patient use, test the whole system for leaks and ensure no part of the system is occluded or blocked.
3. **DO NOT** attempt to clean this device.
4. **REPLACE** this device if it become soiled or otherwise unfit for its application.
5. **NEVER** attempt to 'dry out' a breathing system or a breathing system filter.
6. **DISPOSE** of all breathing system components immediately after use on highly infectious patients regardless of option of multiple use. (E.g. Tuberculosis (TB), HIV, Hepatitis C, Jacob-Creutzfeldt variant (CJD) and for all ICU patients. Breathing systems and components must be removed after use and safely disguard, even if a filter is used.

## THERMOSHIELD BACTERIAL / VIRAL HME FILTERS & HME'S

	038-41-350	038-41-330	038-41-355	038-41-335	038-41-355LS	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	038-43-355	038-43-150	038-41-250
<b>Description</b>	Filter	Angled Filter	Filter	Angled Filter	Filter	Angled Filter	Filter & Elbow	Filter & Elbow Cath Mt	Filter & Elasto Cap Cath Mt	Filter	Filter	Filter	Filter & Elbow	Filter & Elbow	Filter & Elasto Cap Cath Mt	Neonatal Filter	Neonatal HME	Tracheostomy HME
<b>Brand</b>	ThermoShield	ThermoShield	ThermoShield	ThermoShield	ThermoShield - LuerSafe*	ThermoShield - LuerSafe*	ThermoShield	ThermoShield	ThermoShield	ThermoShield	ThermoShield - Mini	ThermoShield - Mini LuerSafe*	ThermoShield - Mini	ThermoShield - Mini LuerSafe*	ThermoShield - Mini	ThermoShield - Neonatal	ThermoShield - Neonatal HME	Thermotrach
<b>Efficiency</b>	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	99.99%	99.99%	99.99%	99.99%	99.99%	99.99%	99.999%	N/A	N/A
<b>Humidification on (Moisture Output)</b>																		
1 - 3 hr	33.6	33.6	33.6	33.6	33.6	33.6	33.6	33.6	33.6	30.3	30.3	30.3	30.3	30.3	30.3	31	25.2	32.0
1 - 24hr (g/m <sup>3</sup> )	31.2	31.2	31.2	31.2	31.2	31.2	31.2	31.2	31.2	30.8	30.8	30.8	30.8	30.8	30.8	30.8	28 at 25 B/min	at 20 B/min
<b>Type</b> (eg: Hydrophobic mechanical filter)	Adult Electrostatic Filter with Hydrophobic HME	Adult Electrostatic Filter with Hydrophobic HME	Adult Electrostatic Filter with Hydrophobic HME	Adult Electrostatic Filter with Hydrophobic HME	Adult Electrostatic Filter with Hydrophobic HME	Adult Electrostatic Filter with Hydrophobic HME	Adult Electrostatic Filter with Hydrophobic HME	Adult Electrostatic Filter with Hydrophobic HME	Adult Electrostatic Filter with Hydrophobic HME	Mini electrostatic bacterial/viral Filter with Hydrophobic HME	Mini electrostatic bacterial/viral Filter with Hydrophobic HME	Mini electrostatic bacterial/viral Filter with Hydrophobic HME	Mini electrostatic bacterial/viral Filter with Hydrophobic HME	Mini electrostatic bacterial/viral Filter with Hydrophobic HME	Mini electrostatic bacterial/viral Filter with Hydrophobic HME	Neonatal bacterial/viral Filter with Hydrophobic HME	Neonatal Hydrophobic HME	Adult Tracheostomy HME
<b>Expiratory resistance Before use:</b>	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)
30L/min	1.4	1.7	1.4	1.7	1.4	1.7	2.0	2.0	3.1	1.4 at 15 L/min	1.4 at 15 L/min	1.4 at 15 L/min	3.1	3.1	4.0	0.8 at 7.5 LPM	0.1 at 2.5 LPM	0.11
60L/min	3.5	3.5	3.5	3.5	3.5	3.5	5.4	5.7	9.5	2.9 at 30 L/min	2.9 at 30 L/min	2.9 at 30 L/min	3.1	3.1	4.0	0.2 at 5 LPM	0.2 at 5 LPM	1.0
90L/min	6.4	7.1	6.4	7.1	6.4	7.1	10.8	11.7	20.6	4.5 at 45 L/min	4.5 at 45 L/min	4.5 at 45 L/min	3.1	3.1	4.0	0.3 at 7.5LPM	0.3 at 7.5LPM	
<b>After 24hr:</b>																		
30L/min	1.7		1.7		1.7					1.7 at 15 L/min	1.7 at 15 L/min	1.7 at 15 L/min					0.1 at 2.5 LPM	
60L/min	3.9		3.9		3.9					3.5 at 30 L/min	3.5 at 30 L/min	3.5 at 30 L/min					0.2 at 5 LPM	
90L/min	7.0		7.0		7.0					5.3 at 45 L/min	5.3 at 45 L/min	5.3 at 45 L/min					0.4 at 7.5LPM	
<b>Dead Space</b>	66ml	52ml	66ml	52ml	66ml	52ml	76ml	96ml	87-105ml	25ml	25ml	25ml	35ml	35ml	46-64ml	8ml	2ml	17ml
<b>Minimum Recommended Vt*</b>	198ml	156ml	198ml	156ml	198ml	156ml	228ml	288ml	261ml	75ml	75ml	75ml	105ml	105ml	138ml	>35ml	N/A	N/A
<b>Weight (g)</b>	39g	38g	41g	40g	41g	40g	45g	55g	59g	22g	25g	25g	32g	32g	45g	9g	3.6g	5.1g
<b>CO<sub>2</sub> Monitoring Port</b>	No	No	Yes Tethered Cap	Yes Tethered Cap	Yes LuerSafe* Valve	Yes LuerSafe* Valve	Yes Tethered Cap	Yes Tethered Cap	Yes Tethered Cap	No	Yes Tethered Cap	Yes LuerSafe* Valve	Yes Tethered Cap	Yes LuerSafe* Valve	Yes Tethered Cap	Yes Tethered Cap	No	No

## ELECTROSTATIC FILTERS & HME'S

ThermoShield. Anti-Bacterial / Viral Filter HME (Heat Moisture Exchange), Neonatal HME only and Adult Tracheostomy HME only.

VentiShield. Anti-Bacterial / Viral Filters.

LuerSafe™ Cap-less design prevents loss of ventilation when monitoring port not in use and eliminates the risk of mis-connection by not accepting a standard luer.

## MECHANICAL FILTERS

HepaShield. Mechanical filters (pleated paper) utilising a tightly packed medium of hydrophobic paper providing a small pore size membrane that physically stops the passage of organisms passing through. These filters offer the highest levels of filtration efficiency together with a certain amount of humidification (moisture output) for the patient.

## VENTISHIELD ANTI BACTERIAL VIRAL FILTERS

	038-41-360	038-41-340	038-41-365	038-41-345	038-41-365LS	038-41-345LS	038-41-366	038-41-366LS	038-42-360	038-42-365	038-42-366	038-42-365LS	038-43-360
<b>Description</b>	Filter	Angled Filter	Filter	Angled Filter	Filter	Angled Filter	Filter & Elbow	Filter & Elbow	Filter	Filter	Filter & Elbow	Filter	Filter
<b>Brand</b>	VentiShield	VentiShield	VentiShield	VentiShield	VentiShield - LuerSafe*	VentiShield - LuerSafe*	VentiShield	VentiShield - LuerSafe*	VentiShield	VentiShield - Mini	VentiShield - Mini	VentiShield Mini - LuerSafe*	VentiShield Neonatal
<b>Efficiency</b>	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	99.999%	99.99%	99.99%	99.99%	99.99%	99.999%
<b>Humidification</b>													
1 - 3 hr	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1 - 24hr (g/m <sup>3</sup> )	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<b>Type</b> (eg: Hydrophobic mechanical filter)	Adult electrostatic Bacterial / Viral Filter	Adult electrostatic Bacterial / Viral Filter	Adult electrostatic Bacterial / Viral Filter	Adult electrostatic Bacterial / Viral Filter	Adult electrostatic Bacterial / Viral Filter	Adult electrostatic Bacterial / Viral Filter	Adult electrostatic Bacterial / Viral Filter	Adult electrostatic Bacterial / Viral Filter	Mini electrostatic Bacterial / Viral Filter	Mini electrostatic Bacterial / Viral Filter	Mini electrostatic Bacterial / Viral Filter	Mini electrostatic Bacterial / Viral Filter	Neonatal Anti-Bacterial / Viral Filter
<b>Expiratory resistance Before use:</b>	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)
30L/min	1.2	1.4	1.2	1.4	1.2	1.4	1.5	1.5	1.9	1.9	2.2	1.9	0.8 at flow rate of 7.5 LPM
60L/min	3.5	3.8	3.5	3.8	3.5	3.8	4.5	4.5	9.4	9.4	9.4	9.4	
90L/min	7.0	7.7	7.0	7.7	7.0	7.7	9.4	9.4					
<b>After 24hr:</b>													
30L/min													
60L/min													
90L/min													
<b>Dead Space</b>	66ml	52ml	66ml	52ml	66ml	52ml	76ml	76ml	25ml	25ml	35ml	25ml	8ml
<b>Minimum Recommended Vt*</b>	198ml	156ml	198ml	156ml	198ml	156ml	228ml	228ml	75ml	75ml	105ml	75ml	>35ml
<b>Weight (g)</b>	30g	31g	32g	33g	33g	31g	38g	38g	19g	20g	28g	21g	9g
<b>CO<sub>2</sub> Monitoring Port</b>	No	No	Yes Tethered Cap	Yes Tethered Cap	Yes LuerSafe* Valve	Yes LuerSafe* Valve	Yes Tethered Cap	Yes LuerSafe* Valve	No	Yes Tethered Cap	Yes Tethered Cap	Yes LuerSafe* Valve	Yes Tethered Cap

\*Minimum recommended tidal volume (Vt) is based on 3x the dead space; use of capnography is recommended to highlight rebreathing

## HEPASHIELD (HEPA FILTERS) PLEATED PAPER / MECHANICAL FILTERS

	038-41-370	038-41-375	038-41-376	038-42-380	038-42-385	038-42-386
<b>Description</b>	Filter	Filter	Filter & Elasto Cap Cath Mt	Filter	Filter	Filter & Elbow Cath Mt
<b>Brand</b>	HepaShield	HepaShield	HepaShield	HepaShield Paediatric	HepaShield Paediatric	HepaShield Paediatric
<b>Efficiency</b>	99.99999%	99.99999%	99.99999%	99.99999%	99.99999%	99.99999%
<b>Humidification</b>						
1 - 3 hr	25.3	25.3	25.3	25.3	25.3	25.3
1 - 24hr (g/m <sup>3</sup> )	26.1	26.1	26.1	26.1	26.1	26.1
<b>Type</b> (eg: Hydrophobic mechanical filter)	Hydrophobic Mechanical Bacterial / Viral Filter	Hydrophobic Mechanical Bacterial / Viral Filter	Hydrophobic Mechanical Bacterial / Viral Filter	Paediatric Mechanical Bacterial / Viral Filter	Paediatric Mechanical Bacterial / Viral Filter	Paediatric Mechanical Bacterial / Viral Filter
<b>Expiratory resistance Before use:</b>	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)	(cmH <sub>2</sub> O)
30L/min	1.4	1.4	1.4	2.7	2.7	2.8
<b>Dead Space</b>	47ml	47ml	74-85ml	35ml	35ml	56-74ml
<b>Minimum Recommended Vt*</b>	141ml	141ml	222ml	105ml	105ml	168ml
<b>Weight (g)</b>	42g	43g	61g	26g	29g	47g
<b>CO<sub>2</sub> Monitoring Port</b>	No	Yes Tethered Cap	Yes Tethered Cap	No	Yes Tethered Cap	Yes Tethered Cap

\*LuerSafe filters supplied with LuerSafe sample line. Re-Order code 010-720 2m Male Luer & 010-725 2m Female Luer.