Breathing filters, HMEs and HMEFs





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Filtration and humidification

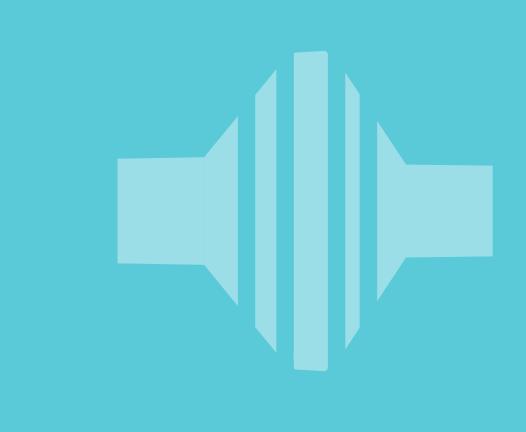
Proven filtration efficiency and optimum humidification help to meet all patients' clinical requirements.

Breathing filters provide an effective barrier that prevent cross contamination between patients, breathing systems, respiratory and anaesthetic equipment, and the clinical environment. Their use is widely recognised as beneficial and is recommended by a number of Anaesthetic Associations¹. They are widely used across the hospital particularly in the operating theatre, critical care, lung function units, and respiratory care units.

Heat and Moisture Exchangers (HMEs) minimise loss from patient expired gases. When combined with a filter (Heat and Moisture Exchanging Filter, HMEF) this will also reduce the risk of cross contamination in the clinical environment.

Reference

1. Association of Anaesthetists of Great Britain and Ireland 1996. Danish Society of Anaesthetists 1998. French Society of Anaesthetists 1998









Clinical environment

The normal function of the body's upper airway is to filter, humidify and warm the air we breathe in. Air is warmed by passing over a vast network of capillaries in the nose. Mucus membranes line the upper airways and help to moisten the air and trap airborne particles (dust and microbes). Cilia move the mucus away from the lungs and towards the pharynx for removal.

The upper airways also help conserve heat and humidity, which would otherwise be lost during normal respiration. Gas leaving the lungs during expiration will be at body temperature (37°C) and have an Absolute Humidity (AH) of 44mg/I H₂O and a Relative Humidity (RH) of 100%. As the patient breaths out, heat and moisture is retained by the upper airways and then transferred to the inspired gas, which is normally cooler and drier depending upon the ambient conditions. The large surface area of the upper airways makes it particularly efficient. This helps minimise any potential side effects associated with breathing cold dry gases over a prolonged period.

This natural physiological protection is bypassed when an artificial airway device is inserted, for example a tracheal tube, a supraglottic airway or tracheostomy tube. This means the gas source has a direct route to the delicate and sensitive lungs, which can result in an increased risk of infection and potential microbial cross contamination.

It could also result in a cooling and drying out of the airways as a result of breathing cold dry medical gases over a prolonged period of time. Room air would normally be approximately 23°C with an RH of 60% and an AH of 21mg/l. Medical gases would normally be 10-15°C with a RH of 0-2 % and an AH of 0.5 mg/l, which would further increase the risk. This can lead to damaged cilia, thicker mucus, mucus crusts leading to an increased risk of tube occlusion, increased risk of infection, atelectasis and increased cost due to prolonged hospital stay.

Particulate

Mucus cell

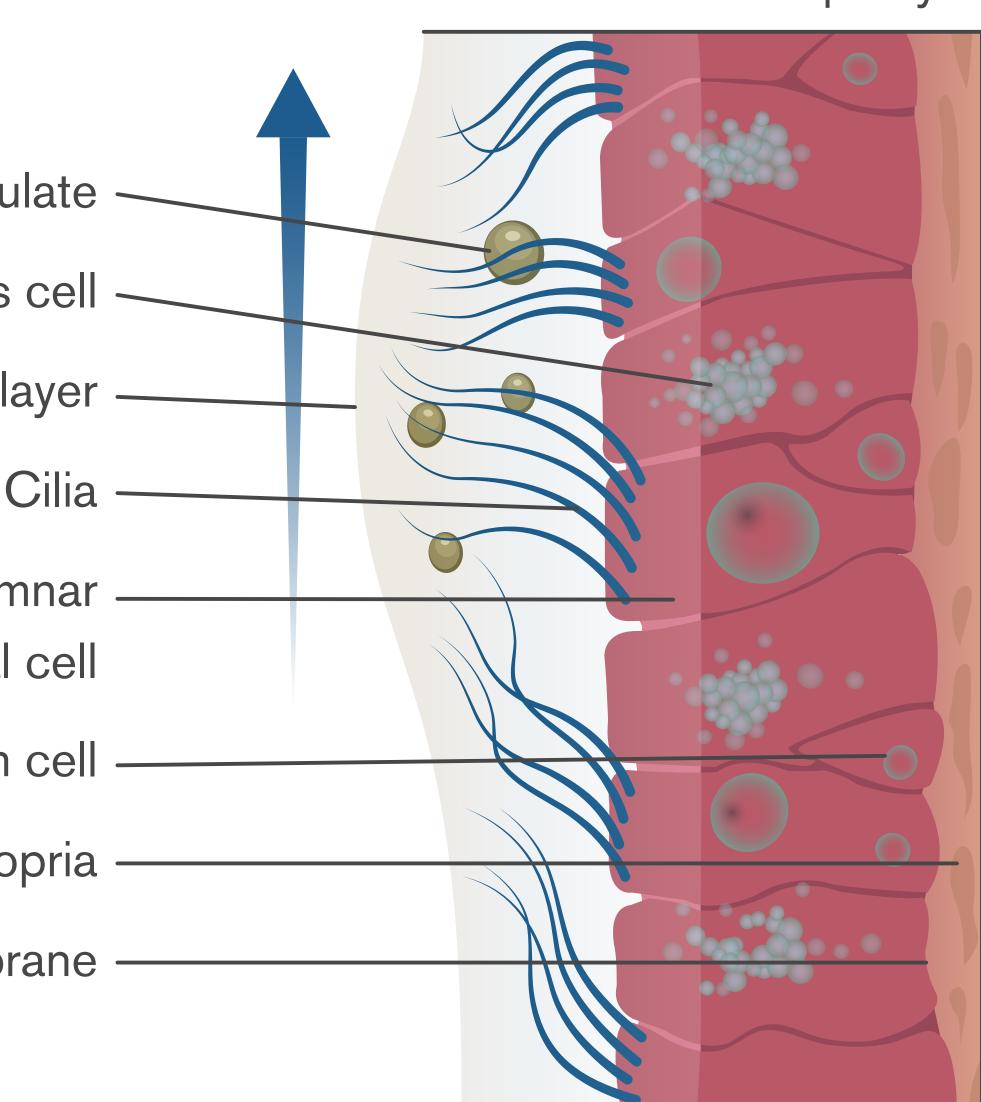
Mucus layer

Ciliated columnar epithelial cell

Stem cell

Lamina propria

Basement membrane



Movement of mucus to the pharynx







Infection (protecting the patient)

Those patients who require an artificial airway Critically ill patients with reduced immunity are have their natural physiological protection commonly at an increased risk of infections. These nosocomial infections result in increased by-passed. This will increase the risk of morbidity and potential mortality as well as infection and cross contamination between having a significant impact on the cost of patients and healthcare equipment. The cross treating the patient due to increased hospital contamination of patients via an anaesthetic stay. The strategic use of an efficient, properly system has been reported and documented². Areas of concern regarding infection include validated breathing filter provides an effective Hepatitis C, Mycobacterium tuberculosis, blood barrier between patient, breathing systems and in sputum and the SARS virus. respiratory equipment, which reduces the risk of cross contamination.

Reference

2. Chant K, Kociuba K, Munro R, et al. Investigation of possible patient-to-patient transmission of hepatitis C in a hospital. NSW Public Health Bull 1994; 5:47-51.

Cross contamination (protecting the breathing system)



Protection of respiratory equipment and clinical environment (protecting the equipment)

The use of appropriate and effective breathing filters can provide protection to delicate and expensive equipment, helping to preserve functionality, reduce running costs and reduce potential cross contamination.





Proven efficiency

Increasingly the only way that a clinician can determine the efficiency and effectiveness of the performance of a breathing filter, HME and HMEF is via standard test protocols and results. Ensuring the data is clinically relevant, up-to-date and reflective of the product that the customer is using is vital.

Our range of breathing filters, HMEs and HMEFs have been independently tested and proven to be highly efficient in preventing the passage of bacteria and viruses. These tests provide clinically relevant information to allow evidence-based decisions to be made on the most appropriate product to meet your clinical requirements.



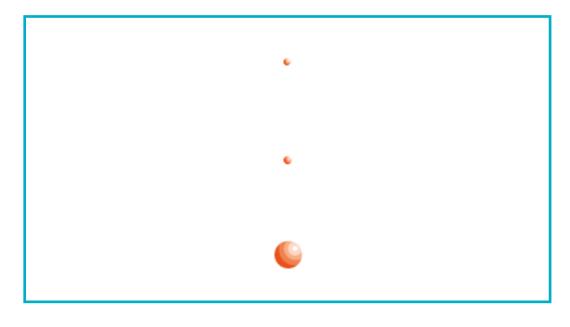


Microbiology testing

All our filters are tested at specialist microbiology laboratory facilities against clinically relevant bacterial and viral challenges. This is normally performed at an independent test facility that develops specific protocols to simulate the types of challenges that a filter may see in the clinical setting.

A challenge particle is chosen to simulate the size of the commonly occurring bacteria and viruses. Each individual Intersurgical filter and HMEF is tested and their performance verified in this way.

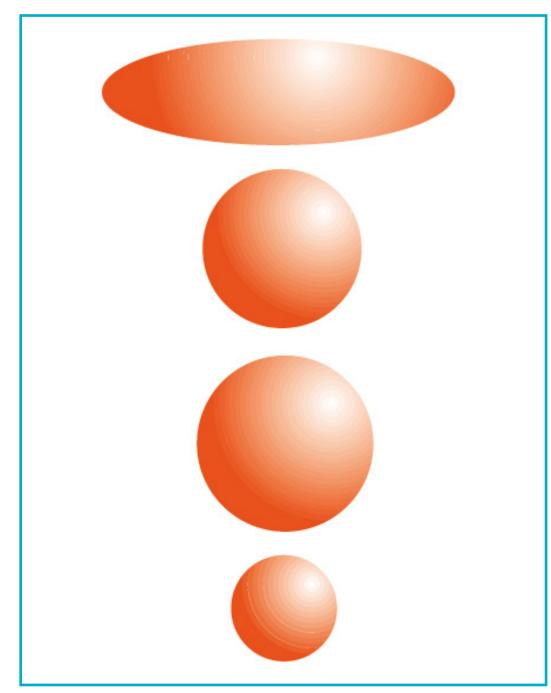
Potential infectious viruses [Particle sizes µ microns]



Ø174 bacteriophage [0.027µm] Hepatitis C [0.03µ]

Adenovirus [0.07µ]

Potential infectious bacteria [Particle sizes µ microns]



Mycobacterium tuberculosis $[0.3\mu \times 1.0\mu \text{ smallest size}]$

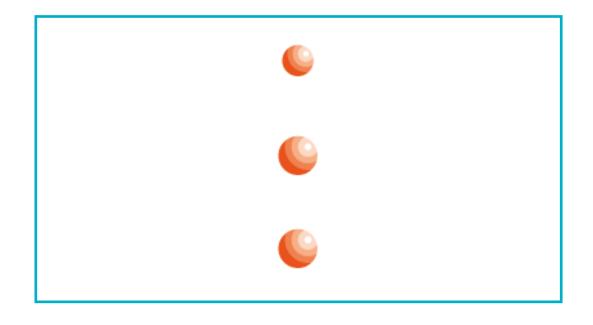
Serratia marcescens [0.45µ]

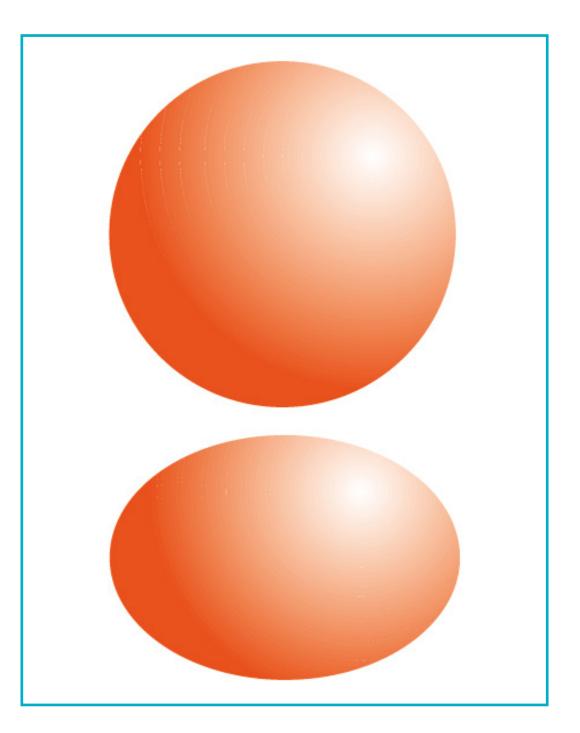
Pseudomonas aeruginosa [0.5µ]

Brevundimonas diminuta [0.3µ]

Clinically relevant testing is carried out on all products using Mycobacterium tuberculosis (TB), Bacillus subtilis (1.0µm x 0.7µm) and Ø174 bacteriophage ($0.027\mu m$).

These tests provide clinically relevant information to allow evidence-based decisions to be made on the most appropriate product to meet clinical requirements, and results with relevant particle sizes of other commonly occurring organisms found in the clinical environment.





*ΗΙV***[0.11**μ] Cytomegalovirus (CMV) [0.1µ] Orthomyxovirus [0.1µ]

Staphylococcus aureus [1.0µ]

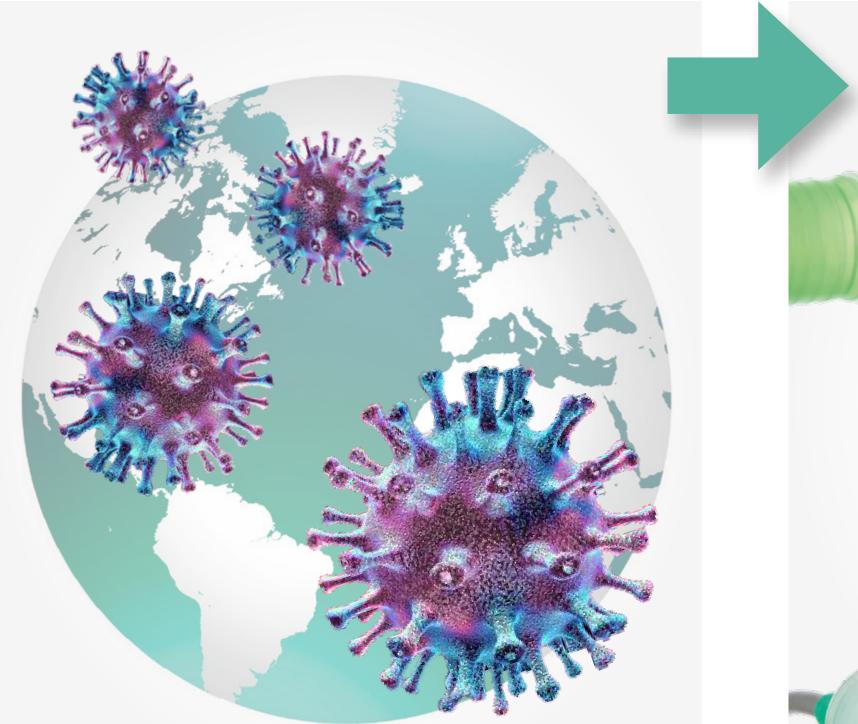
Bacillus subtilis [1.0µ x 0.7µ]





Filtration and humidification

The challenge presented in the virus test protocol (Ø174 bacteriophage, 0.027µm) will be at least as severe as that posed by the Coronavirus (COVID-19). Performance statements are available <u>upon request</u> for individual products.



The Covid-19 outbreak has affected the majority of countries and sadly lead to thousands of deaths globally.





Breathing filters

Proven filtration efficiency providing an effective barrier reducing the risk of cross contamination in the clinical environment

Breathing filters provide an effective barrier that prevent cross contamination between patients, breathing systems, respiratory and anaesthetic equipment, and the clinical environment. Their use is widely recognised as beneficial and is recommended by a number of Anaesthetic Associations¹. They are widely used across the hospital particularly in the operating theatre, critical care, lung function units, and respiratory care units.

We offer a wide and comprehensive choice of breathing filters with a variety of filtration efficiencies, sizes, volumes and shapes to ensure maximum customer choice. We provide both electrostatic and pleated mechanical filters, with a range of patient connections, providing a choice of products to meet the majority of clinical situations.

The essential requirements for our breathing filters include:

- Independently validated bacterial and viral filtration efficiency
- Proven filtration effectiveness against Coronavirus, Mycobacterium tuberculosis and Hepatitis C
- Proven efficiency within the intended clinical environment
- Low compressible volume reducing rebreathing of expired carbon dioxide



- the work of breathing
- Lightweight reducing potential patient trauma
- Safe inert material



Watch a video on our push and twist feature for safe and secure connections everytime.

All of our filters are tested at independent microbiology laboratory facilities against clinically relevant bacterial and viral challenges. To find out more about this process visit our <u>filtration and humidification page</u>.

We offer two types of breathing filters: electrostatic and pleated membrane. It is often asked which of the two filter materials give the best filtration efficiency. Despite differences in the method of filtration, electrostatic and pleated membrane filters can both offer high efficiency and a high level of protection to patients.

Low resistance to flow over its intended period of use - to reduce

Option of patient connections – conveniently packed and ready for use reducing environmental impact of the packaging

Compliance to all relevant international standards Safe, secure ISO connectors – to minimise potential disconnection and leakage



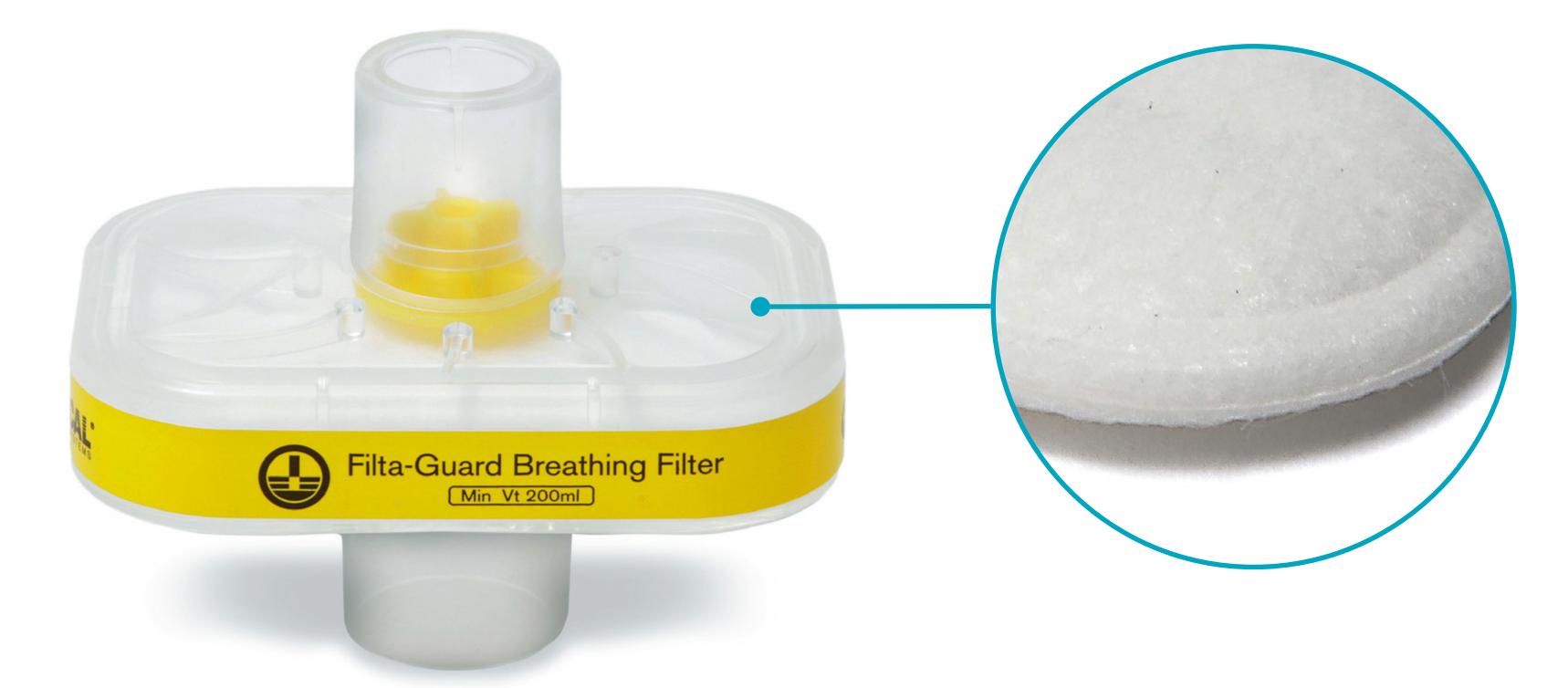


Breathing filters with electrostatic media

To discover our range of breathing filters with electrostatic media select your appropriate range from the below images.











Flo-Guard™ low resistance breathing filter







Breathing filters with pleated membrane media

To discover our range of breathing filters with pleated membrane media select your appropriate range from the below images.



Combining performance with safety

When choosing a breathing filter it is important to consider all of the clinically relevant independent information which will allow you to make an evidence based decision on what is the most appropriate breathing filter for the protection and safety of your patients.

Intersurgical will be pleased provide you with independent documentation to verify the bacterial, viral and humidification performance of the complete range.





HME and HMEFs

HMEs minimise the moisture loss from the patient's expired gases and when combined with a filter (HMEF) will also reduce the risk of cross contamination in the clinical environment.

In normal respiration the anatomy of the upper airway helps to warm and humidify inspired air, and to retain the warmth and moisture contained in expired air. During inspiration, even cold or dry air is typically heated to 37°C and when fully saturated, contains $44 \text{mg H}_2\text{O/L}$. In normal respiration, the anatomy of the upper airway helps to warm and humidify inspired gas, and to retain the warmth and moisture contained in expired air. When you inhale, even cold or dry gas is heated to body temperature and by the time it reaches your lungs, it contains the correct amount of moisture. In mechanical ventilation or anaesthesia, the patient's upper airway may be bypassed by the introduction of a tracheal tube. As a result the patient's lungs may be confronted with cold, dry inspired gas. Prolonged exposure to dry ventilatory gases can lead to:

- Localised inflammation of the trachea
- A reduction in ciliary function
- Retention and thickening of secretions
- Lowering of patient temperature
- Reduction in cardiopulmonary function
- Increased risk of tracheostomy tube occlusion
- Extended duration and cost of care

Reference 5. Technologie Institut Medizin GmbH (TiM)





HME and HMEF Media

Our range of Heat and Moisture Exchangers (HMEs) and Heat and Moisture Exchanging Filters (HMEFs) include foam or corrugated paper in combination with a filter pad. Regardless of which type of material, the aim is to provide a large surface area with low resistance to flow making them effective as a heat and moisture exchanger.

Humidification Effectiveness

The Intersurgical range of HMEs and HMEFs has been tested independently at TIM⁵ Germany in accordance with the test methodology described in ISO 9360-1:2000. Visit our <u>filtration and humidification page</u> for further details.



Corrugated Paper

Foam Media





Heat and Moisture Exchangers (HMEs)

Our range of HMEs for ventilation and spontaneously breathing patients improve the humidification of inspired gases. Also known as passive humidification, this requires an HME to be positioned within the breathing system close to the patient's airway.

The HME is designed to replicate the functions of the upper airway, conserving the patient's own expired heat and moisture and returning it to the patient on their next inspiration.

We offer a wide and comprehensive range of HMEs with a variety of efficiencies, sizes and shapes to ensure maximum customer choice whilst meeting all clinical requirements.

The common features of Intersurgical's HMEs include:

- Designed for use within anaesthesia, intensive care and home care environments
- Whilst providing some physical protection they do not provide bacterial or viral protection for the patient
- The humidity output for all HMEs is tested and validated in accordance with ISO 9360-1:2000⁶

Reference

6. Anaesthetic and respiratory equipment, Heat and moisture exchangers (HMEs) for humidifying respired gases in humans. Part 1: HMEs for use with minimum tidal volumes for 250ml.







HME and HMEFs

Our HME product range

The products included in this range are listed below and they are available to order with various accessories:



Hydro-Therm[™] HME is a small volume, lightweight device clinically suitable over a wide range of patient sizes.



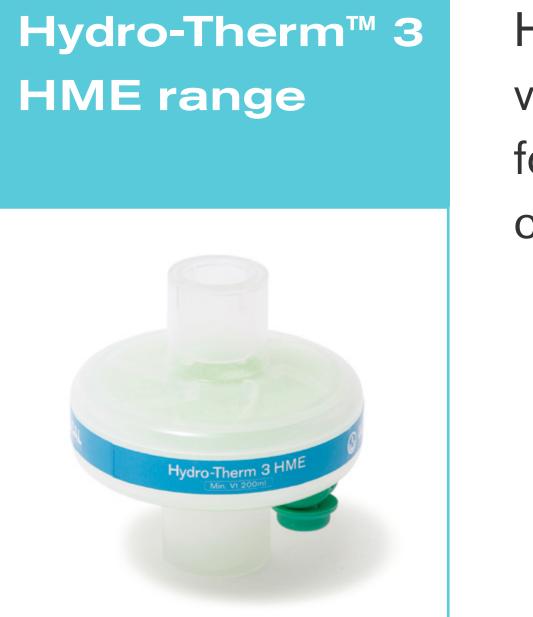
spontaneously breathing patients.

The Hydro-Trach[™] T is available in the following options:

- Safety blow off mechanism Swivel oxygen stem
- Suction port

The Hydro-Trach T is a small volume, lightweight device which is clinically suitable over a wide range of patient sizes. The normal system of temperature and moisture maintenance is bypassed by the insertion of a tracheostomy tube. The possible loss of heat and moisture can lead to serious complications, notably damage to cilia and the mucus glands.

This in turn may result in atelectasis, the retention of sputum, production of mucus plugs and potential tube occasion.



- A heat and moisture exchanger designed for use on tracheostomised patients, the Hydro-Trach™ T is an ideal product for prolonged use with



Hydro-Therm[™] 3 HME is a larger volume HME with rounded housing for use in anaesthesia and intensive care.





Heat and Moisture Exchanging Filters (HMEFs)

The Intersurgical range of heat and moisture exchanging filters (HMEFs) combines the filtration efficiency of dedicated breathing filters with optimum moisture return provided by the addition of an HME element. Designed for use at the patient connection.

We offer a wide and comprehensive choice of HMEFs with a variety of efficiencies, sizes and shapes to ensure maximum customer choice whilst meeting all clinicial requirements.

The common features of Intersurgical's HMEFs include:

- Range of filtration efficiency between 99.9% and 99.999%
- Independently validated against clinically relevant bacterial and viral challenges
- Optimum level of humidification of medical gases
- Independently tested to ISO9360⁷
- For use in breathing systems within intensive care and anaesthesia
- Maximum recommended use of 24 hours

Reference

7. Anaesthetic and respiratory equipment, Heat and moisture exchangers (HMEs) for humidifying respired gases in humans. Part 1: HMEs for use with minimum tidal volumes for 250ml.







HME and HMEFs

Our HMEF product range



A high-efficiency HMEF offered with a variety of patient connections. Filta-Therm[™] Plus (1941001) provides the optimum solution for intensive care with improved HME performance and high filtration efficiency.

Clear-Therm[™] range – medium efficiency



Clear-Therm[™] 3 and Clear-Therm[™] Angled - HMEF for use in anaesthesia and intensive care with the option of an integral 90° elbow, reducing the need for an additional catheter mount or separate patient elbow.



Clear-Therm[™] Mini - A low volume option for optimum care and protection of ventilated paediatric and neonatal patients.

The products included in this range are listed below and they are available to order with various accessories:



The Inter-Therm[™] range of sterile HMEFs is designed for use in breathing systems in the operating theatre and intensive care unit. The Inter-Therm includes corrugated paper HME media, providing excellent humidification and low resistance properties. Inter-Therm Mini angled offers an easy to use option with an integral 90° elbow for paediatrics, reducing the need for an additional catheter mount or separate patient elbow.

Clear-Therm[™] Midi - A low volume option for minimising bulk and dead space in anaesthesia.

Clear-Therm[™] Micro - An ultra low volume option for optimum care and protection of ventilated paediatric and neonatal patients.





Glossary

Absolute Humidity (AH)	Describes the water content of air.
Alveoli	Tiny air sacs in the lungs that allow for rapid gaseous exchange.
Artificial airway	Plastic or rubber device that can be inserted into the upper or lower respiratory tract to facilitate ventilation or the removal of secretions.
Atelectasis	Partial collapse or incomplete inflation of the lung.
Bacteria	Unicellular microorganisms with cell walls but no organelles and an organized nucleus, including some that can cause disease.
Barotrauma	Injury caused by a change in air pressure, affecting typically the ear or the lung.
Capillaries	Fine branching blood vessels that form a network between the arterioles and venules.
Carbon dioxide	A colourless, odourless gas produced by respiration.
Cardiac output	The amount of blood the heart pumps through the circulatory system in a minute.
Carina	A ridge of cartilage in the trachea that occurs between the division of the two main bronchi
Cilia	Short, microscopic hair-like vibrating structure found in large numbers on the surface of cells in the upper airways.

Compressible volume	The me ado sur
Continuous positive airway pressure (CPAP) Electrostatic	A fo sup ope Rel
Electrostatic media	sur We cha the mai
Efficiency	The the nor mic whe
Hepatitis C	Infla (HC hae
HIV	Acc chr by t

he internal volume of the device and the added echanical dead space that the use of the device will ad to the breathing system causing currents in the irrounding fluid.

form of positive airway pressure ventilator that pplies continuous pressure to keep the airways oen in patients who cannot breathe spontaneously.

elating to charge of electricity that is attracted to the rface of some objects.

Web of Polypropylene fibres with an electrostatic harge. These positive and negative charges enhance e filter's ability to trap microbial contaminants whilst aintaining a relatively low resistance to flow.

he level of filtration protection or function that e device can deliver. The efficiency of the filter is formally expressed as a reflection of the number of cro organisms that pass through the filter media hen it is challenged. This filter is then described as eing X% efficient.

flammation of the liver due to the Hepatitis C virus ICV), which is usually spread via blood transfusion, emodialysis and needles.

equired immunodeficiency syndrome (AIDS) is a ronic, potentially life-threatening condition caused the human immunodeficiency virus (HIV).





Glossary

Humidification	The process of increasin atmosphere around a pa or steam inhalers.
Hydrophobic	Resistance to water. Hydrodyddiad yn repel water, meaning wa stay on the surface or th
Intrathoracic	Situated or occurring wit
Lungs	A pair of organs situated of elastic sacs with bran is drawn, so that oxygen carbon dioxide be remov
Mechanical dead space	The compressible/internation the breathing systems in the volume of the systemeter exchange.
Microbial	Relating to or characteris especially a bacterium ca
Microbiologically	Refers to studies or tests effects on humans.
Mucus membranes	An epithelial tissue that a body cavities and tubula respiratory passages.
Nosocomial	Any airborne disease con medical care.

ing the relative humidity of the atient with aerosol generators

ydrophobic filter materials thus ater droplets and condensation he filter.

ithin the thorax.

ed within the ribcage, consisting nching passages into which air n can pass into the blood and oved.

nal volume of devices added as which results in an increase stem that is not involved in gas

istic of a microorganism, causing disease or fermentation.

ts relating to bacteria and their

secretes mucus, and lines ar organs including the gut and

ntracted by a patient while under

Obstructive	Par
	to t
	infe
PEEP	Abl
	Ver
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	by
	wit
Pharynx	The
	mo
Pulmonary oedema	Flu
	the
Relative Humidity (RH)	Exp
	of a
	give
	ma
	cor
	hav
Resistance	Airv
	anc
	of e
	exp

artial or complete blockage of the breathing passages the lungs caused by foreign matter, allergic reactions, fections, anatomical abnormalities and trauma.

breviation for positive end-expiratory pressure. Initiation in which airway pressure is maintained ove atmospheric pressure at the end of exhalation means of a mechanical impedance, usually a valve, thin the circuit.

e membrane-lined cavity behind the nose and outh, connecting them to the oesophagus.

uid accumulation in the tissue and air spaces of e lungs.

absolute humidity relative to a maximum humidity wen the same temperature i.e. at 37 degress gas has aximum absolute humidity of 44mg/l. If the humidity ontent of the gas were only 33mg/l then it would ave a relative humidity of 75%.

rway resistance of the respiratory tract to inhalation of expiration. This is an expression of the amount effort that is required to make an inspiratory or an piratory breath.





Glossary

Supraglottic airway devices (SADs)	Airway devices used to k provide unobstructed ver
Tidal volume	The volume of gas inhale during one respiratory cy adult is 500 ml.
Tracheal tube	A catheter inserted into t maintain a patent airway exchange of oxygen and
Tracheostomy tube	A breathing tube inserted
Virus	An organism which caus
Work of breathing (WoB)	The energy expended to gas. In a normal resting s about 5% of the total bo can increase considerab resistance within a breat by breathing apparatus.

keep the upper airway open to entilation.

led and exhaled by the patient cycle. The average for a 70 Kg

the trachea to establish and y and to ensure the adequate d carbon dioxide.

ed into a tracheotomy.

uses infection and disease.

o inhale and exhale a breathing y state the WoB constitutes ody oxygen consumption. It ably due to illness or increased athing system gas flow imposed

