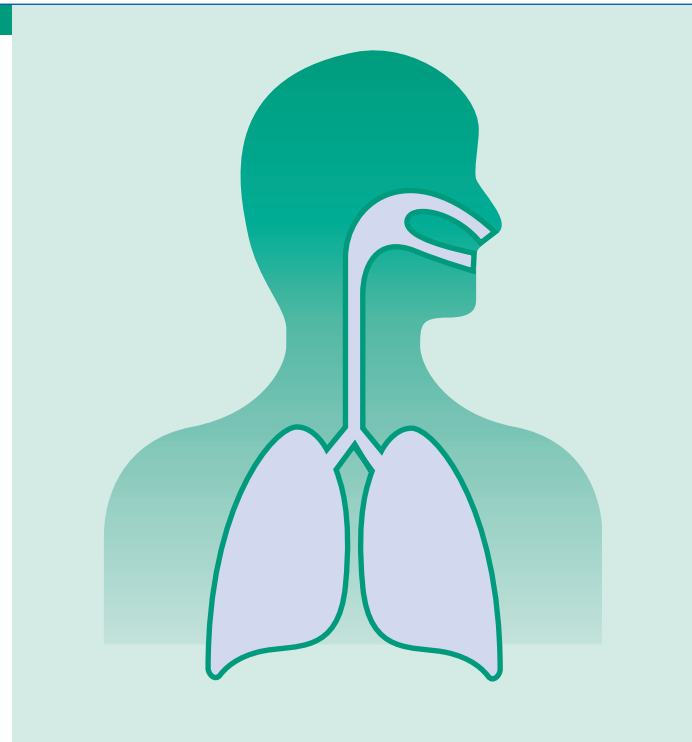




Medical



technical update



**Technical Update
on Breathing System
Filters**

Introduction

Breathing system filters are widely used in anaesthesia and intensive care. This bulletin addresses the technical features and manufacturing standards that define the ability of a filter to provide reliable protection for the patient, the environment and healthcare personnel.

There are several types of breathing system filter available; Heat and Moisture Exchanging Filters combine the ability to protect the airway against heat and moisture loss with a barrier to microbial contamination. The level of protection against micro-organisms varies with the type of filter and the means of construction. There are also simple heat and moisture exchangers that have little or no filtration capability.

The use of effective filtration, as a means of preventing patient-to-patient transmission of pathogens, has been recommended by several authoritative bodies, such as the Netherlands Department of Health Working Party on Infection Prevention (WIP)¹, the Association of Anaesthetists of Great Britain and Ireland², the Société Française d'Anesthésie et de Réanimation³ and the Australian and New Zealand College of Anaesthetists⁴. The Dutch, British and French recommendations contain particular reference to one specific technical capability of filters that meet the requirement to prevent cross infection; that is total hydrophobicity.

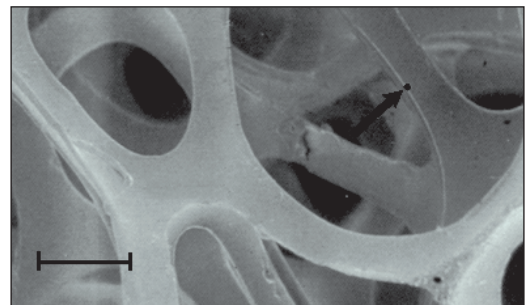
Filter Materials

Simple heat and moisture exchangers can be made from a variety of materials, including foam or paper, which may be coated with hygroscopic (moisture retaining) chemicals such as lithium chloride. These devices have poor filtration capability⁵, but hygroscopic elements are often combined with filter material in composite devices. In some devices a single material can act as a filter and heat and moisture exchanger.

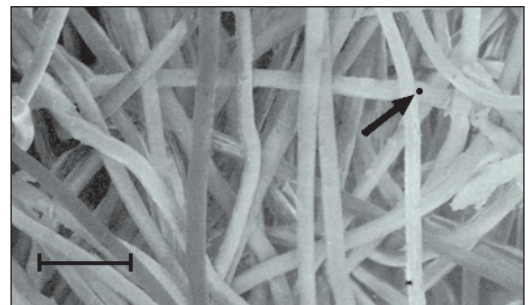
Apart from materials used to add HME capability, the two most commonly used filter materials are:

- *electrostatically charged, large-pore, felt-like material usually used in a flat sheet.*
- *a small-pore membrane that is pleated to enable a large surface area to be used.*

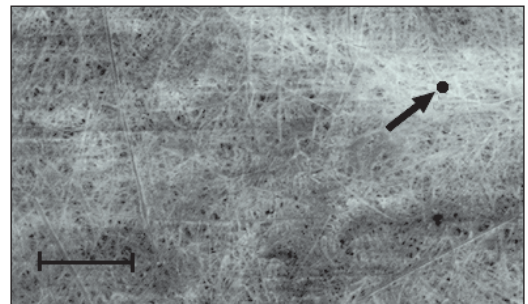
Electron Micrographs of Filter Materials



Hygroscopic



Electret



Hydrophobic

This enables identical pleats to be produced, literally side-by-side as the sheet is fed through the assembly line, conferring rigidity on the material which makes it easier to handle and enabling it to be held in place ready for precise placing within the housing.



Pall Breathing System Filters - reliability by design

Of equal importance to the preparation and pleating of the membrane, are the filter housing design and the technology used to ensure that the membrane is fully sealed within it. The four part **Pall** filter housing design ensures that the four edges of the pleated media 'pack' are reliably sealed into the housing. The sides of the two outer pleats are captured in the weld that holds the inlet and outlet sections of the housing. The pleats are held in place in integral combs in these housing sections. The filters are then separated between the housings. Two end caps are then added using unique welding technology, under precise pressure control that ensures that the ends of the pleats are fully sealed into the housing. 100% testing ensures that each seal is complete.

Pleated membrane filters could also be made using manual placement of the filter pack into a layer of adhesive laid around the inside of the housing. The reliability of the seal is dependant on the correct application of the adhesive; too little adhesive could compromise the seal and too much could reduce the effective membrane surface area of the filter. The reliability of the filter as a complete barrier to contaminated liquid is therefore dependant on the sealing technology used.

Two configurations of pleated membrane filter are commonly in use today, the rectangular design with the pleats presented transversely across the gas flow path, and a cylindrical arrangement where the gas flow bends as it passes through the housing. The rectangular design allows a large area of membrane to be placed in the housing, gives a low resistance to gas flow and lends itself to automated manufacture with careful in-process control.

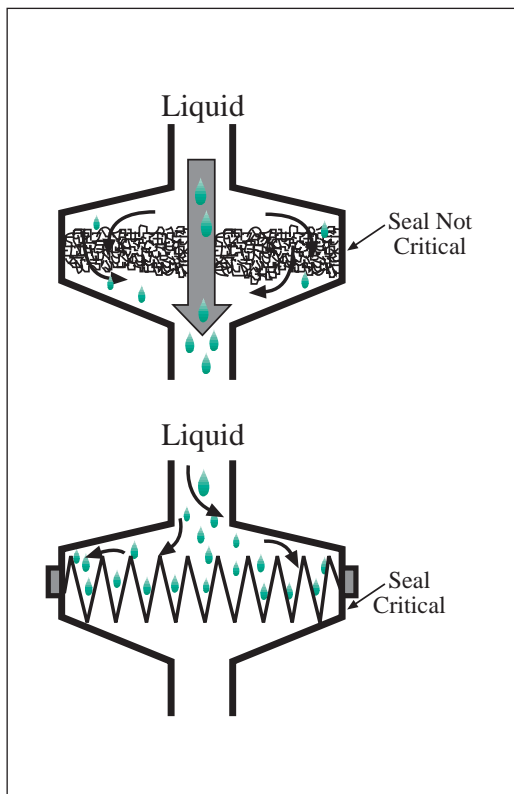
The final part of the manufacturing process is testing. All **Pall** breathing system filters are 100% integrity tested using three non-destructive methods. These test membrane and seal integrity, device resistance and housing integrity and they ensure that every single filter sold by **Pall** can be guaranteed to provide patient protection against microbiological contamination, including liquids contaminated with bloodborne viruses. Each delivery of filters is accompanied with a lot-specific Product Validation Certificate that is the customers' guarantee of product quality, reliability and performance.

Pall manufacture many millions of pleated hydrophobic breathing system filters for patient care, worldwide, every year. The experience that comes from this level of production ensures that users of these devices can rely on the knowledge that these products are made in highly controlled conditions, providing consistently reliable performance. This assurance is essential for products that are used in critical applications in patient care.



Electrostatic 'electret' felt

Electret felt filters are made from synthetic fibres that are electrostatically charged to enable the fibres to attract and hold microbes and other particles. Filter efficiency for airborne contamination is high in dry conditions, but the electrostatic charges are dissipated in the presence of liquid. It has been reported that the presence of liquid reduces the ability to retain microorganisms^{5,6,7} and the passage of bloodborne viruses through electrostatic filters has been reported⁷. Since the filter material in these devices does not prevent the passage of liquid, the need for a water-tight seal holding the filter medium in the housing is less crucial.



Pleated membranes


Pleated membrane filters are designed to prevent the passage of contaminated liquids, as well as airborne micro-organisms. The membrane material used and the means of sealing the membrane into the housing will determine their ability to prevent the ingress of liquid and remain watertight.

The proprietary membranes used in **Pall** breathing system filters are truly hydrophobic. The manufacturing process begins with the mixing of an organic resin with synthetic mineral fibres, to form a liquid mass. This coats the fibres and captures them within a matrix from which they are unable to escape. The matrix is turned into a flat hydrophobic membrane which is flexible enough to be pleated. The use of these fibres captured in a resin matrix has been established as a reliable way of ensuring true hydrophobicity of the resulting material, with good heat and moisture exchanging properties of the finished device.

Extensive testing for biocompatibility has demonstrated the suitability of this proprietary material for use in medical devices (see table 1).

Table 1.

Test	Standard
Systemic injection of elute	US Pharmacopoeia Class VI Biocompatibility testing
Intracutaneous injection of elute	US Pharmacopoeia Class VI Biocompatibility testing
Implantation	US Pharmacopoeia Class VI Biocompatibility testing
Elution cytotoxicity	US Pharmacopoeia 23rd issue Chapter 87
Sensitisation test	ISO10993-10 guinea pig maximisation test
Haemolysis	American Dental Association Document 41
Physicochemistry tests	US Pharmacopoeia 23rd issue Chapter 661
Abnormal toxicity test	European Pharmacopoeia 3rd Edition



Other types of pleated membranes are also available. However, there are several important technical and clinical capabilities that are required of a pleated membrane for good performance in a breathing system filter:

Technical considerations include:

- pleating must not compromise the integrity of the material.
- the pleated material must be able to be effectively and reliably sealed into the filter housing.

Clinical requirements include:

- the ability of the membrane to completely retain contaminated liquid^{5,7}
- the ability to maintain low resistance to gas flow when dry and, equally importantly, after exposure to liquid⁵
- the ability to provide physiological humidification if it is to be used in an HMEF⁵
- biocompatibility

Filter Construction and Manufacture

There are various methods of pleating membranes for use in breathing system filters. The material can be pleated transversely as it is unrolled, but this can lead to variability between the pleats produced. The lack of rigidity of a transversely pleated sheet can also cause handling problems, so Pall have developed a patented technology for longitudinal pleating of a membrane directly off a roll.

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