Comparison of manufacturers’ specifications for 44 types of heat and moisture exchanging filters

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Background. Although heat and moisture exchanging filters (HMEF) are recommended for use during anaesthesia, the criteria for choosing a filter are not clearly defined. Manufacturers offer many different types of HMEF with various technical characteristics. We compared the technical specifications provided by the manufacturers for different types of HMEF.

Methods. Filter manufacturers were asked to provide technical information. Additional information was obtained from websites. Information about 44 filters (16 mechanical and 28 electrostatic) was collated.

Results. Filter performances were estimated with different sizes of microorganism and durations of challenge. Twenty-eight filters had not been tested by independent laboratories. For 12 of the filters, information obtained from websites and from the manufacturers differed. Most filter specifications claimed high efficiency, particularly for filtration, microbial challenge number and test duration. Electrostatic filters used in anaesthesia were claimed to have high filtration efficiency, similar to the efficiency provided by mechanical filters. Excluding moisture output values did not alter the general conclusions.

Conclusions. Technical aspects of the tests, international standards, and independent validation should be considered when a filter is chosen.

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Many authorities recommend the use of a bacterial and viral airway filter during anaesthesia to prevent cross-contamination and reduce the need to change breathing circuits.1,2 Some bacterial and viral filters also allow humidification and heat-exchange.3 The criteria for choosing a filter are not well defined and differ between anaesthesia and intensive care. In addition, the large choice available makes choice difficult, and function, design, and the tests used to assess filter efficiency all vary. In addition, there is no internationally accepted minimum performance value for filtration. The two standards for breathing system filters are the International Standards Organisation ISO 9360-1 and the European standard norm EN 13328-1.4,5 These standards specify methods of measuring moisture output and filtration performance. We compared technical data for the principal commercially available filters, either provided by the manufacturers or measured independently.6–12

Methods

We contacted by mail either the international headquarters or, if necessary, the different country offices of companies selling heat and moisture exchange filters (HMEF) in the European Economic Community during the first third of 2002. We requested technical data, particularly the test methods used. Additional information was obtained from websites (Appendix). Manufacturers were identified from responses to public tenders and websites, and National Health Service evaluations. We then contacted the distributors. The sales literature provided for each device was compared with technical files obtained directly from the manufacturer or their Internet sites. The information supplied by the manufacturer was compared for the following:1,2,6–12 dead space, resistance, weight, moisture return; the presence of chemical additives (such as lithium, calcium chloride and chlorhexidine); filtration efficiency, calculated as [(number of colony-forming units (c.f.u.) collected...
Results
We compiled details of 44 filters, 16 mechanical and 28 electrostatic, marketed by nine companies. Their details are shown in Table 1. We used documents provided in English or French. The specifications listed a variety of tests used by each manufacturer. Sixteen filters had been tested by independent organizations or laboratories. Only eight filters had been tested after preconditioning (i.e. after exposure to simulated clinical conditions of pressure, temperature, humidity) for 24 h. In 15, antibacterial capacity was tested using Bacillus subtilis (1 µm) and in 10 virus-filtering ability was tested with bacteriophage MS-2, which is a non-enveloped single-strand RNA with a size close to that of virus particles (0.02 µm). Among the six HMEF tested with Mycobacterium tuberculosis and HCV, only two were tested for 24 h. Only three manufacturers’ reports contained independent test results of filter efficiency (Appendix). Bacterial and viral filtration efficiency rates were <99.99% for 21 HMEF, and ≥99.9999% for five, each value representing the lowest rates reported by the companies. Some results given in the commercial brochures were greater than those given in the technical documents (n=12). These differences generally concerned filtering efficiency, and were of the order of 10⁻². The sales brochures of several manufacturers gave the efficiency of the non-preconditioned filter and not the result after 24 h of testing. Differences in other features of the products, such as dead space, resistance and weight, were less.

Discussion
Two basic designs of HMEF are available: mechanical filters, which stop particles because of the small size of their pores, and electrostatic filters, which are electrostatically charged and thus attract and capture charged particles. Some manufacturers add an inert sponge-like material to the filter membrane, which retains heat and increases water absorption. This material can be chemically coated to increase water retention and enhance humidification.

Assessment of the microbial filtration of breathing system filters is typically based on tests using particles similar in size to those of bacteria (Bacillus subtilis, 1 µm) and viruses (bacteriophage MS-2, 0.023 µm).²¹ Testing filters with these non-pathogenic organisms is popular because these organisms were specified in an early draft standard for breathing system filters. A test method using sodium chloride particles was published in 2001, and was recently used to compare filters.¹⁵ Many manufacturers claim 99.95% efficiency for their filters. However, Lumley and colleagues suggested that filters should be at least 99.9977% efficient¹⁶ and the French Society of Anaesthesia and Intensive Care proposed an efficiency of 99.9999% (i.e. only one organism in 10⁷ could pass through).² In addition, the filtration efficiency values given by some manufacturers must be viewed with caution. Analysis of the specifications showed diverse tests used by manufacturers and poor accuracy of reporting. Some companies gave higher values in their commercial brochures than those reported in their technical files, or even no reference publication for some filters. Although these tests should be conducted independently, this was not so for 64% of the HMEF. It is useful to compare the data provided by the manufacturers with those published independently¹² or those given by the UK body, the Medicines and Healthcare Products Regulatory Agency (MHRA, formerly the Medical Devices Agency and the Medicines Control Agency). It must be kept in mind that filter efficacy for bacteria and viruses depends very much on the experimental conditions of the test.

The size of the inoculum, the type of microorganism used and the experimental conditions (material used, type of suspension, gas flow and duration of the test) can affect the testing of these devices. The more microorganisms (i.e. the greater the inoculum) filtered and removed, the more efficient the filter is. Considering the concentrations in secretions that can transmit infections, only a value ≥10⁻⁷ c.f.u. is acceptable. The type of microbial suspension passed into the filter is also important. The most extreme is a monodispersed aerosol, in which each droplet contains a single microorganism and the droplet evaporates before it reaches the filter.¹⁰ If the aerosol has not dried before reaching the filter, the ‘particle’ test will be assessing the aerosol droplet size. In addition, because the greater the gas flow used, the more severe the test is for the filter, for the same microbial removal value it is preferable to test the filter with the highest gas flow. These flow rates can vary from 5 to 60 litres min⁻¹. The flow typically used is 25 to 30 litres min⁻¹.¹³

The potential transmission of infectious agents, such as HIV (0.14 µm), HCV (0.06 µm) and M. tuberculosis (0.4 µm), requires supplementary validation of the capacity to filter pathogenic agents. In 1994, Ragg¹⁷ reported that a patient with hepatitis C infected four other patients in the same operating session. In the light of the recent resurgence of tuberculosis and the distinct threat of cross-infection by mechanical devices, HMEF removal of M. tuberculosis is important.¹⁸ Outbreaks of multiresistant strains associated with the enhanced vulnerability of HIV-positive individuals to this bacterium, as well as socio-economic factors, have contributed to increased tuberculosis, with an estimated 3 million deaths per year.¹⁹

Most HMEF are recommended for use for 24 h and should be tested for this period. However, anaesthesia does not often exceed 2.5 h and is often for less than 1 h.²⁰ Thus, the need to test an HMEF for 24 h should be judged in...
<table>
<thead>
<tr>
<th>Brand, trade name</th>
<th>Filter type</th>
<th>MO (mg H₂O litre⁻¹)</th>
<th>Dead space (ml)</th>
<th>Resist at 60 litres min⁻¹ (cm H₂O)</th>
<th>Weight (g)</th>
<th>Lowest claimed microbial removal (%)</th>
<th>HIV (0.14 µm)</th>
<th>HCV (0.06 µm)</th>
<th>SM-2 (0.023 µm)</th>
<th>MS-2 (0.023 µm)</th>
<th>ØX174 (0.027 µm)</th>
<th>TB (0.4 µm)</th>
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<td>HCV (0.06 μm)</td>
<td>Sm (0.45 μm)</td>
<td>BS (1.0 μm)</td>
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<tr>
<td>FE12P and FE30P</td>
<td>Electrostatic, 3 M polypropylene</td>
<td>Loss of 7 84</td>
<td>1.8 at 50 litres min⁻¹</td>
<td>46.5</td>
<td>99.9</td>
<td>Not PreC, 2.6 μm humid aerosol; Nelson: 99.999</td>
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relation to the real times and conditions of use. Intensive care requirements differ and only filters validated for 24 h should be used. Studies now show that filters can be used for more than 24 h. Humidification lasts more than 48 h21–23 or even 96 h. 24 Features such as tracheal tube obstruction, frequency of atelectasis, or nosocomial pneumonia are not different when HMEF are changed every 24 h, every 48 h21 or every 4 or 7 days. 25 26 In one study, duration of intensive care unit (ICU) stay, organ failure rate, the duration of mechanical ventilation, and mortality were not affected by changing the filter every 7 days. 24 Other criteria to be considered include the hydrophobicity of the filter, conditioning of inspired gases, the ergonomic requirements and the possible value of using a sterile filter. All HMEF are hydrophobic, the hydrophobicity varying in degree according to the type and quality of the filter, its thickness and its surface area. Although previously mechanical devices were considered to perform better,7 this notion is now contested by progress in electrostatic HMEF technology. Mechanical filters remain the most hydrophobic, with a hydrophobicity of more than 50 cm H2O (the filtering membrane is impermeable to a 50 cm high column of water), while that of electrostatic filters is between 10 and 25 cm H2O.11 In terms of patient safety, in the extreme case of total saturation of the filter by fluids or secretions, the mechanical filter would fill until it was blocked and the patient could no longer be ventilated. 27–33 This possibility would be more serious if the volume of the filter were small. 33 On the other hand, the membrane of an electrostatic filter will give way and permit ventilation of the patient but with contamination of the ventilator circuit and even the respirator. However, these arguments are more theoretical than practical, since generally patients are closely observed, and mechanical ventilators monitor airway pressure and delivered volume.

The International Standards Organisation standard ISO 93604 set the following humidification characteristics of HMEF: control of humidity at entry into the filter; temperature; duration of the test (24 h); gas flows (30, 60 and 90 litres min−1); tidal volume (250, 500, 750 and 1000 ml); and resistance at the end of the test. The standard for heated humidifiers suggests a minimum humidity of 33 mg H2O litre−1 for long-term mechanical ventilation. 34 Application of this standard to HMEF is not very helpful. 3 The minimal temperature and humidity required to preserve the functional integrity of the airways and lungs are not known. Other factors are important, such as the temperature and humidity of the inspired gases, the tidal volume, minute ventilation, patient temperature, and tracheobronchial blood flow.35 The American Association for Respiratory Care recommends that the required moisture output should be determined relative to the application and duration of use. A patient with normal respiratory function requiring intubation for a 2-h surgical procedure probably only requires humidification to 15–20 mg H2O litre−1.8
Heat and moisture exchanging filters

appear to require a minimum of 26 mg H₂O litre⁻¹ to prevent drying of secretions and maintain mucociliary function.³ For long-term ventilation of an adult patient with normal temperature, inspired gases at 33°C and absolute humidity >30 mg H₂O litre⁻¹ are sufficient.⁵⁶–⁵¹ In our review, only 13 HMEF claimed humidity provision of more than 30 mg H₂O litre⁻¹.

Hygroscopic HMEF contain a hygroscopic chemical that enhances water retention. Their efficiency may be better than that of hydrophobic HMEF devices, but this is controversial.⁴³–⁴⁴ Humidity restitution is more relevant for open-circuit ventilation or intensive care use. During anaesthesia, the role of humidification is less clear and microbial filtration capacity more important. In a low-flow circuit with a fresh gas flow of 0.5 litre min⁻¹, the conditioning of the inspired gases is comparable to that obtained with a heated humidifier.⁴⁵ An HMEF remains useful because equilibrium is reached slowly and gas cooling in the circuit reduces humidity.⁴⁶ A high-performance HMEF might also prevent moisture accumulation in ventilator circuits. Two studies in intensive care,⁴⁴–⁴⁶ showed that currently available HMEF, hydrophobic or hygroscopic, allow adequate conditioning of inspired gases. Obstruction of the tracheal tube is a very rare event and a heated humidifier is needed for very few patients.⁴⁴ If bronchial secretions are thick, a heated humidifier is necessary.

During anaesthesia with mechanical ventilation, added dead space from an HMEF is less important.⁴⁷–⁵⁸ The dead space is usually >35 ml for adults (over 25 kg), 10–35 ml for children between 3 and 25 kg, <3–5 ml for newborns and <1 ml for premature infants.⁴⁹ If ventilator weaning is difficult, dead space may be more important in intensive care, and an HMEF can also increase inspiratory resistance.⁵⁰ For patients ventilated with assisted inspiration, minute ventilation is significantly enhanced and the increase can be greater than 1 litre min⁻¹.⁴⁷–⁵⁰ Hurni and colleagues reported highly significant reductions of PaCO₂ after removal of HMEF from two patients with severe ARDS when permissive hypercapnia was applied.⁵²

Filter resistance depends on the flow rate used. Most of these filters were tested in adults using a flow rate of 60 litre min⁻¹, but flow rates of about 30 litre min⁻¹ were used for several filters, so that comparisons are difficult. Most of the filters we studied were low-resistance devices (0.8–3.6 cm H₂O for a gas-flow rate of 60 litre min⁻¹, ≈0.85 cm H₂O for use in pediatrics). Compared with endotracheal tube resistance, this resistance is small and does not affect expiration.³

HMEF can increase expiratory resistance if intrinsic positive end-expiratory pressure (PEEPi) is present in patients without chronic obstructive pulmonary disease (COPD).⁴⁷–⁵¹ In contrast, use of an HMEF does not increase PEEPi in patients with COPD.⁵²

Some companies can supply sterile filters but, to date, no standards recommend this. The Medical Committee of the Medical Devices Agency considers that sterile ventilator systems are not required. On the other hand, HMEF must be bacteriologically clean and made to conform with ISO or European standards and good manufacturing practice.

In summary, the features required of an HMEF are not clear. There are different needs for anaesthesia and for intensive care. Sales literature is often insufficient to allow evaluation of these devices and even technical information may be difficult to compare, so independent validation of their characteristics is needed.

Appendix

List of websites consulted
www.anselethecare.com
www.gibeck.com
www.intersurgical.com
www.mallinckrodt.com
www.pall.com
www.medisize.com
www.portex.com
www.ansellhealthcare.com
www.gibeck.com
www.mallinckrodt.com
www.portex.com
www.ansellhealthcare.com
www.vygon.com

List of publications validating the filtering efficiencies of 15 HMEF (DAR, Intersurgical, Pall)
Efficacy of a pleated hydrophobic filter as a barrier to Mycobacterium tuberculosis transmission within breathing systems. Pall, Centre for Applied Microbiology and Research (CAMR), 1995
Efficacy of a pleated hydrophobic filter as a barrier to human immunodeficiency virus within breathing systems. Pall, CAMR, 1997
Efficacy of a pleated hydrophobic filter as a barrier to human immunodeficiency virus within breathing systems. Pall, CAMR, 1997
Evaluation of Sterivent Mini as a filter preventing the transmission of hepatitis C virus. DAR, CAMR, 1997
Test protocol and evaluation of Intersurgical’s Clear-Guard II as a bacterial filter for prolonged periods. CAMR, 1993
A protocol and evaluation of Intersurgical’s Clear-Guard II as a filter preventing the transmission of hepatitis C virus. CAMR, 1997
A protocol and evaluation of Intersurgical’s Clear-Guard II as a filter against Mycobacterium tuberculosis. CAMR, 1996
A 24-hour test protocol designed to evaluate Intersurgical’s Filta-Guard as a viral filter. CAMR, 1993
A 24-hour test protocol designed to evaluate Intersurgical’s Filta-Guard as a viral filter. CAMR, 1993
A 24-hour test protocol designed to evaluate Intersurgical’s Filta-Guard as a viral filter. CAMR, 1993
A protocol test and evaluation of Intersurgical’s Filta-Therm as a filter against Mycobacterium tuberculosis. CAMR, 1996

A 24-hour test protocol and evaluation of Intersurgical’s Clear-Therm Mini as a bacterial filter. CAMR, 1996

A test protocol and evaluation of the Intersurgical’s Filta-Guard as a filter preventing the transmission of hepatitis C virus. CAMR, 1997

Evaluation of Intersurgical Hydro-Guard Mini as a viral filter, before and after simulated use for 24 h. CAMR, 1999

Evaluation of Intersurgical Hydro-Guard Mini as a bacterial filter, before and after simulated use for 24 h. CAMR, 1999

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