

## Breathing Filters and Heat and Moisture Exchangers: Current Thinking Exposed!

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### Abstract

Breathing filters are becoming a standard tool used in the hospital environment to combat the possibility of the spread of nosocomial infection in ventilated patients around the world. This review includes an update on current thinking concerning breathing filters, a re-evaluation of currently used terminology and correct validation and use of product, as viewed from a manufacturers perspective.

Perhaps the two main issues this presentation attempts to draw attention to includes challenging the traditional models describing the way breathing filters function as well as discussing the preferred test protocol by which breathing filters can be evaluated in terms of bacterial and viral efficiency.

**Key words:** current terminology – traditional models of filter's function – test protocol

### Souhrn

#### Současný pohled na dýchací filtry a výměníky tepla a vlhkosti

Dýchací filtry se postupně stávají standardním nástrojem používaným v nemocničním prostředí na celém světě a slouží k omezení možnosti šíření nozokomiální infekce u ventilovaných pacientů. Tento přehled shrnuje současné názory na dýchací filtry, přehodnocuje současně používanou terminologii a uvádí správné validace a používání výrobku z pohledu výrobců.

Sdělení se snaží soustředit pozornost na dvě hlavní otázky – přehodnocení tradičních modelů, které popisují způsob fungování dýchacích filtrů, a diskusi o preferovaném testovacím protokolu, pomocí kterého mohou být dýchací filtry hodnoceny z hlediska bakteriální a virové účinnosti.

**Klíčová slova:** současná terminologie – tradiční modely fungování filtrů – testovací protokol

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### Introduction

The Breathing Filter product group is often subdivided into the three categories including heat and moisture exchangers (HMEs), breathing filters and heat and moisture exchanging filters (HMEFs). Heat and moisture exchanging devices are designed to replicate the function of the nasal passages of a ventilated patient in the warming and humidification of inspired gases on the inspiratory phase. Heat and moisture exchangers also cool and dehumidify the expired gases on the expiratory phase. This helps maintain homeostasis and prevents water loss in ventilated patients where the nasal passages have been by-passed by the endotracheal tube or laryngeal mask.

Breathing filter products are designed to prevent contamination in breathing systems through the retention of bacteria, viruses and other potentially infectious microbes.

#### Labelling of breathing filter products

In the absence of any advice from a competent

authority or an international standard describing how these products should be labelled, manufacturers adopt a variety of ways for the end user to identify the product. At present manufacturers have no agreed policy as to the labelling of breathing filters. One manufacturer allocates HMEs a blue label – representing moisture, bearing in mind the multilingual world. The same manufacturer allocates the filter products a yellow label, another primary colour. The combined HMEFs are allocated the resulting secondary colour of green as a label. Another manufacturer allocates the filter product a red label, an HME product a green label and an HMEF product a blue label.

Many other manufacturers have no colour coding to differentiate breathing filters from heat and moisture exchangers.

#### Maximum period of use

While breathing filters and HMEs are likely to retain their claimed efficiency when used over extended periods of time (in terms of moisture return to the patient and filtration efficiency), it is never the less contraindicated to use many of these filter/HME products for periods of use exceeding 24 hours due to

reasons of correct procedure. After a filter has been used for an extended period of time there may be an accumulation of organic secretions in the filter providing a suitable medium for growth of bacteria, possibly compromising the patient. A second reason for replacing the filter after 24 hours is to reduce the possibility of product occlusion, which will increase by extending the period of time the product, is in use.

### Contraindications

Literature suggests [1] that while heat and moisture exchangers may provide a good option in terms of meeting a ventilated patients heat and moisture requirements, there is also a requirement for short term over humidification in the form of a water bath or "active" form of humidification.

It should be noted that heat and moisture exchanger products are contraindicated for use by many manufacturers for use on patients with thick and tenacious secretions. Dehydrated patients may require a higher than usual moisture return and some form of active humidification would be more suitable for this type of patient.

During administration of nebulised antibiotics a breathing filter can be used to prevent the often viscous aerosol from contaminating the ventilator as well as protecting the environment from pollution. Viscous nebulised antibiotics can increase the resistance to flow of breathing filters, resulting in a shortening of the recommended period of use of the product. Some manufacturers recommend monitoring the resistance to flow in a breathing system, which contains a breathing filter and/or HME when nebulised drugs are being administered. A breathing filter should never be positioned between the source of nebulisation and the patient as the filter will prevent the passage of the required drug.

### Why use a HME

As humans inhale cold dry gases from the environment during normal respiration the air is warmed to a temperature of 37 Celsius and humidified to an absolute humidity of 44 mg H<sub>2</sub>O/L by the body's own natural heat and moisture exchanging process of the respiratory system. It has been estimated that up to 75% of the heat and moisture added to the inhaled air comes from the passage of gases through the nasal passages. During intubation of a ventilated patient the nasal passages are by-passed by the endotracheal tube and so it seems reasonable that an additional form of heat and moisture exchange is required for intubated patients in order to maintain homeostasis, such as a heat and moisture exchanger or even some form of active humidification.

### Effects of under humidification

The effects of under humidification are well recognised and include: the mucous becoming thick and tenacious, swelling of the mucosa which depresses ciliary's activity, obstruction by mucous plugs of the

lower airways and endotracheal tube, lung infection and necrosis in the respiratory tract.

### A comparative study of Condenser Humidifiers

Many investigations have been carried out over recent years to compare the effectiveness of heat and moisture exchangers with a water bath [2]. Even during the earlier years of development of heat and moisture exchangers it was suggested [3] that unless short term respiratory over hydration is required, the condenser humidifier system is the best choice for all patients with endotracheal tubes or tracheostomies.

### How much humidification is recommended

AARC Clinical Practice Guidelines [4] recommend that in the following arenas the chosen device should provide a minimum moisture return of 30 mg H<sub>2</sub>O/L of delivered gas at 30 degrees C: critical care, extended care, home care and prolonged transport.

Current international standards recommend that for active humidification the device should be capable of returning 33 mg H<sub>2</sub>O/L of air [5].

There is no International Standard recommendation to advise the minimum moisture requirement for an HME designed for use in the operating theatre.

In 2001 the effect of humidification on incidence of adverse airway events was studied in the operating theatre environment by comparing the incidence of adverse airway events when using either a heat and moisture exchanger with a high performance or a low performance in terms of moisture return [6].

Adverse airway events were determined by the incidence of coughing or laryngospasm after extubation. It was found that with a low humidity HME the incidence of adverse airway events was 59% as compared to 35% with a high humidity HME (P < 0.05).

It was concluded that high humidity HMEs significantly reduce the incidence of adverse airway events.

### How Heat and Moisture Exchangers work

The most popular material used to retain moisture in heat and moisture exchangers includes wound paper, wool and polyurethane foam.

A patient will exhale a hot wet gas onto the relatively cool HME media, where condensation occurs and water gas is converted to water liquid, thus warming the HME. During inspiration the water evaporates and is carried back to the patient by the flow of air. During evaporation the latent heat of vaporisation cools the HME, temporarily, preparing it for the next expired breath. This can clearly be described as the physical mechanism, which enables the product to work.

In order to further increase the efficiency of the heat and moisture exchanger in terms of moisture return a hygroscopic salt can also be added to the media. This salt has in the past included both lithium chloride and calcium chloride. Due to concerns over lithium chloride being a known depressant it is more common for manufacturers to use calcium chloride. This is the chemical mechanism of operation. Some

HMEs include calcium chloride whereas some rely purely on the physical characteristics of the foam to return moisture to the patient and so may be described as being salt free.

### **Why breathing filters are used in the market**

Breathing filters are used to prevent infection through the retention of bacteria and viruses, which would otherwise be released into the breathing circuit and associated equipment. There are a number of reasons why the routine use of breathing filters has been so widely accepted on a filter per patient basis (a new filter for each patient) in operating theatres around the world:

1. In January 1994 the South West Sydney Area Health Service Public Health Unit was notified of two patients who experienced acute hepatitis five to seven weeks after undergoing minor orthopaedic procedures on the same day at the same private hospital in southwest Sydney. It was subsequently found that five out of ten patients on the same theatre list were found to be Hepatitis C positive and it was reported as the first recorded case of patient-to-patient transmission of a virus by the anaesthetic circuit. Breathing filters were not being used in the hospital at the time. It was further pointed out by the New South Wales Public Health Bulletin [7] "The NSW Infection Control Policy for HIV, AIDS and associated conditions, published in 1992 states that" a filter for the anaesthetic circuit must be used to prevent cross infection of the anaesthetic circuit.

2. In 1989 at the University of California, workers investigated the incidence of bleeding after oral endotracheal intubation. Tests for the presence of blood were performed on one hundred surgical patients following oral intubation and extubation. Eighty-six per cent of patients were positive for the presence of blood in the sputum. Breathing filters are useful tool in preventing the passage of blood into the breathing circuit [8].

3. It was reported that in 1995 more people died as a result of *Mycobacterium tuberculosis* than in any other year in human history (three million) [9]. Infection is caused by the inhalation of airborne infectious droplet nuclei. In the 1980s it was thought that tuberculosis was to be eradicated but due to complacency it is back, with some strains being virtually untreatable. It should be noted that high efficiency breathing filters could be used to prevent infectious particles like *Mycobacterium tuberculosis* getting into the breathing circuit. Three companies have validated their breathing filters against the passage of *Mycobacterium tuberculosis* although not all validations follow an independent test procedure.

4. Various recommendations have been made concerning the use of breathing filters by different associations of anaesthetists around the world in order to guide their members following a review of literature available.

In 1996 the Association of Anaesthetists of Great

Britain & Ireland recommended that "Either an appropriate filter should be placed between the patient and the system, a new filter being used for each patient or that a new breathing system be used for each patient" [10].

In 1998 the French Society of Anaesthetists recommended, "For each patient, a bacterial filter should be placed after each patient..."

In 1998 the Danish Society of Anaesthetists recommended "Replace the system for every patient and/or use a filter and replace it for each patient" [11].

5. In the intensive care unit scenario the water bath has in the past been a well-documented source of infection. The use of breathing filters/HMEs in the intensive care unit has been shown to reduce the incidence of nosocomial pneumonia from 16% down to 7% as compared with the water bath type of humidifier [12].

6. In 1995 the Public Health Laboratory Services in the U. K. carried out research into the "Socio-Economic Burden of Hospital Acquired Infection" [13].

In summary this is a financial study where the additional costs incurred by a hospital, following a hospital-acquired infection were determined.

The most costly type of infection was found to be a blood infection. The second-most costly infection was an infection of the lower respiratory tract. This type of infection was found to cost the hospital an extra GBP 2,000 per patient, adding an extra GBP 450,000 to the study hospitals costs per year.

Clearly this demonstrates that for every breathing filter used in the intensive care unit, which prevents an infection of the lower respiratory tract, the hospital will save GBP 2,000.

### **Future requirements of breathing system filters**

Apart from the traditional reasons for using breathing filters, mentioned above, there are new challenges being presented to the control of infection in breathing circuits and associated equipment each year. New issues concerning breathing filters have arisen in recent years including the prion and SARS outbreaks.

Prions are, of course, proteinacious infectious particles, which do not contain DNA and so according to traditional thinking, could not be capable of causing infection. In the case of Creutzfeldt Jacobs disease (CJD) there are four areas of infection of concern, which include sporadic CJD (unexplained flip in protein structure), Variant CJD (ingestion), iatrogenic CJD (surgery/transplants) and genetic CJD (predisposition to infection).

The disease has been described as progressive and always fatal with an incubation period, which may exceed fifty years.

Clearly prophylactic use of breathing filters would appear a reasonable precaution should there be any possibility of patients being infected by this rogue protein.

It is probable that a good quality breathing filter will be highly efficient at preventing the passage of this type of challenge, particularly bearing in mind that the prion particle will not be presented as an individual unit to the filter but will be associated with a larger "carrier".

The out-break of Severe Acute Respiratory Syndrome (SARS virus) in various parts of the world during 2003 caused much concern with respect to the public health. The Ministry of Health in Ontario (Canada) and the Taiwan Respiratory Society issued directives to hospitals „To use high efficiency breathing filters for SARS patients to protect patients and healthcare workers“. It was also recommended for healthy patients in isolation from SARS (no symptoms) to wear a mask whenever in the same room as another member of your household [14].

Breathing filters have not been validated against the passage of any of the coronavirus family of viruses though due to the relatively large size of these viruses we can be confident that filters validated against the passage of the MS2 virus would be highly efficient in preventing the passage of the SARS virus. The MS2 virus has a diameter of 23 nm whereas the SARS virus has a diameter of between 80 nm and 160 nm.

The SARS virus can be spread through the inhalation of air-borne droplets or spread by touch.

#### **Mechanisms of filtration: Do you believe traditional models?**

Current literature describe both a "mechanical" type of breathing filter as well as an "electrostatic" type of breathing filter in order to differentiate between a filter with a pleated membrane (folded filter membrane) and a filter with a flat membrane (Fig. 1). It is suggested that both terms "mechanical" and "electrostatic" are inaccurate and misleading when describing breathing filters in terms of how they work and there is another better model for consideration. By definition, a mechanical filter requires a pore size smaller than the particle, which is to be retained in order to filter the particle "mechanically". In the case of bacteria the pore size would be around 0.2 microns and for viruses the pore size would be around 0.02 microns. By inspection it can be seen that no



**Fig. 1.** Physical sieving of particulate material versus Electrostatic attraction of particulate material (Traditional theory)

breathing filter on the market has a pore size anywhere near as small as this. A mechanical filter can also be described as a screen filter or an absolute filter and the filtration performance should be given as a rating. For example, a mechanical breathing filter designed to prevent the passage of bacteria should have a rating of 0.2 micron.

Traditionally "electrostatic" breathing filters consist of a non-woven pad of different plastic fibres. Some manufacturers claim this type of filter contains positive and negative fibres, which are held apart or insulated by polypropylene fibres. In this scenario the particles to be retained adhere to the fibre through electrostatic forces in much the same way as a rubber balloon adheres to the ceiling through electrostatic forces when placed there after being rubbed on woollen fabric.

Electrostatic forces are short-term forces, which dissipate with time. This can be demonstrated by the afore mentioned balloon which only adheres to the ceiling for a short time, until the imbalance of electrons between the two surfaces equalises. If breathing filters truly operated through electrostatic forces then they should be contraindicated for use unless used within the first few hours of manufacture before any short-term charge diminishes. It can be seen that breathing filters are unaffected by years of storage in terms of bacterial retention performance indicating that breathing filters do not retain a bacterial challenge primarily by electrostatic forces.

In order to understand how breathing filters truly work we need to consider another type of force of attraction, which can be described as intermolecular forces [15]. Intermolecular forces do not dissipate in the same way as short-term electrostatic forces, allowing breathing filters to have an indefinite shelf life.

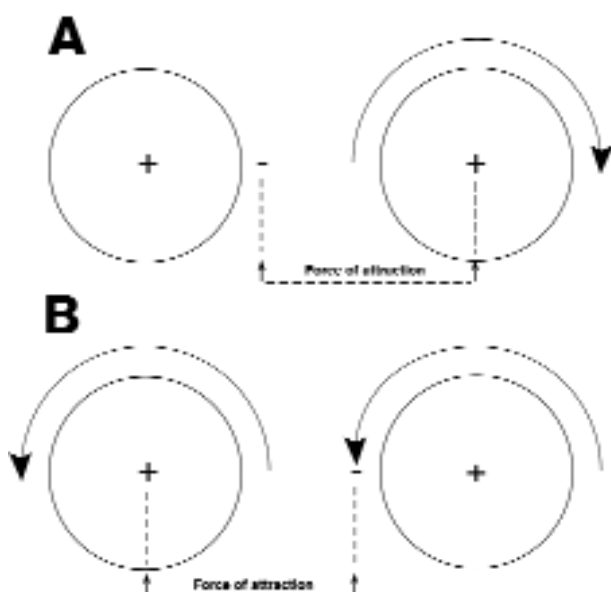
An example of intermolecular forces is well demonstrated by the water molecule in its liquid phase,  $H_2O$  (L).

As the water molecule is much smaller than alcohol ( $C_2H_5OH$ ) it should in theory have a lower boiling point, in terms of physical dynamics. The reverse is true due to intermolecular forces, which partially bind the oxygen atom of one molecule to the hydrogen molecule of its neighbouring molecule. The resulting increased stability thus gives the water molecule a higher boiling point than expected... before water (liquid) vibrates with enough energy to become water (gas).

It is also possible to demonstrate with other models that even two neutrally charged particles can have a theoretical attraction between each other in terms of intermolecular forces. It therefore follows that a bacterium or virus does not need a positive or negative charge associated with it to be retained by a breathing filter, as is sometimes inferred.

In the following diagram (Fig. 2) two theoretical atoms are represented at two different moments in time (A and B). This model is not intended to offend any physicist or represent any known atom or to infer





**Fig. 2.** Model of intermolecular forces of attraction between two neutrally charged particles

that electrons exist as discrete particles. It can be seen that although each atom is neutrally charged, nevertheless the electron of one molecule could theoretically be in the right place in relation to the proton of its neighbouring atom and create a force of attraction at a specific moment in time. This is a theoretical model purely introduced to emphasize that fibres in a breathing filter media do not have to be positively or negatively charged to retain particles as a force of attraction can be demonstrated between two neutrally charged particles.

This raises the question as to whether it matters how a breathing filter works so long as it does the job for which it is designed. This issue hinges on the way filters are sometimes conceptually promoted, on the basis that “finer filtration must be more efficient than a filter with a larger pore size”. Sometimes filtration efficiency is erroneously demonstrated visually through electron micrograph pictures rather than validation through proper test procedures [16].

Breathing filters containing a flat filter medium are generally constructed of plastic fibres, which are more polarisable than the ceramic or glass fibres contained in many pleated membrane filters. As plastic is more polarisable than glass it should be more bacterially retentive on a fibre to fibre basis and so a filter medium with finer pore size does not always have a higher level of retention than a filter media with a larger pore size. Perhaps the reason why pleated membrane filters are often observed to be more retentive than flat filters is due to the often-increased number of fibres in a pleated membrane filter and the resultant larger first surface area of the media. The surface area of the media in a pleated membrane filter is often immense in comparison to the surface area of a flat filter media if the surface of each fibre is

taken into account.

In order to determine the filtration efficiency of a breathing filter it is clear the performance should be determined in a laboratory through following a test procedure, being independent of a manufacturer.

### **The concerns associated with glass micro fibres**

Based on theoretical arguments, glass micro fibre is not the ideal medium to be used in a breathing filter.

Although glass is a hydrophobic material and unlikely to block when subjected to conditions of high humidity when presented in the form of water vapour, it is never the less a recognised carcinogen when inhaled in the form of fibres. Glass microfibre was given a classification pertaining to carcinogenic materials as long ago as 1993 [17]. It is therefore important for manufacturers of pleated membrane breathing filters to be able to validate their product for “zero fibre release”. Any verbal assurances may be considered as insufficient without the presentation of a full evaluation report including test results.

### **The anti-occlusion failsafe mechanism for patient safety**

Occasionally breathing filters will be presented with a gross liquid challenge in the form of excess sputum, pulmonary oedema or water. In this scenario a pleated membrane breathing filter will become occluded and potentially act as a one way valve if positioned at the Wye piece, close to the patient. Air could then pass from the ventilator into the patient but not leave the patient due to the fluid on the patient side of the filter.

Even though pressure alarms are a standard safety feature in breathing systems pneumothorax can result. Some flat filter manufacturers build a safety feature into the filter medium so that the media will break at a pre-determined pressure in order to protect the patient, although this feature is not seen in pleated membrane filters due to the strength of the ceramic micro fibres.

### **Test protocols to validate efficiency of bacterial and viral breathing filters**

There is still no international standard protocol available to advise a filter manufacturer how to validate breathing filters against a bacterial or viral challenge. The result is that manufacturers tend to follow in-house test procedures, which they design themselves; sometimes with the objective of ensuring the product is highly marketable. For instance to improve the perceived bacterial retention efficiency a breathing filter could be tested erroneously at a lower flow rate, or the bacterium selected could be of the *Staphylococcus* genus (small in size but they aggregate in suspension thus making the challenge easier to filter). With manufacturers following their own test protocols it is difficult for the end user to differentiate between various filters in terms of bacterial

or viral efficiency. What the end user requires is for all manufacturers to validate their own products through following a recognised bacterial and viral test procedure in order to create a level playing field on which to market commercially available product. In March 2004 the Medicines and Healthcare Products Regulatory Agency (MHRA) issued an Alert to all U. K. hospitals warning of "Inconsistencies in the methods used for testing filter efficiency..." [18].

Perhaps the only obvious test protocol for a manufacture to follow is best described as the Draft European standard BS EN 13328-1 (Bacterial/viral version). This test protocol was designed over a period of eight years by an independent group of experts for presentation as an international standard.

The objective was to determine the relative bacterial and viral retention efficiencies of filters on the market, which was accomplished at perhaps more severe conditions than would have been seen under clinical conditions. In summary, the Draft European standard BS EN 13328-1 (Bacterial/viral version) has two separate stages:

At a flow rate of 30 lpm, either *Bacillus subtilis* (Bacterium) or *MS 2 coliphage* (virus) challenge the filter as an aerosol. The challenge must contain 10,000 000 microorganisms delivered over a period of one minute: This will provide the fresh test result. After a 24 hour conditioning of the filter with humidified gases the filter is challenged again under the above conditions at 30 lpm in order to determine the second test result: This will provide the conditioned test result. For example, the same filter could be described as having a bacterial efficiency of 99.999% (F). "F" refers to the fresh or unconditioned state of the filter in the first test and 99.99% (c), "c" refers to the conditioned or humidified state of the filter in the second test; giving the two results through following the same test protocol.

The above protocol was recorded in Anaesthesia [19].

The article was written by independent workers from the Medical Devices Agency (U. K.) and the Centre for Applied Microbiology at Porton Down, U. K. The authors commented that acceptance of the Draft European standard BS EN13328-1 should allow the efficiency of different types of filters to be compared objectively. Another way of describing this protocol is Pr EN13328-1 (Bacterial/viral version).

BS indicates a British Standard. EN indicates a European Standard. Pr indicates a proposed or draft standard.

A certain amount of confusion and controversy has recently arisen with the advent of a new international standard protocol for the evaluation of filtration efficiencies of breathing filters. The protocol can be described as ISO 23328-1 and the challenge particle is not a bacterium or virus but a sodium chloride crystal! As no correlation has been demonstrated between the retention of a bacterium and sodium chloride crystal, manufacturers cannot use this test to

validate the bacterial or viral performance of their products. In order for a manufacturer to meet the requirements of the Medical Devices Directive (A legal requirement for manufacturers in the European Community [20]), breathing filters must be validated against a bacterial or viral challenge unless a correlation has been achieved between bacteria and sodium chloride crystals. As such this international standard could be a "non-conforming standard", which cannot legally be used to validate breathing filters bacterially or virally. The sodium chloride challenge test is however an invaluable manufacturing test as it can be used routinely to test every filter in a production run to ensure the filter medium is intact in the filter housing as well as free of tears or pinholes.

In summary, the sodium chloride test involves the nebulisation of sodium chloride solution. The aerosol is passed down a heated tube, which dries out the aerosol in order to present the resulting sodium chloride crystal to the filter medium for analysis of retention efficiency. If the crystal passes through the filter it is detected using a photosensitive cell, which is activated by light, when the sodium chloride crystal passes through a laser beam. This method of testing a breathing filter is useful as the filter can be used in a clinical situation having been tested for quality during the production phase.

#### **Filters as a tool for the retention of latex proteins and nebulised antibiotics**

While breathing filters have been specifically designed to retain bacteria and viruses when presented as a challenge in a breathing system they are never the less effective at retaining other challenges such as nebulised antibiotics or latex proteins. Nebulised drugs often tend to be viscous and in order to protect equipment in the breathing system from being contaminated or damaged a breathing filter is often used.

Due to the wide range of nebulised drugs available it is not practical to validate breathing filters against all challenges, particularly bearing in mind there is no recognised test procedure for carrying out this task.

Breathing filters represent a useful tool in the retention of nebulised drugs thus protecting equipment as well as the environment from contamination. By observation it appears generally true that pleated membrane filters provide a higher efficiency at retaining nebulised drugs than flat filters though a well validated flat filter can also be used for this purpose.

Some breathing filters on the market are validated against the passage of latex proteins (Pall and Intersurgical filters including some flat and pleated filters) thus providing further protection to the patient against the possibility of anaphylactic shock through latex allergy.

#### **Sterilisation of breathing system components**

For some time now it has been debated in marke-

ting circles in some countries as to whether a breathing filter should be provided sterile or not. As breathing filters are non invasive devices used in a non-sterile field and connected to often non-sterile catheter mounts and non-sterile breathing circuits some manufacturers have always supplied non-sterile breathing filters to the market. In-house investigations have shown that when sterilising breathing filters, using ethylene oxide, the filtration efficiency of the product is affected adversely by a factor of ten. It is interesting to note that the manufacturers who promote both sterile and non-sterile filters do not differentiate any differences in filtration efficiency between these two items, which are otherwise identical, apart from the sterilisation process.

## Conclusions

Although this article argues the case for breathing filters to be evaluated through following a standard bacterial and viral test protocol it is never the less relevant to draw the readers attention to one of the better evaluation reports concerning breathing filters carried out in recent years.

The Medicines and Healthcare products Regulatory Agency (MHRA) published a report [21] evaluating 104 different breathing filters on sale in the United Kingdom in March 2004. This 52-page report is well presented with colour photographs of each product and outlines the filter specifications including the filtration efficiency in terms of sodium chloride retention.

While it is not within the scope of this article to promote the necessity for bacterial and viral validation of breathing filters further, it is worth noting that the recent MHRA report has a real value in that it is the first time so many filters have been evaluated in terms of retention efficiency (albeit salt retention) through following the same protocol. This allows the end user access to a correct ranking of product in terms of retention efficiency.

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