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APPARATUS

Measuring the filtration performance of breathing system filters using sodium chloride particles*

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Summary

The filtration performance of 33 breathing system filters (nine pleated hydrophobic and 24 electrostatic filters) was measured using sodium chloride particles. The particles had a size distribution with a count median diameter of 0.07 μm and a geometric standard deviation not exceeding 1.83. The geometric mean penetration values ranged from 0.002 to 0.67% for the nine pleated hydrophobic filters and from 0.25 to 35% for the 24 electrostatic filters ($p < 0.0001$ for the difference between the two filter types). The filtration performance obtained when filters are challenged with either sodium chloride particles or microbes is compared and discussed.

Keywords *Infection*, *bacterial*: viral; *Mycobacterium tuberculosis*. *Equipment*: heat and moisture exchange filters.

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Breathing system filters are recommended for use during anaesthesia to prevent cross-infection when breathing systems are used for more than one patient [1]. However, wide variations in the filtration performance of different breathing system filters have been reported [2–8]. Comparing the results from the various studies is difficult because of the use of different test methods and organisms [9]. In particular, the filtration efficiency of filter media varies with the size of the particles in the challenge to the filter. The efficiency is generally at a minimum for particles in the size range 0.05–0.5 μm [10].

Respiratory protective devices are used to protect the wearer against the inhalation of harmful particles, such as infective aerosol droplets and dust. A standard for respiratory protective devices has been published by the National Institute for Occupational Safety and Health (NIOSH) [11]. In this standard, the filtration efficiency of the device is measured by challenging the device with sodium chloride particles having a diameter in the most penetrating particle size range for the filter media.

A standard test method is required for breathing system filters to enable an objective comparison to be made between filters supplied by different manufacturers [12]. The test method specified in the draft European standard for breathing system filters [13] is now based on the test published by NIOSH [14]. Test equipment is available commercially to determine the filtration performance of filter media used in respiratory protective devices according to the NIOSH standard. This equipment was used to determine the filtration performance of breathing system filters available on the UK market.

Method

Test equipment intended for measuring the filtration performance of respiratory protective devices was used following a minor modification to enable a breathing system filter to be connected (Model AFT 8130, TSI Inc., St. Paul, USA) (Fig. 1).

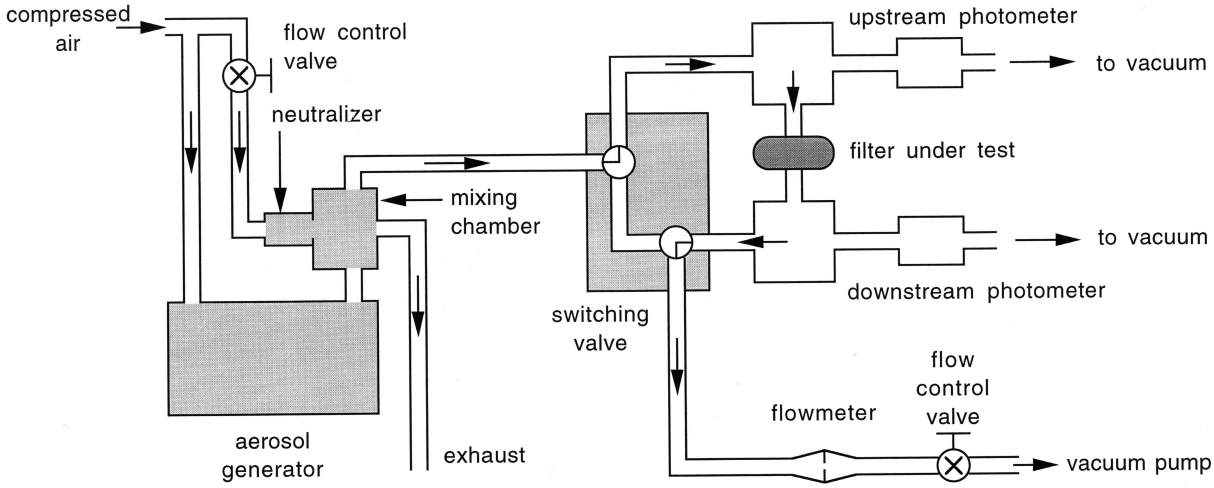

Figure 1 Schematic diagram of the TSI AFT 8130 filter tester.

Table 1 The manufacturers of the filters used in the study and their addresses.

Manufacturer	Filter	Address
Cory Bros	Bacterial Filter	London, UK
	Bacterial Filter Child	
	Filtervent	
	Filtervent Child	
	HEPA Filter/HME	
DAR	Barrierbac	Mirandola, Italy
	Barrierbac S	
	Hygrobac	
	Hygrobac S	
	Sterivent Mini	
	Sterivent S	
Datex-Ohmeda	HMEF1000	Bromma, Sweden
Gibeck	HEPA Filter Light	Upplands-Väsby, Sweden
	Humid-Vent Filter Compact A	
	Humid-Vent Filter Light	
	Iso Gard Filter	
Intersurgical	Clear-Guard II	Wokingham, UK
	Clear-Guard Midi	
	Clear-Therm	
	Filta-Guard	
	Filta-Therm	
Intertech	Filtered HME	Fort Myers, USA
Medisise	Barr-Vent	Hillegom, The Netherlands
	Hygrovent	
	Hygrovent Child	
Pall	BB100	Portsmouth, UK
	BB22-15	
	BB25	
Pharma Systems	Bact-HME	Knivsta, Sweden
	Bact-Trap	
Portex	Thermovent HEPA	Hythe, UK
	Thermovent HEPA+	
Ventalink	Adult	Derby, UK

Thirty-three breathing system filters available on the UK market were obtained from a number of manufacturers (Table 1). These filters contained filter media that were either pleated hydrophobic (nine filters) or electrostatic (24 filters). The filtration efficiency of five samples of each filter was measured in an unused state. Each sample was placed in the test equipment such that the flow of air was from the patient side to the machine side of the filter.

An aerosol of sodium chloride particles with a count median diameter (CMD) of 0.07 μm and a geometric standard deviation (σ_g) not exceeding 1.83 (see Appendix) was generated from a 2% sodium chloride solution (Model 8118A sodium chloride aerosol generator, TSI Inc.). When generated using this type of apparatus, the aerosol particles are highly charged electrostatically. The overall electrostatic charge was reduced to the Boltzmann equilibrium level by mixing the particles in a chamber with a stream of air ions produced in the neutraliser (Fig. 1) [10]. A vacuum pump removed 30 $l.min^{-1}$ of air from the mixing chamber. Excess air from the mixing chamber passed out of the test apparatus.

During each test, the switching valve directed the flow of air containing the particles through the filter. The test on each sample of filter lasted for 26 s. The first 20 s were to stabilise the test equipment, and the measurement of penetration was then made over the next 6 s. Samples of air were drawn from the upstream (challenge) and downstream (penetration) sides of the filter through two forward-scattering laser photometers. The photometers measured the concentration (mass of sodium chloride particles per unit volume of air) of sodium chloride particles in the challenge (challenge number, *C*) and in the air that had passed through the filter (penetration number, *P*). The penetration value, *PV* (%), was

calculated from $PV = P/C \times 100$. The filtration efficiency (%) is then $100 - PV$.

The penetration value was displayed on the screen of the AFT 8130. The sensitivity of the equipment was 0.001%, and penetration values up to 100% could be measured.

The aerosol generator produced a mass concentration of sodium chloride particles in the flow of air of 15 $mg.m^{-3}$. Therefore, over each 26 s test at a flow of 30 $l.min^{-1}$, the filter was challenged with about 0.2 mg of sodium chloride particles. The majority of these particles were retained within the filter layer, although the actual mass retained obviously depended on the filtration performance of the filter layer.

Although the flow of air was kept constant, the face velocity (flow per unit area of filter media) varied with the different filters, as the surface area of the filter media varied in the different filters. From theory [10], the penetration value will depend upon the face velocity. Therefore, the surface area of the filter layer was calculated from its dimensions for one sample of each breathing system filter.

Statistical analysis

All calculations for statistical significance were carried out on $\log_{10}$(penetration value) because of the wide range of penetration values. Therefore, the results for penetration are expressed as the geometric mean. The Mann–Whitney test for two independent samples was used for analysis when comparing the results from the two different types of filters (StatView 5, SAS Institute Inc., SAS Campus Drive, Cary, USA). Spearman's rank correlation was used to determine whether there was a correlation between filter area and $\log_{10}$(penetration value) for each of the two types of filter. A p value of < 0.01 was considered significant.

Results

The penetration values varied from less than 0.001% (0.001% being the limit of sensitivity of the test apparatus) to about 40%, so that some filters allowed over 40 000 times more particles (by mass) to pass through than other filters. For the few samples of filters that had penetration values below 0.001%, the geometric means were calculated by assuming the penetration value for these samples to be 0.0005%.

Pleated hydrophobic filters allowed significantly fewer particles to pass through than electrostatic filters. The geometric mean penetration values ranged from 0.002 to 0.67% for the nine pleated hydrophobic filters and from 0.25 to 35% for the 24 electrostatic filters ($p < 0.0001$ for the difference between the filter types) (Table 2 and Fig. 2).

The surface area of the filters varied from 241 to 708 cm^2 for the pleated hydrophobic filters and from 4.3 to 38 cm^2 for the electrostatic filters (Table 2). There was a significant correlation between the filter area and the $\log_{10}$(penetration value) for each of the two types of filter; 0.0009 and < 0.0001 for the pleated hydrophobic and electrostatic filters, respectively.

Discussion

A significant difference in the filtration performance between pleated hydrophobic and electrostatic filters has been demonstrated by challenging the filters with sodium chloride particles in the most penetrating particle size range. As expected, the penetration values measured in the present study were much higher than those reported previously using microbial challenges [2–8], where the size of the microbes in those challenges were either larger or smaller than the size of the sodium chloride particles used in this

Table 2 The filter areas and penetration values for the filters tested. The filters are in order of increasing filter area.

Filter	Filter area; cm^2	Penetration; % (geomean, $n = 5$)
Electrostatic		
Hygrovent Child	4.3	35.3
Filtervent Child	7.9	28.8
Bacterial Filter Child	7.9	20.1
Clear-Guard Midi	18	6.19
Iso Gard Filter	19	7.05
Humid-Vent Filter Compact A	20	8.54
Hygrobac S	20	11.4
Barrierbac S	20	6.90
Clear-Guard II	22	2.99
Bact-HME	22	3.75
Bact-Trap	22	3.72
Clear-Therm	23	2.85
Humid-Vent Filter Light	23	22.6
HMEF1000	24	4.49
Filtered HME	24	7.34
Adult	24	6.15
Filtervent	25	8.17
Bacterial Filter	25	6.77
Barr-Vent	36	2.48
Barrierbac	36	1.16
Hygrobac	36	1.39
Hygrovent	37	1.48
Filta-Guard	38	0.252
Filta-Therm	38	0.275
Pleated hydrophobic		
BB25	241	0.056
Sterivent Mini	266	0.679
Thermovent HEPA	286	0.015
Sterivent S	385	0.394
HEPA Filter/HME	439	0.087
HEPA Filter Light	537	0.002
Thermovent HEPA +	665	0.004
BB100	699	0.022
BB22-15	708	0.019

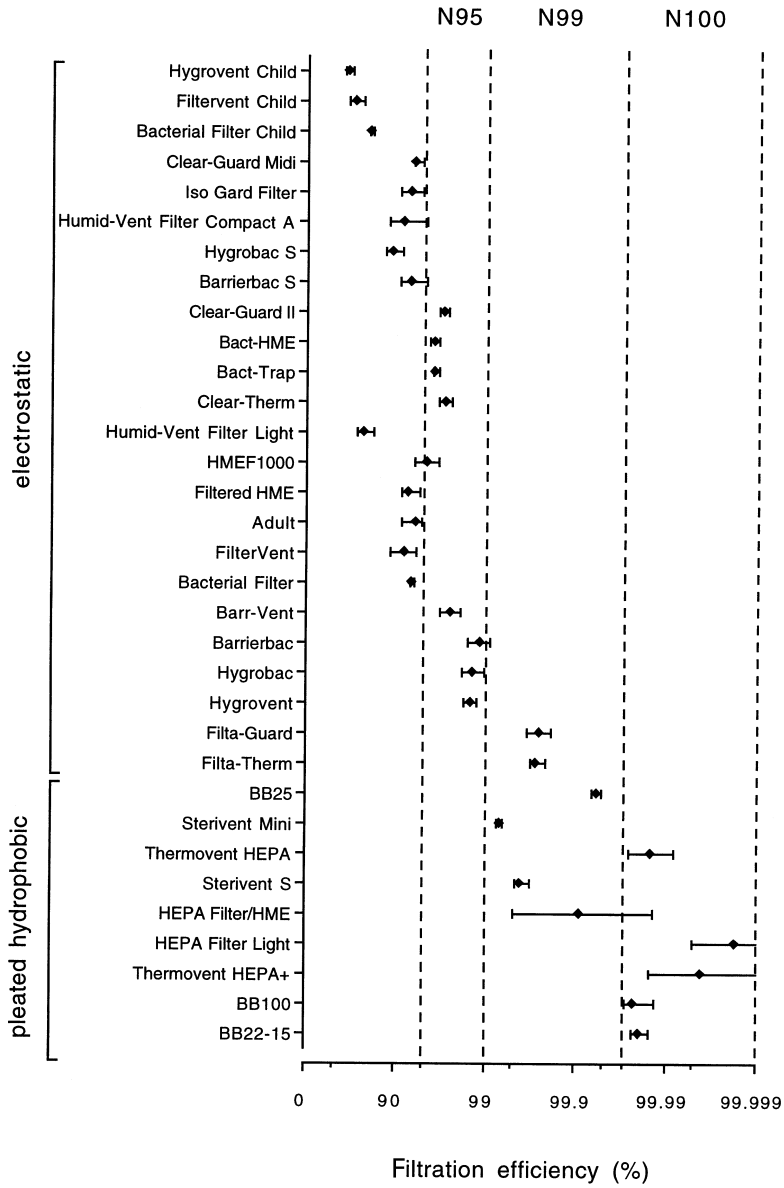

Figure 2 Geometric means and ranges (minimum to maximum) of the filtration efficiencies for the filters, calculated from the penetration values ($n = 5$ for each filter). The filters are arranged in order of increasing filter area. N95, N99 and N100 refer to the three classes of respiratory protective devices specified by NIOSH (see text). The maximum filtration efficiency that could be measured is 99.999%.

study. In the present study, larger filters were generally more effective than smaller filters of the same type.

The most penetrating particle size for filter media is in the range 0.05–0.5 μm [10]. Larger particles are directly intercepted by the fibres in the filter media. Particles smaller than about 0.1 μm in size undergo significant Brownian motion, so that they randomly traverse areas much larger than their diameters, and can therefore be captured comparatively easily by the filter media. Particles in the most penetrating particle size range are too small to be easily captured by direct interception, and too large to undergo significant Brownian motion. The results from tests using sodium chloride particles in the most penetrating particle size range therefore provide a rapid, comparative, worst-case indication of the performance of breathing system filters.

The test method used in the present study was based on that specified by NIOSH for testing respiratory protective devices [11], on which the new draft standard for breathing system filters is based [13]. The NIOSH standard groups devices into different categories according to the type of test used and their efficiency [11]. For respiratory protective devices used to protect the wearer against particles, such as infective droplets, that do not markedly degrade the performance of the filter, the devices are challenged with sodium chloride particles. The results from testing with the sodium chloride particles to the NIOSH specification enables the respiratory

protective device to be placed in one of four categories: less than 95% efficiency, at least 95% efficiency (N95), at least 99% efficiency (N99) or at least 99.97% efficiency (N100).

When treating and caring for patients who have tuberculosis, medical staff are encouraged to wear respiratory protective devices to reduce the likelihood of inhaling tubercle bacilli present in the air. In 1994, the Centers for Disease Control and Prevention (CDC) issued recommendations on the effectiveness required for respiratory protective devices when used by medical staff caring for patients with active tuberculosis [15]. The CDC stated that these devices must have a filtration efficiency of at least 95% for 1-μm particles at a flow of 50 $l.min^{-1}$.

NIOSH stated that, when all 20 samples of a device meet at least the N95 level of efficiency when tested according to the NIOSH test procedure, that device complies with the CDC requirements for respiratory protective devices. That is, a respiratory protective device that has a filtration efficiency of at least 95% when tested with sodium chloride particles of the most penetrating particle size is deemed to be able to adequately protect the wearer against the inhalation of *Mycobacterium tuberculosis*. The filtration efficiency for *M. tuberculosis* is much greater than 95% as the size of *M. tuberculosis* is much larger than the sodium chloride particles used in the test.

Tuberculosis is re-emerging as a threat to human health [16, 17]. When anaesthetising patients who have tuberculosis, Breslin recommended placing a breathing system filter on the tracheal tube to help reduce the risk of contamination of the anaesthetic equipment and of discharging tubercle bacilli into the ambient air [16]. However, Breslin did not specify a minimum level of performance for the filter, and it is clear from the present study, and other studies, that there is a wide variation in the performance of breathing system filters. From the CDC recommendations, it could be considered that a breathing system filter that has a filtration efficiency of at least 95% when using a test method based on that published by NIOSH is an effective barrier against the air-borne transmission of tuberculosis. In the present study, all the pleated hydrophobic filters, but only 10 of the 24 electrostatic filters, reliably met this requirement (Fig. 2 and Table 3). Moreover, all the pleated hydrophobic filters had efficiencies greater than 99%.

For breathing system filters, the differences in filtration efficiency between that measured when challenging with sodium chloride particles in the most penetrating size range and when challenging with microbes can be illustrated as follows. A filter (the HMEF1000) that had a geometric mean filtration efficiency of 95% when challenged with sodium chloride particles in the present study (with some of the five filters tested having a filtration efficiency of less than 95%) had a filtration efficiency of 99.86% when challenged with an aerosol of *Bacillus subtilis* var niger using the same flow of air [8]. However, a filter (the Clear-Therm) with a filtration efficiency of 97% in the present study had a bacterial filtration efficiency of 99.997% when challenged with an aerosol of *B. subtilis* var niger [8]. Therefore, the CDC requirement that the filtration efficiency must be at least 95% appears to imply a bacterial filtration efficiency of at least 99.9% when challenging the filter with *B. subtilis* var niger. In contrast, the efficiency of pleated hydrophobic filters was generally at least 99.9999% when challenged with *B. subtilis* var niger [8]. As *M. tuberculosis* is larger than *B. subtilis* var niger, the filtration efficiency against *M. tuberculosis* should be even greater.

Table 3 Classification of filters according to the NIOSH specifications (see text) when tested at a flow of 30 $l.min^{-1}$.

	Classification				
Filter type	**< N95**	**N95**	**N99**	**N100**	**Total**
Electrostatic	14	8	2	0	24
Pleated hydrophobic	0	0	4	5	9

The transmission of *M. tuberculosis* is thought to occur following the expulsion during a cough of large droplets infected with tubercle bacilli from an infected person. These large droplets rapidly settle out and then dry due to evaporation of water. Raising infected dust then releases the tubercle bacilli, which can remain air-borne for long periods, as they are much smaller than the original droplets. Inhalation of the tubercle bacilli then causes infection [16]. The infective dose of tuberculosis is fewer than 10 bacilli [18].

The risk of cross-infection is reduced by limiting the number of bacilli expelled by an infected patient. During normal mouth breathing, very few infected droplets are expelled [19]. However, infected droplets tend to be expelled during coughing or sneezing [19]. The CDC recommends that, during the treatment and care of patients with tuberculosis, cough-inducing procedures should be avoided wherever possible [15]. In anaesthesia, coughing occurs during intubation, extubation and during inhalational induction with volatile anaesthetics. Techniques should therefore be employed to reduce the incidence of coughing during these procedures. For example, using a breathing system filter with a higher moisture output has been shown to decrease the incidence of coughing during over-pressure with des-flurane in non-smokers [20].

The CDC chose a flow of 50 $l.min^{-1}$ for the specification for respiratory protective devices as this represents a typical inspiratory flow for a health care worker when working. The NIOSH test specification is to use a flow of air of 85 $l.min^{-1}$ (3 $ft^3.min^{-1}$). A flow of 30 $l.min^{-1}$ was chosen in the present study as this represents a typical peak expiratory flow of an anaesthetised patient during normal breathing. However, during episodes of coughing, the expiratory flows will obviously be much greater.

The requirements for respiratory protective devices are to ensure protection of the wearer against the inhalation of particles or droplets from the air. In contrast, a breathing system filter is intended to prevent the transmission of microbes from the patient to the breathing system. If this is achieved, then the filter will not have to protect the patient from air-borne microbes in the breathing system, as the breathing system will not have become contaminated. However, in this case, breathing system filters will only have to prevent the transmission of comparatively small numbers of large droplets that are expelled just during coughing by the patient. Therefore, it may be considered too stringent to use the CDC specification for respiratory protective devices to provide an indication of adequate performance for filters used during anaesthesia, particularly as the draft European Standard does not specify a minimum level of performance. However, in the absence of any other recommendations, it may be considered appropriate to use a breathing system filter that has a filtration efficiency of at least 95% when challenged with sodium chloride particles in the most penetrating particle size range to prevent the air-borne transmission of microbes. This minimum level of performance was met by all nine of the pleated hydrophobic filters, but only 10 of the 24 electrostatic filters, tested in the present study. The efficiency was significantly lower for filters with smaller filter areas. This decrease in efficiency is probably due to the increase in the face velocity with smaller filter areas. Therefore, for maximum protection, the largest filter should be used, provided the deadspace is not excessive.

The European Standard specifies that breathing system filters are challenged with an aerosol of sodium chloride particles having a CMD of 0.075 ± 0.020 μm and a σ_g not exceeding 1.86 in an appropriate flow of air depending on the intended use of the filter (30 $l.min^{-1}$ for adult use and 15 $l.min^{-1}$ for paediatric use) [13]. The TSI equipment used in this study generates an aerosol of sodium chloride particles with a CMD of 0.07 μm and a σ_g of less than 1.83, and therefore complies with the requirements of the standard. The use of the European Standard for breathing system filters will enable useful comparisons to be made between the performances of different filters.

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Appendix

Particle size terminology

The lognormal distribution is used in situations where the distributed quantity can have only positive values and covers a wide range of values, with the ratio of the largest to the smallest being greater than 10. This is the case for aerosolised particles. With a lognormal distribution, when frequency is plotted against the logarithm of particle size, the shape of the frequency distribution is normal. However, unlike the normal distribution, the mode, median and mean sizes of the particles are not the same. The count median diameter (CMD) is the diameter of the particle for which 50% of the particles in the aerosol have a diameter larger and 50% have a diameter smaller than this value. For a lognormal distribution, 95% of the particles are within a size range defined by $\exp(\ln \mathrm{CMD} \pm 2 \ln \sigma_g)$, where σ_g is the geometric standard deviation. The frequency distribution is asymmetrical. For example, if CMD = 0.07 μm and $\sigma_g = 1.83$, then 95% of the particles lie between 0.02 and 0.23 μm. The photometers used in this study measured the mass concentration of particles. The mass median diameter (MMD) is different to the CMD as the mass of the particle is proportional to diameter^3: as the diameter of a particle increases 10-fold, the mass of the particle increases 1000-fold. The MMD is the diameter for which 50% of the total mass is contributed by particles with a diameter larger and 50% by particles with a diameter smaller than this value. The MMD can be obtained from CMD from the following Hatch-Choate equation [10]:

$$\mathrm{MMD} = \mathrm{CMD}\exp(3\ln^2\sigma_g).$$

For example, if CMD = 0.07 μm and $\sigma_g = 1.83$, then MMD = 0.21 μm.