

Review of Standards for Evaluating Filters

The test methodology to determine the efficiency of a filter (i.e. its effectiveness at preventing particles of a known size penetrating the media) has hitherto been outside the remit of existing standards, making it difficult to properly compare the performance of filters. Whilst manufacturers have traditionally declared a filtration efficiency, this has been against an unspecified microbiological test protocol although individual manufacturers may release copies of their test reports to clients.

The CEN committee responsible for developing the standard identified the following weaknesses under this type of testing with the need to standardise the following:

- how the test organism is grown and prepared;
- the equipment used for aerolising the microbiological culture;
- the time of exposure to the challenge;
- the method used to recover and incubate the test organism.

Unable to reach a consensus on an acceptable microbiological test method, the committee eventually agreed that the well-established NIOSH protocol for respiratory protective devices (BS EN 13328-1: 2001) which used sodium chloride provided the best method available for assessing and providing a comparison table of filter performance.

To assist evaluators through the transition phase, Air Safety will continue to supply details on bacterial/viral efficiency (test data is available upon request) alongside the efficiency derived from the sodium chloride penetration test.

New Standards Applied to Filter Evaluation

Filter Efficiency: BS EN 13328-1:2001

The filter is challenged with sodium chloride particles within the range of 0.1-0.3 micron, with 0.3 micron being considered the most penetrating particle size and the result therefore providing the worse-case level of performance. The test measures the penetration of particles through the filter, the level of penetration thereby denoting the efficiency of the filter.

Penetration varies as the load on the filter increases (i.e. number of particles in the challenge) and increases as the flow increases.

The mass concentration of particles must therefore be standardised. In the MHRA evaluation the mass concentration of particles was 13mg.m^{-3} , or 0.013mg.L^{-1} (the manufacturer's calibration figure).

The flow also required standardisation, being set at 15L.min^{-1} for paediatric filters and 30L.min^{-1} for those intended for adult use.

Filters are tested in their clean state (i.e. unused), and then conditioned and re-tested. Conditioning occurs by connecting the filter to a patient model 'breathing' with either a tidal volume of 0.25L per minute (representing 20 breaths per minute) or 0.5L per minute (15 breaths per minute) depending on whether the filter is for paediatric or adult use. Expired air and machine-side air is fully saturated with water vapour at temperatures as set out in the standard, being 34°C and 26°C respectively. While the standard requires conditioning for the period of recommended maximum use by the manufacturer (usually 24 hours), conditioning under the MHRA evaluation was for 3 hours only in order to assess all filters in the time available but also because this represented the usual period of use for a filter.

Pressure Drop: BS EN 13328-2:2002

The higher the pressure drop, the greater the work the patient must do in order to breathe. A filter with lower pressure drop during use is therefore more beneficial to the patient and reduces the risk of a ventilator having to be used.

Pressure drop is measured in pascals (Pa), and measured at flows of either 15L.min^{-1} for paediatric filters and 30L.min^{-1} for those intended for adult use.

The pressure drop can increase markedly as condensation is collected within the device.

Moisture Output: BS EN ISO 9360-1:2000

A high moisture output reduces the risk of mucosal damage and thickening of secretions in a ventilated patient.

In testing the patient model 'inspires' dry air, the moisture output value being that which would arise in a non-breathing system, such as in intensive care. During anaesthesia, gas entering the machine side will include some moisture.

Other Factors Assessed

The MHRA evaluation also measured the weight, dimensions, and internal volume (dead-space) of the filters submitted for assessment.

Full details of test methodology, filters tested and their results are published as follows:

Medicines and Healthcare products Regulatory Agency (MHRA), MHRA Evaluation Number 04005, published March 2004. The report is available from: MHRA, Business Services, Room 1207, Hannibal House, Elephant and Castle, London SE1 6TQ.

Price: £60. Available free of charge to NHS Trusts and Clinics.