Breathing Filters and HMEF's - COVID-19 Frequently asked Questions

Do the Intersurgcial breathing filters and HMEF's provide effective protection against Covid19?

Our range of breathing filters and HMEFs have been independently tested and proven to be highly efficient in preventing the passage of bacteria and viruses. All filtration devices have been independently tested and validated against the passage of Bacillus subtilis (1.0µm x 0.7µm) and Ð174 bacteriophage (0.027µm) to represent the bacterial and viral challenge it may face in the clinical environment. These tests all confirm the level of efficiency that the filter/HMEF will provide against these challenge organisms.

The challenge presented in the viral test protocol (Ð174 bacteriophage, 0.027 µm) will be at least as severe as that posed by COVID-19 (0.05 - 0.1µm).

As such, it can be concluded that the range of filtration products will provide at least the same level of efficiency as reported in the independent microbiology tests when challenged with Coronavirus. Copies of the original microbiological test reports and the Covid-19 performance statements are available for each product upon request.

What is ISO 13328 / ISO 23328?

In 2001 an international standard was developed (ISO 13328-1) that allowed a direct comparison of filtration performance to be assessed in a non-clinical environment. This was updated in 2003 to **ISO 23328-1 Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance**. This provides a short-term airborne sodium chloride particle challenge test method for assessing the filtration performance of breathing system filters intended for the filtration of respired gases.

Part 2 of the standard specifies some of the non-filtration aspects of performance that the product should comply with in order to be safe in clinical use.

This standard is only a test method and **does not** specify any minimum or maximum performance that a filter should achieve.

All of the Intersurgical products have been tested in accordance with and comply with this standard and test reports are available upon request.

How long can a breathing filter/HMEF be safely used for?

The maximum recommended usage for filters/HMEs is 24 hours, after which point the filter or HME should be replaced.

This recommendation is based on validation testing carried out to confirm that the resistance to flow of the product remains within a safe, clinically acceptable level throughout the maximum recommended period of use. After 24 hours use, the product will continue to perform, however, it cannot be guaranteed that the resistance will remain within clinically safe levels.

The resistance of the products can be adversely affected by the levels of humidity and or nebulised drugs present within the gas flow and the resistance of the product should be monitored throughout the period of use. The recommended usage is detailed within the instructions for use (IFU) which is provided per box of products and test protocols are available to support this data.

The strategy of adopting anaesthesia ventilators to provide safe and effective ICU ventilation for Covid-19 may increase the potential for the resistance of the filter to increase.

Further consideration should be given to this possibility if the total fresh gas flow is reduced substantially below minute ventilation e.g. 1-2 litres per minute. This will result in the absorbent actively removing the expired Carbon Dioxide a by-product of which will be increased relative humidity of the inspired gases. The presence of humidity and / or condensate within the breathing system and its components over a 24-hour period would be increased which could increase condensate in the HMEF at the patient end of breathing system increasing resistance and potentially leading it to block.

Please monitor the filter/ HMEF throughout use and replace if visual contamination or increased resistance occurs.

In addition the use of a breathing system with water traps will further reduce the risks associated with excessive condensate formation in the system.

Does it need to be a HEPA filter?

HEPA is an acronym that stands for High Efficiency Particulate Air. In order for a filter to be classified as providing true HEPA performance it must have been tested and proven to provide a filtration performance of ≥ 99.97% when challenged with particles of 0.3 micron or greater.

Due to the nature of the test only a pleated mechanical filter will achieve the required performance to be classified as a true HEPA filter. All Intersurgical pleated filters are 100% tested against this standard during manufacture.

HEPA is widely used as a term used when a high efficiency filter is required. Please consider do you actually requires a HEPA rated product, or do you require a high efficiency filter as described in a number of the clinical recommendations around Covid-19. Intersurgical offer a range of products with a range of efficiencies to meet all of the clinical circumstances of the customer.

In these challenging times, it is understandable there is a heightened focus upon the protection that the breathing filter provides.

Despite technically not being termed as a HEPA, Intersurgical do supply electrostatic filters that provide high efficient protection to the breathing system, equipment and environment.

Are the Intersurgical products hydrophobic?

Hydrophobic means that the filter membrane has a natural resistance to water and body fluid that may be present in the breathing system.

The level of hydrophobicity will vary between filtration devices. In normal clinical conditions electrostatic filters offer a **clinically safe** hydrophobic level of protection, whilst pleated mechanical filters provide a more complete hydrophobic barrier.

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COMPLETE RESPIRATORY SYSTEMS

Intersurgical Ltd, Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK
T: +44 (0)118 965 6300 F: +44 (0)118 965 6356 info@intersurgical.com www.intersurgical.com

The manufacturer Intersurgical Ltd is certified to ISO 9001:2015, ISO 13485:2016 and ISO 14001:2015