Viral & Bacterial Filtration Efficiency of Fisher & Paykel Healthcare Filters and F&P Evaqua™ 2 Circuits

COVID-19 INFORMATION & RESOURCES

Key messages

- Filtration efficiency of filters can be different based on the temperature and humidity testing conditions. See FAQs below for further details.
- Replace F&P filters every 24 hours (or earlier if required).
- Use F&P filters with F&P Evaqua 2 circuits to minimize the effect of water vapor and maximize its filtration efficiency.
- The material used in F&P Evaqua 2 circuits is permeable to water vapour. External laboratory testing shows even microscopic viruses (0.027 µm) cannot permeate through the expiratory limb material of the circuit.

Fisher & Paykel Healthcare (F&P) provides respiratory filters both individually and in many breathing circuit kits

These filters can be placed in an inspiratory position, expiratory position, or both within a breathing circuit. They are designed to prevent pathogens (viruses and bacteria) from being transported in the breathing circuit and to minimize the amount of condensation entering the expiratory block of the ventilator.

Part Number	Position	Description	Included in Circuit Kits
RT016	Inspiratory	Inspiratory/single limb use only	950A61, RT319
RT019	Inspiratory & Expiratory	Inspiratory or end-expiratory use with an insulating filter housing to reduce condensation	950A81, 950A82, RT380, RT385, RT301
RT020	Expiratory	End-expiratory use with an insulating filter housing to reduce condensation	

Note: Not all filters and circuit kits are available in all countries. Filters are available for purchase in boxes of 20. Consult your local Fisher & Paykel Healthcare representative for information on availability.

How do filters prevent pathogen transfer?

The filter media within the filter housing is responsible for stopping pathogens moving through the filter. There are several mechanisms by which filter media work. The RT016, RT019, and RT020 filters use an electrostatic media which attracts pathogens and particles to stick to the filter media (and not pass through the filter) via electrostatic attraction. Our filters are also hydrophobic, so they repel water to protect filter performance. An electrostatic filter has the advantage of requiring less material to trap pathogens which reduces resistance to flow.

How is filtration efficiency determined?

Filtration efficiency reported as a percentage can be determined using both viruses and bacteria, and it reflects how effectively the filter blocks pathogens from passing through. This percentage is usually very high (>98%). However, it is crucial to understand the filter testing conditions when comparing filtration efficiency in filters.

Independent external laboratories tested F&P filters using methods from the following standards:

- **Draft BS EN 13328-1:1998 - Breathing system filters for anaesthetic and respiratory use – Part 1: Test method for monodispersed microbial challenge to assess filtration performance.**

  The viral and bacterial filter efficiency tests are performed by connecting the filter to a ventilator circuit, placing a specific virus or bacteria particle into aerosolized droplets of water, and measuring the filtration efficiency of the filter. The water droplet transports the pathogen to the filter. This situation also replicates how these pathogens are commonly transported outside the lab.

  The Mean Particle Size (MPS) is reported as part of this test. MPS is the size of the aerosolized water droplet used to transport the pathogen. The MPS is stated in our material, but it is important to remember the actual size of tested bacteria and virus is significantly smaller.

- **BS EN ISO 23328-1:2008 – Breathing system filters for anaesthetic and respiratory use – Part 1: Salt test method to assess filtration performance.**

  This standard sets out a standardized test method for filtration efficiency, which ensures that different filters can be compared to each other. Particles of salt 0.3 µm (microns) in size replace the pathogen. This aerosol size is generally accepted as the most penetrating size. Filter conditioning at simulated usage environment then takes place.

  Testing of the RT019 and RT020 used the RT380 Evaqua 2 dual limb breathing circuit with the filter placed at the end-expiratory port of the ventilator. Heated and humidified gas (37 °C, 100% RH) was passed through the filter for 25 hours and then the filtration efficiency test was performed.

  Testing of the RT016 simulated conditions where the filter is attached to the inspiratory port of the ventilator.

What are the filtration efficiencies of F&P filters?

These filters can be placed in an inspiratory position, expiratory position, or both within a breathing circuit. They are designed to prevent pathogens (viruses and bacteria) from being transported in the breathing circuit and to minimize the amount of condensation entering the expiratory block of the ventilator.

Pathogen/Test	Filter & Position	Pathogen Size	Nebulized Size	Filtration Efficiency (95% CI)
Draft BS EN 13328-1 Bacterial Test: Bacillus subtillus	RT016, RT019 & RT020 (End-expiratory position)	0.5–0.8 by 1.0–1.5 µm	3.1 µm	99.9997%
Draft BS EN 13328-1 Viral Test: ΦX174 bacteriophage	RT016, RT019 & RT020 (End-expiratory position)	0.025–0.027 µm	2.9 µm	99.99%
BS EN ISO 23328-1 Test	RT016, RT019 & RT020 (Inspiratory position)	0.26 µm	Not applicable	98.17%
BS EN ISO 23328-1 Test (25 hours use with Evaqua circuit)	RT019 & RT020 (End-expiratory position)	0.26 µm	Not applicable	98.04%

Note: Inspiratory position represents the filter attached to inspiratory port of ventilator, end-expiratory position represents the filter attached to the expiratory port of the ventilator.

Note 2: BS EN ISO 23328-1 filtration efficiencies are listed in the latest RT016, 950A81 and 950A61 user instructions. Updates to the remaining existing user instructions are currently planned or in progress.

What is the difference between the Draft BS EN 13328-1 bacterial and viral tests, and the BS EN ISO 23328-1 test?

Draft BS EN 13328-1 determines filtration efficiency using viruses and bacteria to simulate real-world results. The chosen bacteria and virus pathogens used for the F&P tests are relatively small and mimic pathogens of clinical significance. They are also stable both in liquid suspension and when aerosolized.

The BS EN ISO 23328-1 test uses tiny salt particles to test filtration efficiency and provide a standardized test for comparing different filters. However, this test does not specify the testing conditions; instead, the manufacturer determines these. F&P conditioned our filters for 25 hours using heated and humidified gas to simulate 24 hours constant use in a ventilator circuit.

If selecting a filter from another manufacturer, compare filtration efficiency using BS EN ISO 23328-1 and ensure it is tested under heated and humidified conditions.

Why is there a difference in filtration efficiency between the Draft BS EN 13328-1 bacterial and viral tests, and the BS EN ISO 23328-1 test?

The standard viral and bacterial tests use dry medical gas to measure filtration efficiency at a point in time.
The BS EN ISO 23328-1 test simulates exposure of the filter to heated and humidified gas (37 °C, 100% RH) for 25 hours and then measuring filtration efficiency.

This data also shows that F&P filters have very high filtration efficiencies when they are used 'dry' with only a small reduction in efficiency over 25 hours. This minimal reduction in filtration efficiency is due to the filter trapping humidity from the expiratory limb.

The BS EN ISO 23328-1 test uses salt particles approximately 0.3 µm in size as this is the most penetrating particle size and therefore, an excellent size to test filtration efficiency.

Can I use an HME in conjunction with a heated humidifier?

The simultaneous use of heated humidification and an HME should not be used as per a patient safety alert (PSA) notification issued in 2015 by the NHS and MHRA. For further information please refer to the PSA: Risk of using different airway humidification devices simultaneously

Based on these test results, do you recommend changing the filter every 24 hours?

Yes. As per the User Instructions for our filters, F&P recommends changing the filter every 24 hours to ensure filtration efficiency remains very high.

Can I use F&P filters on F&P Neonatal circuits?

The RT016, RT019 and RT020 F&P filters are designed for use with the F&P adult invasive ventilation circuits. They are not intended for use with F&P neonatal invasive ventilation circuits. F&P recommends extreme caution when using filters in unapproved or improvised ways. If you use choose to use these filters with our neonatal invasive ventilation circuits, consider that resistance to flow and filter volume may affect ventilator performance.

What else does F&P do to try to minimize filters from getting wet and potentially reducing filtration efficiency?

F&P Evaqua 2 circuits (RT380, RT280, RT285, RT385, RT481) are designed so that exhaled humidity diffuses through the wall of the expiratory limb. This diffusion results in considerably less humidity reaching the expiratory filter, keeping it drier and ensuring high filtration efficiency. The RT019 and RT020 filters have also been designed with a double wall to provide additional insulation aimed at reducing condensation formation within them.

The filter media itself is also made from hydrophobic material to reduce the absorption of water.

F&P Evaqua 2 circuits are permeable, does this mean viruses and bacteria can diffuse or permeate through the circuit wall as well?

No. F&P Evaqua 2 incorporates technology that allows water vapor to diffuse through the material of the expiratory limb. To verify that viruses and bacteria cannot permeate or diffuse through the material, F&P commissioned an independent external laboratory to test the circuits. They found that even incredibly small viruses particles (0.027 µm) cannot permeate through the material of the circuit wall. This test method utilized an organism that represents the smallest known viruses; tinier than any known pathogen.

Can I use filters on F&P Bubble CPAP systems?

The placement of a filter on the expiratory limb of the bubble CPAP system is not advised. F&P Healthcare recommends extreme caution when using filters in unapproved or improvised ways. Resistance to flow, filtration efficiency in different conditions, instrumental dead-space, flow dynamics through the system, and the potential for gas-trapping are just some of the important safety factors healthcare professionals should consider.

Can I use filters on F&P T-piece resuscitation setups?

The placement of a filter between the T-piece and resuscitation mask is not advised. F&P Healthcare recommends extreme caution when using filters in unapproved or improvised ways. Resistance to flow, filter efficacy in different conditions, instrumental dead-space, flow dynamics through the system, and the potential for gas-trapping are just some of the important safety factors healthcare professionals should consider.

Can I use filters from other manufacturers with F&P circuits?

F&P has tested filtration efficiency and resistance to flow in accordance with BS EN ISO 23328-1 under the conditions it will be used. We make recommendations for replacing the filter based on these results. F&P have not tested filtration efficiency and resistance to flow of other manufacturers filters. As such, we can make no recommendations regarding other manufacturers filters on F&P adult, pediatric or neonatal circuits. If using a filter from another manufacturer, please consider the following:

There are many types of filter media available using different mechanisms of filtration. Some may be more affected by the conditions experienced in a humidified breathing circuit than others, and many may not have been tested under these conditions.

Before choosing a filter from another manufacturer ensure that your requirements for filtration efficiency are determined using temperature, and humidity conditions approximating real-life usage (e.g. 37 °C, 100% RH) and ensure that the manufacturer's recommendation for replacement period has also considered this.

Consideration should also be given to the resistance to flow of the filter and that any difference does not negatively impact on therapy delivery

When comparing different filters, always remember to compare filtration efficiency and resistance to flow at usage conditions.

Do F&P filters meet HEPA filter standards?

No. If a HEPA filter is required, consider the impact on resistance to flow in addition to filtration efficiency.

Have F&P filters been tested using a COVID-19 (SARS-CoV-2) pathogen?

No. When we conducted our viral filtration efficiency testing we used a ΦX174 bacteriophage virus particle. This is commonly used in testing as it is very small and mimics pathogens of clinical significance. ΦX174 bacteriophage is 0.027 µm and the SARS-CoV-2 is over twice the size at 0.06-0.14 µm.