

Filters in Mechanical Breathing Systems

As the COVID-19 pandemic evolves, filtration of mechanical ventilation, such as used in intensive care and anesthesia settings, has become an essential factor in infection control. Although face mask respirators are subject to internationally recognized standards and testing based on MPPS measures, filters in breathing circuits are not. As of the beginning of May 2020, no data exist examining the efficacy of breathing circuit filters in preventing SARS-CoV-2 transmission to patients or healthcare workers.

In the meantime, we want to convey information in this letter about filter design, function, efficacy and duration of use in clinical applications, including when filter conservation is necessary due to supply shortages. In sending you this letter, Vyaire is not seeking to promote, endorse or advise the off-label use of its products. However, we recognize the unusual and acute circumstances created by the COVID-19 pandemic and the needs of health care professionals to consider modifications to standard clinical practices in an effort to address the needs of patients with respiratory exacerbations.

IMPORTANT: The information presented here is based on the current understanding of the potential risks and functionality of the filtration in mechanical ventilation systems based on a literature review. The selection and use of filters must first be reviewed and evaluated by each facility's medical and administrative staff, in consultation with manufacturers' instructions for use with its respective machinery, before implementation. As care for patients diagnosed with COVID-19 evolves, Vyaire will update information on our web site, so please bookmark it for easy access: US: www.vyaire.com/Covid-19; International: intl.vyaire.com/Covid-19.

Filter Function

Filters in mechanical breathing systems are designed to capture pathogens and particles that range from 0.1 μm to larger than 10 μm . A SARS-CoV-2 virion is between 0.06 to 0.14 μm in diameter,¹ while one of hepatitis C is 0.03 μm ; a *Staphylococcus aureus* bacterium, 1.0 μm ; and a red blood cell, 5.0 μm .²

Respiratory transmissions of pathogens occur via carrier particles, classified as either a droplet or an aerosol. Respiratory droplets are particles sized larger than 5 to 10 μm in diameter,^{3,4} and aerosols are particles sized smaller than 5 μm .⁵ Filters capture particles larger than 1.0 μm via inertial impact and interception, and particles ranging from 0.1 to 1.0 μm via diffusion.

However, the combined effects of interception, inertia and diffusion have the least ability to efficiently capture particles sized 0.3 μm , well within the range of aerosols. Subsequently, 0.3 μm is a demarcation for filtration and is referred to as the most penetrating particle size (MPPS) for its ability to slip through the individual fibers in a filter without capture.⁶

The percentage of particles that fail to pass entirely through a filter defines its efficiency. The fewer particles that pass, the higher the efficiency. For example, if an airflow directs 1,000 particles to a filter and only five particles pass, the filter's efficiency is 99.5 percent.

Filter Testing

Manufacturers frequently use two current efficiency test methods to evaluate filters. The methods are similar and address different sized particles.

- **ASTM** (3.0 μm): The Bacterial Filtration Efficiency (BFE) and Viral Filtration Efficiency (VFE) tests compare bacterial counts of *Staphylococcus aureus* aerosols or viral counts as the challenge organisms delivered at a constant airflow rate against a filter.⁷
 - Droplets are aerosolized to have a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. Each particle contains 1,700 to 3,000 colony-forming units (CFU) *Staphylococcus aureus* or 1,100 to 3,300 plaque-forming units (PFU) of a test virus. This particle size challenge permits reported filtration efficiencies up to more than 99.9 percent.
 - BFE and VFE may use higher concentrations of bacteria or viruses, equal to or greater than 1×10^6 CFU or 1×10^6 PFU, which permit claims of efficiency measurements up to more than 99.9999 percent.
 - [A limitation with these methods](#) is the challenge only tests one particle size, regardless of pathogen load. That particle size is not only 10 times larger than MPPS but also is 1,000 times greater in mass, easily subject to inertial impact filtration. While such tests consequently can assert significant efficiencies, such generalized claims may overestimate the filter function against far smaller particles and pathogens.^{8,9}
- **ISO 23328-1:2003** (0.3 μm): The ISO test uses as a challenge an aerosol of "short-term airborne sodium chloride" particles with a median diameter of 0.3 μm , much closer to the size of actual virions. After aerosolization but prior to filtration, the particles pass through a neutralizer to reduce any electrostatic charges. The test also uses a new filter and one that was humidified for 24 hours or for longer, depending on the filter's duration of use as defined by the manufacturer. The test also counts MPPS at the start and after the filter's duration of use.¹⁰

HEPA and B/V Filters

HEPA (high-efficiency particle air) specifically refers to the efficiency of capturing particles with a MPPS diameter size of 0.3 μm .¹¹ Bacterial and viral (B/V) filters are defined by their ability to filter particles with a diameter size of 3.0 μm . [No international standard requires a specific HEPA filtration efficiency for filters on breathing circuits.](#)

However, the Centers for Disease Control and Prevention recommends filters with a 95 percent or greater efficiency for MPPS particles of 0.3 μm (*i.e., ISO testing method*) in both the unloaded and loaded states at the ventilator's maximum flow rate.¹² To prevent transmission of the SARS virus, B/V filters with 99.97 percent ATSM efficiency are recommended.¹³

Testing vs Clinical Experience

In testing, efficacy ratings of 99.9999 percent for a HEPA or B/V filter are better than ratings of 99.97 percent. However, in clinical settings, the efficacy of filtration can differ from that anticipated by performance in controlled lab tests.

Clinical reports have been equivocal as to whether the decrease in bacterial and viral contamination due to filtration of breathing circuits results in decreases of infections, such as post-operative infections or ventilator-associated pneumonia (VAP).^{14,15,16}

Filter Use Best Practices

For more than 24 hour use:

Investigations of heat and moisture exchangers (HME) filters in breathing circuits have found that continuous use in an intensive care setting for three days, in comparison to 24 hours, did not diminish filter efficacy, nor increase bacterial colonization or hospital-acquired pneumonia.¹⁷ Additional studies have documented HME filters used continuously retained efficacy for seven days of patient care.^{18,19,20,21}

The use of HME filters in breathing circuits for more than 24 hours is off-label and increases the following risks:

- **Occlusion risk:** Tracheal secretions or circuit condensation can both contribute to an HME filter reaching its maximum moisture saturation, creating notable air resistance to a ventilator circuit. When saturated, an HME filter can resist "both inspiration and expiration presenting as high peak airway pressures and incomplete exhalation."²² If occlusion is suspected, immediately replace the filter.
- **EtCO₂ Risk:** HME filters extend the dead space of the breathing circuit, which can create the risk of the patient rebreathing CO₂.²³ It is important to continuously monitor EtCO₂ and compare it to the patient's PaCO₂ from an arterial blood gas (ABG).

Filter placement

Ideally, two filters should be used and changed with every patient use:^{24,25}

1. **Expiratory filter:** placed between the machine and the expiratory limb of the ventilator circuit.
2. **Patient filter:** placed between the Wye connector of the circuit and the patient.

Placing filters at these two locations protects against contamination of the circuit as well as the machine.

Conserving filters and circuits

If filters or circuits or both are in short supply and need to be reused, recommended placement and duration are:²⁶

- **Expiratory filter.** This location has been left in place for up to seven days and maintained the same efficacy and prevention of cross-contamination if the patient filter is replaced when the patient changes.^{27,28,29,30}
- **Patient filter.** The patient side of the filter contains particles the patient exhaled, including virus, if present. This filter must be changed for each patient to prevent cross-contamination.^{31,32}
- **Filter saturation.** Both filters should be discarded if they become saturated to avoid increased resistance and occlusion.

Are filters effective against SARS-CoV-2?

As of the beginning of May 2020, no data exist examining the efficacy of breathing circuit filters in preventing SARS-CoV-2 transmission to patients or healthcare workers. Such an evaluation would require using live virus, and has yet to be concluded.

If you have any additional questions, please reach out to your local Vyaire representative.

As a world leader in respiratory care, we take our critical role in the response to this global health crisis seriously. At Vyaire, our goal is to meet the demand as best we can and ensure our customers have the products they need. We are truly proud to partner with you on the frontlines of the COVID-19 global health crisis. The work you are doing is improving outcomes for patients around the world.

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GLOBAL HEADQUARTERS

Vyaire Medical, Inc.
26125 North Riverwoods Blvd
Mettawa, IL 60045
USA

vyaire.com

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