

Medtronic

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Subject: Emergency Preparedness Planning—Wuhan Coronavirus

Dear Valued Customer:

The purpose of this communication is to support our customers' efforts to ensure adequate preparedness in the event of an infectious disease pandemic.

We understand that the identification of the new Wuhan coronavirus is creating a sense of urgency for health care institutions to ensure they have an adequate reserve of critical items. As a leader in respiratory filtration, Medtronic is working to ensure our customers' and patients' needs are met. The core functionality of respiratory filtration is to contain pathogens and prevent contamination of the immediate environment. We learned from the SARS outbreak of 2003 that preparedness and informed practice are key to containment efforts and health care worker safety. This letter provides a short overview of the two main types of filters, as well as product and ordering information specific to our critical care ventilator filters and general-use respiratory filters.

TYPES OF FILTERS

Mechanical Filters

The efficacy of mechanical filters is based upon a membrane composed of a dense weave of microfibrils that create very small micropores. A large filtration surface area provides high filtration efficiency and low resistance to airflow. This large surface area is accommodated in a low-volume housing by incorporating a pleated membrane. The physical specifications of this material make it an *ideal filter medium for both low-humidity and high-humidity environments*, such as for critical care ventilators or manual resuscitators.

Electrostatic Filters

Electrostatic filters offer a high level of microbial removal and low resistance to airflow, however have notable limitations. The filter membrane is made of a thin, hydrophobic, non-woven polypropylene material which has a permanent electrical charge induced during the manufacturing process. The superficial electrostatic charge attracts bacteria and viruses to oppositely charged sites on the membrane, causing them to become trapped.

Although some electrostatic filters offer a high efficiency rating, their effectiveness may be reduced in humid environments. In circumstances where both moisture accumulation and large pressure changes across the filter medium exist—such as with a cough from a patient on a ventilator or manual resuscitator—the integrity and efficacy of the filter may become compromised. These conditions may allow moisture droplets to pass through the filter, creating the possibility of pathogens to pass as well. *Electrostatic filters perform best under low-humidity clinical conditions*, such as when used at the wye of an anesthesia breathing circuit.

GENERAL-USE RESPIRATORY FILTERS

It is not always straightforward to determine the best filter for a given clinical application. When considering emergency preparedness and the unknowns that are often in play, holding inventory of the most versatile filters can ease decision-making and reduce the potential for errors. As such, it may be reasonable to consider mechanical filters to be the ideal product for pandemic/emergency preparedness planning.

Medtronic has a long history of expertise in filtration with its DAR™ filter portfolio. Below is a chart of the mechanical filters that offer the high quality and efficiency you have come to expect.

	HYGROSTER™	STERIVENT™ MINI	STERIVENT™
			
Type of Filtration	Mechanical	Mechanical	Mechanical
Heat-Moister Exchanger (HME)	Yes	No	No
Application Example	Manual resuscitator (bag-valve-mask); HME required; non-heated ventilator circuits	Pediatric anesthesia	Anesthesia; ventilator/NIV/HFOT inspiratory outlet
Tidal volume range	300 – 1500 ml	150 – 1200 ml	300 - 1500 ml
NaCl Filtration Efficiency	≥99.764%	≥99.512	≥99.978%
Bacterial Filtration Efficiency	≥99.9999%	≥99.9999%	≥99.9999%
Viral Filtration Efficiency	≥99.9999%	≥99.999%	≥99.999%
Resistance to flow		0.5 cm H ₂ O at 15 l/min	
	1.1 cm H ₂ O at 30 l/min	1.2 cm H ₂ O at 30 l/min	0.8 cm H ₂ O at 30 l/min
	2.5 cm H ₂ O at 60 l/min	2.7 cm H ₂ O at 60 l/min	2.0 cm H ₂ O at 60 l/min
	4.2 cm H ₂ O at 90 l/min	4.5 cm H ₂ O at 90 l/min	3.6 cm H ₂ O at 90 l/min
Moisture loss	6 mg H ₂ O/l at Vt 500 ml	17 mg H ₂ O/l at Vt 500 ml	13 mg H ₂ O/l at Vt 500 ml
Moisture output	34 mg H ₂ O/l at Vt 500 ml	16 mg H ₂ O/l at Vt 500 ml	23 mg H ₂ O/l at Vt 500 ml
Internal volume	96 ml	42 ml	92 ml
Weight	49 g	24 g	47 g
Item numbers	354/5876	351/5979 351/5987	351/5410

CRITICAL CARE VENTILATOR FILTRATION

The PB980 and PB840 critical care ventilators incorporate an integrated N100 expiratory filter. This filter is integral to the functioning of these Medtronic ventilators. In the absence of leaks at the patient interface, this ensures that *any patient receiving invasive or non-invasive, dual-limb ventilatory support is exhaling through an N100 filter*. Efficient filtration of exhaled patient gases is vital to protecting health care workers and hospital visitors from infectious diseases spread by respiratory transmission.

Managing water accumulation safely when using heated breathing circuits and high-humidity can be a clinical challenge. The PB980 and PB840 incorporate an expiratory filter to reduce condensation, while

allowing any excess water to be accumulated in a collection vial. This water can be easily drained without breaking the patient circuit or exchanging the expiratory filter, adding to the infection control benefits of these devices. This design enhances infection control efforts by avoiding the need for routine circuit disconnections simply to manage water accumulation. In addition, the Short Self-Test (SST, or pre-use check) of the PB980 and PB840 incorporates filter-specific testing to validate that each new expiratory filter is free from leaks and has an acceptable level of resistance. Adding a filter following a pre-use check may not capture filter deficiencies (e.g. cracks in filter housing) that could reduce its efficacy.

In uncertain circumstances, such as the current situation with the Wuhan coronavirus, it is possible for health care manufacturers to experience a surge in demand for product. We would like to extend our support to ensure your institution has sufficient inventory of ventilator filters (disposable and/or reusable) so that your facility can take full advantage of the infection control capabilities of the PB980 and PB840. For hospitals that exclusively use either disposable or reusable filters, it may be reasonable to consider holding inventory of the opposite version as a backup. The tables below list the reusable/disposable filters for each ventilator and suggested back-up quantities. These are in addition to your normal stock levels.

PB980—SUGGESTED QUANTITIES PER VENTILATOR				
	Reusable Expiratory Filter AND Collection Vial (each)	Disposable Expiratory Filter (12/case)	Reusable Inspiratory Filter(each)	Disposable Inspiratory Filter(12/case)
Product Code	10063033 <u>and</u> 10063031	10043551	4-074600-00	4-074601-00
Suggested Backup Quantity	2 pairs	2 cases	2 each	2 cases

PB840—SUGGESTED QUANTITIES PER VENTILATOR				
	Reusable Expiratory Filter AND Collection Vial (each)	Disposable Expiratory Filter(12/case)	Reusable Inspiratory Filter(each)	Disposable Inspiratory Filter(12/case)
Product Code	4-070305-00 <u>and</u> 4-074647-00	4-076887-00	4-074600-00	4-074601-00
Suggested Backup Quantity	2 pairs	2 cases	2 each	2 cases

Please contact your local sales representative or our customer service team should you require further information.

Best regards,



Patrick Nellis
Marketing Manager – Respiratory Interventions & Advanced Parameters