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Freevent® XtraCare and Freevent® XtraCare Mini



Figure 1- FreeVent XtraCare Blue



Figure 2- FreeVent XtraCare Mini Blue

Product description:

Freevent XtraCare and Freevent XtraCare Mini are Heat and Moisture Exchangers combined with an electrostatic filter (HMEF). The HME is impregnated with a hygroscopic salt and conditions the inhaled air. The electrostatic filter reduces the inhalation of particles such as viruses, bacteria, pollen and other particulate matter through the tracheostoma. Freevent XtraCare and Freevent XtraCare Mini have a 15 mm ISO connector for connection to a tracheostomy tube.

Freevent XtraCare comes in two colors, white and blue. Each color comes in two package sizes, 5 pcs and 30 pcs.

Freevent XtraCare Mini comes in three colors, white, blue and pink. Each color comes in a package size of 30 pcs. Freevent XtraCare Mini White come in an additional package size of 5 pcs.

Freevent XtraCare and XtraCare Mini can be connected to oxygen tubing using the Freevent O2 Adaptor respectively O2 Adaptor mini (accessory).

Product Information

Document ID:	PF069-01-TechInfo	Edition:	05
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (Rule 1)		
Intended Use:	Freevent® XtraCare and Freevent® XtraCare Mini are single use Heat and Moisture Exchangers with electrostatic filters (HMEF) that condition and filter inhaled air in patients spontaneously breathing through a tracheostoma		
Use specifications:	<p>Intended medical indication: Patients breathing through a tracheostoma, long-term and short-term, independent of underlying condition. Especially intended for patients with a need for enhanced protection against microorganisms/pathogens, pollen, and other particles.</p> <p>Intended patient population: For patients with any health condition who breathe spontaneously through a tracheostoma and can tolerate the added dead space of the product and the added breathing resistance.</p> <p>Intended usage: Disposable single use product. Can be used 24/7 and shall be replaced if the breathing resistance has become too high e.g. when saturated with mucus, or if the 24 hours limit has been reached. Prescription only.</p> <p>Intended part of the body/type of tissue applied to or interacted with: To be applied on a tracheostomy tube or similar device with a 15mm connector.</p> <p>Intended user profile: Clinicians, caregivers, patient, depending on the condition of the patient.</p> <p>Intended conditions of use: Environment of use: Hospitals, ICU, Sub-acute care institutions, and home, indoors and outdoors. It does not affect the patient's mobility.</p>		
Contraindications:	<p>patients who:</p> <ul style="list-style-type: none"> • are under any form of mechanical ventilation. • are unable to handle or remove the device themselves when needed, and who are not under constant supervision of a clinician or a trained caregiver. • cannot tolerate the added dead space. 		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	58705 (Tracheostoma protective filter)		
Sterilization:	Non-Sterile		
Raw material:	<p>Plastic parts (Base and Housing): Polypropylene (PP) with white, blue or pink PP masterbatch.</p> <p>Foam: Polyurethane (PUR) with Calcium Chloride (CaCl₂)</p> <p>Filter: Acrylic fiber attached to Polypropylene (PP) spunbonded scrim</p>		
Latex information:	Not manufactured with natural rubber latex		

Product Information

Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None
Expiration date:	3 years after manufacturing.
Packaging:	<p>Freevent XtraCare 5pcs/30pcs (1pc/bag) are packed in plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.</p> <p>Freevent XtraCare Mini 5pcs/30pcs (1pc/bag) are packed in plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.</p>

Devices under Basic UDI-DI: 7331791-HME-0-000-0004-XM

REF	Name	UDI-DI
7767	Freevent XtraCare, white (30 pcs)	07331791008948
7768	Freevent XtraCare, blue (30 pcs)	07331791008955
7789	Freevent XtraCare, white (5 pcs)	07331791008962
7788	Freevent XtraCare, blue (5 pcs)	07331791008979
8004	Freevent XtraCare Mini white (30 pcs)	07331791014901
8005	Freevent XtraCare Mini blue (30 pcs)	07331791014918
8006	Freevent XtraCare Mini pink (30 pcs)	07331791014925
8008	Freevent XtraCare Mini white (5 pcs)	07331791014932

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Freevent O2 Adaptor	7331791-HME-A-000-0001-EX
Freevent O2 Adaptor mini	7331791-HME-A-000-0001-EX
Provox BasePlate Adaptor	7331791-HME-A-000-0003-F5