Product Information

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Issued:	QA	Adel Khwatmi - ADEKHW	2023-01-20 - 10:04
Reviewed:	QA	Abdallah Almashharawi - ABDALM	2023-01-20 - 10:55
Approved:	QA	Elin Andersson - ELIAND	2023-01-25 - 07:58
Released:	QA	Adel Khwatmi - ADEKHW	2023-02-07 - 08:52

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TrachPhone®

Product description:

TrachPhone heats and humidifies the inhaled air and partially restores breathing resistance. It can be occluded with a finger to facilitate speech. After release the valve will open automatically. TrachPhone is connected to an ISO 15 tube. An integrated suction port makes it possible to clean the tracheostomy tube from mucus as needed. An oxygen tubing can be connected via the oxygen connector present on TrachPhone.

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Document Number: XV-0545213 Status: Effective Version: 1.0
Name: PF023-01-TechInfo TrachPhone

Product Information

Document ID:	PF023-01-TechInfo	**Edition:**	07

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden

Classification: (EU) (MDD 93/42/EEC) Class IIa (1.2 Rule 2)

Intended Use: For patients breathing spontaneously via an ET tube or a tracheostomy tube in the hospital or at home.

Use specifications:

Intended medical indication: Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population: Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient. Not intended for patients with mechanical ventilation. Not intended for patients with a low tidal volume.

Intended usage: Single use. Over the counter.

Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin and mucosal membrane and as external communicating device the contact mode with tissue is indirect via air.

Intended user profile: The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use:
Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.). Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max usage for 24 hours. Replacement is performed by the patient, clinician or caregiver.

Contraindications: Do not use beyond recommended tidal volume range, as the added dead space may cause CO2 retention at too low tidal volumes. A too high tidal volume may lead to unsatisfactory humidification.
Do not use on dehydrated patients or patients with very heavy secretions from the lungs and airways.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-Sterile

Raw material: Polypropylene (PP), thermoplastic elastomers (TPE) and polyurethane (PUR).

Latex information: Not manufactured with natural rubber latex.

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.

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Product Information

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: TrachPhone is available as 50, 30 and 5 pack.
Each TrachPhone is packed in a plastic bag.
50 / 30 / 5 plastic bags are packed in an inner box (a total of 50 /30 / 5 cassettes).

Devices under Basic UDI-DI: 7331791-HME-0-000-0006-XT

REF	Name	UDI-DI
7704	TrachPhone (50 pcs)	07331791002861
7707	TrachPhone (30 pcs)	07331791009693
7723	TrachPhone (5 pcs)	07331791015854

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Fits on standard 15 mm ISO connector.	N/A

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Approved:	DD	Fredrik Calais - FRECAL	2020-05-25 - 19:49
Released:	DD	Pontus Eklund - X-PONEKL	2020-05-26 - 08:13

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Product Information

Freevent® DualCare

Product description:

Freevent DualCare Speaking valve is a valve with a silicone membrane and a rotatable lid. HME DigiTop is a top that can be occluded with two digits to enable speech. Both these speaking devices are attached to either Freevent HME 15 or HME 22 before use.

Freevent Connection Strap is a clip with a string that is used to secure Freevent DualCare to the patient's neckband.

Removal aid is a plastic clamp that is pressed together by finger force to clamp the HME at HME removal from the speaking devices.

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Product Information

Document ID:	PF068-01-TechInfo	**Edition:**	06

Manufacturer: Atos Medical AB
Kraftgatan 8, P.O. Box 183,
SE-242 22 Hörby, Sweden

Classification: (EU) 2017/745 Class I (1.1 rule 1)

Intended Use: Freevent DualCare is a combined Speaking Valve and Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a
tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff.
In HME-mode the device conditions inhaled air by retaining heat and moisture from the exhaled air.
By turning the lid of the Speaking Valve into speaking mode air is re-directed to enable speech.
The entire device is for single patient use and the HME-part is for single use.
Patient Population: For spontaneously breathing tracheostomized patients (adults and pediatric patients greater than 10 kg in weight) using a tracheostomy tube with a
deflated cuff, or a tracheostomy tube without cuff.
Environment of Use: Hospitals, ICU, sub-acute care institutions and home.

Freevent HME 15 is a Heat and Moisture Exchanger HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a ISO 15 mm connector. The HME conditions inhaled air by retaining heat and moisture from the exhaled air. The device also partially restores lost breathing resistance.
The HME is used in combination with Freevent DualCare Speaking valve/ Freevent DualCare Speaking Valve Blue, with Freevent HME DigiTop/ Freevent HME DigiTop Blue, or with HME DigiTop O2.
The HME is for single use, i.e. it has to be exchanged at least every 24 hours.

Freevent HME 22 Regular is a Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a Ø22mm connector. The HME conditions inhaled air by retaining heat and moisture from the exhaled air. The device also partially restores lost breathing resistance.
The HME is used in combination with Freevent DualCare Speaking Valve/ Freevent DualCare Speaking Valve Blue, with Freevent HME DigiTop/ Freevent HME DigiTop Blue, or with HME DigiTop O2.
The HME is for single use, i.e. it has to be exchanged at least every 24 hours.

CE Mark: Yes, the devices are CE marked.

GMDN code: 36071

Sterilization: Non-Sterile

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Product Information

Raw material: Freevent Speaking Valve: PP, Silicone, and POM.
Freevent Speaking Valve Blue: PP, Silicone, and POM
Freevent DigiTop: POM.
Freevent HME 15 Regular: POM, HDPE, and Polyester-based Polyurethane foam.
Freevent HME 22 Regular: Styrene–Ethylene/Butylene–Styrene copolymer, Epoxide glue, and Polyester-based Polyurethane foam.
Freevent Connection Strap: Polyester braided suture, POM, and PP.
Removal Aid: POM.

Latex information: Not manufactured with natural rubber latex

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:

Product		Contents
7740 Freevent DualCare Set 22	Box:	3x10 pcs HME 22 Regular in plastic bag 1 pc Speaking Valve in plastic jar 1 pc HME DigiTop in plastic bag 1 pc Removal Aid in plastic bag 1 pc Connection Strap in plastic bag 2 pcs Warning label sheets REF 10737 1 pc IFU REF 10721
7741 Freevent DualCare Set 15	Box:	3x10 pcs HME 15 Regular in plastic bag 1 pc Speaking Valve in plastic jar 1 pc HME DigiTop in plastic bag 1 pc Removal Aid in plastic bag 1 pc Connection Strap in plastic bag 2 pcs Warning label sheets REF 10737 1 pc IFU REF 10721
7742 Freevent HME 15 Regular (30pcs)	Box:	3x10 pcs HME 15 Regular in plastic bag
7744 Freevent DualCare Speaking Valve	Box:	1 pc Speaking Valve in plastic jar 1 pc HME DigiTop in plastic bag 1 pc Connection Strap in plastic bag 2 pcs Warning label sheets REF 10737 1 pc IFU REF 10721
7745 Removal Aid	Bubble plastic bag:	1 pc Removal Aid 1 pc IFU REF 10725
7746 Freevent Connection strap	Bubble plastic bag:	2x1 pc Connection Strap in plastic bag 1 pc IFU REF 10721
7747 Freevent HME 22 Regular (30pcs)	Box:	3x10 pcs HME 22 Regular in plastic bag
7755 Freevent DualCare Speaking Valve Blue	Box:	1 pc Speaking Valve Blue in plastic jar 1 pc HME DigiTop Blue in plastic bag 1 pc Connection Strap in plastic bag 2 pcs Warning label sheets REF 10737 1 pc IFU REF 10721

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Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0005-XQ

REF	Name	UDI-DI
7740	Freevent DualCare Set 22	07331791015038
7741	Freevent DualCare Set 15	07331791015021
7742	Freevent HME 15 Regular (30pcs)	07331791015069
7744	Freevent DualCare Speaking Valve	07331791015045
7745	Removal Aid	07331791008221
7746	Freevent Connection strap	07331791008238
7747	Freevent HME 22 Regular (30pcs)	07331791015076
7755	Freevent DualCare Speaking Valve Blue	07331791015052

HME 15

HME 22

Speaking Valve (Blue)

DigiTop (Blue)

Connection strap

Removal aid

Atos Medical AB compatible products:

Range	BASIC UDI-DI
HME DigiTop O2	7331791-HME-A-000-0001-EX

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Document No: 10000043401 Edition: 07 Release date: 2020-05-26

Technical Info / Material Data Sheet

Document ID: PF068-07-Tech Info	Edition: 00

REF Number	7756
Product Name	HME DigiTop O2 (REF7756)
Models:	One variant, fitting for 22mm HME Cassette. One product, each containing one DigiTop O2 + Instructions For Use.
Classification: (MDD 93/42/EEC)	Class IIa, 1.2 rule 2
CE Mark:	Yes
GMDN code:	58705
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The HME DigiTop O2 is an accessory to ProTrach HMEs and Provox FreeHands HME's. For patients spontaneously breathing through a tracheostoma and having a need of extra oxygen.
Description:	HME DigiTop O2 is a top that can be occluded with two digits to enable speech. The device shall be attached to either ProTrach HME 15 or HME 22 before use. The oxygen connector port on the device shall be connected to an oxygen supply via a tube
Sterilization:	Non-sterile
Raw material:	HME DigiTop O2: Blue POM .
Latex information	The device is not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit: 2-42 °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:	REF 7756, HME DigiTop O2: – box with 1 pcs plastic jar with 1 pc HME DigiTop O2 + 1 pc IFU REF 10721.

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Technical Info / Material Data Sheet

Reviewed by:

.....

Vice President QA&RA

2014-03-28

.....

Date

Approved by:

.....

Vice President Design Control

2014-04-01

.....

Date

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Product Information

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).

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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:

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.

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.

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.

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.

Intended user profile:
Clinicians, caregivers, patient, depending on the condition of the patient.

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.

Contraindications: patients who:
- 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: Plastic parts (Base and Housing): Polypropylene (PP) with white, blue or pink PP masterbatch.
Foam: Polyurethane (PUR) with Calcium Chloride (CaCl2)
Filter: Acrylic fiber attached to Polypropylene (PP) spunbonded scrim

Latex information: Not manufactured with natural rubber latex

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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: **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.

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.

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

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Approved:	QA	Elin Andersson - ELIAND	2022-11-28 - 11:27
Released:	QA	Abdallah Almashharawi - ABDALM	2022-12-14 - 10:10

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Product Information

Freevent® O2 Adaptors

Product description:

Freevent O2 Adaptors are accessories that fit Freevent XtraCare and Freevent XtraCare Mini. They are clicked over the base of the HME and the combined device is attached to the patient´s tracheostomy tube, or similar device. Additional oxygen can then be supplied via the oxygen port of the O2 Adaptor. Freevent O2 Adaptors are single use devices and should be replaced if they become dirty, or at least every 24 hours.

The O2 Adaptor mounted on a Blue Freevent XtraCare

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Document Number: XV-0543439 Status: Effective Version: 1.0
Name: PF069-02-TECHINFO Freevent O2 Adaptors

Product Information

Document ID:	PF069-02-TechInfo	**Edition:**	04
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class IIa (1.2 rule 2)		
Intended Use:	Freevent O2 Adaptor and Freevent O2 Adaptor Mini are single use accessories used together with Freevent XtraCare or Freevent XtraCare Mini respectively. The devices are intended to enable additional oxygen supply for patients breathing through a tracheostoma during use of Freevent XtraCare and Freevent XtraCare Mini.		
Use specifications:	**Intended medical indication** Patients breathing through a tracheostoma, long-term and short-term, independent of underlying condition. **Intended patient population** For patients with any health condition who breathe spontaneously through a tracheostoma and use applicable Freevent product. **Intended usage** Disposable single use product. Should be changed at least every 24 hours. For prescription only. **Intended part of the body/type of tissue applied to or interacted with:** To be applied on applicable Freevent XtraCare, which in turn is connected to a tracheostomy tube or similar device. **Intended user profile** Clinicians, caregivers, patients, depending on the condition of the patient. **Intended conditions of use** Environment of use: Hospitals, ICU, Sub-acute care institutions, and home, indoors and outdoors. The device itself does not affect the patient´s mobility.		
Contraindications:	No known contraindications.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	58705 (Tracheostoma protective filter)		
Sterilization:	Non-Sterile		
Raw material:	Polypropylene (PP)		
Latex information:	Not manufactured with natural rubber latex		
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.		

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Product Information

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: Freevent O2 Adaptors are single packed in a plastic bag of polyethylene and then 10 pieces in a cardboard box together with IFU.

Devices under Basic UDI-DI:

REF	Name	UDI-DI
7769	Freevent O2 Adaptor 10pcs	07331791008986
8007	Freevent O2 Adaptor Mini 10pcs	07331791015311

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Freevent XtraCare White/Blue	7331791-HME-0-000-0004-XM
Freevent XtraCare Mini White/Blue/Pink *(for O2 adaptor Mini)*	7331791-HME-0-000-0004-XM

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