

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: Class IIa, 1.2 rule 2
 (MDD 93/42/EEC)

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.

Technical Info / Material Data Sheet

Reviewed by:


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Vice President QA&RA

2014-03-28
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Date

Approved by:


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Vice President Design Control

2014-04-01
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Date

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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This document has been electronically signed by the persons above.

Released

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.

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:	<p>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.</p> <p>By turning the lid of the Speaking Valve into speaking mode air is re-directed to enable speech.</p> <p>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.</p> <p>Environment of Use: Hospitals, ICU, sub-acute care institutions and home.</p> <p>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.</p> <p>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.</p> <p>The HME is for single use, i.e. it has to be exchanged at least every 24 hours.</p> <p>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.</p> <p>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.</p> <p>The HME is for single use, i.e. it has to be exchanged at least every 24 hours.</p>		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	36071		
Sterilization:	Non-Sterile		

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

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



Atos Medical AB compatible products:

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

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This document has been electronically signed by the persons above.

Released

Product Information

Freevent® O2 Adaptor



Product description:

Freevent O2 Adaptor is an accessory to Freevent XtraCare for patients requiring additional oxygen. The adaptor connects oxygen tubing of 1/8 inch (3.2 mm) diameter to the oxygen port. The device is for single use and should be replaced at least every 24 h, when it becomes dirty, contaminated or shows any signs of damage.



The O2 Adaptor mounted on a Blue Freevent XtraCare

Product Information

Document ID:	PF069-02-TechInfo	Edition:	02
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class IIa (1.2 rule 2)		
Intended Use:	The Freevent O2 Adaptor is a single use accessory used together with Freevent XtraCare. The device is intended to enable additional oxygen supply for patients breathing through a tracheostoma during use of the Freevent XtraCare.		
CE Mark:	Yes, the 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.		
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 Adaptor is single packed in a plastic bag and then 10 pieces in a cardboard box together with IFU.		

Product Information

Devices under Basic UDI-DI: 7331791-HME-A-000-0001-EX

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

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Freevent XtraCare White White/Blue 5/30 pcs	7331791-HME-0-000-0004-XM

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Released:	DD	Jon Berg - JONBER	2020-05-28 - 13:57

This document has been electronically signed by the persons above.

Released

Freevent® XtraCare**Product description:**

The Freevent XtraCare is a Heat and Moisture Exchanger 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 has a 15 mm ISO connector for connection to a tracheostomy tube.

The device comes in two colors, white and blue, and each color comes in two package sizes, 5 pcs and 30 pcs.

The Freevent XtraCare can be connected to oxygen tubing using the Freevent O2 Adaptor (accessory).

Product Information

Document ID:	PF069-01-TechInfo	Edition:	03
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 XtraCare is a single use Heat and Moisture Exchanger with electrostatic filter (HMEF) that conditions and filters inhaled air in patients spontaneously breathing through a tracheostoma.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	58705 (Tracheostoma protective filter)		
Sterilization:	Non-Sterile		
Raw material:	Plastic parts (Base and Housing): Polypropylene (PP) with white or blue PP masterbatch. Foam: Polyurethane (PUR) with Calcium Chloride (CaCl ₂) Filter: Acrylic fiber attached to Polypropylene (PP) spunbonded scrim		
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:	Freevent XtraCare is single packed in a plastic bag and then 5 or 30 pieces in a cardboard box together with IFU.		

Product Information

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

Atos Medical AB compatible products:

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

Technical Info / Material Data Sheet

Document ID: PF023-03-TechInfo

Edition: 01

REF Number	7707
Product Name	TrachPhone (30 pack)
Models:	One model.
Classification: (MDD 93/42/EEC)	IIa (1.2 Rule 2)
CE Mark:	Yes
GMDN code:	58705 (Tracheostoma protective filter)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The TrachPhone is used for patients breathing spontaneously via an ET tube or a tracheostomy tube in the hospital or at home.
Description:	The TrachPhone heats and humidifies the inhaled air and partially restores breathing resistance. The TrachPhone contains a valve with a spring that can easily be occluded with a finger to facilitate speech. After releasing the finger, the valve will open automatically. The unit comes with an integrated suction port and an integrated oxygen connector.
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 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.

Technical Info / Material Data Sheet

Packaging: Each TrachPhone is packed in a plastic bag.
30 plastic bags are packed in an inner box (a total of 30 cassettes).

Reviewed by:



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Vice President QA&RA

2014-04-14

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Date

Approved by:



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Vice President Design Control

2014-04-14

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Date

Technical Info / Material Data Sheet

Document ID: PF023-01-TechInfo

Edition: 05

REF Number	7704
Product Name	TrachPhone (50 pack)
Models:	One model
Classification: (MDD 93/42/EEC)	IIa (1.2 Rule 2)
CE Mark:	Yes
GMDN code:	58705 (Tracheostoma protective filter)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The TrachPhone is used for patients breathing spontaneously via an ET tube or a tracheostomy tube in the hospital or at home.
Description:	The TrachPhone heats and humidifies the inhaled air and partially restores breathing resistance. The TrachPhone contains a valve with a spring that can easily be occluded with a finger to facilitate speech. After releasing the finger, the valve will open automatically. The unit comes with an integrated suction port and an integrated oxygen connector.
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 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.

Technical Info / Material Data Sheet

Packaging: Each TrachPhone is packed in a plastic bag.
50 plastic bags are packed in an inner box (a total of 50 cassettes).

Reviewed by:

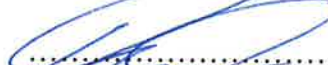


Vice President QA&RA

2014-04-14

Date

Approved by:



Vice President Design Control

2014-04-14

Date