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 Regular or Freevent HME 22 Regular 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:**	3.0
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class I (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.

Freevent HME 15 Regular is a Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with an 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.

Product Information

Use specifications: **Freevent DualCare**

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
HME: Single use, Prescription only .
Speaking Valve: Single patient multiple use, Prescription only.
Removal Aid and Connection Strap: Single patient multiple 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 for HME. Replacement is performed by the patient, clinician or caregiver.

Product Information

Freevent HME 15 Regular and Freevent HME 22 Regular

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, Prescription only.

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: **Freevent DualCare**

General

Freevent HME 15 or 22 in combination with either Freevent DualCare Speaking Valve or Freevent HME DigiTop are contraindicated for:
Use in combination with an in-line ventilator.
- Patients without the physical, cognitive, or mental ability required to attach, remove, or operate the devices themselves, should not use the devices independently and should only use them if they are under sufficient supervision of a clinician or a trained caregiver.
- The devices should not be used by patients with a low tidal volume, as the added dead space may cause CO2 (Carbon dioxide) retention.
- Unresponsive or sedated patients.

The HME 15 or 22 in combination with either Speaking Valve or HME DigiTop must NOT be used on a single lumen tube (tube without an inner tube), unless the patient or caregiver is able to reinsert the tube themselves after accidental dislodgment or emergency replacement.

Speaking valve specific

The use of Speaking Valve (in combination with HME 15 or 22) is additionally contraindicated for the following patient groups:
- Laryngectomized patients since the device will prevent the ability to exhale if the Speaking Valve is unintentionally set to speaking mode.
- Patients suffering from severe aspiration.
- Patients with severe laryngeal or upper airway obstruction such as significant tracheal and/or laryngeal stenosis, since this may cause air trapping.
- Patients with very thick and copious secretions which might block the device.

DO NOT use the Speaking Valve:
- In combination with a tracheostomy tube with the cuff inflated. The cuff must be completely deflated before placing and during all use of the Speaking Valve.
- In combination with a tracheostomy tube with a foam cuff.
- In combination with a tracheostomy tube with a self-inflating cuff.
- When the size of the tracheostomy tube does not allow for airflow through the upper airways.
- In combination with an endotracheal tube.

Use of the Speaking Valve in these circumstances can restrict exhalation through the upper airways and cause suffocation!

DO NOT use the Speaking Valve during sleep since the airway could be blocked unintentionally. During sleep the HME DigiTop (in combination with HME 15 or 22) should be used instead.

Product Information

Freevent HME 15 Regular and Freevent HME 22 Regular
Freevent HME 22 in combination with either Freevent DualCare Speaking Valve or Freevent HME DigiTop is contraindicated for:
- Use in combination with an in-line ventilator.
- Patients who are unable to handle or remove the device themselves when needed, unless the patient is under constant supervision of a clinician or a trained caregiver. For example, patients who are unable to move their arms, patients with decreased levels of consciousness, or patients with diseases that put them at risk for unpredictable periodic loss of consciousness.
- Patients who cannot tolerate the added dead space of 5 ml, or who cannot tolerate the added breathing resistance of 170 Pa / 1.7 cm H2O. This should be evaluated by a clinician.
- Unresponsive or sedated patients. The patient must be responsive and attempting to communicate in order to use the device. The patient should be able to follow instructions.

The HME 22 in combination with either Speaking Valve or HME DigiTop must NOT be used on a single lumen tube (tube without an inner tube), unless the patient or caregiver is able to reinsert the tube themselves after emergency removal.

CE Mark:	Yes. Devices are CE-marked.
GMDN code:	58705 (Tracheostoma protective filter) for REF 7742, 7745 and 7747. 36071 (Tracheostomy tube speech valve) for REF 7740, 7741, 7744, 7746 and 7755.
Sterilization:	Non-Sterile
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: Polypropylene (PP) with white masterbatch, 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.

Product Information

Packaging:

Product	Contents
7740 Freevent DualCare Set 22	HME 22 Regular, 30 pcs (10 pcs/bag) are packed in plastic bag of polyethylene. Speaking Valve, 1 pc is packed in a plastic jar of polypropylene. HME DigiTop, 1 pc is packed in a plastic bag of polyethylene. Removal Aid, 1 pc is packed in a plastic bag polyethylene. Connection Strap,1 pc is packed in a plastic bag of polyethylene. The products, 2 pcs warning label sheets and instructions for use are packed in a cardboard box.
7741 Freevent DualCare Set 15	HME 15 Regular, 30 pcs (10 pcs/bag) are packed in plastic bag of polyethylene. Speaking Valve, 1 pc is packed in a plastic jar of polypropylene. HME DigiTop, 1 pc is packed in a plastic bag polyethylene. Removal Aid, 1 pc is packed in a plastic bag polyethylene. Connection Strap, 1 pc is packed in a plastic bag polyethylene. The products, 2 pcs warning label sheets and instructions for use are packed in a cardboard box.
7742 Freevent HME 15 Regular (30pcs)	HME 15 Regular, 30 pcs (10 pcs/bag) are packed in plastic bag of polyethylene. The products are packed in a cardboard box.
7744 Freevent DualCare Speaking Valve	Speaking Valve,1 pc is packed in a plastic jar of polypropylene. HME DigiTop,1 pc is packed in a plastic bag polyethylene. Connection Strap, 1 pc is packed in a plastic bag polyethylene. The products, 2 pcs warning label sheets and instructions for use are packed in a cardboard box.
7745 Removal Aid	Removal Aid, 1 pc is packed in a plastic bag polyethylene. The product and instructions for use are packed in a bubble plastic bag.
7746 Freevent Connection strap	Connection Strap, 2 pcs (1 pc/bag) are packed in plastic bag polyethylene. The products and instructions for use are packed in a bubble plastic bag
7747 Freevent HME 22 Regular (30pcs)	HME 22 Regular, 30 pcs (10 pcs/bag) are packed in plastic bag of polyethylene. The products are packed in a cardboard box.
7755 Freevent DualCare Speaking Valve Blue	Speaking Valve Blue, 1 pc is packed in a plastic jar of polypropylene. HME DigiTop Blue, 1 pc is packed in a plastic bag polyethylene. Connection Strap, 1 pc is packed in a plastic bag polyethylene. The products, 2 pcs warning label sheets and instructions for use are packed in a cardboard box.

Product Information

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

REF	Name	UDI-DI
7740	Freevent DualCare Set 22	7331791015038
7741	Freevent DualCare Set 15	7331791015021
7744	Freevent DualCare Speaking Valve	7331791015045
7745	Removal Aid	7331791008221
7746	Freevent Connection strap	7331791008238
7755	Freevent DualCare Speaking Valve Blue	7331791015052

Devices under Basic UDI-DI: 7331791-HME-0-000-0010-XE

REF	Name	UDI-DI
7742	Freevent HME 15 Regular (30pcs)	7331791015069

Devices under Basic UDI-DI: 7331791-HME-0-000-0011-XH

REF	Name	UDI-DI
7747	Freevent HME 22 Regular (30pcs)	7331791015076

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-000-0007-FH

Document Approvals
Approved Date: 2024-06-10

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Task: Final Approval Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 10-Jun-2024 09:17:19 GMT+0000