Product Information

Provox FreeHands® HME

Product description:

Provox FreeHands HME Cassette, Flow and Moist (referred to as Provox FreeHands HME cassettes) are single-use devices which have to be connected to the interface of Provox FreeHands speaking valves, Provox HME Cap or HME DigiTop O2/Freevent HME DigiTop before being attached to a Provox attachment device. FreeHands HME cassettes do not have a top lid that can be pushed down for speech and must be assembled with Provox speaking valves in order to achieve the function of speech.

Product Information

Document ID:	PF022-02-TechInfo	**Edition:**	2.0

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

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: Provox FreeHands HME Cassette/Moist/Flow is intended for single use for spontaneously breathing laryngectomized patients, utilizing a voice prosthesis and must be used in combination with a Provox FreeHands speaking valve, a Provox cap or Digitop O2. Provox FreeHands combines pulmonary rehabilitation with its Heat and Moisture Exchanging functionality with voice rehabilitation using an Automatic Speaking Valve or Manual Occlusion. The HME conditions inhaled air by retaining heat and moisture from the exhaled air. The device also partially restores lost breathing resistance.

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. Not for use during sleep unless in combination with a cap.

Replacement rate: Max usage for 24 hours. Replacement is performed by the patient, clinician or caregiver.

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Contraindications:	The device must not be used if there is no properly functioning voice prosthesis in place or if the laryngectomee is unable to speak with such a device. The user must be able to produce intelligible voicing by means of digital stoma occlusion. Consequently, all contraindications for prosthetic voice rehabilitation also contraindicate the use of a Provox FreeHands HME. Absolute and relative contraindications for prosthetic voice rehabilitation include, but are not limited to: Radiotherapy doses greater than 70 Gy in 7 weeks, poor overall physical condition, heart insufficiency, coagulopathy or anticoagulant therapy, mental diseases, hypersensitivity to the material of the voice prosthesis. Allergy or hypersensitivity against any of the following materials contraindicates the use of the Provox FreeHands HME: metals, polycarbonate, compound thermoplastics and silicone. Lung emphysema, asthma, and other pulmonary diseases, which affect lung capacity, are contraindications for breath-controlled automatic speech valves. Patients suffering from such diseases should only use Provox FreeHands HME if it has been determined by their physician that the benefits of the device clearly outweigh the risk of its use. The stoma size and the condition of the peristomal skin may be factors contraindicating the use of the device and its required accessories. A stoma, which is too small, can limit the inhaled airflow and thereby lead to too low a tidal volume. Hypersensitive skin may make it impossible to attach the valve properly.
CE Mark:	Yes. Devices are CE-marked.
GMDN code:	58705 (Tracheostoma protective filter)
Sterilization:	Non-sterile.
Raw material:	Cassette: Polypropylene (PP) with white masterbatch. Foam: Polyurethane (PUR) with calcium chloride (CaCl2).
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:	HMEs are packed in plastic bags made of polyethylene that are placed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0003-XJ

REF	Name	UDI-DI
8220	Provox FreeHands HME Moist (30 pcs)	07331791008368
8221	Provox FreeHands HME Flow (30 pcs)	07331791008375
8220-18	Provox FreeHands HME Moist (30 pcs)	07331791012372
8221-18	Provox FreeHands HME Flow (30 pcs)	07331791013553

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox XtraBase	7331791-ADH-0-000-0000-CQ
Provox StabiliBase OptiDerm	7331791-ADH-0-000-0000-CQ
Provox FlexiDerm	7331791-ADH-0-000-0000-CQ
Provox OptiDerm	7331791-ADH-0-000-0000-CQ
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox HME Cassette Adaptor	7331791-HME-A-000-0008-FL
Provox HME Cap	7331791-HME-A-000-0002-F2
Provox FreeHands FlexiVoice	7331791-HME-0-000-0007-XW

Document Approvals
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