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Product Information

Provox® HME Cap

Product description:

Provox HME Cap is a dome-shaped titanium ring for rehabilitation after total laryngectomy. It allows use of the Provox FreeHands HME Cassettes without the Provox FreeHands HME Speech Valve. The front opening of the cap can be occluded manually to speak.

Document No: 10000043358 Edition: 05 Release date: 2020-06-23

Atos Medical AB
Kraftgatan 8, P.O Box 183
SE-242 22 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Product Information

Document ID:	PF019-01-TechInfo	**Edition:**	05

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

Classification: (EU) 2017/745 Class I (1.1 Rule)

Intended Use: Provox HME Cap is a single patient use, dome-shaped titanium ring, that allows use of Provox FreeHands HME cassette (REF 8220, 8221) without Provox FreeHands FlexiVoice.

Provox HME Cap is only intended for use when using Provox FreeHands FlexiVoice is not recommended, i.e. when sleeping.

Provox HME Cap cannot be used with any other type of HME cassette. The front opening of the cap can be occluded manually to speak. Provox HME Cap can be cleaned and reused.

CE Mark: Yes, the devices are CE marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-Sterile

Raw material: Titanium

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: 5 years after manufacturing.

Packaging: HME Cap is separately packed in a mini grip plastic bag, then a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-HME-A-000-0002-F2

REF	Name	UDI-DI
7730	Provox HME Cap	07331791003011

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands HME Cassette	7331791-HME-0-000-0003-XJ

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Approved:	DD	Fredrik Calais - FRECAL	2020-04-23 - 09:11
Released:	QA	Peter Sundsten - X-PETSUN	2020-05-13 - 14:27

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Product Information

Provox® FreeHands HME

Product description:

Provox FreeHands HMEs are designed to allow automatic tracheostoma closure (instead of digital stoma occlusion) for voice prosthesis users (e.g. Provox, Voice Prosthesis), while providing heat-and-moisture-exchange (HME, via the Provox FreeHands Cassette) for pulmonary rehabilitation. The device should be adjusted for the end user by a clinician trained in voice and pulmonary rehabilitation, e.g. a speech pathologist, before it can be used without supervision – *this does not apply for Provox FreeHands FlexiVoice*.

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Atos Medical AB
Kraftgatan 8, P.O Box 183
SE-242 22 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Product Information

Document ID: PF022-02-TechInfo **Edition:** 07

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

CE Mark: Yes, the devices are CE marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

Raw material: Cassette: Styrene-ethylene-butadiene-styrene (SEBS) and Polyurethane (PUR).
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. The following configurations are present:

REF	#HMEs per plastic bag	#Plastic bags in cardboard box	#HMEs in product
8220, 8221	10	3	30
8220-18, 8221-18	10	3	30
8222-18, 8223-18	10	2	20

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
8222-18	Provox FreeHands HME Moist (20 pcs)	07331791013560
8223-18	Provox FreeHands HME Flow (20 pcs)	07331791013577

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-000-0003-F5
Provox HME Cap	7331791-HME-A-000-0002-F2
Provox FreeHands FlexiVoice	7331791-HME-0-000-0003-XJ

Document No: 10000042795 Edition: 07 Release date: 2020-05-13

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Released:	DD	Peter Sundsten - PETSUN	2021-02-18 - 10:16

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Product Information

Provox® FreeHands FlexiVoice

Product description:

The Provox FreeHands FlexiVoice consists of two parts assembled together, a speaking valve for single patient use and a disposable HME cassette.
The speaking valve is made of plastic and the membrane is made of silicone. The HME cassette is also made of plastic and a salt treated polyurethane foam.
The speaking valve has two modes; Automatic Speaking Mode and Locked Mode. Rotating the top of the speaking valve moves the device into the automatic speaking or the locked position. Speaking can be done both by using the automatic speaking valve and by manual occlusion of the opening in the front. Manual occlusion is possible in both modes.

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Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID: PF058-01-TechInfo **Edition:** 05

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

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

Intended Use: The Provox FreeHands FlexiVoice combines pulmonary rehabilitation using a Heat and Moisture Exchanger with voice rehabilitation using an Automatic Speaking Valve or Manual Occlusion, in laryngectomized patients using a voice prosthesis.

Use specifications:

Intended medical indication:
Total laryngectomy with a voice prosthesis in situ.
Intended patient population:
Male and female 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.
Intended usage:
Single patient use, prescription.
Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin 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:
The HME cassette /moist/flow/Life FreeHands HME is for single use. The Speaking valve, Arch and HME Removal Aid are for single patient use. Should only be used when awake. Only intended for laryngectomized patients using a voice prosthesis. Only intended for laryngectomized patients who can tolerate using an HME.
Environment including hygienic requirements: Primarily: Home use.
Secondary: Hospital use.
Frequency of use: Daily continous use, not during sleep.
Location: Ambient temperature -20°C to +45°C.
Mobility: Only intended for use by patients with sufficient manual dexterity to handle rotation of the speaking valve, assembly/disassembly of the device and insertion/removal of the device.

Contraindications: The product shall not be used by patients with a decreased level of consciousness, patients with reduced mobility of the arms and/or hands, or patients who are unable to remove the device themselves.

CE Mark: Yes, the devices are CE marked.

GMDN code: 36071

Sterilization: Non-sterile

Raw material: Speaking valve: PP, Silicone and POM.
Arch: MABS

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Product Information

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:	**Ref 7757:** Box with 6 pcs [plastic bag with 5 pcs Provox FreeHands HME Cassette] + 3 plastic jars with 1 pc Speaking Valve of each version (light, medium, strong) + plastic bag with 1 pc Removal Aid + plastic bag with 2 pc Arch + 1 pc IFU Ref 10740. **Ref 7760:** Box with 3 plastic jars with 1 pc Speaking Valve of each version (light, medium, strong) + plastic bag with 1 pc Removal Aid + plastic bag with 2 pc Arch + 1 pc IFU Ref 10740. **Ref 8161:** Box with 1 plastic jars with 1 pc Speaking Valve Provox FreeHands FlexiVoice Light + plastic bag with 1 pc Removal Aid + plastic bag with 1 pc Arch + 1 pc IFU Ref 10740. **Ref 8162:** Box with 1 plastic jars with 1 pc Speaking Valve Provox FreeHands FlexiVoice Medium + plastic bag with 1 pc Removal Aid + plastic bag with 1 pc Arch + 1 pc IFU Ref 10740. **Ref 8163:** Box with 1 plastic jars with 1 pc Speaking Valve Provox FreeHands FlexiVoice Strong + plastic bag with 1 pc Removal Aid + plastic bag with 1 pc Arch + 1 pc IFU Ref 10740. **Ref 8165:** Box with 5 plastic bag with1 pc Arch in each bag. **Ref 8166:** Box with 1 plastic jars with 1 pc Speaking Valve Provox FreeHands FlexiVoice XtraStrong + plastic bag with 1 pc Removal Aid + plastic bag with 1 pc Arch + 1 pc IFU Ref 10740. **Ref 8210:** Box with 2 blisters (FreeHands HME 10pcs) + 3 plastic jars with 1 pc Speaking Valve of each version (light, medium, strong) + plastic bag with 2 pcs Arch + 1 pc IFU Ref 10740.

Document No: 10000019244 Edition: 05 Release date: 2021-02-18

Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0007-XW

REF	Name	UDI-DI
7757	Provox FreeHands FlexiVoice Set Plus	07331791008276
7760	Provox FreeHands FlexiVoice Set	07331791008283
8161	Provox FreeHands FlexiVoice Light	07331791008290
8162	Provox FreeHands FlexiVoice Medium	07331791008306
8163	Provox FreeHands FlexiVoice Strong	07331791008313
8165	Provox FreeHands FlexiVoice Arch (5 pcs)	07331791010408
8166	Provox FreeHands FlexiVoice XtraStrong	07331791010668
7757-18	Provox FreeHands FlexiVoice Set Plus	07331791013508
7760-18	Provox FreeHands FlexiVoice Set	07331791013515
8161-18	Provox FreeHands FlexiVoice Light	07331791013461
8162-18	Provox FreeHands FlexiVoice Medium	07331791012365
8163-18	Provox FreeHands FlexiVoice Strong	07331791013485
8166-18	Provox FreeHands FlexiVoice XtraStrong	07331791013492
8210	Provox Life FreeHands FV Set Plus	07331791015175

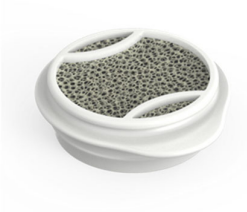

Light


Medium


Strong


XtraStrong

Arch


Life FreeHands HME

HME Cassette

Removal aid

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands HME	7331791-HME-0-000-0003-XJ
Provox Life FreeHands HME	7331791-HME-0-000-0008-XZ

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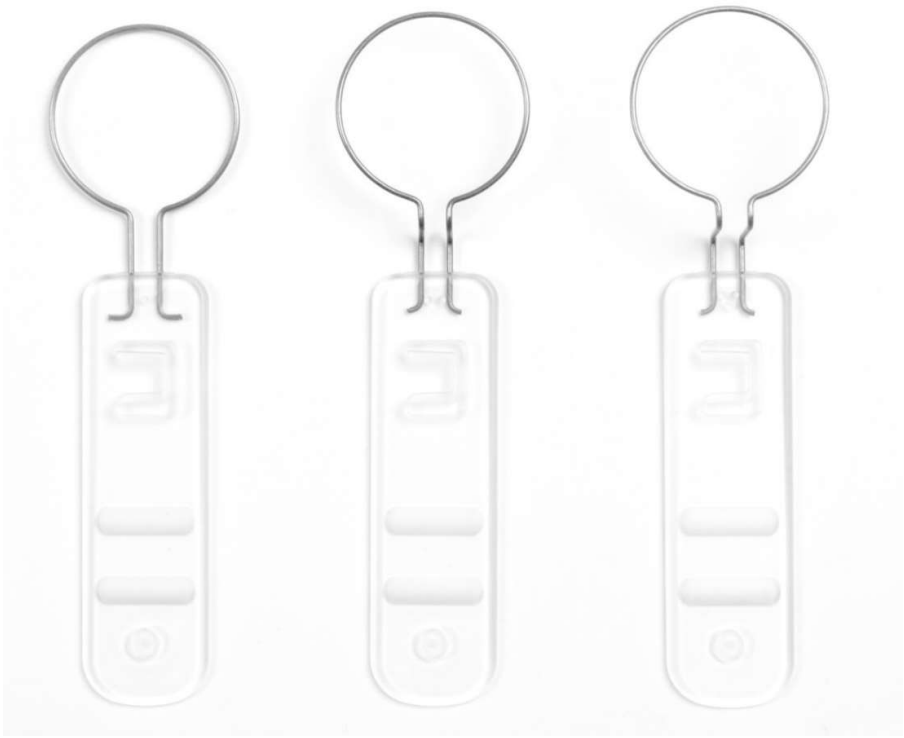
Product Information

Provox® FreeHands Support™



Product description:

The Provox FreeHands Support system consists of two parts; Provox FreeHands Support and Provox FreeHands Support Adhesive.
The reusable Provox FreeHands Support is available in three different variants; 'Flat', 'Medium' and 'Deep'. The three variants, as well as the possibility to adjust the metal ring and plastic parts, enable personal fit. Provox FreeHands Support Adhesive is a single-use adhesive that is attached to the skin, beneath the Provox Adhesive.

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Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID: PF078-01-TechInfo **Edition:** 05

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

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

Intended Use: Provox FreeHands Support provides support to the Provox adhesive when using a Provox hands-free speaking valve after total laryngectomy. The device is a single patient use device with a single use adhesive.

Use specifications:
Intended medical indication:
Product for rehabilitation for patients breathing through a tracheostoma after a total laryngectomy.
Intended patient population:
Patients of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.
Intended usage:
The FreeHands Support is a reusable single patient device whereas the FreeHands Support Adhesive is a (disposable) single use device.
The product is intended to be available to patients over-the-counter.
Should only be used when awake (i.e., not during sleep). Intended for laryngectomized patients using Provox hands free speaking valves. The product should only be used by patients with sufficient manual dexterity to handle attachment/removal of the device.
Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin.
Intended user profile:
Patient (Nurse, physician or other caregiver only for fitting and instructions).
Intended conditions of use:
Environment of use: (Primarily) Home use, secondary hospital use.
Frequency of use: Daily use, not during sleep.
Location: Ambient temperature -20°C to +45°C
Mobility: The product should only be used by patients with sufficient manual dexterity to handle attachment/removal of the device."

Contraindications: Do not use Provox FreeHands Support on breached skin.
Provox FreeHands Support is NOT intended to be in place during MRI examination (Magnetic Resonance Imaging), or during the period of Radiation Therapy treatment.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 62155 (Tracheostomy base plate, reusable)

Sterilization: Non-sterile

Raw material: Provox FreeHands Support consists of a ring of stainless steel and a plastic part (Polycarbonate, PC).

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Product Information

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:	Provox FreeHands Support is packed in a cardboard box together with instructions for use.

Product Information

Devices under Basic UDI-DI: 7331791-HME-A-000-0000-EU

REF	Name	UDI-DI
8020	Provox FreeHands Support Starter Set	07331791009266
8021	Provox FreeHands Support Flat	07331791009273
8022	Provox FreeHands Support Medium	07331791009280
8023	Provox FreeHands Support Deep	07331791009297

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands Support Adhesive	7331791-HME-A-000-0004-F8
Provox FreeHands FlexiVoice	7331791-HME-0-000-0007-XW

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Product Information

Provox® FreeHands Support™ Adhesive

Product description:

The Provox FreeHands Support system consists of two parts; Provox FreeHands Support and Provox FreeHands Support Adhesive.

The reusable Provox FreeHands Support is available in three different variants; 'Flat', 'Medium' and 'Deep'. The three variants, as well as the possibility to adjust the metal ring and plastic parts, enable personal fit. Provox FreeHands Support Adhesive is a single-use adhesive that is attached to the skin, beneath the Provox Adhesive.

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Atos Medical AB
Kraftgatan 8, P.O Box 183
SE-242 22 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

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atosmedical.com

Product Information

Document ID:	PF078-02-TechInfo	**Edition:**	05

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

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

Intended Use: Provox FreeHands Support provides support to the Provox Adhesive when using a Provox hands-free speaking valve after total laryngectomy. The device is a single patient use device with a single use adhesive.

CE Mark: Yes, the devices are CE marked.

GMDN code: 62175 (Stomal appliance skin-adherent patch, non-sterile)

Sterilization: Non-sterile

Raw material: Provox FreeHands Support Adhesive consists of a plastic plate (Polycarbonate, PC) and an adhesive tape (Acrylate and Polyester film).

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: Provox FreeHands Support Adhesive is packed in a blister package made of PET film and with a re-sealable top film (PP). It is then packed in a cardboard box.

Document No: 10000038354 Edition: 05 Release date: 2020-10-28

Product Information

Devices under Basic UDI-DI: 7331791-HME-A-000-0004-F8

REF	Name	UDI-DI
8024	Provox FreeHands Support Adhesive (15pc)	07331791009303

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands Support	7331791-HME-A-000-0000-EU

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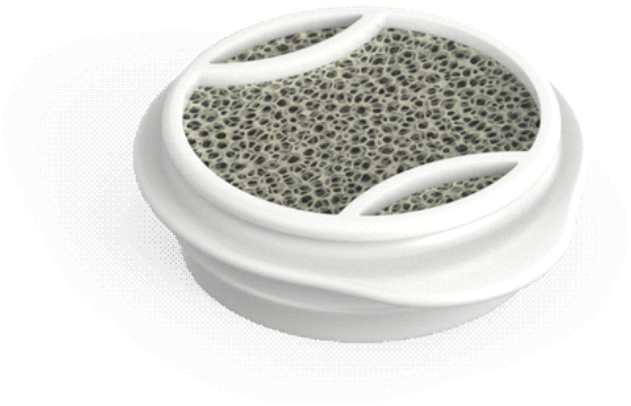
Product Information

Provox® Life™ Sample Packs



Product description:

Provox Life Sample Pack FreeHands HME consists of Provox Life FreeHands HME: Provox Life FreeHands HME is a heat- and moisture exchanger facilitating pulmonary rehabilitation by humidifying the inhaled air, which helps to keep the lungs healthy.

Document No: 10000045639 Edition: 00 Release date: 2021-02-04

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID:	PF099-02-TechInfo	**Edition:**	00

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

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

Intended Use: Provox Life FreeHands HME is a single use heat- and moisture exchanger intended for spontaneously breathing laryngectomized patients, utilizing a voice prosthesis and in combination with a Provox speaking valve or a DigiTop.

Use specifications: *Intended medical indication:* Product for rehabilitation after total laryngectomy.
Intended patient population: Male and female 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 part of the body/type of tissue applied to or interacted with: The product is placed in front of the tracheostoma to condition respiratory air. The tissue contact is indirect via inhaled air.
Intended user profile: The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs.
Intended conditions of use Environment: Home use (normal daily environment without any hygienic 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. Not for use during sleep unless in combination with a HME DigiTop.

Contraindications: The products are not intended to be used by patients unable to remove or operate the device, 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.
The product shall not be used by patients with a low tidal volume, as the added dead space may cause CO2 (Carbon dioxide) retention.

CE Mark: Yes, the devices are CE marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-Sterile

Raw material: Provox Life FreeHands HME is composed of an injection molded polypropylene Housing, assembled with a polyurethane foam (which is impregnated with calcium chloride).

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: 20 months after manufacturing.

Packaging: The HMEs are single packed 10 pieces in a LD-Polyethylen blister sealed with a high barrier polyester-based lidding film. 1 blisters (10 cassettes) are then packed in a cardboard box together with a paper IFU.

Devices under Basic UDI-DI: 7331791-HME-0-000-0008-XZ

REF	Name	UDI-DI
7477	Provox Life Sample Pack FreeHands HME	07331791015298

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands FlexiVoice	7331791-HME-0-000-0007-XW
Provox Life Adhesives	7331791-ADH-0-000-0001-CT
Provox Life LaryTube	7331791-LTU-0-000-0004-3L

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