Technical Info / Material Data Sheet

Document ID: PF022-05-TechInfo | Edition: 03

REF Number	7719
Product Name	Provox® FreeHands HME® Adjustment Kit
Models:	One model.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	To be used for adjustment of the FreeHands HME Speech Valve.
Description:	Safety Screwdriver and Membrane Replacement Forceps.
Sterilization:	Non-sterile.
Raw material:	Acrylonitrile-Butadiene-Styrene (ABS), Polyamide (PA) and Glass.
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:	5 years after manufacturing.
Packaging:	The instruments are packed in a plastic bag and then packed in a cardboard box.

Reviewed by:

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Vice President QA&RA

2014-05-21

Date

Approved by:

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Vice President Design Control

2014-05-23

Date

Technical Info / Material Data Sheet

Document ID: PF022-05-TechInfo | Edition: 03

REF Number	7719
Product Name	Provox® FreeHands HME® Adjustment Kit
Models:	One model.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	To be used for adjustment of the FreeHands HME Speech Valve.
Description:	Safety Screwdriver and Membrane Replacement Forceps.
Sterilization:	Non-sterile.
Raw material:	Acrylonitrile-Butadiene-Styrene (ABS), Polyamide (PA) and Glass.
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:	5 years after manufacturing.
Packaging:	The instruments are packed in a plastic bag and then packed in a cardboard box.

Reviewed by:

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Vice President QA&RA

2014-05-21

Date

Approved by:

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Vice President Design Control

2014-05-23

Date

Atos Medical Your voice

Quality Management System

Technical Info / Material Data Sheet

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Released:	DD	Mårten Cervin - SEHRBCNM	2016-11-22 - 09:41

This document has been electronically signed by the persons above.

Document ID: PF058-01-TechInfo	Edition: 01

REF Number 7757, 7760, 8161, 8162, 8163 and 8166

Product Name Provox FreeHands FlexiVoice

Models: 4 strengths of membranes Light, Medium, Strong and XtraStrong.

Classification: (MDD 93/42/EEC) I

CE Mark: Yes

GMDN code: 36071

(U)DI code:
7331791008276
7331791008283
7331791008290
7331791008306
7331791008313
7331791010668

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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.

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.

Released

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Technical Info / Material Data Sheet

Sterilization:	Non-Sterile
Raw material:	Speaking valve: PP, Silicone and POM. Arch: MABS
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
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 + 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 + 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 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.

Document No: 10000019244 Edition: 01 Release date: 2016-11-22

Technical Info / Material Data Sheet

Document ID: PF022-02-TechInfo	Edition: 05

REF Number	7711, 7712, 8220, 8221, 8222, 8223
Product Name	Provox® FreeHands HME® Cassette (30 pc) Provox® FreeHands HME® Cassette (20 pc) Provox® FreeHands HME® Moist (30 pc) Provox® FreeHands HME® Flow (30 pc) Provox® FreeHands HME® Moist (20 pc) Provox® FreeHands HME® Flow (20 pc)
Models:	7711 and 7712 (Cassette) for Provox FreeHands, 8220 and 8222 (Moist) for Provox FreeHands FlexiVoice, 8221 and 8223 (Flow) for Provox FreeHands FlexiVoice.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
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:	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.
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.* The Provox FreeHands HME is intended for single patient use.
Sterilization:	Non-sterile.
Raw material:	Styrene-ethylene-butadiene-styrene (SEBS) 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

Release date: 2015-01-16 Edition: 05 Document No: 10000019023

Technical Info / Material Data Sheet

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 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
7711	10	3	30
7712	10	2	20
8220	10	3	30
8221	10	3	30
8222	10	2	20
8223	10	2	20

Reviewed by:

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Vice President QA&RA

2015-01-12

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Date

Approved by:

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Vice President Design Control

2015-01-13

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Date

Document No: 10000019023 Edition: 05 Release date: 2015-01-16

Released

Technical Info / Material Data Sheet

Document ID: PF022-04-TechInfo	Edition: 03

REF Number	7718
Product Name	Provox® FreeHands HME® Cleaning and Storage Box
Models:	One model.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox FreeHands HME Cleaning and Storage Box is a device for cleaning of the Provox FreeHands HME speech valve. The device comes with the Provox FreeHands HME and the intended use is described in the IFU for Provox FreeHands HME.
Description:	A container for cleaning and storage of the re-usable FreeHands HME Speech Valve.
Sterilization:	Non-sterile
Raw material:	Polycarbonate (PC), Polyoxymethylene (POM) and Steel.
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:	5 years after manufacturing.
Packaging:	The cleaning and Storage Box is single-packed in a cardboard box.

Reviewed by:

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Vice President QA&RA

2014-04-14

Date

Approved by:

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Vice President Design Control

2014-04-14

Date

Technical Info / Material Data Sheet

Document ID: PF022-01-TechInfo	Edition: 03

REF Number	7710
Product Name	Provox® FreeHands HME®
Models:	1 model with 3 models of membrane.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox FreeHands HME is an accessory to prosthetic vocal and pulmonary rehabilitation after a total laryngectomy. It is 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) 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. THE PROVOX FREEHANDS HME IS INTENDED FOR SINGLE PATIENT USE.
Description:	Provox FreeHands HME is an automatic, reusable multi-magnet valve system that keeps the valve closed during speech. The Provox FreeHands HME included the following accessories: Freehands HME Cassettes (REF 7712), Speech Valve Membrane, light (REF 7713), Speech Valve Membrane, medium (REF 7714), Speech Valve Membrane, strong (REF 7715), Cleaning and Storage Box (REF 7718), Adjustment Kit (REF 7719), Provox Xtrabase Adhesive (REF 7265) and Skin-Prep (REF 59420425).
Sterilization:	Non-sterile.
Raw material:	Speech Valve: Polyoxymethylene (POM), Polycarbonate (PC), Titanium, Silicone, Magnet Each accessory included in the Provox FreeHands HME has its own description of raw material. Please see each individual Technical Info.
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.

Technical Info / Material Data Sheet

Hazardous components: None.

Expiration date: 3 years after manufacturing.

Packaging: Provox FreeHands HME is single packed in a plastic jar lined with foam rubber. It is then packed in a cardboard box together with its accessories.

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

REF Number	7713, 7714, 7715
Product Name	Provox® FreeHands HME® Speech Valve Membrane
Models:	Three models: 7713 (light), 7714 (medium), 7715 (strong)
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox FreeHands HME Speech Valve is an accessory to prosthetic vocal and pulmonary rehabilitation after a total laryngectomy. The Membrane temporarily closes the Freehands HME Speech Valve, allowing the patient to produce voice without manually occluding the stoma.
Description:	The difference in the membranes (light/medium/strong) is due to the hardness of the silicone. A strong membrane is more hard compared to a light one and a smaller air pressure is required in order to open the valve.
Sterilization:	Non-sterile.
Raw material:	Silicone, magnet
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:	5 years after manufacturing.

Technical Info / Material Data Sheet

Packaging: The Membrane is single-packed in a plastic jar and then, together with a adjustment kit, in a cardboard box.

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: PF022-06-TechInfo | Edition: 02

REF Number	7716, 7717, 7721, 7722
Product Name	Provox FreeHands HME Replacement Device light (7716) Provox FreeHands HME Replacement Device medium (7717) Provox FreeHands HME Replacement Device strong (7721) Provox FreeHands HME Replacement Device (7722)
Models:	4 models; with Membrane light, medium or strong, or without Membrane.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox FreeHands HME is an accessory to prosthetic vocal and pulmonary rehabilitation after a total laryngectomy. It is 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) for pulmonary rehabilitation.
Description:	The Provox FreeHands speech valve unit comes in a reusable housing, containing two independent valves; an internal, exchangeable valve membrane (speaking valve), and a cough-relief valve. The product is a replacement device. To ensure that all accessories are available for proper handling and care, a full Provox FreeHands HME set should be in possession.
Sterilization:	Non-sterile.
Raw material:	Speech Valve: Polyoxymethylene (POM), Polycarbonate (PC), Titanium, Silicone, Magnet Membrane: Silicone, Magnet
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: Provox FreeHands HME is single packed in a plastic jar lined with foam rubber. It is then packed in a cardboard box together with a membrane and screwdriver (if applicable).

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

Quality Management System

Technical Info / Material Data Sheet

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Alexandra Holmberg - ALEHOL	2018-11-21 - 13:29
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Released:	DD	Alexandra Holmberg - ALEHOL	2018-12-12 - 15:51

This document has been electronically signed by the persons above.

Document ID: PF078-02-TechInfo	Edition: 03

REF Number 8024

Product Name Provox® FreeHands Support™ Adhesive

Models: 1 variant (15 pcs).
8024 Provox FreeHands Support Adhesive (15pc)

Classification: (MDD 93/42/EEC) I (1.1 Rule 1)

CE Mark: Yes

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

EAN code:

REF	Description	EAN code
8024	Provox FreeHands Support Adhesive (15pc)	7331791009303

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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.

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.

Sterilization: Non-sterile

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

Document No: 10000038354 Edition: 03 Release date: 2018-12-12

Released

Technical Info / Material Data Sheet

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
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.

Release date: 2018-12-12
Edition: 03
Document No: 1000038354

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Released:	DD	Alexandra Holmberg - ALEHOL	2018-12-12 - 15:52

This document has been electronically signed by the persons above.

Document ID: PF078-01-TechInfo	Edition: 02

REF Number 8020, 8021, 8022, 8023

Product Name Provox® FreeHands Support™

Models: 1 starter set and 3 variants (flat, medium and deep).
8020 Provox FreeHands Support Starter Set
8021 Provox FreeHands Support Flat
8022 Provox FreeHands Support Medium
8023 Provox FreeHands Support Deep

Classification: (MDD 93/42/EEC) I (1.1 Rule 1)

CE Mark: Yes

GMDN code: 62155 (Tracheostomy base plate, reusable)

EAN code:

REF	Description	EAN code
8020	Provox FreeHands Support Starter Set	7331791009266
8021	Provox FreeHands Support Flat	7331791009273
8022	Provox FreeHands Support Medium	7331791009280
8023	Provox FreeHands Support Deep	7331791009297

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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.

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.

Released
Document No: 10000038353 Edition: 02 Release date: 2018-12-12

Sterilization:	Non-sterile
Raw material:	Provox FreeHands Support consists of a ring of stainless steel and a plastic part (Polycarbonate, PC).
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:	The metal ring contains nickel, although the amount of free nickel in the material is below the level which would normally give a reaction in people with nickel-allergy. If you experience any allergy, stop using the device and consult your clinician.
Expiration date:	3 years after manufacturing
Packaging:	Provox FreeHands Support is packed in a cardboard box together with instructions for use.

Release date: 2018-12-12
Edition: 02
Document No: 1000038353

Technical Info / Material Data Sheet

REF Number	7730
Product Name	Provox® HME Cap
Models:	One model.
Classification: (MDD 93/42/EEC)	I (1.1 Rule)
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:	Device for rehabilitation after total laryngectomy. The Provox HME Cap is a dome-shaped titanium ring that allows you to use a special Provox FreeHands HME cassette (REF 7711, 7712) without a FreeHands valve unit. It cannot be used with any other type of HME cassette. Attach the device by means of any Provox Adhesive base plate or Provox LaryTube. Close the front opening of the cap manually when speaking with a voice prosthesis. Replace the HME cassette every 24 hours (more frequently if needed). The cap itself can be cleaned and reused.
Description:	Provox HME Cap allows use of the Provox FreeHands HME Cassettes without the Provox FreeHands HME Speech Valve.
Sterilization:	Non-sterile.
Raw material:	Titanium.
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:	5 years after manufacturing.

Technical Info / Material Data Sheet

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

Reviewed by:

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Vice President QA&RA

2014-04-14

Date

Approved by:

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Vice President Design Control

2014-04-14

Date

Atos Medical Your voice

Quality Management System

Technical Info / Material Data Sheet

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Released:	DD	Mårten Cervin - SEHRBCNM	2016-11-22 - 09:41

This document has been electronically signed by the persons above.

Document ID: PF058-01-TechInfo	Edition: 01

REF Number 7757, 7760, 8161, 8162, 8163 and 8166

Product Name Provox FreeHands FlexiVoice

Models: 4 strengths of membranes Light, Medium, Strong and XtraStrong.

Classification: (MDD 93/42/EEC) I

CE Mark: Yes

GMDN code: 36071

(U)DI code:
7331791008276
7331791008283
7331791008290
7331791008306
7331791008313
7331791010668

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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.

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.

Released

Document No: 10000019244 Edition: 01 Release date: 2016-11-22

Technical Info / Material Data Sheet

Sterilization:	Non-Sterile
Raw material:	Speaking valve: PP, Silicone and POM. Arch: MABS
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
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 + 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 + 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 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.

Document No: 10000019244 Edition: 01 Release date: 2016-11-22

Technical Info / Material Data Sheet

Document ID: PF022-02-TechInfo	Edition: 05

REF Number	7711, 7712, 8220, 8221, 8222, 8223
Product Name	Provox® FreeHands HME® Cassette (30 pc) Provox® FreeHands HME® Cassette (20 pc) Provox® FreeHands HME® Moist (30 pc) Provox® FreeHands HME® Flow (30 pc) Provox® FreeHands HME® Moist (20 pc) Provox® FreeHands HME® Flow (20 pc)
Models:	7711 and 7712 (Cassette) for Provox FreeHands, 8220 and 8222 (Moist) for Provox FreeHands FlexiVoice, 8221 and 8223 (Flow) for Provox FreeHands FlexiVoice.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
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:	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.
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.* The Provox FreeHands HME is intended for single patient use.
Sterilization:	Non-sterile.
Raw material:	Styrene-ethylene-butadiene-styrene (SEBS) 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

Release date: 2015-01-16 Edition: 05 Document No: 10000019023

Technical Info / Material Data Sheet

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 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
7711	10	3	30
7712	10	2	20
8220	10	3	30
8221	10	3	30
8222	10	2	20
8223	10	2	20

Reviewed by:

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Vice President QA&RA

2015-01-12

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Date

Approved by:

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Vice President Design Control

2015-01-13

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Date

Document No: 10000019023 Edition: 05 Release date: 2015-01-16

Released

Technical Info / Material Data Sheet

Document ID: PF022-04-TechInfo	Edition: 03

REF Number	7718
Product Name	Provox® FreeHands HME® Cleaning and Storage Box
Models:	One model.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox FreeHands HME Cleaning and Storage Box is a device for cleaning of the Provox FreeHands HME speech valve. The device comes with the Provox FreeHands HME and the intended use is described in the IFU for Provox FreeHands HME.
Description:	A container for cleaning and storage of the re-usable FreeHands HME Speech Valve.
Sterilization:	Non-sterile
Raw material:	Polycarbonate (PC), Polyoxymethylene (POM) and Steel.
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:	5 years after manufacturing.
Packaging:	The cleaning and Storage Box is single-packed in a cardboard box.

Reviewed by:

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Vice President QA&RA

2014-04-14

Date

Approved by:

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Vice President Design Control

2014-04-14

Date

Technical Info / Material Data Sheet

Document ID: PF022-01-TechInfo	Edition: 03

REF Number	7710
Product Name	Provox® FreeHands HME®
Models:	1 model with 3 models of membrane.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox FreeHands HME is an accessory to prosthetic vocal and pulmonary rehabilitation after a total laryngectomy. It is 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) 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. THE PROVOX FREEHANDS HME IS INTENDED FOR SINGLE PATIENT USE.
Description:	Provox FreeHands HME is an automatic, reusable multi-magnet valve system that keeps the valve closed during speech. The Provox FreeHands HME included the following accessories: Freehands HME Cassettes (REF 7712), Speech Valve Membrane, light (REF 7713), Speech Valve Membrane, medium (REF 7714), Speech Valve Membrane, strong (REF 7715), Cleaning and Storage Box (REF 7718), Adjustment Kit (REF 7719), Provox Xtrabase Adhesive (REF 7265) and Skin-Prep (REF 59420425).
Sterilization:	Non-sterile.
Raw material:	Speech Valve: Polyoxymethylene (POM), Polycarbonate (PC), Titanium, Silicone, Magnet Each accessory included in the Provox FreeHands HME has its own description of raw material. Please see each individual Technical Info.
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.

Technical Info / Material Data Sheet

Hazardous components: None.

Expiration date: 3 years after manufacturing.

Packaging: Provox FreeHands HME is single packed in a plastic jar lined with foam rubber. It is then packed in a cardboard box together with its accessories.

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

REF Number	7713, 7714, 7715
Product Name	Provox® FreeHands HME® Speech Valve Membrane
Models:	Three models: 7713 (light), 7714 (medium), 7715 (strong)
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox FreeHands HME Speech Valve is an accessory to prosthetic vocal and pulmonary rehabilitation after a total laryngectomy. The Membrane temporarily closes the Freehands HME Speech Valve, allowing the patient to produce voice without manually occluding the stoma.
Description:	The difference in the membranes (light/medium/strong) is due to the hardness of the silicone. A strong membrane is more hard compared to a light one and a smaller air pressure is required in order to open the valve.
Sterilization:	Non-sterile.
Raw material:	Silicone, magnet
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:	5 years after manufacturing.

Technical Info / Material Data Sheet

Packaging: The Membrane is single-packed in a plastic jar and then, together with a adjustment kit, in a cardboard box.

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: PF022-06-TechInfo | Edition: 02

REF Number	7716, 7717, 7721, 7722
Product Name	Provox FreeHands HME Replacement Device light (7716) Provox FreeHands HME Replacement Device medium (7717) Provox FreeHands HME Replacement Device strong (7721) Provox FreeHands HME Replacement Device (7722)
Models:	4 models; with Membrane light, medium or strong, or without Membrane.
Classification: (MDD 93/42/EEC)	I (1.1 Rule 1)
CE Mark:	Yes
GMDN code:	36071 (Tracheostomy tube speech valve)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox FreeHands HME is an accessory to prosthetic vocal and pulmonary rehabilitation after a total laryngectomy. It is 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) for pulmonary rehabilitation.
Description:	The Provox FreeHands speech valve unit comes in a reusable housing, containing two independent valves; an internal, exchangeable valve membrane (speaking valve), and a cough-relief valve. The product is a replacement device. To ensure that all accessories are available for proper handling and care, a full Provox FreeHands HME set should be in possession.
Sterilization:	Non-sterile.
Raw material:	Speech Valve: Polyoxymethylene (POM), Polycarbonate (PC), Titanium, Silicone, Magnet Membrane: Silicone, Magnet
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: Provox FreeHands HME is single packed in a plastic jar lined with foam rubber. It is then packed in a cardboard box together with a membrane and screwdriver (if applicable).

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

Quality Management System

Technical Info / Material Data Sheet

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Alexandra Holmberg - ALEHOL	2018-11-21 - 13:29
Reviewed:	QA	John Wennborg - JOHWEN	2018-11-23 - 12:20
Approved:	DD	Mikael Melefors - SEHRBSGM	2018-11-29 - 20:01
Released:	DD	Alexandra Holmberg - ALEHOL	2018-12-12 - 15:51

This document has been electronically signed by the persons above.

Document ID: PF078-02-TechInfo	Edition: 03

REF Number 8024

Product Name Provox® FreeHands Support™ Adhesive

Models: 1 variant (15 pcs).
8024 Provox FreeHands Support Adhesive (15pc)

Classification: (MDD 93/42/EEC) I (1.1 Rule 1)

CE Mark: Yes

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

EAN code:

REF	Description	EAN code
8024	Provox FreeHands Support Adhesive (15pc)	7331791009303

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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.

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.

Sterilization: Non-sterile

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

Document No: 10000038354 Edition: 03 Release date: 2018-12-12

Released

Technical Info / Material Data Sheet

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
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.

Release date: 2018-12-12
Edition: 03
Document No: 1000038354

Quality Management System

Technical Info / Material Data Sheet

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Approved:	DD	Mikael Melefors - SEHRBSGM	2018-11-29 - 20:01
Released:	DD	Alexandra Holmberg - ALEHOL	2018-12-12 - 15:52

This document has been electronically signed by the persons above.

Document ID: PF078-01-TechInfo	Edition: 02

REF Number 8020, 8021, 8022, 8023

Product Name Provox® FreeHands Support™

Models: 1 starter set and 3 variants (flat, medium and deep).
8020 Provox FreeHands Support Starter Set
8021 Provox FreeHands Support Flat
8022 Provox FreeHands Support Medium
8023 Provox FreeHands Support Deep

Classification: (MDD 93/42/EEC) I (1.1 Rule 1)

CE Mark: Yes

GMDN code: 62155 (Tracheostomy base plate, reusable)

EAN code:

REF	Description	EAN code
8020	Provox FreeHands Support Starter Set	7331791009266
8021	Provox FreeHands Support Flat	7331791009273
8022	Provox FreeHands Support Medium	7331791009280
8023	Provox FreeHands Support Deep	7331791009297

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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.

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.

Released
Document No: 10000038353 Edition: 02 Release date: 2018-12-12

Sterilization:	Non-sterile
Raw material:	Provox FreeHands Support consists of a ring of stainless steel and a plastic part (Polycarbonate, PC).
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:	The metal ring contains nickel, although the amount of free nickel in the material is below the level which would normally give a reaction in people with nickel-allergy. If you experience any allergy, stop using the device and consult your clinician.
Expiration date:	3 years after manufacturing
Packaging:	Provox FreeHands Support is packed in a cardboard box together with instructions for use.

Release date: 2018-12-12
Edition: 02
Document No: 1000038353

Technical Info / Material Data Sheet

REF Number	7730
Product Name	Provox® HME Cap
Models:	One model.
Classification: (MDD 93/42/EEC)	I (1.1 Rule)
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:	Device for rehabilitation after total laryngectomy. The Provox HME Cap is a dome-shaped titanium ring that allows you to use a special Provox FreeHands HME cassette (REF 7711, 7712) without a FreeHands valve unit. It cannot be used with any other type of HME cassette. Attach the device by means of any Provox Adhesive base plate or Provox LaryTube. Close the front opening of the cap manually when speaking with a voice prosthesis. Replace the HME cassette every 24 hours (more frequently if needed). The cap itself can be cleaned and reused.
Description:	Provox HME Cap allows use of the Provox FreeHands HME Cassettes without the Provox FreeHands HME Speech Valve.
Sterilization:	Non-sterile.
Raw material:	Titanium.
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:	5 years after manufacturing.

Technical Info / Material Data Sheet

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

Reviewed by:

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Vice President QA&RA

2014-04-14

Date

Approved by:

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Vice President Design Control

2014-04-14

Date