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Technical Info / Material Data Sheet

Document ID:
 PF068-07-Tech Info

Edition: 00

REF Number 7756

Product Name HME DigiTop O2 (REF7756)

Models: One variant, fitting for 22mm HME Cassette.
 One product, each containing one DigiTop O2 + Instructions For Use.

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

CE Mark: Yes

GMDN code: 58705

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

Intended Use: The HME DigiTop O2 is an accessory to ProTrach HMEs and Provox FreeHands HME's. For patients spontaneously breathing through a tracheostoma and having a need of extra oxygen.

Description: HME DigiTop O2 is a top that can be occluded with two digits to enable speech. The device shall be attached to either ProTrach HME 15 or HME 22 before use. The oxygen connector port on the device shall be connected to an oxygen supply via a tube

Sterilization: Non-sterile

Raw material: HME DigiTop O2: Blue POM .

Latex information The device is not manufactured with natural rubber latex.

Biological origin: The device is not manufactured with any materials derived from human or animal source.

Handling and storage: Keep dry and away from sunlight. Temperature limit: 2-42 °C.

Waste handling and disposal: Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.

Hazardous components: None.

Expiration date: 3 years after manufacturing.

Packaging: REF 7756, HME DigiTop O2: – box with 1 pcs plastic jar with 1 pc HME DigiTop O2 + 1 pc IFU REF 10721.

Technical Info / Material Data Sheet

Reviewed by:


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Vice President QA&RA


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Date

Approved by:


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Vice President Design Control


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Date

Atos

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Quality Management System

Page No. 1 of 2

Technical Info / Material Data Sheet

Document ID: PF068-01-TechInfo

Edition: 04

REF Number 7740, 7741, 7742, 7744, 7746, 7747, 7743, 7755, 7766

Product Name ProTrach® DualCare™ Set 22 (REF 7740)
 ProTrach® DualCare™ Set 15 (REF 7741)
 ProTrach® HME 15 Regular (REF 7742)
 ProTrach® DualCare™ Speaking valve (REF 7744)
 ProTrach® Connection strap (REF 7746)
 ProTrach® HME 22 Regular (REF 7747)
 ProTrach® HME 15 Regular (BigPack) (REF 7743)
 ProTrach® DualCare™ Speaking valve Blue (REF 7755)
 ProTrach® HME 15 XtraMoist (REF 7766)

Models: Three HME variants (HME 15 Regular/ HME 15 XtraMoist /HME 22 Regular) fitting 15mm/22mm trach tube connectors.
 Two sets, each containing either of the two HME Regular variants (15/22) + Speaking valve + HME DigiTop + Connection strap + Removal aid.

Classification: Class I, 1.1 rule 1
 (MDD 93/42/EEC)

CE Mark: Yes

GMDN code: 36071

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

Intended Use: ProTrach 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.
 Patient Population: For spontaneously breathing tracheostomized patients (adults and pediatric patients greater than 10 kg in weight) using a tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff.
 Environment of Use: Hospitals, ICU, sub-acute care institutions and home.

Description: ProTrach 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 ProTrach HME 15 or HME 22 before use. The ProTrach HME 15 XtraMoist offers high humidification while the ProTrach HME 15 Regular offers a higher airflow.
 ProTrach Connection Strap is a clip with a string that is used to secure ProTrach 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.

Sterilization: Non-Sterile

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Technical Info / Material Data Sheet

Raw material:	<p><u>ProTrach Speaking Valve</u>: PP, Silicone, and POM. <u>ProTrach Speaking Valve Blue</u>: PP, Silicone, and POM <u>ProTrach DigiTop</u>: POM. <u>ProTrach HME 15 Regular</u>: POM, HDPE, and Polyester-based Polyurethane foam. <u>ProTrach HME 15 XtraMoist</u>: POM, HDPE, and Polyester-based Polyurethane foam. <u>ProTrach HME 22 Regular</u>: Styrene-Ethylene/Butylene-Styrene copolymer, Epoxide glue, and Polyester-based Polyurethane foam. <u>ProTrach Connection Strap</u>: Polyester braided suture, POM, and PP.</p>
Latex information	The devices are not manufactured with natural rubber latex.
Biological origin:	The devices are 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:	<p><u>REF 7740, ProTrach DualCare Set 22</u> – box with 3 pcs [plastic bag with 10 pcs HME 22 Regular] + plastic jar with 1 pc Speaking Valve + plastic bag with 1 pc HME DigiTop + plastic bag with 1 pc Removal Aid + plastic bag with 1 pc Connection Strap + 2 pcs Warning label sheets REF 10737 + 1 pc IFU REF 10721.</p> <p><u>REF 7741, ProTrach DualCare Set 15</u> – box with 3 pcs [plastic bag with 10 pcs HME 15 Regular] + plastic jar with 1 pc Speaking Valve + plastic bag with 1 pc HME DigiTop + plastic bag with 1 pc Removal Aid + plastic bag with 1 pc Connection Strap + 2 pcs Warning label sheets REF 10737 + 1 pc IFU REF 10721.</p> <p><u>REF 7742</u> - Box with 3 pcs [plastic bag with 10 pcs HME 15 Regular].</p> <p><u>REF 7744, ProTrach DualCare Speaking Valve</u> – box with plastic jar with 1 pc Speaking Valve + plastic bag with 1 pc HME DigiTop + plastic bag with 1 pc Connection Strap + 2 pcs Warning label sheets REF 10737 + 1 pc IFU REF 10721</p> <p><u>REF 7746, ProTrach Connection Strap</u> - bubble plastic bag with 2 pcs [plastic bag with 1 pc Connection Strap] + 1 pc IFU REF 10722.</p> <p><u>REF 7747</u> - Box with 3 pcs [plastic bag with 10 pcs HME 22].</p> <p><u>REF 7743</u> - Box with 3 boxes with each 3 pcs [plastic bag with 10 pcs HME 15 Regular].</p> <p><u>REF 7755, ProTrach DualCare Speaking Valve Blue</u> – box with plastic jar with 1 pc Speaking Valve Blue+ plastic bag with 1 pc HME DigiTop Blue + plastic bag with 1 pc Connection Strap + 2 pcs Warning label sheets REF 10737 + 1 pc IFU REF 10721</p> <p><u>REF 7766</u> - Box with 3 pcs [plastic bag with 10 pcs HME 15 XtraMoist].</p>

Reviewed by:

Vice President QA&RA

Date

Approved by:

Vice President Design & Development

Date

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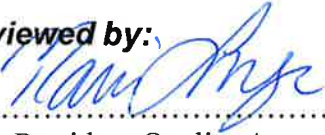
Technical Info / Material Data Sheet

Document ID: PF068-02-TechInfo	Edition: 00
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REF Number	7745.
Product Name	Removal aid.
Models:	N/A.
Classification: (MDD 93/42/EEC)	Class I, 1.1 rule 1.
CE Mark:	Yes.
GMDN code:	58705.
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	Removal aid is a reusable accessory that facilitates HME removal from ProTrach DualCare Speaking Valve, or ProTrach HME DigiTop, or Provox FlexiVoice.
Description:	Removal aid is a plastic clamp that is pressed together by finger force to clamp a ProTrach HME 15, or a ProTrach HME 22, or a FreeHands HME Cassette.
Sterilization:	Non-sterile.
Raw material:	POM.
Latex information	The device is not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit: 2-42 °C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None.
Expiration date:	3 years after manufacturing.
Packaging:	<u>REF 7745, Removal Aid</u> - bubble plastic bag with 2 pcs [plastic bag with 1 pc Removal Aid] + 1 pc IFU REF 10725.

Technical Info / Material Data Sheet

Reviewed by:

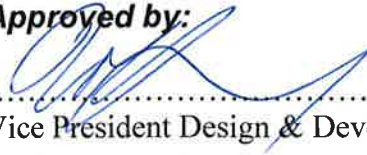


Vice President Quality Assurance

2014-01-20

Date

Approved by:



Vice President Design & Development

2014-01-20

Date

Technical Info / Material Data Sheet

Document ID: PF023-03-TechInfo

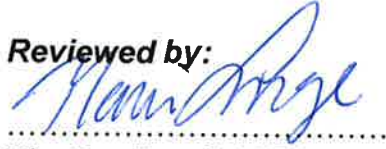
Edition: 01

REF Number	7707
Product Name	TrachPhone (30 pack)
Models:	One model.
Classification: (MDD 93/42/EEC)	IIa (1.2 Rule 2)
CE Mark:	Yes
GMDN code:	58705 (Tracheostoma protective filter)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The TrachPhone is used for patients breathing spontaneously via an ET tube or a tracheostomy tube in the hospital or at home.
Description:	The TrachPhone heats and humidifies the inhaled air and partially restores breathing resistance. The TrachPhone contains a valve with a spring that can easily be occluded with a finger to facilitate speech. After releasing the finger, the valve will open automatically. The unit comes with an integrated suction port and an integrated oxygen connector.
Sterilization:	Non-sterile.
Raw material:	Polypropylene (PP), thermoplastic elastomers (TPE) and polyurethane (PUR).
Latex information	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2-42°C
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None.
Expiration date:	3 years after manufacturing.

Technical Info / Material Data Sheet

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

Reviewed by:



Vice President QA&RA

2014-04-14

Date

Approved by:



Vice President Design Control

2014-04-14

Date

Technical Info / Material Data Sheet

Document ID: PF023-01-TechInfo

Edition: 05

REF Number	7704
Product Name	TrachPhone (50 pack)
Models:	One model
Classification: (MDD 93/42/EEC)	IIa (1.2 Rule 2)
CE Mark:	Yes
GMDN code:	58705 (Tracheostoma protective filter)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The TrachPhone is used for patients breathing spontaneously via an ET tube or a tracheostomy tube in the hospital or at home.
Description:	The TrachPhone heats and humidifies the inhaled air and partially restores breathing resistance. The TrachPhone contains a valve with a spring that can easily be occluded with a finger to facilitate speech. After releasing the finger, the valve will open automatically. The unit comes with an integrated suction port and an integrated oxygen connector.
Sterilization:	Non-sterile
Raw material:	Polypropylene (PP), thermoplastic elastomers (TPE) and polyurethane (PUR).
Latex information	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2-42°C
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None.
Expiration date:	3 years after manufacturing.

Technical Info / Material Data Sheet

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

Reviewed by:


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Vice President QA&RA


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Date

Approved by:


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Vice President Design Control


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Date