Product Information

Provox Life Oxygen

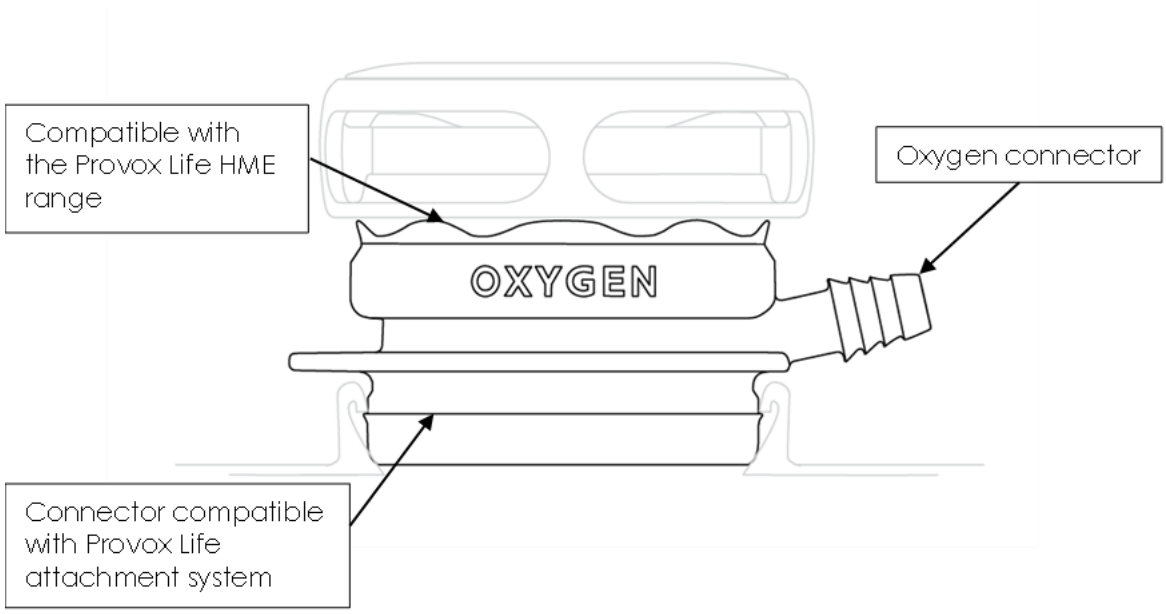

Figure 1. Provox Life Oxygen together a Provox Life HME.

Product description:

Provox Life Oxygen is a single-use accessory to Provox Life HMEs for adult patients requiring supplemental oxygen. The device is used between the HME and the Provox Life attachments (see Provox Life Oxygen Overview). Supplemental oxygen (non-humidified) can then be supplied via the oxygen connector of Provox Life Oxygen. Oxygen tubing with an inner diameter of 3.2 mm (1/8 in.) is recommended. Other diameters of oxygen tubing can be used but must be assessed on a case-by-case basis by the responsible healthcare professional. Flow rates of up to 6 l/min can be used. However, the HME effect will be reduced as the oxygen flow increases.

Product Information

Document ID:	PF123-01-TechInfo	**Edition:**	2.0

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

Classification: (EU) 2017/745 Class IIa, Rule 2.

Intended Use: Provox Life Oxygen is a single-use accessory to Provox Life HMEs. It allows additional oxygen supply for patients breathing through a tracheostoma using Provox Life HMEs.

Use specifications:

Intended medical indication
Device for pulmonary rehabilitation for patients breathing through a tracheostoma.

Intended patient population
Adult patients, 18 + years.
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 use, prescription only.

Intended part of the body/type of tissue applied to or interacted with
The device may contact skin directly.
Contact made with tissue will be indirect via airflow from the medical device.

Intended user profile
Intended user groups are healthcare professionals (physicians, nurses, speech language pathologists), as well as patients and lay caregivers (who have been trained by a healthcare professional).

Intended conditions of use
Provox Life Oxygen will be used in a hospital (clinical work environment), in an outpatient hospital setting (non-clinical work environment), in the patient's own home, or in public spaces.

Product Information

Operating principles	First, the device is removed from the secondary and primary packaging. The second step is to attach an HME from the Provox Life range on top of the device. An oxygen hose is then attached to the device via the oxygen connector. The oxygen hose provides supplemental oxygen to the patient. The device is then placed on a Provox Life attachment that is already fitted on the patient. It is a single use device that is replaced if clogged or dirty, but at least replaced every 24 hours. The device enables speaking by pressing or occluding the HME but if no oxygen hose is attached then additional occlusion of the oxygen port is needed to get a good seal for speaking. Information about usage is provided in the Instructions for Use (IFU).
Contraindications:	The device shall not be used by patients with reduced mental or physical cognitive ability. Patients who are unable to attach or remove the device themselves, or without sufficient knowledge how to use the device, or the cognitive ability to understand the risks connected to the use, should not use the device. The device shall not be used in patients who have a low tidal volume as the extra dead space may cause carbon dioxide retention.
CE Mark:	Yes. Devices are CE-marked.
GMDN code:	67419 (Tracheostoma device adaptor, single-use)
Sterilization:	Non-sterile.
Raw material:	Polypropylene (indirect contact with the patient).
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.
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:	N/A.
Expiration date:	3 years after manufacturing.
Packaging:	Provox Life Oxygen is packed in plastic bags made of polyethylene with 10 pieces in each bag. The bag is then packed together with instructions for use in a cardboard box. A box may contain either one bag or three bags of Provox Life Oxygen (ie. 10 pieces or 30 pieces, respectively).

Product Information

Devices under Basic UDI-DI: 7331791-HME-A-000-0009-FP

REF	Name	UDI-DI
7620	Provox Life Oxygen (10 pcs)	07331791018107
7621	Provox Life Oxygen (30 pcs)	07331791018114

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Life HME (not compatible with FreeHands)	7331791-HME-0-000-0001-XC
Provox Life Adhesives	7331791-ADH-0-000-0001-CT
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryButton	7331791-LTU-0-000-0005-3P
Provox Life Comfort	7331791-ADH-0-000-0003-CZ

Document Approvals

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