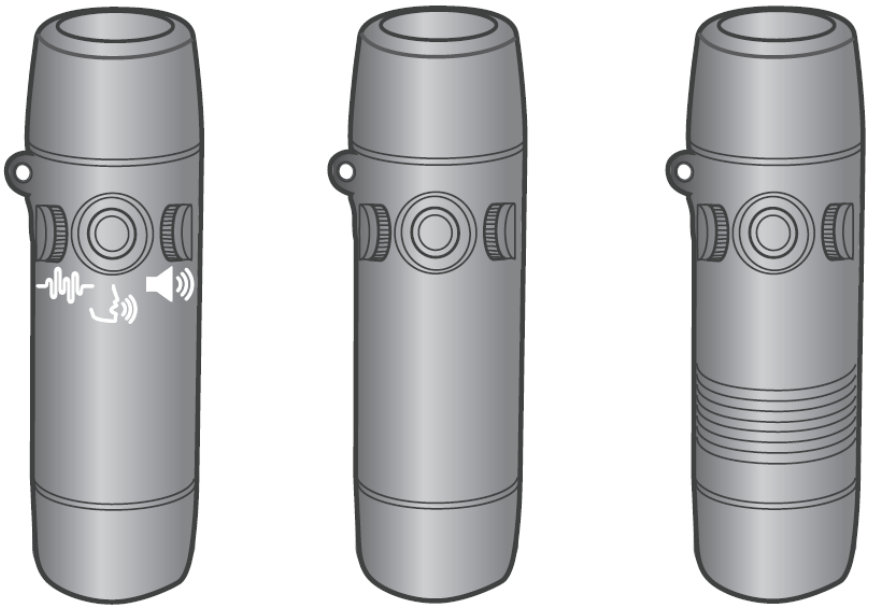
Product Information

Provox TruTone Emote, Provox SolaTone Plus and Provox TruTone Plus



TruTone Emote TruTone Plus SolaTone Plus

Product description:

An electrolarynx is a battery-powered artificial larynx that is applied externally on undamaged skin and intended for use in the absence of the anatomical larynx or the inability to use the larynx to produce sound.

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Product Information

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Manufacturer:
Atos Medical AB
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Classification: (EU) 2017/745 Medical device class I

Intended Use: An electrolarynx is a battery-powered artificial larynx that is applied externally and intended for use in the absence of the ability to use the anatomical larynx to produce sound. When held against the skin in the area of the voice box, or by inserting the oral tube into the oral cavity (with an oral adapter), the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.

Use specifications:

Intended medical indication
Voice rehabilitation for patients without the ability to use the larynx to produce sound.

Intended patient population
Adult patients of 18+ years.

Cognitive ability, by a clinician judged as sufficient.

Manual dexterity, by a clinician judged as sufficient.

Intended usage
Intended for single patient multiple use and demonstrational use. The oral tubes, oral adaptor and sound head are intended for single use only. Available over-the-counter.

Intended part of the body/type of tissue applied to or interacted with
The medical device is handheld by the user, and the head of the device is pressed against the (intact) skin of the front or side of the neck and/or underneath the chin. The optional oral tube is inserted into the mouth and comes in contact with lips, teeth and oral mucosa.

Intended user profile

The device is primarily to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use
Environment: Home, indoor and outdoor use, hospital use.

Operating temperature (to maintain optimal battery life): 5°C to 40°C

Operating humidity (to maintain optimal battery life): 15% to 90% relative humidity

Frequency of use: Daily use or upon need.

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Operating principles

The Provox Electrolarynxes are battery-powered artificial larynxes that are externally applied and intended for use in the absence of the ability to use the anatomic larynx to produce sound. When held against the skin in the area of the voice box, or by insertion of a tube in the oral cavity (with an oral adapter), the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.

The Provox Electrolarynx's models with their respective abbreviation given within the brackets are Provox TruTone Plus (TTP), Provox TruTone Emote (TTE), Provox SolaTone Plus (STP) are seen in figure 1. From this point forward the models will be referred to by their abbreviation.

Figure 1: From left to right are the three Provox Electrolarynx's models Provox TruTone Plus (TTP), Provox TruTone Emote (TTE) and Provox SolaTone Plus (STP).

Contraindications: The device should only be used in accordance with this IFU (Instructions for Use). Users without the physical, cognitive, or mental ability required to operate the device themselves should not use the device independently and should only use it if they are under sufficient supervision of a clinician or a trained caregiver. The device should not be directly applied over frail neck tissue with weak blood vessels, as this can cause tissue damage or bleeding. Patients with this condition should only use the device when they have been specifically instructed by their clinician on how to use the device and where to safely apply it.

GMDN code: 34857 Artificial larynx

Sterilization: Non-sterile

Raw material: Acrylonitrile butadiene styrene, Polycarbonate and Aluminium

Latex information: Not manufactured with natural rubber latex

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Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Storage and transport temperature: -25°C to +70°C Storage humidity: 0% to 45% relative humidity
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 device contains a magnet that generates magnetic and electromagnetic fields that may interfere with pacemakers or other implantable devices as well as certain procedures or treatments. Maintain a minimum distance of 15 cm (6 in.) between the device and any medically implanted devices. Consult with your physician before any medical procedure or treatment. If interference between the device and any medically implanted device is suspected, discontinue use and consult with your physician.
Expiration date:	Expected service life of 3 years depending on use frequency and care taken to prevent wear and damage.
Packaging:	One Electrolarynx, Lanyard, Sound head, Oral Adaptor, Oral Tube Varity Pack and a Power cord are packed in a cardboard box.

Product Information

Devices under Basic UDI-DI:

REF	Name	UDI-DI
7438	Provox SolaTone Plus	7331791015823
7439	Provox TruTone Emote	7331791015830
7444	Provox TruTone Plus	7331791015571

Atos Medical AB compatible products:

Range	BASIC UDI-DI
None	-

Document Approvals
Approved Date: 2024-09-13

Task: Approval Task Verdict: Approve	MAHTA.ESMAEILZADEH Mahta Esmaeilzadeh, R&D Engineer (Electronics) (mahta.esmaeilzadeh-atosmedical@coloplast.com) Issuer 10-Sep-2024 14:00:34 GMT+0000

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