



SolaTone Plus™

SolaTone Lite®

Electrolarynx

Instructions for Use



Atos

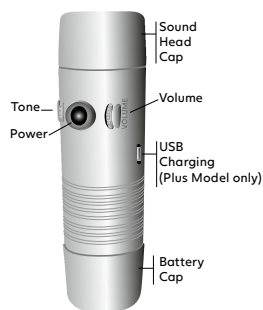
Atos Medical **Your voice**

SolaTone Plus™ and SolaTone Lite® Electrolarynx Instructions

Basic Instructions

TONE:

Turn the Tone control UP towards the Sound-Head Cap for a higher tone voice (feminine), and DOWN for a lower tone (masculine).



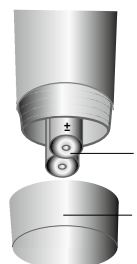
VOLUME:

Turn the volume control UP for a louder voice and DOWN for a quieter voice. Lower volume settings will help you be understood better.



Electrolarynx Use On The Neck

- Place the Sound-Head against your neck and activate. Do Not Cover Stoma.
- Speak as sound is transmitted into your mouth.
- Ensure an airtight seal against your neck and try different positions until you achieve the best sound. Even a small change in position can greatly effect the voice.
- Use the oral adapter in cases of a tender neck or excess buzzing.



Battery Installation and Charging

- AA batteries required, either Alkaline (disposable) or NiMH (rechargeable).
- Slide each battery **on top** of the arrow inside of the unit.
- **Note:** Make sure the “+” end of the battery is at the same end as the “+” end of the arrow.
- **SolaTone Plus™ ONLY:** USB Charging: Insert micro-USB cord into port, ensuring proper orientation. Solid GREEN light indicates charging. Blinking GREEN light indicated charging complete.
- **SolaTone Lite®** batteries must be removed for disposal or charging. Optional rechargeable batteries sold separately. Follow instructions for your charger.
- **Caution:** Do **NOT** attempt to charge alkaline or other “non-rechargeable” batteries. They must be disposed of properly. Recycle batteries according to local requirements.

Oral Adapter Use (optional)

- The Oral Tube is optional in the oral adapter. To use the adapter without the tube, press it onto Sound-Head cap (do not twist it on), and position at corner of mouth allowing sound to enter mouth. Activate the device with the power button and speak.

- To use with the oral tube, Insert Oral Tube into top of Oral Cap.

NOTE: Do not insert beyond the stop.

The rigid tube is easier to use quickly. The soft tube is more comfortable and is easier to articulate around after you have practice.

Press Oral Adapter onto Sound-Head (do not twist it on).
Place Oral Tube in mouth, at the corner of your mouth.
You may bend the tube for comfort.
If using the soft tube, the end may be cut at angles to suit the user, to prevent blocking the tube in the mouth.
Activate Electrolarynx, and speak around Oral Tube.
Oral adaptor use may require reduced volume settings.

Warning: Do Not Insert Tube or any other part into Stoma.

General Care and Troubleshooting

Cleaning: Use an alcohol wipe to clean unit. You may also use a damp cloth. Do not use Oils, Electrical Contact Cleaners, or Chemicals as they may cause damage. Do not permit liquid or moisture to enter into the device.

Water Damage: DO NOT ACTIVATE THE DEVICE!

Remove the caps from the body and place the device in a bowl of dry, uncooked rice for two days before testing.

Excessive Buzzing: Maintain a complete seal against the skin. Try different positions—1/8" (3mm) can make a very big difference. Adjust the tone and volume. If excessive buzzing continues, try the Oral Adapter.

Limited Warranty

For international warranty contact your local distributor.



Electrolarynx Speech Aid Information

Intended Use: An electrolarynx is a battery-powered artificial larynx that is externally applied and intended for use in the absence of the larynx to produce sound. When held against the skin in the area of the voicebox, 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.

Intended operator: The patient is the intended operator.

Applied Part: The entire device is considered a Type BF Applied Part

Environmental Conditions for Operation: +5°C to +25°C; 15% to 93% relative humidity; 700 hPa to 1060 hPa

Environmental Conditions for Transportation and Storage: To maintain optimal battery life, maintain the following environmental conditions: -20°C to +25°C; 0% to 45% relative humidity.

Mode of Operation: 30 minutes of activation during a 24 hour period

Power Source: Internally powered. See your devices user manual for full details.

Expected Service life: The expected service life is between 1-5 years, depending on the model.

Magnetic and Electromagnetic fields:

- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

- Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

- This device complies with CAN ICES-3(B)/NMB-3(B)

For Assistance With Your Electrolarynx Speech Aid:

- Please contact Griffin Laboratories, your distributor or representative if assistance is required in using or maintaining your electrolarynx, or to report any issues with your electrolarynx.

Warnings:

- Do not insert any part of the electrolarynx or any accessories into the stoma.
- Do not burn or physically damage the battery.
- Do not charge non-rechargeable batteries.
- Devices and batteries may become warm (up to 45°C) during charging. Allow the device to cool before use if it becomes too warm.
- Do not short-circuit a cell or battery. Do not store cells or batteries haphazardly in a pocket, purse, box or drawer where they may short-circuit each other or be short-circuited by conductive materials such as coins or keys.
- Use caution when replacing the battery. Incorrect installation of the battery may result in a hazardous situation, such as extreme heat or fire.

- Electrolarynx devices contain a magnet that may interfere with pacemakers or other implantable devices. Consult with your physician before use. Maintain a minimum distance of 6” between your electrolarynx and any implanted devices. If interference between the devices is suspected, discontinue use and consult with your physician.
- Electrolarynx devices generate magnetic and electromagnetic fields that may interfere with certain procedures or treatments. Consult with your physician before any procedure or treatment.
- No modification of this equipment is allowed. Modifying your electrolarynx or using it with other equipment not described in the instructions may result in unsafe operation.
- Electrolarynx devices contain small parts that may become dislodged and present a choking hazard. Keep away from small children.

Symbol meanings:



Type BF applied Part



Keep Dry



Refer to instruction Manual



Manufacturer



Date of Manufacture



• Used electrical and electronic products should not be mixed with general household waste. For proper treatment, recovery and recycling, please take this product to a local collection point or recycling location.

• Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling.

Other information:

Please note that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the national authority of the country in which the user and/or patient resides.