



Support Details

Please contact your prescribing healthcare professional for support with your Lenire device.

Neuromod Contact Details:

Neuromod USA inc.
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Lisle, IL 60532, USA.

Website: www.lenire.com

Designed & Manufactured by:

Neuromod Devices Limited,
Rainsford St, Dublin,
D08 R2YP, Ireland.

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To avoid the risk of electrical shock or burns, do not connect the Tonguetip to any equipment other than the Lenire Controller.

Adjusting the stimulus settings

It is recommended to leave the tongue stimulus level set to the default level unless either:

- There is a strong sensation from the Tonguetip that causes discomfort. In this case the tongue stimulus level can be adjusted downwards to a comfortable level.
- There is a weaker tongue sensation than was perceived during the initial training you received as part of the device fitting. In this case the tongue stimulus level may be adjusted upwards.

Cleaning



Before cleaning the Tonguetip ensure that it is disconnected from the Controller.



Do not expose the plug of the Tonguetip to liquids.

It is advisable to clean the Tonguetip after prolonged disuse or storage, or after exposure to conditions which could affect their hygiene.

- Prepare a cleaning solution by diluting a small amount of liquid soap in lukewarm water.
- Dip the head of a soft-bristled brush (e.g. toothbrush) into the cleaning solution and brush the surfaces of the Tonguetip for approximately 30 seconds, while repeatedly dipping the brush into the solution.
- The Tonguetip should then be rinsed thoroughly under running tap/faucet water for approximately 30 seconds.
- You may use the Tonguetip immediately after rinsing.
- If you do not intend to use the Tonguetip immediately after cleaning, place on a clean, dry surface and allow it to air-dry.
- Alternatively, the Tonguetip may be cleaned by gently rubbing its surfaces, including the electrodes and the plug using 70% IPA (Isopropyl alcohol) wipes.

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Note: For additional information related to the cleaning of the Tonguetip please refer to the Lenire User Manual.

Storage, Transport & Maintenance

- Store the Tonguetip in the Lenire Carry Case supplied as it has been specially designed to protect the device during storage and transport.
- Carry out a weekly visual inspection to ensure there is no evidence of discoloration or damage to the Tonguetip.

Note: If you have any concerns following these inspections, cease using the device and request assistance from your prescribing healthcare professional.

Tonguetip service life

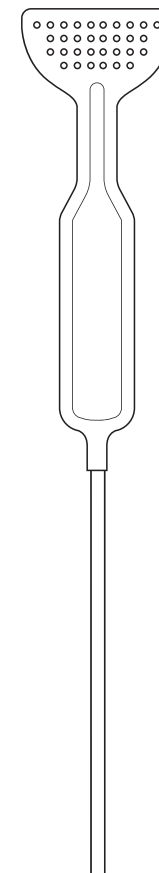
- The Tonguetip has an expected service life of three years. It is recommended not to use the Tonguetip after this as the electrodes may not function as effectively.
- The Tonguetip will expire after 180 cumulative hours of actual use. If an expired Tonguetip is connected to the Controller, the Tonguetip Indicator will flash red.

Disposal

Please consider your personal safety and the environment when disposing of the Tonguetip. When the device has reached the end of its service life, it should be disposed of in accordance with local regulations, or returned to the manufacturer.

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TONGUETIP®



Rx only

TP-101

Introduction

Your audiologist or physician has prescribed the Lenire® Device for your use to alleviate the symptoms of tinnitus. Please read the Lenire User Manual carefully before use. These instructions will show you how to use and care for your Tonguetip® TP-101. The Tonguetip TP-101 should only be used in conjunction with the Lenire Device.

Intended Use

The Tonguetip device is an accessory to, and is intended to be used with the Lenire Device.
See Lenire User Manual for device Indications for Use.

Contraindications



Do not use the device:

- If you have a pacemaker, defibrillator or any other active implantable device, unless directed by a physician.
- If you are pregnant, unless directed by a physician.
- If you have epilepsy or any other condition that may result in loss of consciousness, unless directed by a physician.
- If you have any condition that causes impaired sensitivity of the tongue, unless directed by a physician or dentist.
- If you have lesions, sores, or inflammation of the oral cavity that could be in contact with the Tonguetip (i.e., tip of tongue and lip area), unless directed by a physician or dentist.
- If you have any intermittent or chronic neuralgia in the head and neck area, unless directed by a physician.
- If you have tinnitus caused by Ménière's disease, unless directed by a physician. The use of this device has not been evaluated in the TENT clinical studies for Meniere's disease.
- If you have tinnitus confirmed to be from an objective source.
- In the presence of oral piercings.

Risks Associated with Use

Potential risks associated with use of the Lenire device include:

- Contact between the Tonguetip and dental retainers or metal fillings may cause temporary discomfort. Patients should be advised to reposition the Tonguetip so the electrodes only make contact with the tongue.
- There is a possibility that some patients may experience a mild allergic reaction to the materials in the device. If this occurs, stop treatment and the patient should be referred to an appropriate physician or dentist.
- Some patients may experience a mild numbing sensation

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or a discomfort on the tongue during treatment. If this occurs, reduce the tongue stimulation. If the discomfort persists or there is discomfort in the oral cavity, stop treatment and the patient should be referred to an appropriate physician or dentist.

- Use of the treatment may result in fluctuations in tinnitus symptoms, such as tinnitus loudness or bothersome severity. If this happens, reduce the volume on the controller and tongue stimulation settings. If the fluctuations persists, stop treatment and the patient should be referred to an appropriate physician.
- Headaches may accompany use of the treatment device. If this happens, reduce the volume on the controller and tongue stimulation settings. If the headaches persist, stop treatment and the patient should be referred to an appropriate physician.
- Some patients may experience glossodynia [tongue pain or unusual sensitivity to touch], dry throat or salivary hypersecretion. If a patient reports any of these symptoms, instruct them to stop treatment and refer the patient to an appropriate physician or dentist.
- Some patients may experience dizziness during or after use of the device. If this happens, reduce the volume on the controller and tongue stimulation settings. If the dizziness persists, stop treatment and the patient should be referred to an appropriate physician.
- Some patients may experience skin irritation from the headphones. If this happens the patient should stop using the headphones. If the irritation persists the patient should be referred to an appropriate physician.

Warnings

- Do not use the Tonguetip when going to sleep or under the influence of alcohol or other substances that cause drowsiness.
- Keep the Tonguetip and Charger out of the reach of children, to avoid possible choking and strangulation hazards.
- To avoid the risk of cross-contamination, the Tonguetip should not be shared with any other person, as it is a single-patient, multi-use device.
- Do not use the Tonguetip if you have lesions, sores, or inflammation of the oral cavity. Discontinue use of the device and consult your audiologist or physician.
- Do not leave the device in the sun, near an open fire or on a radiator.
- Do not use in conjunction with a hearing aid.

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- Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the Tonguetip electrodes and possible damage to the Tonguetip.
- Operation in close proximity (e.g., 1 meter or 3 feet) to shortwave or microwave therapy equipment may produce instability in the tongue stimulation output.

Package Labelling



Caution: Federal law restricts this device to sale by or on the order of a qualified audiologist or physician.



Medical Device



Do not use if the packaging is damaged or previously opened.



Consult the User Manual.



This symbol indicates the need for the user to consult the User Manual for warnings and precautions associated with this medical device.



Manufacturer's details (name and address) and date of manufacture (year, month and day).



The device's Serial Number, Lot Number and Model Number appears next to these symbols. You will need these numbers when requesting assistance from your prescribing healthcare professional.

IP22
Ingress Protection (IP) Rating: IP ratings describe how effectively an enclosure is sealed. IP22 rated equipment is protected from objects greater than 12mm (~½ inch) in diameter being inserted e.g., fingers, and against small amounts of vertically dripping water.

IP67

The Tonguetip is IP67-rated equipment, meaning it is resistant to dust and can be submerged in a body of water up to 1 meter (~3 feet) deep for up to 30 minutes.



Non-ionizing radiation



This symbol signifies that the device should not be disposed of as domestic waste.

LENIRE The logo for this product range (Lenire)

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This device conforms to the requirements of the US Federal Communications Commission.



Manufacturing symbol to aid identification of the device SKU



2797

This symbol signifies compliance with applicable EU Directives. (EU Only)

Technical Description

Please read the Lenire User Manual for the device Technical Description.

How the Tonguetip works

The Tonguetip is a medical device accessory that, when connected to a Lenire Controller, delivers gentle, electrical stimulation to the tongue through electrodes which are placed on the tip of your tongue. Your audiologist or physician will set the stimulation level to your individual setting.



If the packaging is damaged, the Tonguetip should not be used and it should be returned to the point of sale.



Before connecting and using the Tonguetip for the first time, it should be cleaned. Please see the Cleaning section for details.

How to use your Tonguetip

1. Open the protective pouch that the Tonguetip is supplied in.
2. The Tonguetip must be connected to the Controller by plugging it into the Controller Port.
3. Once connected, the Tonguetip Indicator should change from pulsing blue to pulsing green.
4. The Tonguetip should be placed in your mouth, just behind your upper front teeth (on the top of tongue towards the front of the mouth) with the electrodes facing down.
5. As you close your mouth, the electrodes should make contact with the tip of your tongue and rest there comfortably.
6. Once adequate contact is made with the tongue, the Tonguetip Indicator should stop pulsing (it should illuminate green without pulsing).

For maximum comfort, the mouth and jaw should remain closed but relaxed for the duration of the treatment session.