



Support Details

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

Australian Sponsor:

MDSS AU Pty Ltd,
Ground Floor, Suite 55,
97-99 Bathurst Street,
Sydney NSW 2000,
Australia.

Website: www.lenire.com

Designed & Manufactured by:

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

Cleaning



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



Do not expose the plug end 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.

1. The Tonguetip should be rinsed thoroughly with water or distilled water.
2. You may use the Tonguetip immediately after rinsing.
3. If you do not intend to use the Tonguetip immediately after cleaning, place on a clean, dry surface and allow it to air-dry.
4. In addition, the Tonguetip may be cleaned by gently rubbing the Tonguetip surfaces, including the electrodes and the plug using 70 IPA (Isopropyl alcohol) wipes.
5. Further information related to the safe cleaning of the Tonguetip are contained within the Lenire user manual.

Storage, transport and 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 by contacting your prescribing healthcare professional.

Tonguetip service life

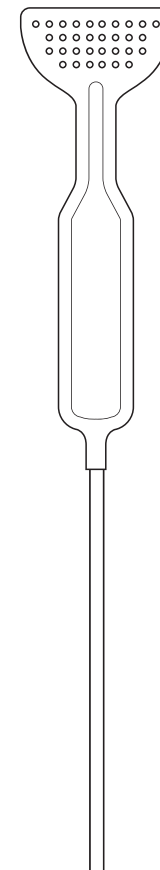
- The Tonguetip has an expected service life of three years. It is recommended not to use the Tonguetip after this as the electrodes may not function as effectively.
- The Tonguetip will expire after 180 cumulative hours of actual use. If an expired Tonguetip is connected to the Controller, the Tonguetip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

Note: Any incident that has occurred in relation to the medical device which has resulted in death, temporary or permanent serious deterioration in health or a serious public health threat should be reported to the manufacturer and Therapeutic Goods Administration. Website: <https://www.tga.gov.au>

TONGUETIP®



TP-101

Introduction

Your healthcare professional has prescribed the Lenire® Device for your use to alleviate the symptoms of chronic, subjective 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.

Contraindications



Do not use the device if...

- You have a pacemaker, defibrillator or any other active, implantable device, unless directed by a doctor.
- You are pregnant, unless directed by a doctor.
- You suffer from epilepsy or any other condition that may result in loss of consciousness.
- You suffer from any condition that causes impaired sensitivity of the tongue.
- You have lesions, sores, or inflammation of the oral cavity unless directed by a doctor.
- If you have any intermittent or chronic neuralgia in the head and neck area, unless directed by a physician.

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.
- Some people may experience a mild allergic reaction to the materials in the device. Note: The electrodes of the Tonguetip contain nickel. You may experience a mild numbing sensation or a discomfort on the tongue during treatment. If this occurs, reduce the tongue

stimulation. If the symptoms persist, contact your prescribing healthcare professional.

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 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.
- If you have lesions, sores, or inflammation of the oral cavity, discontinue use of the device until symptoms have resolved.

Package labelling



Medical Device.



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



Consult the User Manual.



Warnings and precautions associated with this medical device.



Manufacturer's details.



The device Lot Number.



The device Model Number.

IP67

Ingress Protection (IP) Rating:
This describes how effectively an enclosure is sealed.



The device should not be disposed of as domestic waste.



The Tonguetip provides a high degree of protection against electric shock.



Storage and transport temperature limits.
The lower limit is -20°C, the upper limit is 45°C.



Storage and transport humidity limits.
The lower limit is 5%, the upper limit is 85%.



This symbol signifies compliance with applicable EU Regulations.



Manufacturing symbol to aid identification of the device SKU.

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 clinician 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.



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.