

LENIRE[®]



Lenire[®] (CR-201) User Manual

Please read this manual carefully before using Lenire to ensure the device is used safely and effectively.

R_x only

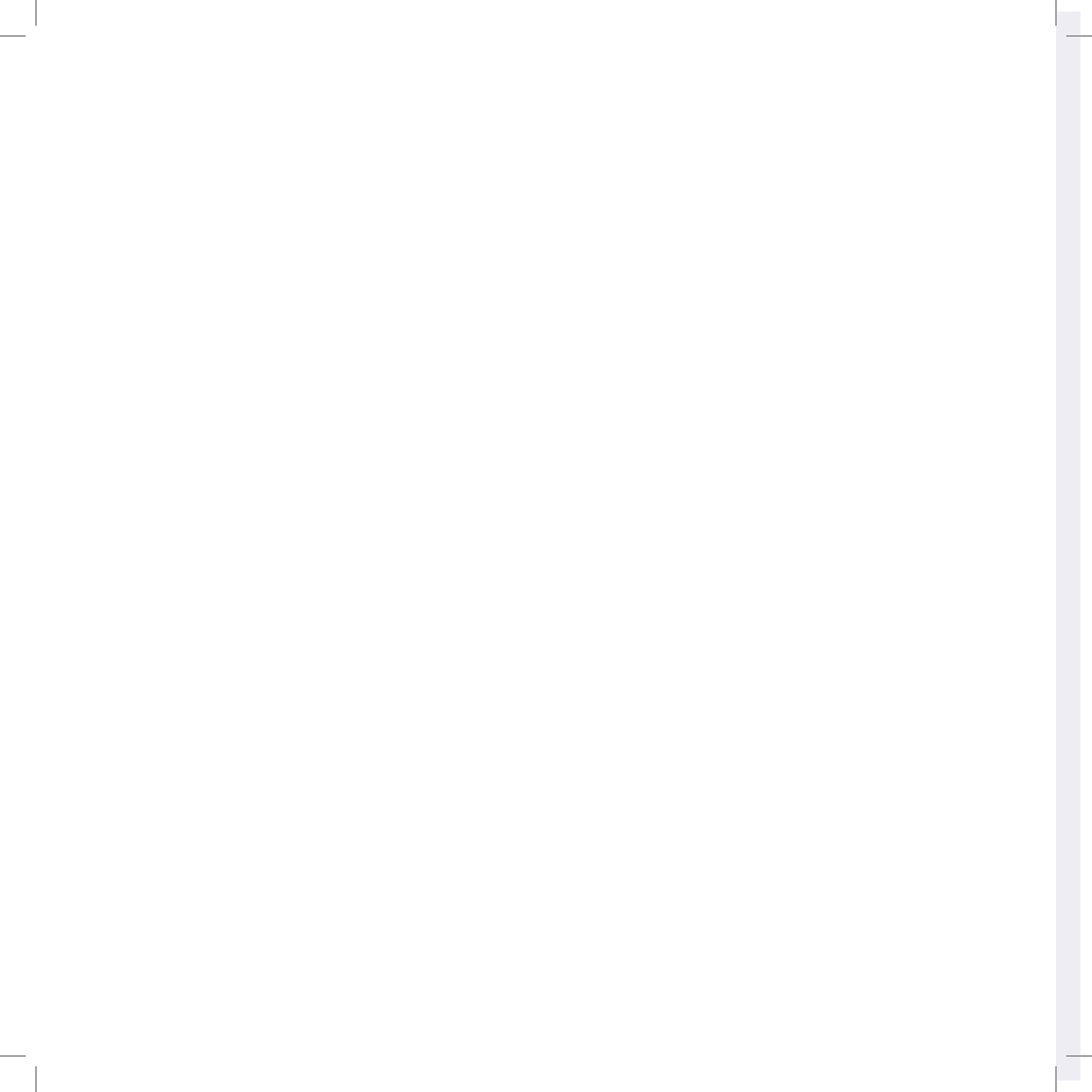


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Using this manual

This manual is supplied with Lenire to provide you with information on the product, treatment regime and instructions for its safe and effective use. You should read and understand these instructions before use.

Section A

General Information

This section outlines the general information relating to Lenire®, including important safety information.

Chapter 1 - Introduction

Lenire is a medical device intended to reduce the symptoms of tinnitus. It comprises a handheld Controller, wireless headphones and a Tonguetip®, which together, deliver bimodal stimulation. The Tonguetip delivers gentle, electrical stimulation to the tongue, and wireless headphones deliver sound stimulation. A Charger is included that can be used to charge both the Controller and the Headphones.

The sound and tongue stimulation are configured and calibrated to your individual characteristics during the initial fitting procedure by a trained healthcare professional.

The Lenire device can be used in the home environment after prescription for use or sale by a suitably qualified audiologist or physician, who are experienced in the evaluation and management of tinnitus.

Use by a person for whom the device has not been configured may cause discomfort, or temporary exacerbation of tinnitus loudness.

Chapter 2 - Indications for Use

Lenire is intended to provide bimodal (sound and transmucosal electrical tongue) stimulation to temporarily relieve the symptoms of tinnitus in patients 18 years of age and older suffering from at least moderate (as defined by Tinnitus Handicap Inventory) tinnitus. The treatment is intended to be self-administered by the patient following prescription by a healthcare professional, who is experienced in the evaluation and management of tinnitus.

Chapter 3 - Contraindications



Caution! – 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 Meniere'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.

Chapter 4 - 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. Contact your qualified audiologist or physician for advice on repositioning the Tonguetip.



There is a possibility that some people may experience a mild allergic reaction to the materials in the device. If this occurs, stop treatment, and contact your qualified audiologist or physician.



You may experience a mild numbing sensation or a discomfort on the tongue during treatment. If this occurs, reduce the tongue stimulation. If the discomfort persists in the oral cavity, stop treatment, and contact your qualified audiologist or physician.



Use of the treatment may result in mild 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 persist, stop treatment, and contact your qualified audiologist or 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 contact your qualified audiologist or physician.



Some people may experience glossodynia [tongue pain or unusual sensitivity to touch], dry throat or salivary hypersecretion. If this occurs, stop treatment and contact your qualified audiologist or physician.



Some people 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 contact your qualified audiologist or physician.

- ⚠ Some people may experience skin irritation from the Headphones. If this happens, stop using the Headphones. If the irritation persists, contact your qualified audiologist or physician.










Chapter 5 - General 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.
- ⚠ To avoid the risk of cross-contamination, the Headphones should not be shared with any other person.
- ⚠ 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 or in an open fire or on a radiator.
- ⚠ The use of rechargeable lithium-ion batteries is very common and they are generally considered safe to use. With any energy storage device, they carry safety risks including overheating. Only use the Charger provided with your device and always follow the instructions in this manual when charging your Lenire device.
- ⚠ Do not attempt to replace the lithium-ion batteries in your Controller and Headphones. Attempts to replace the batteries may result in risks including overheating and fire.
- ⚠ Do not use in conjunction with a hearing aid.
- ⚠ To avoid the risk of a burn do not puncture, crack or crush the Controller and Headphones.
- ⚠ Simultaneous connection of a patient to 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.

- ⚠ The Lenire Controller is a single-patient, multi-use device. To reduce the risks of misconfiguration, under no circumstances should a Controller device be re-assigned to another patient.
- ⚠ For patients with hearing thresholds set at the worst-case configuration of 80dB HL at frequencies from {2k, 3k, 4k, 6k, 8k} Hz, treatment duration should be limited to 30 minutes per day to avoid the risk of potential noise-induced hearing loss.

Chapter 6 - Product and Package Labelling

The label on the Controller, the Tonguetip plug, Carry Case and the product packaging provide important information. The meanings of the associated symbols are described below, or in the context of the relevant sections throughout this User Manual.

	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 (refer to Section F).
	
	
	Ingress Protection (IP) Rating: IP ratings describe how effectively an enclosure is sealed.
IP22	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).



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



Manufacturing symbol to aid identification of the device SKU



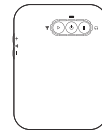
This symbol, the CE Mark, signifies compliance with applicable EU Directives. The number (2797) is the Notified Body number for the British Standards Institute (BSI), who approved Lenire for CE Marking. (EU only)

Section B Using Lenire

This section describes the components, controls and indicators of Lenire and outlines the steps required to prepare for and commence treatment.

Chapter 7 - Product Components & Accessories

In the Lenire device box, you will find the 3 main components of your Lenire device:



Controller

The Lenire Controller (Model Number CR-201) is used to “control” the treatment session i.e. you can start, pause and resume the treatment session, adjust the volume of the sound, adjust the level of the tongue stimulation, and turn the device on or off.



Tonguetip

The Tonguetip (Model Number TP-101) is a device which provides gentle, electrical stimulation to the tongue.



Headphones

The Headphones (Model Number Hi-X25BT) deliver audio stimulation to the ears.

Also included in the box:

Charger

The supplied Charger is used to charge the Controller and the Headphones.

Carry Case and Bag

The Carry Case and Lenire Accessory Bag can be used to store your Lenire device inbetween uses.

Quick Start Guide

The Quick Start Guide outlines the basic steps needed to commence treatment.

7.1 - Headphones

Lenire must be used in conjunction with a set of Bluetooth® Headphones. For best performance, it is essential that you use the supplied Headphones. See Chapter 29 for manufacturer details and technical information.



Note: Lenire is designed to work only with the supplied Headphones, and will not function with any other Bluetooth devices.

7.2 - Batteries

The Controller and Headphones are powered by 3.7V lithium-ion batteries. The batteries are pre-fitted and are not intended to be replaced.

See Chapter 10 for instructions on charging the Controller and Headphones.

7.3 - Charger

The supplied Charger should be used to charge the Controller and may also be used to charge the Headphones in conjunction with the adaptor provided.

The supplied Charger is provided in the following model versions:

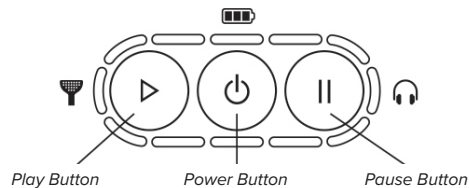
- Manufacturer: XP Power, Model No.: ACM06US05W-XZ1663A

If experiencing difficulties with charging the Controller or the Headphones, consult Chapter 19 Frequently Asked Questions or refer to Section F.

Chapter 8 - Controls and Indicators

8.1 - Treatment Controls

There are three control buttons on the front of the Controller:



1. Power Button

Hold this button for 2 seconds to switch the device on.
Hold this button for 2 seconds to switch the device off.

2. Play Button

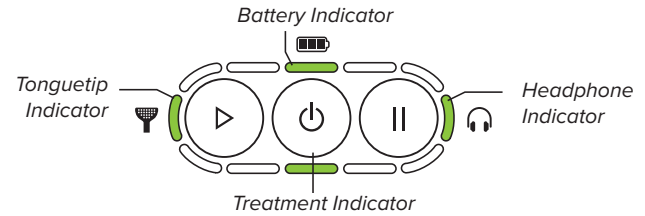
Press this button to start or resume the treatment session.


3. Pause Button


Press this button to pause the treatment session.


8.2 - Indicators

The status of the device is indicated by several lights surrounding the buttons on the top of the Controller.



Battery Indicator 	
Green	The battery power is ok.
Orange	The battery has less than 1 hour of power remaining. Please charge the device before next use (see Chapter 10).
Red	The battery is exhausted. The device will shut off automatically. Please charge the device before next use (see Chapter 10).
Orange (Pulsing)	The Charger is connected and the battery is charging.
Green (Pulsing)	The Charger is connected and the battery is fully charged.

Headphones Indicator 	
Blue (Pulsing)	The Controller is trying to establish a wireless connection to the Headphones.
Green	The Controller is connected wirelessly to the Headphones.
Blue (Pulsing Rapidly)	The Controller is attempting to pair with the Headphones, see Chapter 20 for details.
Orange (Pulsing Rapidly)	An unsupported headphone is connected to the Controller.

Tonguetip Indicator 	
Blue (Pulsing)	There is no Tonguetip connected.
Green (Pulsing)	The Tonguetip is connected but it is not in contact with the tongue.
Green	The Tonguetip is connected and it is in contact with the tongue.
Orange or Orange (Pulsing)	The Tonguetip has less than 10 hours of use remaining after which it will no longer function. A new Tonguetip is required to avoid disruption to your treatment regime.
Red	The Tonguetip has expired and will no longer function. Please purchase a new Tonguetip to continue treatment.

Treatment Indicator	
White (Pulsing)	The treatment session is paused.
White (Animated)	The treatment session is active – the white light rotates around the buttons.
Green (Pulsing)	The treatment session has completed.

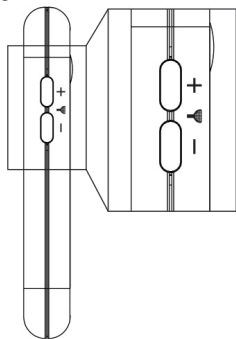
Note: When the device is powered off, none of the lights will be illuminated.

8.3 - Headphones Volume and Tonguetip Stimulus Controls

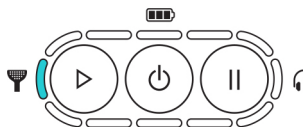
Tonguetip Stimulation Control

The Tonguetip stimulation intensity can be adjusted to a comfortable level by pressing the buttons indicated below. Please see Chapter 13.3 for guidelines on setting the stimulation intensity.

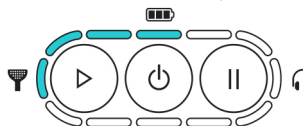
Right Side View



Indication of default (optimum)
Tonguetip stimulus intensity



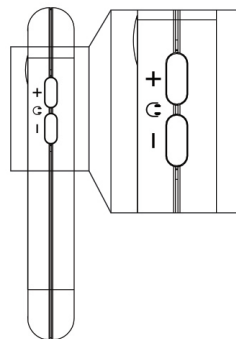
Indication of maximum Tonguetip
stimulus intensity



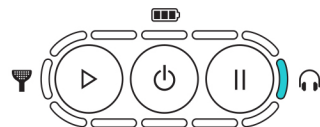
Headphones Volume Control

The Headphones volume can be adjusted to a comfortable level by pressing the buttons indicated below. Please see Chapter 13.3 for guidelines on setting the volume level.

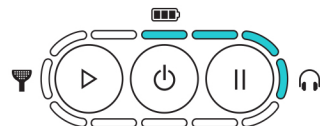
Left Side View



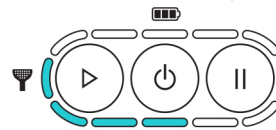
Indication of default (optimum)
Headphones volume level



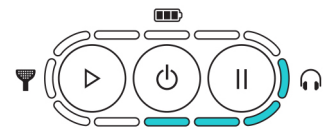
Indication of maximum
Headphones volume level



Indication of minimum Tonguetip
stimulus intensity



Indication of minimum
Headphones volume level

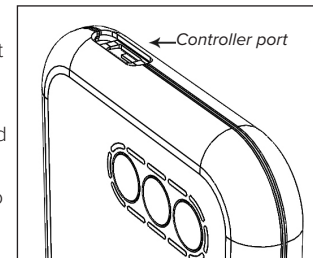


Note: The Headphones volume and Tonguetip stimulus are calibrated to the optimum levels during device fitting by the audiologist or physician. For further details, please see Chapter 13.3.

Chapter 9 - Controller Port

The Controller Port is used to connect the Tonguetip and the Charger to the Controller. For safety, the Tonguetip and the Charger cannot be connected to the Controller at the same time.

The following symbols are adjacent to the Controller Port:



- This symbol (direct current) identifies a charging port.
- This symbol represents the Tonguetip.
- The USB symbol – this is the connection that is used by the healthcare professional when they configure your device.
- This symbol indicates that the Tonguetip provides a high degree of protection against electric shock.

! The Tonguetip and the supplied Charger are the only equipment that should ever be plugged into the Controller Port.

Chapter 10 - Charging the Controller and Headphones

Before Lenire is used for the first time, it is recommended that the Controller and the Headphones be fully charged.

! Only use the supplied Charger with the Lenire device.

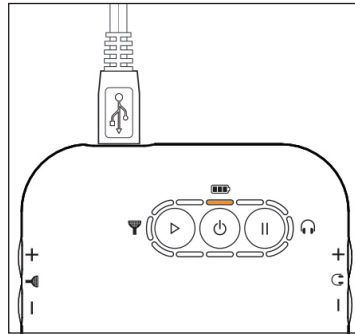
! To avoid the risk of electric shock, do not connect or disconnect the Charger from the outlet if it, or your hands, are wet.

10.1 - Charging the Controller

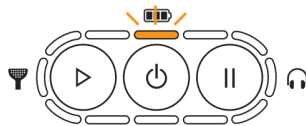
To charge the Controller:

- Plug the cable end of the supplied Charger into the Controller Port of the Controller.
- Plug the Charger into an outlet.

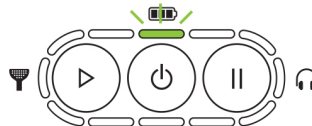
While charging, the Battery Indicator will pulse orange. Once the battery is fully charged, the Battery Indicator will pulse green.



Battery charging



Battery charged



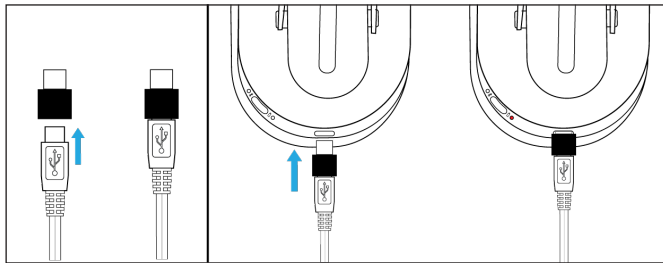
Note: An empty battery should take no more than 3 hours to fully recharge, and a full charge should allow the Lenire device to be used for at least 8 hours.

Note: Once the battery is fully charged, the Charger should be disconnected to help conserve the life of the battery in the Controller.

10.2 - Charging the Headphones

To charge the Headphones:

- Plug the cable end of the supplied Charger into the USB-C® adaptor provided, then insert into the USB-C® Port of the Headphones.

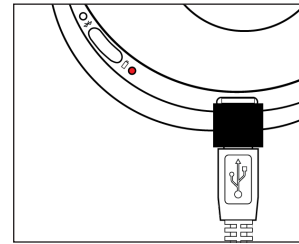


- Plug the Charger into an electrical outlet.

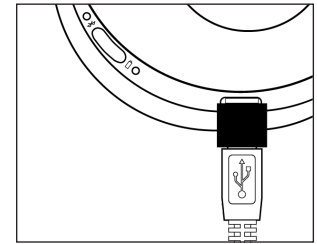
Alternatively you can charge the Headphones using the separate USB-C® cable provided in the packaging. For convenience a USB-A adaptor has also been provided to increase compatibility options for this cable.

While charging, the light on the Headphones will illuminate red. Once the battery is fully charged, the light on the Headphones will turn off.

Battery charging



Battery charged



Note: When the Headphones battery is running low, the battery LED will blink red and the Bluetooth LED will blink blue, you will also hear an audio prompt.

Note: An empty battery should take no more than 3 hours to fully recharge, and a full charge should allow the Headphones to be used for at least 10 hours.

Note: Once the battery is fully charged, the Charger should be disconnected to help conserve the life of the battery in the Headphones.

Chapter 11 - Device Setup

To commence a treatment session, the Lenire device should be set up as follows:

11.1 - Controller and Headphones Setup

The Headphones should be worn so they cover both ears and should be adjusted to maximise comfort before commencing the treatment session.

Note: To adjust the headphone's size, please hold the headband on the glossy parts and slide the headbow carefully outwards/inwards. Please handle with care.



It is essential that the left and right earphones cover the left and right ears, respectively. This is because the device calibration is unique to each ear – it is based on your audiogram. Failure to put on the headphones correctly could result in excessive loudness in one ear, which could cause discomfort, or incorrect loudness that may reduce the effectiveness of the treatment.

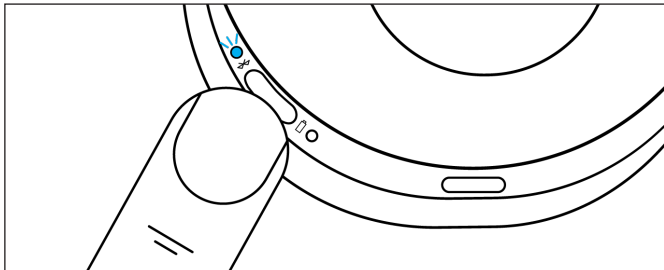
The left and right sides of the headphones are marked L and R respectively on the cloth inside the foam cushions.



11.2 - Connecting the Headphones with the Controller

The Controller connects to the Headphones wirelessly via Bluetooth by following these steps:

- Turn on the Controller by pressing its Power Button for two seconds. The Controller will attempt to connect to the Headphones during which time the Controller's Headphones Indicator will pulse blue.
- Press the Headphones' power button for 2 seconds and wait for the LED Indicator to pulse blue or blue and red if the Headphones battery is low.



- Once the connection to the Headphones has been established, the Controller's Headphones Indicator will illuminate green.

Note: The above instruction assumes that the Headphones are already 'paired' with the Controller. This should be the case in most situations, as your healthcare professional will have paired the Headphones during the device fitting. If they are not paired, or if you are having difficulty connecting to the Headphones, then you should follow the instructions in Chapter 20.

Note: During treatment, the Controller can be kept adjacent to you, e.g. in a pocket or a bag, or in another dry location that is close by, e.g. on a bedside table.

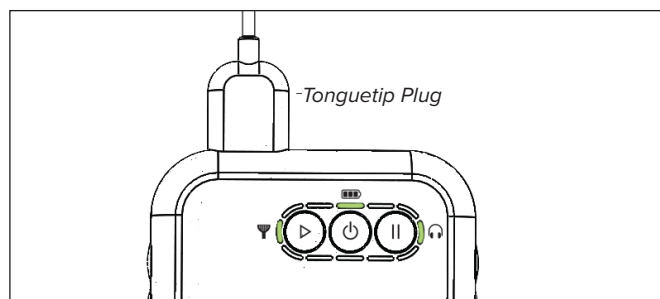
Chapter 12 - Tonguetip Setup

The Tonguetip is supplied within a plastic Carry Case for storage and transportation purposes.

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

Note: Before connecting and using the Tonguetip for the first time, it should be cleaned as per the instructions in Section C.

The Tonguetip must be connected to the Controller by plugging it into the Controller Port, such that the label side of the plug faces away when viewed from the front of the Controller.



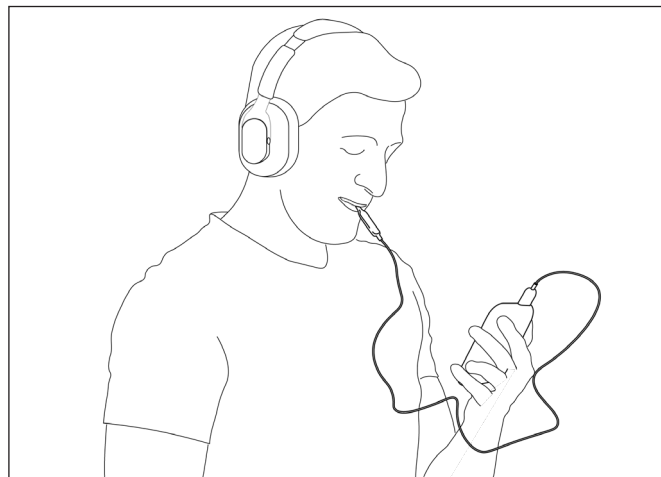
Once connected, the Tonguetip Indicator should change from pulsing blue to pulsing green.

The Tonguetip should be placed in your mouth, just behind your upper front teeth (on the top of the tongue towards the front of the mouth) with the electrodes facing down.

As you close your mouth, the electrodes should make contact with the tip of your tongue and rest there comfortably.

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.



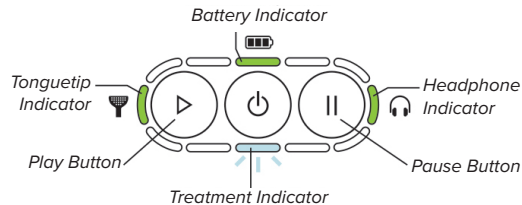
! To avoid the risk of electrical shock or burns, do not connect the Controller or Tonguetip to any equipment other than those specified in this User Manual.

Note: The Tonguetip model TP-101 is designed to function for 360 treatment sessions (180 hours) before expiring. Indications of imminent expiry and actual expiry are outlined in Chapter 8.

Chapter 13 - Starting and Controlling a Treatment Session

13.1 - Starting a Treatment Session

As soon as the Headphones and the Tonguetip are connected, which will be indicated by the Headphones Indicator and the Tonguetip Indicator illuminating green, you are ready to start a treatment session.



Once you are in a comfortable position, press the Play Button to commence the treatment. The Treatment Indicator (white) will rotate around the display.

A single treatment session lasts approximately 30 minutes from the time the Play Button is pressed.

Towards the end of the treatment session, the sound will gradually fade out over a period of 2 minutes to a lower volume level.



It is essential that you continue to listen to the sound during the fade out period, i.e., until the treatment session is complete.

Once the treatment session is complete, the Treatment Indicator will pulse green.

Note: The Controller will power off automatically after 20 minutes of being idle (no treatment session in progress). The Headphones will automatically power off 5 minutes thereafter. It is recommended to power off the Controller and the Headphones after the treatment session has completed.

13.2 - Pausing and Resuming a Treatment Session

It is recommended to complete each treatment in a single, continuous 30-minute session to maximise the effectiveness of the treatment.

However, the treatment session can be paused at any time by pressing the Pause Button. The Treatment Indicator will pulse white instead of rotating around the display.

The treatment session will automatically pause if the Tonguetip loses contact with the tongue for more than 30 seconds.

Note: Pausing the treatment session does not affect the total duration of active stimulation. When treatment is resumed it will provide the remainder of the 30 minutes of stimulation.

To resume treatment, press the Play Button while also ensuring that the Tonguetip is in contact with the tongue.

If you do pause a treatment session, it is recommended that you resume again within 5 minutes. It is also recommended that you do not pause the treatment more than once within a single treatment session in order to maximise the effectiveness of the treatment.

13.3 - Adjusting the Stimulation Levels

13.3.1 - Tonguetip Stimulation Level Control

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.

Note: The tongue stimulus is calibrated to your sensation thresholds during device fitting by the healthcare professional. The treatment stimulus is then set to be sufficient for optimum effectiveness and may not be perceptible. If the stimulus level is set to the default level (i.e., the level that the device defaults to at the start of each treatment session), then the stimulus is functioning properly as long as the Tonguetip Indicator is illuminated green (i.e., when it is not pulsing).

13.3.2 - Headphones Volume Control

The Headphones volume level should be left at the default level unless either:

- The treatment environment is noisy, in which case the volume level can be increased.
- The volume is so high that it causes any discomfort, or prevents you from relaxing, in which case the volume level can be decreased. If the sound causes discomfort even when set to the lowest volume level, please pause treatment and contact your healthcare professional.

Note: The Headphones volume levels are calibrated to your hearing thresholds for optimum effectiveness.

Note: Depending on your audiological profile, you may perceive the sound levels to be soft. It is important that you seek a quiet environment for your treatment sessions.

Note: Depending on your hearing profile, the range over which you can increase the Headphones volume level may be limited. This is because the Headphone volume setting required to compensate for your hearing profile is close to the maximum level supported by the Headphone hardware.

Chapter 14 - Treatment Guidelines

The following guidelines should be followed to maximise the effectiveness of the treatment program:

- While the treatment is intended for up to 60 minutes per day, it is recommended that you try to complete at least two full 30 minutes at each daily treatment.
- Try to keep the tongue stimulation level and the Headphones volume level at the default settings, as these are the optimum levels calibrated to your individual characteristics.
- Try to complete each treatment session in a place that is quiet, relaxing and comfortable. Focusing your attention away from distractions such as the TV may improve the effectiveness of the treatment.
- Try to keep a routine for the treatment sessions, where the treatment is delivered at the same time(s) each day.
- It is not unusual for tinnitus symptoms to worsen or fluctuate. It is recommended that you continue treatment even during periods where the symptoms worsen, for the minimum recommended treatment duration. However, if there is a significant disimprovement in your symptoms it is recommended to seek advice from your audiologist or physician.
- You may experience dizziness, headaches, glossodynia [tongue pain or unusual sensitivity to touch], dry throat, salivary hypersecretion, discomfort, numbing of the tongue or a mild allergic reaction to the materials in the device. It is recommended to stop treatment and seek advice from your audiologist or physician if any of these occur.



Do not use while showering, in rain, or in a damp environment such as a steam bath or sauna. Do not use while applying items such as, perfume, cosmetics, after-shave, hairspray or suntan lotion.

Section C Care, Storage, Maintenance and Disposal

This section details the correct procedures for cleaning, storage, maintenance and disposal of Lenire.

Chapter 15 - Cleaning

It is advisable to clean the Controller, the Headphones, the Carry Case and the Tonguetip after prolonged disuse or storage, or after exposure to conditions that could affect their hygiene.

15.1 - Instructions for Cleaning of the Controller, the Headphones and the Carry Case



Before cleaning the Controller or Headphones, ensure that they are switched off and not connected to the Charger.

- The exterior surfaces of the Controller, the Headphones and Carry Case should be cleaned using a soft cloth to remove debris.

15.2 - Instructions for Cleaning of the Tonguetip

It is recommended to follow the procedure below to clean the Tonguetip prior to first use, and prior to every subsequent re-use.



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









Do not expose the Plug end of the Tonguetip to liquids.

1. Prepare a cleaning solution by diluting a small amount of liquid soap in lukewarm water.
2. 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.
3. The Tonguetip should then be rinsed thoroughly under running tap/ faucet water for approximately 30 seconds.
4. Visually inspect the surfaces of the Tonguetip for soil and repeat from Step 1 if visible soil remains.
5. You may use the Tonguetip immediately after rinsing.
6. If you do not intend to use the Tonguetip immediately after rinsing, place on a clean, dry surface and allow it to air-dry.

Alternatively, the Tonguetip may be cleaned by gently rubbing the Tonguetip surfaces, including the electrodes and the plug using 70% IPA (Isopropyl alcohol) wipes.

Note: 70% IPA wipes are available over-the-counter in pharmacies.

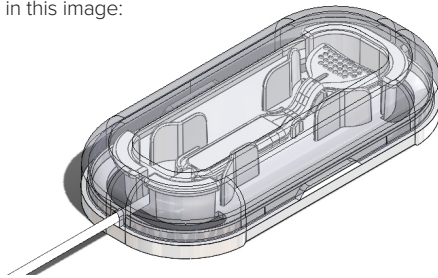
-  After cleaning the Tonguetip with IPA, place on a clean, dry surface to allow to air-dry for at least one minute before use.
-  Do not use any cleaning agents other than IPA or liquid soap (e.g. Dawn or Palmolive dishwashing liquid) diluted in water.
-  Attempting to clean the device using a method other than that described here can damage the device and voids the warranty.
-  Do not scrub or wipe the surfaces forcefully.
-  Do not immerse the Controller, the Charger or the Tonguetip plug in water.
-  To avoid damaging the devices, do not force dry, for example by using a hairdryer, or leaving on top of a heater.

Chapter 16 - Storage and Transport

16.1 - Carry Case and Accessory Bag

It is recommended to store the Tonguetip in the Carry Case supplied as it has been specially designed to protect it during storage. It can also help maintain the cleanliness of the Tonguetip in-between uses.

The Carry Case is designed to hold the Tonguetip and its cable within the body of the case. It is not necessary to disconnect the Tonguetip plug from the Controller port before placing it into the Carry Case. For ease of storage, it is possible to leave the Tonguetip cable outside the case, whereby the cable enters and exits the case through the holes as indicated in this image:



An Accessory Bag is provided in the Lenire packaging. The bag will allow you to store the Controller, Tonguetip and Headphones between uses and aid in the transport of your device.

To fit the Headphones in the bag you can either turn the earcups backwards, so they lay flat, or you can fold the earcups towards the headband for very compact dimensions. Please handle with care.

16.2 - Storage and Transport Information

The environmental limits and precautions pertaining to storage and transport of the device are illustrated on the packaging labels, next to these symbols:



Storage and transport temperature limits. The lower limit is 14°F (-10°C), as indicated near the lower horizontal line and the upper limit, 113°F (45°C), as indicated near the upper line.



Storage and transport relative humidity limits. The lower limit, 5%, as indicated near the lower horizontal line and the upper limit, 85%, as indicated near the upper line.



Keep dry.



Fragile, handle with care.

Chapter 17 - Maintenance

17.1 - Inspections

- Carry out a weekly visual inspection to ensure that the Controller has not been damaged.
- Carry out a weekly visual inspection to ensure there is no evidence of discolouration 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 (refer to Section F).

17.2 - Controller Service Life

- The Controller has an expected service life of three years. Beyond three years, the device will still perform as intended except that the battery capacity may start to deteriorate.
- The Controller should be charged every 6 months if not in use. Not charging the battery for extended periods may reduce the capacity of the battery and shorten the service life of the device.

17.3 - Tonguetip Service Life

- The Tonguetip has an expected service life of three years. It is recommended not to use the Tonguetip after this time period 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 and treatment sessions will not commence until a non-expired Tonguetip is connected. A new Tonguetip (Model TP-101) can be purchased from your prescribing healthcare professional (refer to Section F).

Chapter 18 - Disposal

Please consider your personal safety and the environment when disposing of Lenire. When the device, or any of its components have reached the end of their service life, they should be disposed of in accordance with local regulations or returned to point of sale.



No part of Lenire should be disposed of as domestic waste.

Section D

Troubleshooting

The following section describes problems commonly encountered while using the Lenire device, and their most common solutions. If a particular problem cannot be rectified, you should contact your prescribing healthcare professional.

Chapter 19 - Frequently Asked Questions

19.1 - What should I do if the Controller will not power on?

- Ensure that the Controller is charged (see Chapter 10).
- Ensure the Charger is not connected. The device will not power on while the Charger is connected.
- Make sure you hold the Power Button for at least 2 seconds when attempting to turn on the device.
- It is possible that the Controller is in a state that requires a reset – connect the Charger briefly to reset the Controller and then try to turn the Controller on again once the Charger has been disconnected.
- If none of the above steps resolve the problem, please contact your prescribing healthcare professional.

19.2 - What should I do if there is no sound coming from the Headphones?

- Ensure the Headphones are charged (see Chapter 10).
- Ensure the Headphones are paired to the Controller. If they are not, pair the Headphones with the Controller again (see Chapter 20).
- Check that the Headphones connect to the Controller – the Headphone Indicator should illuminate green when they are connected.
- It is important to confirm that the Headphones are what the Controller is connected to (i.e., it is possible that your Controller is inadvertently connecting to another device). You can verify this by turning the Headphones off while the Controller is still on, and the Headphones Indicator on the Controller should revert to pulsing blue.
- Please ensure that the Tonguetip is connected and that it has not reached expiry i.e., the Tonguetip Indicator is illuminated either green or orange, but not red.
- Ensure that the treatment session is active by pressing the Play Button. The Treatment Indicator will rotate around the light display when the treatment session is active.
- If there is still no sound audible through the Headphones, please contact your prescribing healthcare professional.

19.3 - What should I do if the sound level is too low?

- Try adjusting the volume level using the buttons on the side of the Controller and using the device in a quiet location. See Chapter 13.3 for guidelines on adjusting the volume level.

Note: It is likely that the sound levels will be soft, depending on the device configuration and your audiological profile.

Note: The sound volume is calibrated to the optimum levels appropriate to your hearing thresholds during the device fitting with a trained healthcare professional. The range of adjustment above and below this optimum level is limited in order to maximise the treatment effectiveness and minimise possible hearing damage.

19.4 - What if I find the tongue stimulation level is too low?

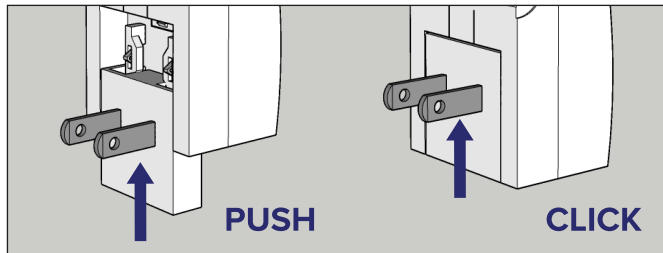
Note: It is possible that there may be little or no perceived sensation from the Tonguetip (see Chapter 13.3).

- Ensure that the Tonguetip Indicator illuminates green (non-pulsing) when the Tonguetip is making contact with your tongue. If it is not, please contact your prescribing healthcare professional.
- Ensure that the Tonguetip status indicator is not flashing red. If it is then please contact your prescribing healthcare professional for replacing the Tonguetip.
- Try adjusting the stimulation level using the buttons on the side of the Controller.

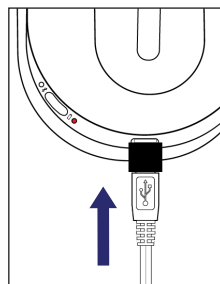
19.5 - What should I do if the Controller is not charging?

If your Controller is not charging, please try the following:

- Check the plug on the Charger is fully 'clicked in'.



- Check if the Charger is working by connecting the Charger to the Headphones. If the red light does not illuminate, then there is possibly a fault with the Charger. Please contact your prescribing healthcare professional.
- Retry charging the Controller - if there is still not an indication of charging, please contact your prescribing healthcare professional.



19.6 - I tend to fall asleep during the treatment - Is this a problem?

Falling asleep during a treatment session is not advised. It is important that the Tonguetip remains in place and contacting your tongue throughout the treatment session.

19.7 - I only received one Charger in the box, is that correct?

Yes. The same Charger is used to charge the Controller and the Headphones. See Chapter 10 for details.

19.8 - What should I do if I miss a treatment session?

To maximise the effectiveness of the treatment, it is important to adhere to the treatment regimen prescribed by your audiologist or physician. If you miss a treatment session on any particular day, it is advisable that you continue treatment as normal the following day.

19.9 - My Headphones won't connect, even though the light on the Headphones indicates that it is connected

It is possible that another device, such as a mobile phone or a personal computer, is connecting to your Headphones thereby preventing the Controller from connecting to them. Try either:

- Turning off any mobile phones, or other computer devices that are close by.
- Moving to a different location, away from any computer devices.

If none of these steps fixes the problem, please contact your prescribing healthcare professional.

19.10 - My Headphones touch controls have re-activated

Touch controls have been deactivated on the headphones by default for use with Lenire. In cases of accidental re-activation of the touch controls on the Headphones, please follow the steps below.

To confirm touch control activation:

- Power the Headphones on by pressing the power button until the "power on" voice command is audible.
- Power on the Controller and confirm connection with a solid green light next to the Headphone icon.
- Begin a treatment session by pressing play and tap the touch control on the right earphone. If a beep is audible, whenever the touch control is tapped, the touch control is activated.

To de-activate Touch Controls:

- Power off the Headphones by pressing and holding down the power button (you will hear the "power off" voice command), do not release the button.
- Continue to hold down the power button for 30 seconds then release the power button.
- Next power the Headphones back on, begin a treatment session by pressing play on the Controller, and tap the touch control on the right earphone, if no beep is audible, the touch controls are now deactivated.

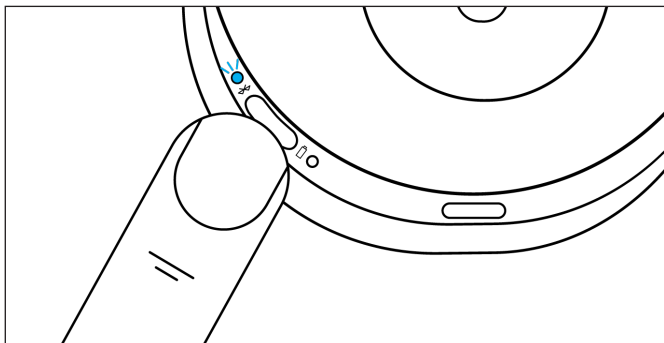
Chapter 20 - Bluetooth Pairing / Un-Pairing

The Controller sends sound to the Headphones wirelessly using Bluetooth, and for this to work, the Controller and the Headphones need to be 'paired', allowing the two devices to connect automatically henceforth.

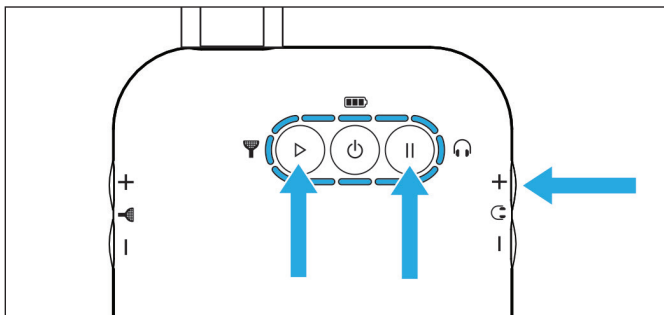
20.1 - Pairing Headphones to the Controller

The first time you try to use the Controller and Headphones together you may need to pair the devices as follows:

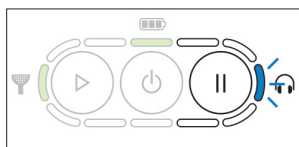
- Put the Headphones into Pairing Mode by first ensuring they are powered off, then hold the power button until the indicator adjacent to the power button rapidly flashes blue.



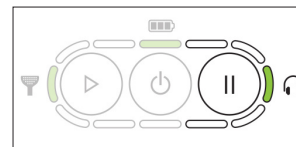
- Switch on the Controller by pressing the Power Button for 2 seconds.
- Place the Controller into Pairing Mode by pressing the Play, Pause and Volume Up [+] Buttons at the same time. All indicator lights will flash blue for 2 seconds.





- The Controller will search for and attempt to pair with the Headphones. The Headphones Indicator on the Controller will pulse rapidly during this procedure.



- If no discoverable Headphones are found within 20 minutes, the Controller will shut down. Otherwise, the Controller will connect to the Headphones and the Headphones Indicator on the Controller will illuminate green.



Chapter 21 - Servicing

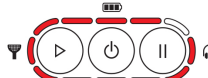
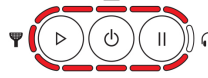
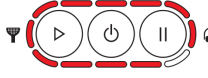


-  The device is not intended to be user-serviced. If it should fail for any reason, please return to your prescribing healthcare professional for repair.
-  This device is not intended to be modified in any way.

Chapter 22 - Device Errors

If any of the following error indicators occur that prevents the use of Lenire, please contact your prescribing healthcare professional. The errors will be indicated via the lights on the Controller. All but one of the lights will turn solid red. The position of the light that is not lit will indicate the error that has occurred.

After displaying the error indicator for 5 seconds, the Controller will shut down.

Error Indicators

- Controller hardware failure. 
- Controller software error. 
- Internal storage error. 
- Tonguetip hardware failure. 
- Tonguetip software error. 

Section E

Technical Information

The following section outlines technical information pertaining to the Lenire device. This information is included in order to conform to international safety standards for medical devices. There is also important information included in the following section relating to environmental operating conditions and use in the vicinity of other electrical devices such as cellphones.

Chapter 23 - Environmental Operating Conditions

Lenire should only be used in environments between 5 and 40 degrees Celsius (41 to 104 degrees Fahrenheit), relative humidity between 15% and 90%, and atmospheric pressure of between 700 and 1060 hPa. This precludes the use at altitudes above 3000 meters (~10,000 feet), unless traveling in an airplane that has the cabin pressurised.

Chapter 24 - Radio Frequency (RF) Specifications

The Lenire Controller contains a Bluetooth wireless radio module that transmits the sound stimulus to the Headphones. If the wireless communication is adversely affected, for example due to obstruction or interference, gaps in sound stimulus may occur. If this should occur during treatment, please try the following:

- Move to a location where likely sources of interference are at least 2 meters (6½ feet) away from the Controller, Tonguetip and Headphones. Likely sources of interference include microwave ovens, Wi-Fi routers and cellphones.
- Ensure there is line-of-sight between the Controller and the Headphones.
- Increase the distance between the Controller and the Headphones. While this may seem counter-intuitive, the Bluetooth system automatically increases the signal power as this distance is increased which may reduce or eliminate gaps in the sound stimulus.

The Bluetooth radio specifications are as follows:

Specification	Description
Frequency Band	2.4 GHz to 2.4835 GHz
Modulation	8 DPSK, PI/4 DQPSK, GFSK
Operating Range (Line-of-Sight)	≥ 10 meters (33 feet)
RF Sensitivity	0.1% BER at -88dBm
Effective Radiated Power (ERP)	<4dBm (2.5 mW) Bluetooth Class 2

Chapter 25 - Guidance and Declaration for Electromagnetic Compatibility

The Lenire Controller, Tonguetip and the Charger have been tested for electromagnetic performance to the requirements of IEC 60601-1-2 which includes testing to the following standards:

- IEC 61000-4-3 (Radiated electromagnetic fields)
 - 80 MHz to 2.7 GHz at 10V/m
 - 2.7 GHz to 6 GHz at 3V/m
 - Spot frequencies per IEC 60601-1-2:2014 Table 9 at up to 28 V/m
- IEC 61000-4-6 (Conducted electromagnetic fields)
 - 150 kHz to 80 MHz at 3V
 - Spot frequencies per IEC 60601-1-2:2014 at 6V
- IEC 61000-4-2 (Electrostatic Discharge)
 - +/- 8kV Contact Discharge
 - +/- 15kV Air Discharge
- IEC 61000-4-8 (50Hz/60Hz magnetic fields) at 30 A/m
- IEC 61000-4-39 (Proximity magnetic fields)
 - 30 kHz @ 8 A/m
 - 134.2 kHz @ 65 A/m
 - 13.56 MHz @ 7.5 A/m
- IEC 61000-4-4 (Electrical Fast Transients)
- IEC 61000-4-5 (Surge)
- IEC 61000-4-11 (Voltage dips and interruptions)


Disturbances higher than these limits are unlikely to be encountered in the home or professional healthcare environments. Electromagnetic interference may result in temporary disruption of the sound stimulus (manifesting as brief gaps of silence) as described in Chapter 24.


In addition, the Headphones have been tested to the requirements of CISPR 35 (EN 55035), which includes testing to the following standards:


- IEC 61000-4-3 (Radiated electromagnetic fields)
 - 80 MHz to 1 GHz at 3 V/m
 - 1.8 GHz, 2.6 GHz, 3.5 GHz and 5 GHz at 3 V/m
- IEC 61000-4-2 (Electrostatic Discharge)
 - +/- 4 kV Contact Discharge
 - +/- 8 kV Air Discharge





Lenire is intended for use in the home and professional healthcare environments only. The performance of the Lenire in environments with high electromagnetic disturbances, e.g., near magnetic resonance imaging (MRI) or high frequency surgical equipment has not been evaluated and the Lenire should not be used in such environments.


 Radio communications equipment (such as Wi-Fi routers, cellphones, wireless charging systems, radio-frequency identification (RFID) systems including anti-theft systems) may interfere with the performance of Lenire and should be kept at least 2 meters (6½ feet) away from the Controller, Tonguetip and Headphones when in use. Otherwise, degradation of the performance of this equipment could result.

 The Lenire device should not be used while in proximity to diathermy, electrocautery, magnetic resonance imaging, security or metal detector systems. Otherwise, degradation of the performance of this equipment could result.

 If interference to the performance of the device occurs, such as a change in the display indicators, gaps or drop-outs in the sound, or a noticeable and unusual change in the tongue stimulation, it is possible that a source of electromagnetic interference is in proximity to the device. Please move to a location that significantly reduces the proximity to the electromagnetic interference source.

 The Headphones may suffer damage if exposed to Electrostatic Discharges of higher than 8 kV. To minimise the risk of damage, please pick up the Headphones by the headband before use.

 Lenire should not be used adjacent to or stacked with other electrical equipment because it could result in improper operation.

 Use of accessories and cables other than those specified for use for Lenire (and as provided by Neuromod Devices Limited) could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Lenire has been tested for electromagnetic emissions and complies with Class B limits of CISPR 11 (Controller and Tonguetip) and CISPR 32 (Headphones) and is therefore unlikely to interfere with the operation of other electrical equipment.

Chapter 26 - FCC Compliance Information Statement

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.

This equipment has been tested and found to comply with the limits of 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 all scenarios.

If this equipment does cause interference with other devices, which may be determined by turning the Lenire Device and the Headphones off and on, the user should try to eliminate the interference by one or more of the following measures:

- Reorient or relocate the device receiving the interference
- Increase the separation between the Lenire device / Headphones and the affected equipment
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the manufacturer or field service technician of the affected equipment for help

Neuromod is not responsible for any radio or communication interference caused by using the device in any way other than specified in these instructions, or using the device with non-recommended cables or charger. Changes or modifications not expressly unauthorized by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC Identification
Lenire device (Model CR-201), contains FCC ID: SSSBC127-X
Headphones (Model Hi-X25BT), FCC ID: 2A28V-19004F

Responsible party:

Name: Neuromod USA Inc.

See Section F for Neuromod contact information.

Headphone Supplier's Declaration of Conformity:

Trade Name: Austrian Audio

Responsible Party – U.S. Contact Information

US Company Name: Group One Limited

Address: 70 Sea Lane, Farmingdale, New York 11735.

Telephone number: +1 631 396 0195,

Email: info@g1limited.com

Chapter 27 - Technical Specifications

The table below provides technical reference information that may be useful to you, your healthcare professional, or regulatory agencies.

Materials	Lenire does not contain phthalates, latex, human blood derivatives or cells or tissues of human or animal origin
Power	Internally powered by a Lithium-Polymer rechargeable batteries (not-user replaceable), 3.7 V, 1150 mA Hour, (Controller) and 500 mA Hour (Headphones).
Tongue Stimulation Parameters	The tongue stimulation parameters listed below are applicable for the typical range of impedances associated with stimulation of the tongue.
Stimulation Waveforms	Pseudo bi-phasic, capacitive coupling
Pulse voltage (per electrode)	3.8 V (peak) 219.9 mV RMS
Pulse duration (leading phase)	6 μ s to 208 μ s
Pulse current (per electrode)	4.65 mA (peak) 0.3 mA (RMS)
Maximum charge per pulse	176 nC
Maximum energy per pulse	0.37 μ J
Maximum pulse frequency	347 Hz
Electrode surface area	0.0078 cm ² (per electrode)
Net direct current (DC)	< 0.1 μ A
Net charge per pulse	< 0.13 nC
Effect of Load Impedance	The stimulation pulse duration or frequency do not vary by more than 3%, and the stimulation output voltage does not vary by more than 15% between no-load and nominal load conditions.

Chapter 28 - Headphone Specific Technical Information

Use these Headphones only for the intended applications. Austrian Audio cannot accept any liability for damages resulting from improper handling or misuse.



Complies with IEC 62368-1:2018 for mobile audio equipment.



Hereby, Austrian Audio GmbH declares that the radio equipment type Hi-X25BT is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: <https://austrian.audio>

Headphone Manufacturer Contact Details:

Austrian Audio GmbH
Eitnergasse 15, 1230 Vienna, Austria.



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Section F

Support Details

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

Neuromod Contact Details:

Neuromod USA inc.
1011 Warrenville Road, Suite 150
Lisle, IL 60532,
USA.

Website: www.lenire.com

Designed & Manufactured by:

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

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www.lenire.com

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