

LENIRE[®]



User Manual

Lenire[®] Tinnitus Treatment System

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

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Using this Manual

This manual is supplied with the *Lenire* system 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 the *Lenire* system, including important safety information.

Chapter 1 - Introduction

Lenire® is a medical device intended to reduce the symptoms of tinnitus. It comprises a handheld *Controller* and a *tonguetip*® which, delivers gentle, electrical stimulation to the tongue, and is used in conjunction with wireless *Headphones* that deliver audio stimulation. A *Charger* is included that can be used to charge both the *Controller* and the *Headphones*.

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

Chapter 2 - Intended Use

The *Lenire* device is intended to be used by tinnitus sufferers of at least 18 years of age to alleviate the symptoms of chronic, subjective tinnitus. It should be used for 30 to 60 minutes per day, every day, for at least 10 weeks, after which you may experience sustained alleviation of your tinnitus symptoms.

The *Lenire* device can be used in the home environment after consultation and fitting by a suitably qualified clinician.

Lenire is intended for prescription use only. Use by a person for whom the device has not been configured may cause discomfort, or temporary exacerbation of tinnitus loudness.



Caution! – 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.

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.



There is a possibility that some people may experience a mild allergic reaction to the materials in the device.



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 clinician.



Use of the treatment may result in mild fluctuations in tinnitus symptoms, such as tinnitus loudness.



Headaches may accompany use of the treatment device.

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.



Do not use the *tonguetip* if you have lesions, sores, or inflammation of the oral cavity. Discontinue use of the device until symptoms have resolved.



Do not leave the device in the sun, near 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 battery in your *Lenire* device. Replacement of the battery should be performed by a qualified individual only; attempts to replace the battery by an inadequately trained person 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*.

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, and in the context of the relevant sections throughout this *User Manual*.



Use-by date (year and month). This is the date after which the device should no longer be used.



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 and month).



The device's Serial Number, Lot Number and Model Number appears next to these symbols. You will need these numbers if you call Customer Support for assistance. See page 53 for the manufacturer's contact details.

IP22

Ingress Protection (IP) Rating: IP ratings describe how effectively an enclosure is sealed.

IP22 rated equipment is protected from objects greater than 12mm in diameter being inserted e.g. fingers, and against small amounts of vertically dripping water.



Non-ionizing radiation.



This symbol appears next to the model number of the Charger which should be used to charge the *Controller*.



This symbol signifies that the device should not be disposed of as domestic waste. This ensures compliance with the Battery Directive 2006/66/EC.

LENIRE

The logo for this product range (*Lenire* tinnitus treatment system).



This symbol (direct current) identifies a charging port.



This symbol represents the *tonguetip*.



The USB (Universal Serial Bus) symbol – this is the connection that is used by the Clinician when they configure your device.



This symbol indicates that the *tonguetip* provides a high degree of protection against electric shock (Type BF Applied Part).



Storage and transport temperature limits. The lower limit is indicated near the lower horizontal line and the upper limit is indicated near the upper line.



Storage and transport humidity limits. The lower limit is indicated near the lower horizontal line and the upper limit is indicated near the upper line.



Keep dry.



Fragile, handle with care.



This symbol, the CE Mark, signifies compliance with applicable EU Directives.

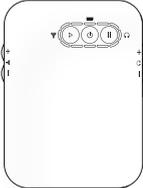
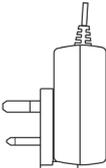
The number (2797) is the Notified Body number for the British Standards Institute (BSI), who approved *Lenire* for CE Marking.

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* system box, you will find:

<p><i>Controller</i></p>	<p>The <i>Lenire Controller</i> (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.</p>	
<p><i>Tonguetip</i></p>	<p>The <i>tonguetip</i> (Model Number TP-101) is a device which provides gentle, electrical stimulation to the tongue.</p>	
<p><i>Charger</i></p>	<p>The <i>Charger</i> (XP Power model VEP08US05-XE0767) is used to charge the <i>Controller</i> and the <i>Headphones</i>.</p>	
<p><i>Carry case</i></p>	<p>The <i>Carry case</i> (Model Number CE-401) is a portable case which can be used to store the <i>Controller</i> and <i>tonguetip</i> in-between uses.</p>	



The *Lenire system* box also contains a *Quick Start Guide* which outlines the basic steps needed to commence a treatment session.

7.1 - Headphones

Lenire must be used in conjunction with a set of Bluetooth *Headphones*. For best performance, it is essential that you use AKG K845BT *Headphones*.

These *headphones* are an accessory that must be used with the *Lenire* system and are made available to you at the time of purchase.



Lenire is designed to work only with the AKG K845 BT *Headphones*, and will not connect to any other Bluetooth devices.

7.2 - Batteries

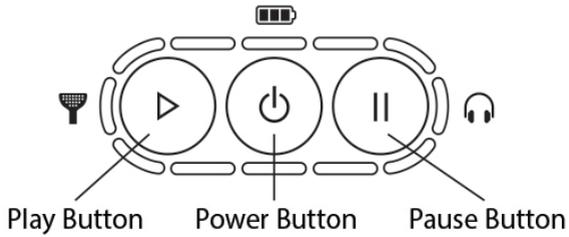
The *Controller* is powered by a 3.7V Lithium Ion battery. The battery is charged using the supplied charger. See chapter 10 for instructions on how to charge the *Controller*. The *Controller* battery is pre-fitted and is not intended to be replaced.

The *headphones* are powered by 3.7V Lithium Ion battery. The *headphones* are also charged using the supplied charger.

See chapter 10 for instructions on charging the *Controller* and *Headphones*. If there are difficulties charging the *Controller* or the *Headphones*, see the section on Troubleshooting or contact Customer Support (See section F).

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**

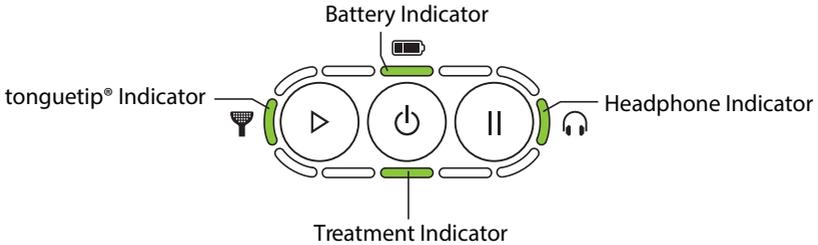
Press this button to start or resume the treatment session.

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 page 20).
Red	The battery is exhausted. The device will shut off automatically. Please charge the device before next use (see page 20).
Orange (Pulsing)	The <i>Charger</i> is connected and the battery is charging.
Green (Pulsing)	The <i>Charger</i> is connected and the battery is fully charged.

Headphones Indicator



Blue (Pulsing)	The <i>Controller</i> is trying to establish a wireless connection to the <i>Headphones</i> .
Green	The <i>Controller</i> is connected wirelessly to the <i>Headphones</i> .
Blue (Pulsing Rapidly)	The <i>Controller</i> is attempting to pair with the <i>Headphones</i> , see page 44 for details.

Tonguetip Indicator



Blue (Pulsing)	There is no <i>tonguetip</i> connected.
Green (Pulsing)	The <i>tonguetip</i> is connected but it is not in contact with the tongue.
Green	The <i>tonguetip</i> is connected and it is in contact with the tongue.
Orange or Orange (Pulsing)	The <i>tonguetip</i> has less than 10 hours of use remaining before expiry. Please purchase a new <i>tonguetip</i> to avoid disruption to your treatment regime.
Red	The <i>tonguetip</i> has expired. Please purchase a new <i>tonguetip</i> 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.

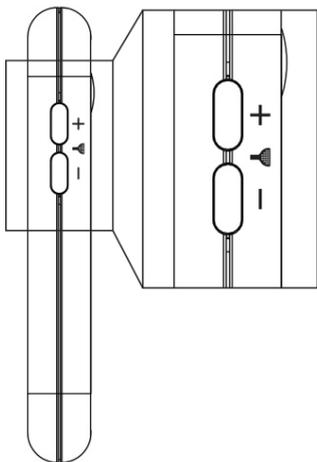


When the device is powered off, none of the lights will be illuminated.

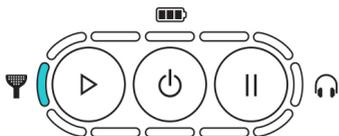
8.3 - Headphones Volume and Tonguetip Stimulus Controls

Tonguetip Stimulation Control

The *tonguetip* stimulation intensity can be adjusted to a comfortable level by pressing the buttons indicated below. Please see page 30 for guidelines on setting the stimulation intensity.

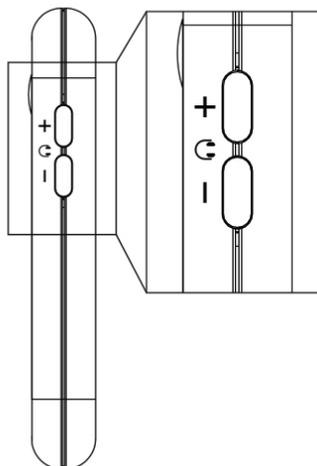


Indication of default (optimum)
tonguetip stimulus intensity

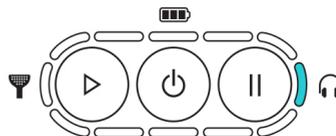


Headphones Volume Control

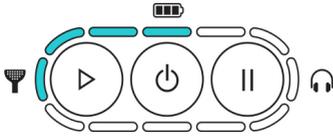
The *Headphones* volume can be adjusted to a comfortable level by pressing the buttons indicated below. Please see page 31 for guidelines on setting the volume level.



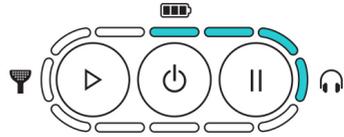
Indication of default (optimum)
Headphones volume level



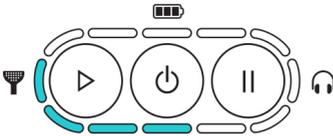
Indication of maximum *tonguetip* stimulus intensity



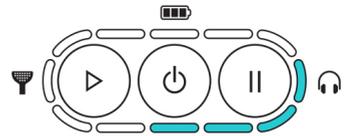
Indication of maximum *Headphones* volume level



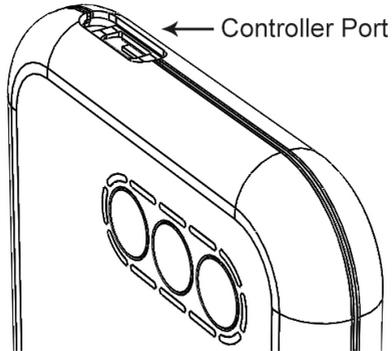
Indication of minimum *tonguetip* stimulus intensity



Indication of minimum *Headphones* volume level



The *Headphones* volume and *tonguetip* stimulus are calibrated to the optimum levels during device fitting by the clinician. For further details, please see page 30.



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 clinician 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 mains if it, or your hands, are wet.

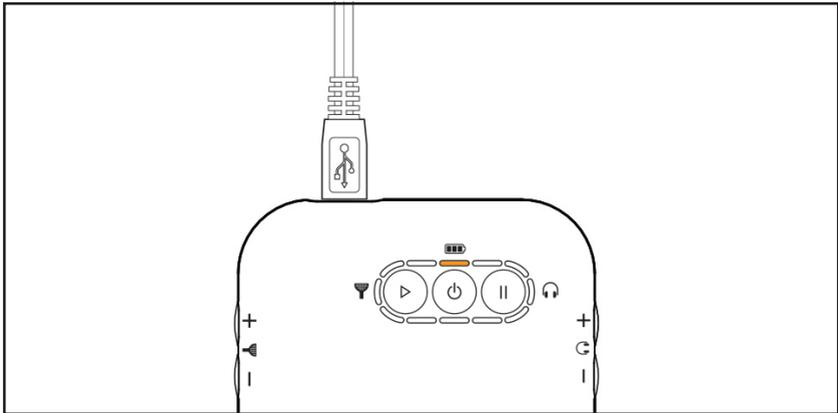


The supplied Charger can be used for charging both the *Headphones* and the *Controller*.

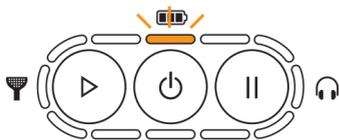
10.1 - Charging the Controller

To charge the *Controller*:

- Plug the cable end of the supplied Charger (XP Power model VEP08US05-XE0767) into the *Controller port* of the *Controller*.
- Plug the Charger into a mains electrical socket.



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





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.

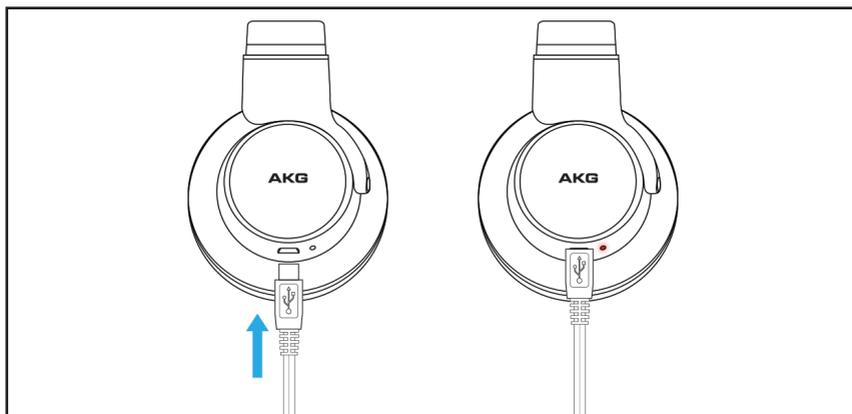


Once the battery is fully charged, the Charger should be disconnected to help conserve the life of the battery in the Controller.

10.2 - Charging the *Headphones*

To charge the *Headphones*:

- Plug the cable end of the supplied Charger (XP Power model VEP08US05-XE0767) into the USB Port of the *Headphones*.
- Plug the Charger into a mains electrical socket.

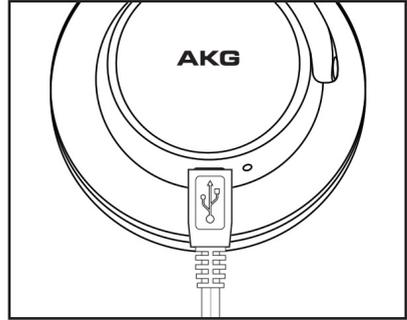


While charging, the light on the *Headphones* will illuminate red. Once the battery is fully charged, the light on the *Headphones* will extinguish.

Battery Charging



Battery Charged



When the *Headphones* battery is running low, the light beside the *Headphones* power button will blink red and the *headphones* will emit a sequence of low-pitch beeps.



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 8 hours.



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.



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.

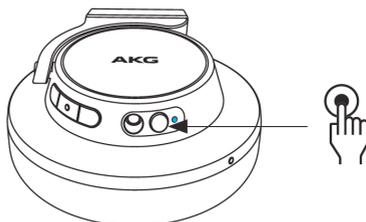
The **left** and **right** sides of the *headphones* are marked **L** and **R** respectively on the cloth inside the foam cushions.



11.2 - Connecting the *Headphones* with the *Controller*

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

- Turn the *Headphones* on by briefly pressing the *power button* (the small circular button). About one second later, the blue light beside this button should start to flash blue, or blue and red if the *headphones* battery is low.



- Turn on the *Controller*, by pressing the *Power Button* for two seconds. The *Controller* will attempt to connect to the *Headphones* during which time the *Headphones Indicator* will pulse blue.
- Once the connection to the *Headphones* has been established, the *Headphones Indicator* on the *Controller* will illuminate green.



The above instruction assumes that the *Headphones* are already 'paired' with the *Controller*. This should be the case in most situations, as the clinician 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 on page 44.



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 protective pouch (made of clear film, designed to be peeled open in the area closest to the V shaped seal).

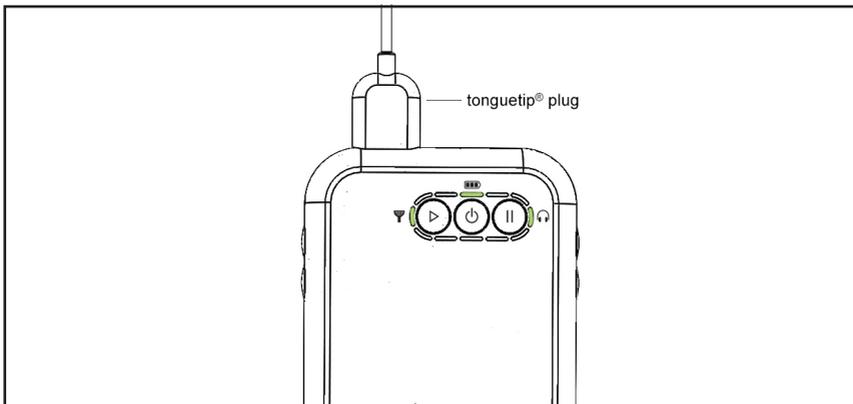


If the packaging is damaged, the *tonguetip* should not be used and it should be returned to the point of sale.



Before connecting and using the *tonguetip* for the first time, it should be cleaned as per the instructions on page 34.

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.

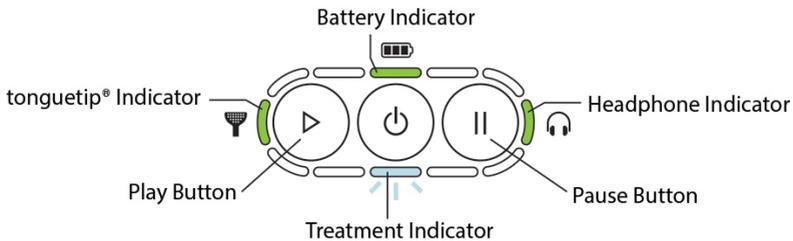


The *tonguetip* model TP-101 is designed to function for 360 treatment sessions (180 hours) before expiring. Indications of imminent expiry and actual expiry are outlined on page 16.

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.



The *Controller* will power off automatically after 20 minutes of being idle (no treatment session in progress). The *Headphones* will automatically power off 30 minutes thereafter. It is not necessary to explicitly power off the *Controller* or 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.



The duration of treatment during a session will remain at 30 active minutes of stimulation. For example, if the treatment is paused for 5 minutes, the total duration of the session would be 35 minutes.

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 Stimulus Levels

13.3.1 - *Tonguetip* Stimulus 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.



The tongue stimulus is calibrated to your sensation thresholds during device fitting by the clinician. 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.



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



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.



The volume control buttons on the *Headphones* should not be used to adjust the volume. Please only use the volume control buttons on the *Controller*.



Depending on your hearing profile, the range over which you can increase the *Headphones* volume level may be limited. This is to ensure that the volume levels remain within safe limits so as not to cause hearing damage.

Chapter 14 - Treatment Guidelines

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

- While the treatment is intended for use 30 to 60 minutes per day, it is recommended that you try to complete at least a 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 disimprove or fluctuate. It is recommended that you continue treatment even during periods where the symptoms disimprove, for the 10 weeks minimum recommended treatment duration. However, if there is a significant disimprovement in your symptoms it is recommended to seek advice from your clinician.



Do not use whilst showering, in rain, or in a moist atmosphere such as a steam bath or sauna. Do not use whilst 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 the *Lenire* system.

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*[®]



Before cleaning the *tonguetip* ensure that it is disconnected from the *Controller*.



Do not expose the Plug end of the *tonguetip* to liquids.

- The *tonguetip* should be rinsed thoroughly with water or distilled water.
- 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.
- 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.

Notes: 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 agent other than IPA or 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.

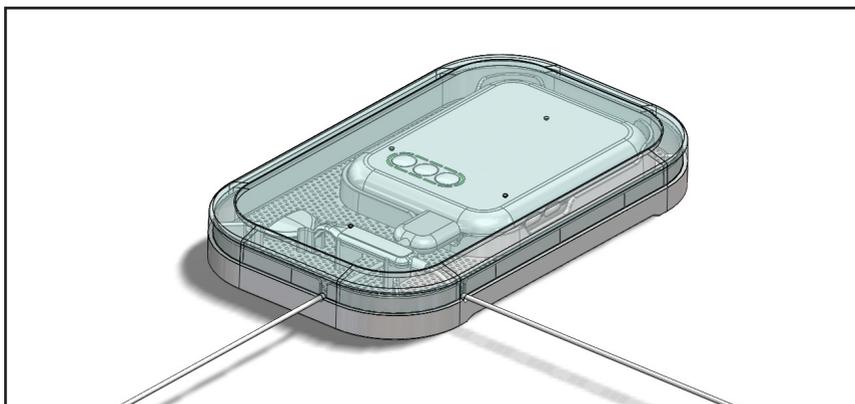


To avoid damaging the devices do not force dry, for example by using a hairdryer, or leaving on top of a heater.

Chapter 16 - Storage and Transport

It is recommended to store the *Controller* and the *tonguetip* in the *Carry Case* (model CE-401) supplied as it has been specially designed to protect them during storage and transport. It can also help maintain the cleanliness of the *tonguetip* in-between uses.

It is not necessary to disconnect the *tonguetip* plug from the *Controller port* before placing them 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:



The *Controller* and the *tonguetip* should be stored in a location that is not too hot, nor too cold (between -20 and 45 degrees Celsius), and that is not excessively humid (relative humidity less than 85%).



The *Controller* has a shelf life of two years, meaning that it should be used for the first time within two years of it being manufactured, otherwise the battery life may deteriorate.

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 -20°C, as indicated near the lower horizontal line and the upper limit, 45°C, as indicated near the upper line.



Storage and transport 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*[®].



If you have any concerns following these inspections, cease using the device and request assistance by contacting Customer Support, see page 53 for contact details.

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 Customer Support. See page 53 for contact details.

Chapter 18 - Disposal

Please consider your personal safety and the environment when disposing of the *Lenire* system. 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 the manufacturer (see page 53 for contact details).



No part of the *Lenire* system 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 Customer Support (see page 53 for contact details).

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 page 20).
- 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 Customer Support (see page 53).

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

- Ensure the *Headphones* are charged (see page 20).
- Ensure the *Headphones* are paired to the *Controller*. If they are not, pair the *Headphones* with the *Controller* again (see page 44).
- 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 Customer Support (see page 53).

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



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



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

- Try adjusting the volume level using the buttons on the side of the *Controller* and using the device in a quiet location. See page 31 for guidelines on adjusting the volume level.

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



It is possible that there may be little or no perceived sensation from the *tonguetip* (see page 30).

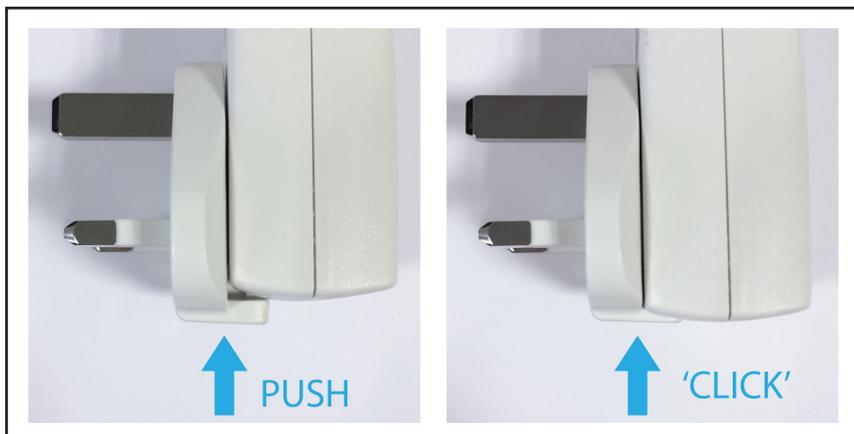
- Ensure that the *tonguetip Indicator* illuminates green (non-pulsing) when the *tonguetip* is making contact with your tongue. If it is not, please contact Customer Support (see page 53).

- Ensure that the *tonguetip* status indicator is not flashing red. If it is then please contact the manufacturer for replacing the *tonguetip* (see page 53).
- Try adjusting the stimulation level using the buttons on the side of the *Controller*.

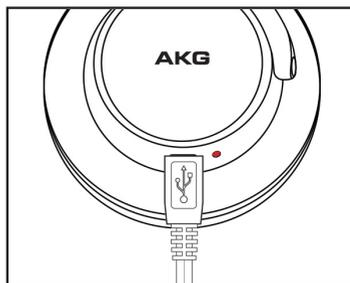
19.5 - What should I do if the *Controller* is not charging?

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

- Check the mains 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 Customer Support (see page 53).



- Retry charging the *Controller* - if there is still not an indication of charging, please contact Customer Support (see page 53).

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 page 20 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 clinician. 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 Customer Support (see page 53).

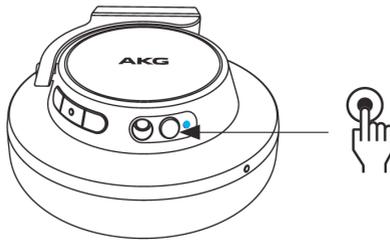
Chapter 20 - Bluetooth Pairing / Un-Pairing

The *Controller* sends audio 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.

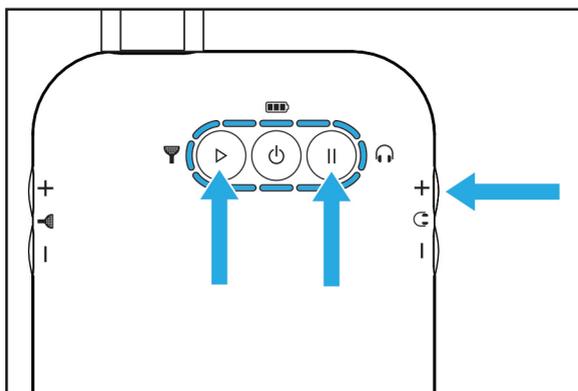
20.1 - Pairing *Headphones* to the *Controller*

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, and then powering them on by briefly pressing the *Headphones* power button as indicated below. The light adjacent to the *Headphones* power button will flash blue rapidly to indicate that the *Headphones* are in pairing mode.



- 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 + 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 Customer Support for repair (see page 53 for contact details).



This device is not intended to be modified in any way.

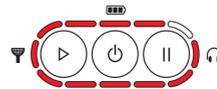
Chapter 22 - Device Errors

If any of the following error indicators occur that prevents the use of the *Lenire* system, please contact Customer Support (see page 53 for contact details). 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.

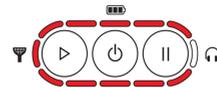
After displaying the error indicator for 5 seconds, the *Controller* will shut down.

Error Indicators

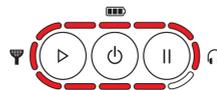
Controller hardware failure.



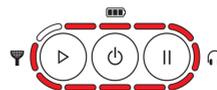
Controller software error.



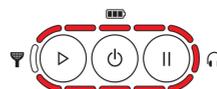
Internal storage error.



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 mobile phones.

Chapter 23 - Environmental Operating Conditions

Lenire should only be used in environments between 5 and 40 degrees Celsius, relative humidity between 15% and 93%, and atmospheric pressure of between 700 and 1060 hPa. This precludes the use at altitudes above 3000m, 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. Its specifications are as follows:

SPECIFICATION	DESCRIPTION
Frequency Band	2.4 GHz to 2.4835 GHz
Modulation	8 DPSK, PI/4 DQPSK, GFSK
Operating Range	20m to 30m
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* system has been tested for electromagnetic performance to the following standards:

- » IEC61000-4-3 (radiated electromagnetic fields)
 - 80 MHz to 2.7 GHz at 10V/m
 - 2.7 GHz to 6 GHz at 3V/m
 - Spot frequencies per EN 60601-1-2:2015 Table 9 at up to 28 V/m

- » IEC 61000-4-2 (Electrostatic Discharge)
 - +/- 8kV Contact Discharge
 - +/- 15kV Air Discharge

- » IEC 61000-4-8 (50Hz/60Hz magnetic fields) at 30 A/m

Disturbances higher than these limits are unlikely to be encountered in the home healthcare or professional healthcare environments.



The *Lenire* system is intended for use in the home healthcare 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.



Portable radio communications equipment (such as mobile phones) may interfere with the performance of the *Lenire* system (including cables as specified by Neuromod Devices Limited) and should be kept at least 30cm away from it when in use. Otherwise, degradation of the performance of this equipment could result.



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 the *Lenire* system (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.

The *Lenire* system has been tested for electromagnetic emissions and complies with CISPR 11 Group 1 Class B and is therefore unlikely to interfere with the operation of other electrical equipment.

Chapter 26 - Materials in Direct Contact with Human Tissue

The *Lenire* system does not contain phthalates, latex, human blood derivatives or cells or tissues of human or animal origin.

The electrodes of the *tonguetip* contain nickel.

Note: For a complete list of materials in contact with human tissue, contact Neuromod Devices Limited.

Chapter 27 - Declaration of Conformity Radio Equipment Directive 2014/53/EU

Hereby Neuromod Devices Limited declares that the radio equipment type are Wideband Data Transmission Equipment in the 2.4 GHz ISM band (operating in the frequency range 2.4 GHz to 2.4835 GHz) per ETSI 300 328 v.2.1.1. is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: www.neuromoddevices.com.

Section F - Customer Support Contact Details

General Contact Details



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



E-mail: info@neuromoddevices.com

Web: www.neuromoddevices.com

Customer Support Contact Details

E-mail: techsupport@neuromoddevices.com

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