



## **Levo<sup>®</sup> System Patient's Manual**

Thank you for choosing Levo. This instruction manual is intended for patient use during idiopathic subjective tinnitus treatment. It is strongly recommended that users read the instruction manual before using Levo.



### **Manufacturer**

Levo Medical Corporation  
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[levomedical.com](http://levomedical.com)

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### Indications for Use

The Levo tinnitus masking device is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

Caution: US federal law restricts this device to sale by or on the order of a physician.













### Contraindications for Use

1. When the patient suffers from secondary tinnitus.
2. When the patient is under 18 years of age.

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## Symbol Definitions

	Manufacturer		Consult instructions for use
	Date of manufacture		Fragile, handle with care
	Serial number		Keep dry
	Unique Device Identifier		Temperature limit
	Rx only		Humidity limit
 No pressure restrictions for shipping and storage	Atmospheric pressure limitation		Applied Part Type B

## Typographical Conventions



**Warning.** Information relating to potential dangers when using the Levo System.



**Information.** Useful information related to the operation of the Levo System.



**Precaution.** Important information to prevent possible harm when using the Levo System.

### Important Safety Information



**AC Power:** The Levo Patient Device (iPod touch ®) is designed to suspend audio output while charging. Users should never attempt to complete therapy while the charging cable is connected to the iPod. Therapy can be resumed once the charging cable is removed. Users should ensure that the iPod touch is fully charged prior to commencing therapy or sound match sessions.



**Radio frequency interference:** Observe signs and notices that prohibit or restrict the use of electronic devices (for example, in healthcare facilities or blasting areas). Although the iPod touch is designed, tested, and manufactured to comply with regulations governing radio frequency emissions, such emissions from iPod touch can negatively affect the operation of other electronic equipment, causing them to malfunction. Turn off iPod touch or use Airplane Mode to turn off the iPod touch wireless transmitters when use is prohibited, such as while traveling in aircraft, or when asked to do so by authorities.



**Medical Devices:** The iPod touch contains radios that emit electromagnetic fields, and contains magnets near the bottom. The included headphones also have magnets in the earbuds. These electromagnetic fields and magnets may interfere with pacemakers, defibrillators, or other medical devices. Maintain at least 6 inches (approximately 15 cm) of separation between your pacemaker or defibrillator and iPod touch or the earbuds. If you suspect iPod touch is interfering with your pacemaker or any other medical device, stop using the device and consult your physician for information specific to your medical device.



**Existing Conditions:** The Levo Patient Device should not be used by patients with physical ear deformities or with ear irritation.



**Damage to Device:** If the Levo Patient Device is damaged in any way, immediately stop using it and contact your healthcare professional.



**Accessories:** Only Levo Medical Corporation-approved accessories should be used with the Levo Patient Device.

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**Earbuds:** Use only earbuds provided with the Levo Patient Device by Levo Medical Corporation. The use of any other earbuds may produce sound volumes that can impair hearing.



**Sound Pressure Levels:** The Levo System can apply sound levels up to 85dB SPL to the patient's ears. In addition to providing temporary relief from tinnitus, this may cause changes to hearing.



**Unexpected Side Effects:** The user should discontinue use and seek medical advice if any of the following conditions occur:

- Chronic skin irritation on, near, or around the site of device placement, e.g. ears.
- Unusual side effects, e.g. dizziness, nausea, headaches, heart palpitations.
- Perceived decrease in auditory function, e.g. decreased loudness, speech not as clear.



**iPod touch Battery:** Do not attempt to replace the iPod touch battery yourself—you may damage the battery, which could cause overheating and injury. The lithium battery in the iPod touch should be replaced only by Apple® or an Apple Authorized Service Provider, and must be recycled or disposed of separately from household waste. Don't incinerate the battery.



**Healthcare Provider's Therapy Plan:** The user should always follow the advice of the healthcare professional and follow the healthcare professional's therapy plan when using the Levo Patient Device.



**Software Failure:** In the unlikely event the software does not start as expected stop using the Levo System and contact your healthcare professional.



**Use Environment:** The Levo System is designed to be used only in home or clinical settings. Usage in any other environment is not recommended. In particular, usage of the Levo Patient Device while driving, operating machinery, or while engaged in any activity that requires concentration or attention to audible signals, is strongly discouraged.

## 1 Description

The Levo software is supplied pre-installed on an Apple iPod touch and comes with a pair of Levo earbuds.

To learn about ear bud safety precautions, please see *Section 5 Ear bud Information*.

The iPod touch running Levo is powered by an internal battery and is intended for continuous operation. See *Important Safety Information* for restrictions on use while the device is charging and while you are engaged in tasks that require concentration or audible attention. Levo Medical Corporation recommends that users ensure the iPod is fully charged before commencing a therapy session.

## 2 Environmental Conditions

Levo and the iPod touch are designed to work in ambient temperatures between 32° and 95° F (0° and 35° C) and stored in temperatures between -4° and 113° F (-20° and 45° C). The iPod touch can be damaged and battery life shortened if stored or operated outside of these temperature ranges. Avoid exposing the iPod touch to dramatic changes in temperature or humidity.

When you are using the iPod touch or charging the battery, it is normal for the iPod touch to get warm.

When using Levo to provide treatment, please confirm the iPod touch is resting in a secure place so that the earbuds will not move or disconnect.



The Levo System should not be used in a wet or humid environment.

### 2.1 Interference



This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference to other radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna (that is, the radio or television antenna that is “receiving” the interference).
- Reorient, or relocate, or increase the separation between the Levo equipment and receiving antenna.
- Connect the Levo equipment into a power outlet on a circuit different from that to which the receiving antenna is connected.

### 3 Set Up

The Levo System includes an iPod touch running the Levo application, a set of earbuds, a cleaning tool for the earbuds, a 5 pack of silicone earbuds tips, a storage pouch, a Quick Reference Guide (QRG) and this owner’s manual.

The first time the Levo application is opened, a Levo End User License Agreement will appear on the screen. To proceed, read and accept the terms of this license, and then tap the *Accept* button. The Levo application will now start.

### 4 Starting Levo

Before starting, it is important to understand how Levo works. Levo has two main modes of operation: Appointment Mode and Therapy Mode.

The **Appointment Mode** allows you to create a connection between your iPod touch and your healthcare professional’s iPad®. This enables your healthcare professional to create and adjust your therapy and to see how it is progressing. A Levo healthcare professional is a qualified healthcare professional in the field of hearing that is familiar with the management of tinnitus, such as audiologists, Ear, Nose and Throat doctors, and audiology technicians.

The **Therapy Mode** is what you use to run your customized therapy.

The **TFI Mode** allows you to take a Tinnitus Functional Index (TFI) questionnaire and save the results for later consultation with your healthcare professional.

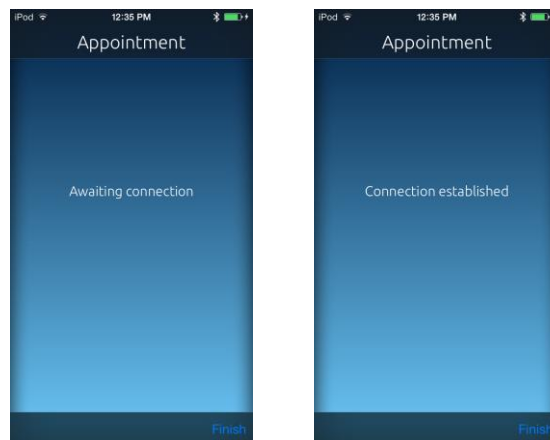
#### 4.1 Appointment Mode

When starting a session with your healthcare professional, a connection between your iPod and the healthcare professional’s iPad® must be made.



### 4.1.1 Creating a Connection

1. Unlock the iPod touch.
2. Make sure Bluetooth and Wi-Fi are enabled in Levo. If you are planning to use Wi-Fi, both your iPod and your health care professional's iPad must be connected to the same network.
3. Start the Levo application.
4. When your healthcare professional instructs you to do so, tap the *Appointment* button on the main screen.
5. The connection will be established.



Wireless communication with your healthcare professional's iPad® should be trouble free. However, if communication problems are experienced, identify any sources of interference in the vicinity; for example, microwave ovens and portable or mobile Radio Frequency communication equipment such as wireless security cameras, cordless phones, baby monitors and cable wireless TV extenders. Either relocate or switch off these items, or use the Levo System in another area.

### 4.1.2 Ending a Connection

You or your healthcare professional can end the connection.

If your healthcare professional ends the connection, a pop-up will appear notifying you that your connection has ended. Tap *OK* when instructed by your healthcare professional.

If you wish to end the connection, you can simply tap on the *Finish* button, however, it is strongly recommended that you wait for your healthcare professional to end the connection to avoid loss of important therapeutic information.



Do not end an appointment connection unless your healthcare professional instructs you to do so. Important information can be lost.

### 4.2 Therapy Mode



The Levo System can introduce loud sounds to your ears. In addition to providing temporary relief from tinnitus, this may cause changes to your hearing. Discontinue use immediately and seek medical advice if you notice a change in your hearing.



Your health provider will provide advice on treatment duration and frequency. Do not exceed these values without consulting your healthcare professional first.

Your therapy can only be performed while you are asleep.

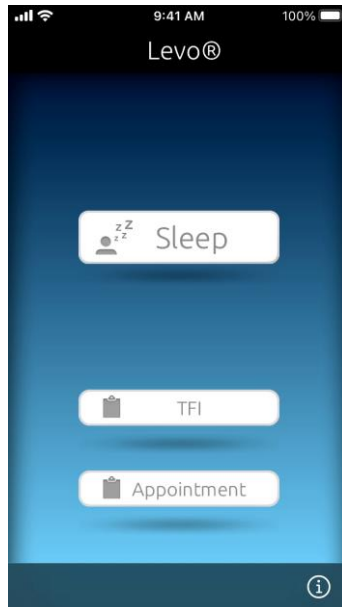


**Use Environment:** The Levo System is designed to be used only in home or clinical settings. Usage in any other environment is not recommended. In particular, usage of the Levo System while driving, operating machinery, or while engaged in any activity that requires concentration or attention to audible signals, is strongly discouraged.

To begin therapy:

1. Connect the earbuds.
2. Unlock the iPod touch.
3. Open the Levo app.
4. Tap on the *Sleep* on the main screen.

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All data regarding your therapy session will be stored automatically on the iPod touch and then transferred to your healthcare professional during your next appointment. This allows the healthcare professional to see your therapy process and progress.

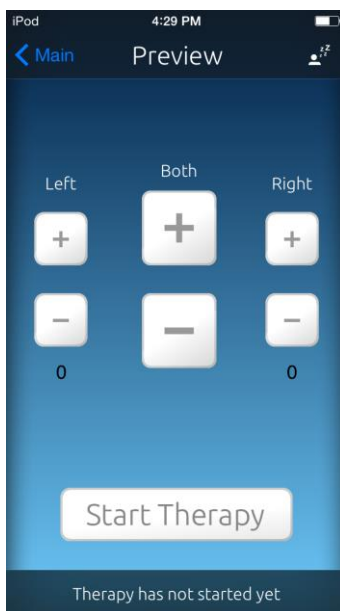
### 4.2.1 Therapy During Sleep

This therapy is to be used during sleeping hours (up to 8 hours). When selecting *Sleep* on the main screen, a Preview screen will appear.

#### 4.2.1.1 Starting Therapy During Sleep

1. Open the Levo application.
2. Select *Sleep* from the main menu. The Preview screen will open. This screen allows you to make volume adjustments before the therapy starts.



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### 4.2.1.2 Modifying the Therapy During Sleep Volume

Therapy volume can only be modified if your healthcare professional has enabled this option during an appointment. If it is not enabled, then you cannot change the volume of your therapy.

Therapy volume can be modified before therapy begins from the Preview screen, or directly during therapy from the Therapy screen.

You can adjust the left or right ear volume separately, or both at the same time. To increase the volume, tap the  button. To decrease the volume, tap the  button.

**Note:** Therapy volume may be lowered as much as necessary. Increasing volume is limited to six steps. The Levo System will not produce sounds exceeding the safe volume limit. When this point is reached, the  button will no longer respond.



Before going to sleep, the Levo System should be placed in a manner that will prevent the cord from becoming tangled with the user and creating a potential strangulation risk.



If the volume is too loud and you are having difficulty changing the volume, or this option is not enabled, please discontinue use and contact your healthcare professional immediately.



Ensure that the battery is fully charged before attempting to use the Levo System.



Ensure that the therapy is started before going to sleep.

### 4.2.1.3 Pausing Therapy

If you need to temporarily interrupt your therapy, you can pause the system and resume afterwards.

1. Tap *Pause* on the Therapy screen.
2. To resume therapy, tap *Play*.



If the earbuds become disconnected from the iPod touch the therapy will pause. To resume therapy, plug in the earbuds and the therapy will continue automatically.

### 4.2.1.4 Ending Therapy

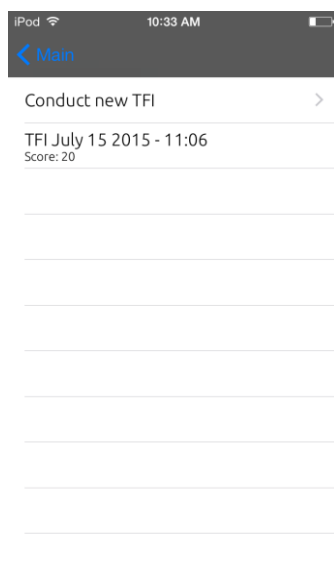
Therapy can be turned off at any time by simply tapping *Finish*.

**Note:** Therapy will conclude automatically after the session has reached its maximum duration. Your healthcare professional will set this predetermined length (8 hours maximum) during your appointment. When you stop listening to the therapy before it reaches the maximum duration, you shall tap *Finish* so your healthcare provider knows the exact stimulation time.

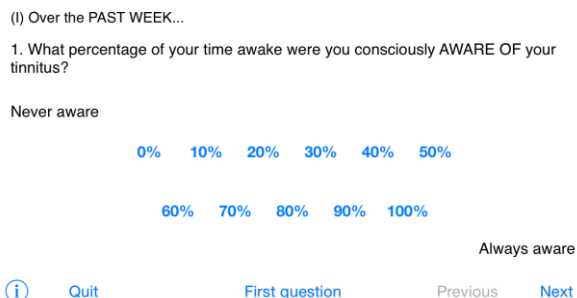
## 4.3 TFI Mode

The **TFI Mode** allows you to take a Tinnitus Functional Index (TFI) questionnaire and save the results for later consultation with your healthcare professional.

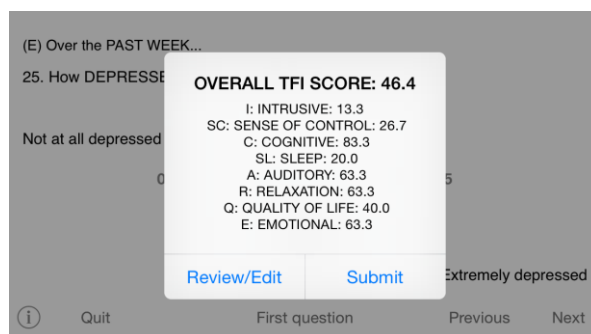
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1. Tap *TFI* on the main screen
2. To begin a new TFI questionnaire, tap *Conduct new TFI*
3. For each question, tap the number that corresponds to your experience over the past week
4. Tap *Next* to continue on to the next question, *Previous* to return to the last question or *First Question* to start over



5. After answering the final question, tap *Next* to see your score. If you have to alter any of your answers, press *Review/Edit*, otherwise, tap *Submit* to log your results



### 5 Ear bud Information

The earbuds are considered a Type B applied part. They are part of a medical device that has been specifically tuned to meet each patient's needs. It is important to operate and maintain this equipment properly.



Type B Applied Part

#### 5.1 Important Safety Precautions



Only use Levo Medical Corporation approved earbuds with the Levo Patient Device.



The earbuds supplied with the Levo System are only intended for use by a single patient. Do not share your earbuds with any other person.



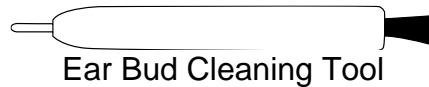
- Avoid dropping or strong impact to the Levo earbuds.
- Do not pull on the cable to remove earbuds.
- Do not leave the ear bud cable where it can be tripped over.
- Do not expose the earbuds to extreme temperatures such as a hairdryer or closed automobile in the sun.
- Keep earbuds away from water and dust. Avoid using the earbuds while showering, swimming, or exercising.
- Periodically inspect the earbuds for cracks or damage. If damaged, stop use and consult your healthcare professional.

#### 5.2 Maintenance and Cleaning

Keeping your earbuds clean is essential! Earwax, body oils and perspiration can clog the sound port located at the tip of the ear bud. A clogged sound port can impair sound transmission.

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To clean the sound ports, use the cleaning tool that comes with the earbuds. Use the wire loop to unclog the residue and then use the brush to clear it away. Do not use other sharp cleaning tools to unclog the ear bud.



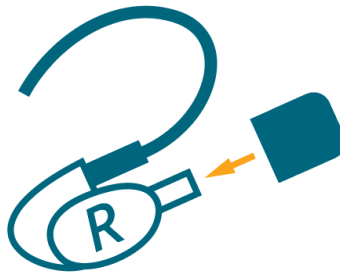
The external portion of the earpieces must be cleaned with alcohol-free wipes only. Alcohol can damage ear bud components.

It is recommended that the cleaning tool be used to clean the earbuds before and after each use to assure a proper sound transmission.

### 5.3 Inserting Earbuds

With a little practice, inserting your Levo earbuds will become quick and easy. Just follow these simple steps:

1. Insert ear tips and identify earbuds marked (R) for Right and (L) for Left.



2. Align earbuds at the ear canal, with cord facing forward and slightly downward.



3. Insert ear tip into ear canal and rotate earpiece backwards into position.





### 5.4 Removing Earbuds

Never pull on the cable to remove the earbuds from your ear! Reach behind the back portion of the ear bud and remove it.

## 6 Contact Information

Please contact your healthcare professional if assistance is needed.

To obtain a list of healthcare professionals, please visit the Levo Medical Corporation website: [www.levomedical.com](http://www.levomedical.com)

## 7 Hardware Specifications

Description	Specification
Communication with Healthcare Professional	Bluetooth 4 (2.4GHz) or WiFi 802.11n (2.4 & 5 GHz)
Maximum Therapy Duration	8 hours
Protection Against Water or Particulate Ingress	None Specified
Protection Against Electric Shock	Applied Part Type B
Levo Patient Maximum Volume	85dB $\pm$ 1dB (SPL)
Levo Patient Frequency Response	100 - 16 000 Hz
Ear Bud Cable Length	1320 +/- 30 mm
Ear Bud Sensitivity	88.0 dB SPL for 0.1V @ 1kHz
Operating Temperature Range	0 to 35°C (32 to 95°F)
Storage Temperature Range	-20 to 45°C (-20 to 113°F)