



Earlens® Contact Hearing Solution Patient Instructions

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1. Introduction

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

Rx ONLY

For hearing healthcare professional instructions, please see *Earlens® Contact Hearing Solution Hearing healthcare professional Instructions*. For physician instructions, please see *Earlens® Contact Hearing Solution Physician Instructions*.

2. Earlens® Contact Hearing Solution Device Description

The *Earlens® Contact Hearing Solution* uses resonant inductive coupling to transmit and receive sound information from a Processor and Ear Tip to a Tympanic Lens (Lens). The Earlens® Contact Hearing Solution includes the following components:

- Lens
- Processor
- Ear Tip
- Earlens® Fitting Software
- Charger with Power Adapter
- Earlens® Impression System
- Mineral Oil
- Earlens® Control Mobile Application

2.1 Tympanic Lens (Lens)

The Lens (Figure 2) is designed to receive electromagnetic energy from the Processor and Ear Tip and convert it into mechanical vibrations of the tympanic membrane (TM). These vibrations are perceived as sound. The Lens is customized for each patient and is placed in to position by a trained physician. It is placed at the end of the ear canal on the skin around the TM.

2.2 Processor and Ear Tip

The Processor features microphones, a digital signal processor, and a rechargeable battery. The Ear Tip connects directly into the Processor via the cable connector (Figure 3). Sound waves are collected by the microphones on the Processor, converted into electrical signals, and digitally processed. The electrical sound information is converted into an electromagnetic signal that is transmitted by a coil located in the Ear Tip and is then received by the Lens.

The Processor also features a wireless antenna that allows for direct connectivity with select smartphones and tablets. The use of this feature is optional. Information on settings and use of the wireless functionality can be found in Section 10 of this IFU. For additional information, please contact your Earlens® support team or visit www.earlens.com/connectivity.

The Ear Tip features a vent and can be physically modified by a hearing healthcare professional to improve fit. The cable can be exchanged by a hearing healthcare professional.

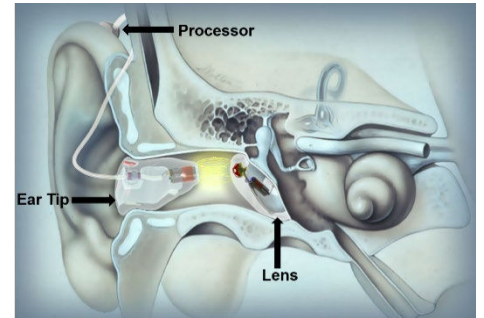


Figure 1: Earlens component schematic

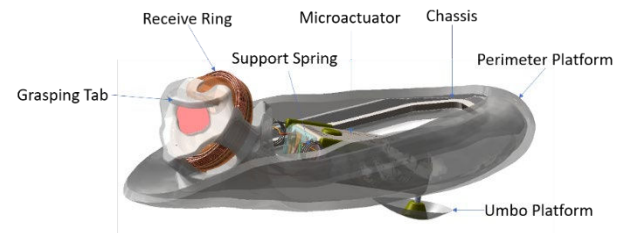


Figure 2: Lens

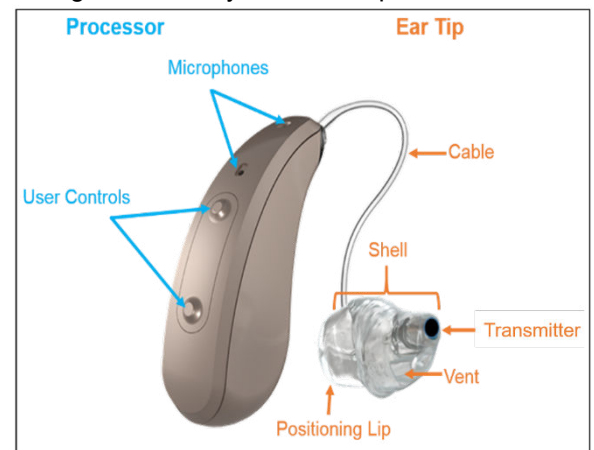


Figure 3: Processor & Ear Tip

2.3 Earlens® Fitting Software

The Earlens® Fitting software is used to program the Processor, enabling the hearing healthcare professional to calibrate and program the device to your specific needs.

2.4 Earlens® Charger and Power Adapter

The Charger is designed to recharge the Processors (Figure 4). When connected to the wall power adapter, the Charger houses and charges either one or two Processors simultaneously. An AC wall power adapter is included.

2.5 Earlens® Impression System

The Earlens® Impression System is used by the physician to collect a deep ear canal impression. The impression is used to manufacture the customized Lens and Ear Tip.

2.6 Mineral Oil

White mineral oil (food grade) is used to lubricate the eardrum to keep the Lens in place and functioning properly. It is recommended that you apply one pump of mineral oil to your ears every other day or as directed by your physician.

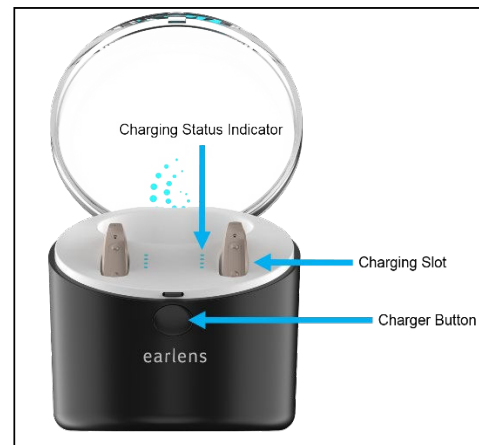


Figure 4: Earlens Charger

3. Indications for Use

The Earlens® Contact Hearing Aid transmits amplified sound by vibrating the eardrum through direct contact. It is indicated for individuals 18 years and older with a mild to severe sensorineural hearing impairment who can benefit from amplification. The device can provide the full spectrum of amplification that includes 125 Hz – 10,000 Hz.

4. Fitting Range

The Earlens® Contact Hearing Solution provides the full spectrum of amplification, providing access to speech signals across a frequency range from 125 Hz – 10,000 Hz. The audiometric fitting range is shown in Figure 5.

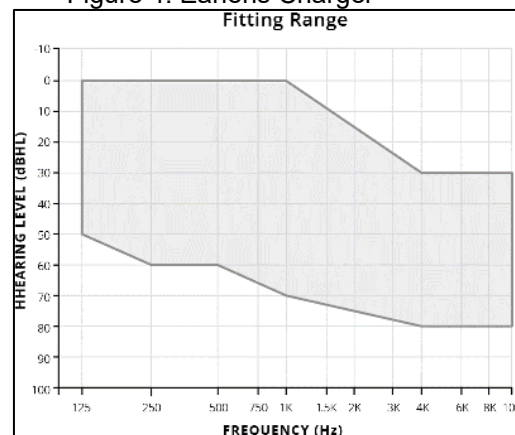


Figure 5: Earlens Fitting Range

5. Contraindications

The patient must not have any known or active medical issues that would preclude them from having a hearing device, including:

- An abnormal TM (deemed perforated, inflamed or has dimeric or monomeric area, or in any other way abnormal).
- An abnormal middle ear or a history of prior middle ear surgery other than tympanostomy tubes.
- An ear canal anatomy that prevents the physician from seeing an adequate amount of the TM.
- An anatomical configuration of the external auditory canal that prevents satisfactory placement of the Lens.
- A history of chronic and recurrent ear infections in the past 24 months.
- A rapidly progressive or fluctuating hearing impairment.
- Diagnosed with having a compromised immune system which may impact the tissue of the auricle or ear canal, such as keratosis obturans, ichthyosis, eczema of the auricle or ear canal, received radiation of the head at any time, or chemotherapy for cancer within the last six years.

Note: Once the otologic and audiologic indications for use were met, approximately 95% of patients were successfully fit with the Earlens® Contact Hearing Solution (5% were unable to anatomically accommodate the Lens).

6. Warnings



Before using the Earlens® Contact Hearing Solution, make sure you read and understand each of the following safety warnings:

- The Earlens® Contact Hearing Solution is considered MR unsafe. The Lens should be removed prior to an MRI exam or MRI exposure. **Only physicians trained in Ear, Nose & Throat procedures should place or remove the Lens.**
- You should not use therapeutic or medical diathermy using electromagnetic radiation (magnetic induction coils or microwave) from the shoulders up with Earlens® Contact Hearing Solution in place.
- Should any part of the Aid become damaged, discontinue use and contact your hearing healthcare professional.
- If you experience discomfort or pain in your ear, you should contact the ENT physician immediately. Only physicians trained in Ear, Nose & Throat procedures should place or remove the Lens.
- Do not insert foreign objects into your ear, such as Q-tips, bobby pins or fingernails. Insertion of foreign objects could result in pain and damage to the ear, damage to the Lens or cause it to operate improperly.
- Contact your hearing healthcare professional if you experience discharge from the ear or persistent discomfort or any other problems.
- Should the Processor become unusually warm or hot, promptly remove it, discontinue use and contact your hearing healthcare professional.
- Do not crush, short circuit, modify or disassemble any component of the Earlens® Contact Hearing Solution. Keep all components of the Earlens® Contact Hearing Solution out of the reach of children, pets and others, to avoid risk of swallowing.
- Do not incinerate any component of the Earlens® Contact Hearing Solution or use near open flame. Handle waste from electronic equipment per local regulations.

7. Precautions

The following section includes technical terminology that may be unfamiliar to you. If you have any questions, contact your physician or hearing health care professional.



Before using the Earlens® Contact Hearing Solution, make sure you read and understand each of the following safety precautions.

- If you have known nickel sensitivity/allergy, please be aware that the Lens and Ear Tip components contain nickel that is coated with a parylene barrier. If you develop an allergic reaction, the Lens and Ear Tip should be promptly removed.
- The Lens and Ear Tip were tested for nickel leaching and found to be compliant and within the safe levels identified in European standard EN1811. Traces of oxidation (discoloration) may be visible on the Lens surface following prolonged wear. Testing indicated the oxidation was not likely to affect the structural integrity of the Lens and Ear Tip within the 1 year expected life.
- Only healthcare professionals trained in the fitting of hearing aids may fit the Processor and Ear Tip.
- The Earlens® Contact Hearing Solution is custom designed and intended to be used only by a single patient.
- The Ear Tip is designed to sit a set distance from the Lens. Sound output may deviate if the Ear Tip is not inserted to the proper depth. If the sound output does deviate, you can reposition the Ear Tip until optimal sound output is achieved.
- Earplugs or headphones can be used with the Lens in place as long as care is taken not to over-insert them and they do not protrude deeply into the ear canal.
- You may shower, bathe or swim with the Lens in place. Ear plugs may be used to prevent water

- from entering your ears so long as care is taken to not over-insert them. Removing water from ears may be more difficult with the Lens in place.
- If you have small or unusually shaped ear canals, you may be at greater risk for ear canal abrasions, either from the ear impression procedure or from Ear Tip use.
 - You should avoid getting the Processor wet, as it may damage the device. You must remove the Processor prior to showering, swimming, or bathing.
 - You may experience a reduction in your hearing levels when the Lens is in place but the Processor is not activated.
 - Do not direct streams of liquid (i.e. isopropyl alcohol, hydrogen peroxide, DeBrox®) into your ears, as this may cause the Lens to become dislodged or cause damage to the device.
 - Failure to oil your ear canal may result in Lens displacement.
 - Do not place any component of the EarLens® Contact Hearing Solution into a microwave, or near a significant source of static electricity.
 - Use only the EarLens® Charger and AC wall adapter provided. Although other adapters may look similar, they may cause damage to the EarLens® Contact Hearing Solution.
 - Handle the components carefully and prevent hard knocks. Do not drop them as it may damage the EarLens® Contact Hearing Solution.
 - If the EarLens® Processor fails to operate or if it appears damaged, including the presence of battery leakage or swelling, promptly remove the Processor, discontinue use and contact your hearing healthcare professional.
 - Only clean the Processor with a soft cloth. Do not use chemicals (i.e. hairspray) in close proximity or to clean the Processor.
 - Keep Charger cord out of reach of individuals who may be at risk of strangulation.
 - Electromagnetic fields produced by other electrical equipment such as cell phones, metal detectors, microwaves, RFID systems and commercial theft detection systems (also known as electronic article surveillance [EAS]) may interfere with the EarLens® Contact Hearing Solution. In the event that you perceive unexpected noise or interference in the presence of these devices, move away from the source to mitigate the potential interference. If you have further concerns you should remove the Processors and contact your hearing healthcare professional.

8. Risk/Benefit (Information summarized from the 2015 Definitive Study)

The following section includes technical terminology that may be unfamiliar to you. If you have any questions, contact your physician or hearing health care professional.

The Definitive Clinical Study of the EarLens® Contact Hearing Solution confirmed the safety and effectiveness of the EarLens® Contact Hearing Solution for individuals with a mild to severe sensorineural hearing impairment between the frequencies of 125 Hz-10,000 Hz. The prospective, single arm study assessed 48 subjects (96 ears) who wore the fully activated EarLens® Contact Hearing Solution in both ears in their daily lives for four months per study protocol. Safety and effectiveness were assessed during the four months.

8.1 Study Demographics

The average age of the study population was 69 years with a gender ratio of 60% for males and 40% for females. All participants were experienced hearing aid users.

8.2 Safety Outcomes

The primary safety endpoint was intended to demonstrate that use of the EarLens® Contact Hearing Solution did not result in a change in residual hearing function. After wearing the Lens for 4 months, no decrease in hearing sensitivity of more than 10 dB was observed. A secondary safety endpoint assessed any decrease in hearing sensitivity of >10 dB by subject per ear at each test frequency. After four months of use no subjects exhibited a decrease of >10 dB at either ear by frequency.

8.3 Adverse Events

No serious device or procedure-related adverse events were reported during the trial. There were 31 adverse events (AEs) reported in 20 subjects for 22 ears. All but one of the adverse events were temporary and resolved. One subject report of a ‘fullness’ sensation when wearing the Earlens® Contact Hearing Solution did not change during the trial. Effectiveness outcomes were not impacted and the subject continued device use throughout the study period of four months. Table 1 identifies the adverse events by type, frequency of occurrence and resolution status at the conclusion of the study.

Adverse Event Category	Number Occurring	Serious AE	Status
Abrasion/blood blister in ear canal	17	No	Resolved
Ear discomfort/pain	5	No	Resolved
Inflammation/granulation tissue on tympanic membrane	3	No	Resolved
Abrasion/blood blister on tympanic membrane	2	No	Resolved
Ear tip-related: ear canal swelling, itching, etc.	2	No	Resolved
Pain upon eructation & valsalva	1	No	Resolved
Sensation of fullness	1	No	Ongoing

Table 1: Adverse events across study period

8.4 Effectiveness Outcomes

The primary efficacy endpoint was intended to demonstrate device effectiveness by improving speech recognition using the Northwestern Auditory Test No.6 (NU-6) test of word recognition with the Earlens® Contact Hearing Solution at a speech level of 45 dB HL. The objective was to show that the Earlens® Contact Hearing Solution provides a statistically significant improvement in mean aided word recognition at 30 days post placement when compared to the baseline unaided condition measured prior to placement. The average baseline unaided score was 52% and the average aided score was 85% (Figure 6); this improvement was statistically significant ($p < 0.0001$). A secondary measure of device effectiveness was defined as more than 10 dB improvement (functional gain) in thresholds over the range of frequencies from 2,000 to 10,000 Hz for aided thresholds measured at 30 days post placement when compared to unaided thresholds measured prior to placement. Mean functional gain was 30.5 dB ($p < 0.0001$), indicating that the Earlens® Contact Hearing Solution was able to deliver significant functional gain (Figure 7). Functional gain reached a maximum of 68 dB at 9,000-10,000 Hz.

Word Recognition (n = 78 ears)

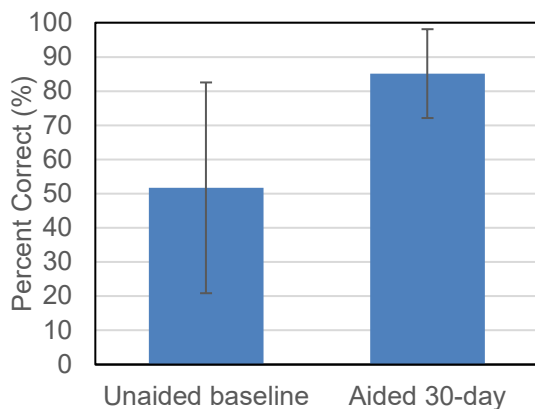


Figure 6: Word Recognition

Soundfield Thresholds (n = 78 ears)

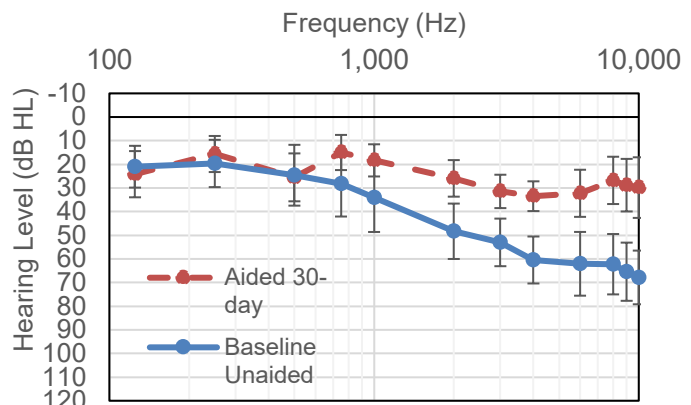


Figure 7: Sound field thresholds

An additional measure of device effectiveness was perceived benefit as measured by the Abbreviated Profile of Hearing Aid Benefit (APHAB). The average baseline unaided percentage of communication difficulties was 58% (standard deviation = 16%), the percentage of difficulties decreased to 30% (standard deviation = 13%) with the subject's own air conduction hearing aid, and for Earlens it was 29% (standard deviation = 14%). 92% of subjects completing the study (35 out of 38) perceived a clinically significant improvement for Earlens relative to unaided as measured by APHAB.

8.5 Temporary TM Damping

The Lens is designed to remain in place even when the Processor is not worn. When the Processor is removed (while swimming, bathing, or sleeping), users may experience TM damping, which would be interpreted as slight reduction of sound, due to the loading effect of the Lens. The effect on PTA (500 Hz, 1000 Hz and 2000 Hz) averaged 4 dB, which is immediately reversed when the Lens is removed. When the Processor is in place, the gain delivered by the Earlens® Contact Hearing Solution more than overcomes the TM damping effect.

8.6 Summary of Extended Study

The safety and effectiveness of the Earlens® Contact Hearing Solution was monitored beyond the 4 months of the Definitive Study. In the Extended Study, 24 subjects (48 ears) opted to continue wearing the Earlens® Contact Hearing Solution after completing the Definitive study. At the conclusion of the Extended Study, 33 ears had at least 12 months of cumulative Lens wear with no change in unaided air conduction hearing thresholds under earphones. Of the 24 active subjects in the Extended Wear Study, 11 related adverse events (AEs) AEs were experienced by 8 subjects in 10 ears. All events were temporary and resolved. Nine of 11 AEs were related to ear cleaning pre-impression (3 AEs), the impression procedure (4 AEs), or the inspection process pre-impression (2 AE). Two of the related AEs were attributed to Ear Tip fit and both were resolved after Ear Tip modification. One subject continues to report a sensation of fullness.

Based on the results of the Definitive study, the Earlens® Contact Hearing Solution has been shown to be safe and effective in delivering the full spectrum of amplification from 125Hz to 10,000Hz

9. Operating Instructions

9.1 Wearing the Lens

- An Ear, Nose and Throat (ENT) physician places the Lens in your ear(s), where it will remain in place 24 hours a day. If needed, the Lens can be removed by the ENT physician.
- The Lens can remain in place during normal activities such as showering, bathing, swimming, flying in a plane, going through a metal detector, etc.
- The Lens is **MR unsafe** and must be removed by an ENT physician prior to undergoing an MRI.
- The Lens requires maintenance by application of mineral oil.

9.2 Daily Maintenance Oiling

Oiling is required to keep the Lens in place and functioning properly.

- Apply one pump of mineral oil to the ear canal every other day or as instructed by your physician.
- Use only the oil and container provided and/or recommended by Earlens.
 1. Prepare the mineral oil dispenser by rotating the nozzle until it is at a right angle.
 2. Depressing the pump until a consistent stream of oil is observed.
 3. With head in an upright position, place the tip of the mineral oil dispenser into the ear canal opening.
 4. Dispense one pumps of oil into the ear canal by depressing the pump.
 5. Remove the dispenser from the ear and tilt head to the side. Allow the oil to run down to the eardrum by keeping your head tilted for approximately 1 minute. You may hear or feel the oil as it touches and wets the eardrum.

6. Repeat above steps for the opposite ear.
 7. After oiling, your ears may feel a little stuffy. This should subside on its own when the oil is absorbed.
 8. Re-apply oil as directed by your physician. Do not flood your ear canals with oil as this will dampen your hearing temporarily.
- Applying mineral oil at night may reduce the damping effect of oil.
 - Regular application of mineral oil will help reduce the presence of ear wax.
 - Reapply oil should you go swimming or do an activity that causes your ear canals to fill with water.

9.3 Ear Cleaning

- Regular application of mineral oil will help reduce the presence of ear wax.
- **You should never insert Q-tips or other foreign objects into your ears to remove ear wax, or clean the ear canal, as over-insertion of foreign objects in the ear canal can cause pain or damage the devices.**
- If you need to have ear wax removed, or your ear canal cleaned, contact your ENT physician.

9.4 Processor and Ear Tip Functions

General Considerations

Your hearing healthcare professional will fit and program the Processors with a gain prescription to suit your individual hearing profile. The gain prescription can be adjusted for your comfort. You will receive instructions on how to use the Processors from your hearing healthcare professional, including how to put them on and take them off, how to turn the power on and off, how to change the program settings, how to recharge them, and how to clean them.

- The Processors are designed to be worn every day and charged at night to ensure the battery lasts all day.
- The Processors must be removed before showering or bathing, as exposure to water can damage the devices.
- All Ear Tips incorporate an indicator: a red indicator identifies the right; a blue indicator identifies the left.
- If the Processor becomes hot during use, promptly remove it from your ear.

Placing the Processors and Ear Tips

It is important that the Ear Tips are placed in your ear properly. Your hearing healthcare professional will fit your Processors and Ear Tips and show you how to place and remove them. To insert the Processor and Ear Tip:

1. Place the Processor behind the ear, it is designed to rest there comfortably.
2. Hold the Ear Tip between your thumb and index finger and slowly insert into the ear canal. You may move the external ear up and downwards to facilitate placement.
3. Once in position, press the Ear Tip to ensure that it has been seated in the correct position.

Removing the Processors and Ear Tips

The Processor and Ear Tip can be removed by grasping the cable between your thumb and index finger near the Ear Tip and gently pulling it out of the ear canal.

Battery Life

- The Processor battery lasts a minimum of 16 hours and an average of 20 hours on a full charge.
- When fully depleted, the Processor requires 4 hours in the Charger to recharge.
- It is recommended that you charge the Processors every day.
- A low battery alert will occur at 60 and/or 15 minutes before the device will shut off. The alert sound can be set to a sequence of tones or a voice indicator that says "Battery."

Powering the Processors On and Off

- To turn OFF the Processors, press and hold the bottom control for 3 seconds; to turn back ON, press and hold any control for 3 seconds.
- Other Processor controls may be configured to turn off the device. Your hearing healthcare professional will explain how the controls have been configured.

Processor Volume and Program Control Button

The Processor user controls are configured by your hearing healthcare professional. The controls can be setup in a variety of configurations. Control options allow you to change volume, programs or turn off the Processor (see Figure 8 for the possible combinations).

- Each control can be pressed in two different ways:
 - Short press = less than 3 second press
 - Long press = over 3 second press
- Volume Control Settings
 - When enabled, pressing the top control will increase the volume and pressing the bottom control will decrease the volume.
 - A variety of alerts can be enabled by the hearing healthcare professional to let you know when the volume has changed, is at default settings and/or minimum and maximum volume settings.
- Program Control Setting:
 - When enabled, the top control will cycle to the next the program (ex. 1→2) and the bottom control will cycle backward (ex. 2→1).
 - An alert can be setup by your hearing healthcare professional to indicate when the program has changed. There are two alert options:
 - Beeps- series of beeps (1, 2, 3, 4) play to indicate the program number.
 - Voice- alerts that voice the name of the program (ex. “Main”, “Restaurant”, “Music”). The voice alerts are the default setting.
- It is recommended that you use the same program for both Processors at the same time.
- The Processors will maintain program and user control settings when they are placed into the Charger.

Button Options	
<input checked="" type="radio"/> Short Press Up <input type="radio"/> Short Press Down <input type="radio"/> Long Press Up <input type="radio"/> Long Press Down	Volume Up Volume Down Cycle Program Power Off
<input type="radio"/> Short Press Up <input type="radio"/> Short Press Down <input type="radio"/> Long Press Up <input type="radio"/> Long Press Down	Volume Up Volume Down Power Off Power Off
<input type="radio"/> Short Press Up <input type="radio"/> Short Press Down <input type="radio"/> Long Press Up <input type="radio"/> Long Press Down	Next Program Previous Program Power Off Power Off
<input type="radio"/> Short Press Up <input type="radio"/> Short Press Down <input type="radio"/> Long Press Up <input type="radio"/> Long Press Down	Do Nothing Do Nothing Power Off Power Off

Figure 8: Use control setting options

Phone Use

- For best results, Earlens recommends using phones in “speaker phone” mode or holding the phone’s speaker next to the Processor microphone.
- The Earlens® Contact Hearing Solution is compatible with select Apple devices. Please see Section 10 of this IFU for further information.

9.5 The Earlens® Charger

The Earlens® Charger is designed to charge the Processors.

- The AC wall adapter (included) is used to plug the Charger into the wall outlet. Do not plug the Charger into an outlet that is difficult to access.
- The Charger can house and charge two Processors at the same time when connected to the wall power adapter.
- **Do not use any other Charger or AC wall adapter with the Earlens® Contact Hearing Solution or use the Earlens® Charger to charge any other devices. Using the incorrect Charger or AC wall adapter can damage the devices. The AC wall adapter cable is plugged into the back of the Earlens® Charger.**
- The lights on the front of the Charger indicate the charge status of each Processor (see Table 2 for a description of light status).

Charging Status Indicators		What It Means
☼	One flashing light	Charger connecting to Processor
•	One solid light	Battery charging; below 33% charged
• •	Two solid lights	Battery charging; above 33% charged
• • •	Three solid lights	Battery charging; above 66% charged
• • • •	Four solid lights	Battery fully charged
☼☼☼☼	Four flashing lights	Processor not charging; remove from Charger, re-insert into charging slot and immediately press top user control
	No lights	Check that Charger is plugged in and Processors are correctly in slots

Table 2: Charger indicator light status

9.6 Care and Maintenance

Storage

- Store the Earlens® Contact Hearing Solution in a clean, dry location out of direct sunlight.
- Avoid exposure to excessively high or low temperatures.
- Store the Earlens® Contact Hearing Solution in the Charger when not in use.

Cleaning

- The Processors and Charger can be cleaned with a soft cloth to remove debris or accumulated ear wax. Do not use liquid cleaners as these can damage the devices
- The clean the Ears Tips may use a soft cloth, a baby wipe or Isopropyl Alcohol (IPA) based wipes to remove wax. If wax accumulates in the vent, use a standard hearing aid cleaning tool to gently remove it. Do not use an abrasive tool.

9.7 Troubleshooting

- If the Ear Tip becomes separated from the cable or Processor, contact your hearing healthcare professional or the Earlens® Concierge 1-844-234-5367.
- If the Ear Tip becomes stuck in your ear canal, contact your hearing healthcare professional.

Processor Malfunctioning

If the Processor stops working, perform the following troubleshooting steps:

- Remove the Processor from your ear and dock it into the Charger.
- Check the battery level of the Processor. If one solid light displays, charge the Processor until at least two lights display. If the Charger lights continually blink when the Processor is properly placed, see the troubleshooting steps for **Four Blinking Lights on the Charger**.
- Ensure that the Ear Tips are placed properly in your ear by removing and reinserting them and checking their position in a mirror.
- If a Program or Volume control is enabled on your Processor, press the control to see if an alert is heard.
- Ensure that the Ear Tip is not blocked by wax by gently wiping any debris off with a soft cloth.
- If, after performing all of the above steps, the Processor does not function, contact your hearing healthcare professional or the Earlens® Concierge 1-844-234-5367.

Feedback/Whistling

“Whistling” can be caused by acoustic feedback. This can occur if the Ear Tip is not inserted properly in the ear. If whistling occurs, remove and reinsert the Ear Tip in your ear, paying careful attention to the placement and alignment. If the whistling continues, contact your hearing healthcare professional.

Four Blinking Lights on the Charger

If the Charger displays 4 blinking lights, the Charger is unable to connect to and charge the Processor. This may occur because the Processor is turned off or because the battery is fully depleted. To commence charging, perform the following steps:

- a. Remove the Processor from the Charger.
- b. Re-dock the Processor into the charging slot.
- c. While 1 light is flashing, quickly press the top user control.
- d. If 1 light becomes solid, the Processor battery is very low and should not be used until at least 2 lights display.
- e. If the Charger continues to blink 4 lights, remove the processor from the charger and replace. Allow the charger to search for the processor until four blinking lights are displayed.
- f. Repeat step a-e 4-5 times, allowing the charger to search until four blinking lights are displayed each time.
- g. Finally, remove the processor from the charger and replace, then press the top button for three seconds while the single light is flashing. The processor should connect to the charger and display one solid light.
- h. Allow the processor to charge for at least four hours.
- i. If the Processor does not connect, please contact your hearing healthcare professional or the Earlens® Concierge 1-(844) 234-5367.

10. Wireless Connectivity- Made for iPhone Feature

10.1 Device Compatibility

The Earlens® Contact Hearing Solution is compatible with Apple® devices that have iOS 15 or later.

Real-time updates for compatibility with newer Apple products can be found at www.earlens.com/connectivity. Some Apple products are not compatible with iOS 15 or newer. Instructions for older versions of Apple iOS are available at www.earlens.com/connectivity.

10.2 Pairing and Connecting an Apple Device

To connect to your Apple device with iOS 13, you must first pair it to your hearing aids.

1. Turn the hearing aids off and back on.
2. On the Apple device, tap on the **Settings** icon > **Accessibility** > **Hearing Devices**.
3. Ensure Bluetooth is enabled. The Apple device will start searching for your hearing aids (Figure 9).
4. Once the hearing aids are discovered, the First Name + Hearing Aid and R+L* will display (Figure 10).
5. Tap on your name.
6. A pairing request window will appear for each device. Select **Pair** (Figure 11).
7. When your hearing aids are paired and connected, you will see the word “Connected” in the main Hearing Devices screen (Figure 12).
8. *If you connect one hearing aid, an L or R will display and only one pairing request window will appear.

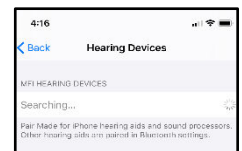


Figure 9



Figure 10

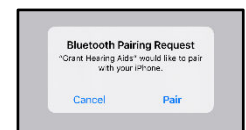


Figure 11

10.3 Reconnecting to an Apple Device

When your hearing aids are placed into a plugged in Charger, they will turn off, which will temporarily disconnect them from the Apple device. Once removed from the Charger, your hearing aids will automatically turn on and re-connect to the Apple device. This behavior is also true when you turn the Processors off/on via the user controls on the Processor. If the hearing aids do not automatically connect to the Apple device, see section 10.6 for further instructions or call the Earlens® Concierge at 1-844-234-5367.

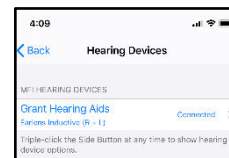


Figure 12

Please note, when updating to new versions of iOS, the hearing aids may lose their pairing to the Apple device requiring the patient to un-pair and re-pair them.


10.4 Streaming Audio

You can directly stream audio from an Apple device to your hearing aids. Once paired and connected, audio will automatically route from your Apple device to your hearing aids.

Streaming Audio Media

In the event the audio stream does not automatically route to the hearing aids or the user would like to change it, perform the following steps:

Open the Control Center (Figure 13).

1. Press the  icon in the upper right corner of the audio card. Select your preferred audio source (Figure 14).

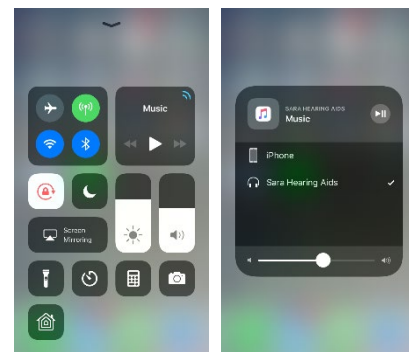



Figure 13

Figure 14

Streaming Phone Calls

Outgoing Call

1. Select the Phone icon .
2. Select the contact name you would like to call or dial a phone number to initiate the call.
3. Once the phone begins to ring, the source display will indicate that the Processors are the active audio source (Figure 15).
Note: The source may be changed from this screen by tapping on the audio button (Figure 16).
4. Select the End icon to disconnect from the call.

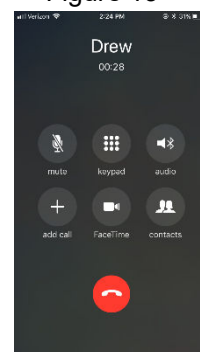


Figure 15

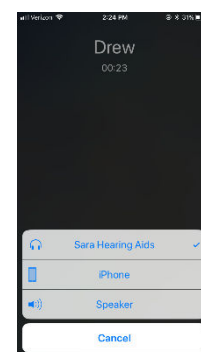


Figure 16


Incoming Call

1. The iPhone will indicate the arrival of an incoming call.
NOTE: If the call is received while streaming media, the stream will be interrupted by the call. Once the call is ended, the stream will resume.
2. Select the Accept or Decline icons on the iPhone.
3. Select the End icon to disconnect.

10.5 Earlens® Control Mobile Application

Download the Earlens® Control App

You must have an iTunes account to download the Earlens® Control mobile application. To set up an account go to www.itunes.com.

1. Select the App Store icon  on the Apple device.
2. In the search field, type Earlens Control.

3. Click *Get*, then *Install*.
4. A window may appear requesting your Apple Password, enter to proceed.

Earlens® Control App Features

The Earlens® Control app allows you to seamlessly interact with your hearing aids to quickly and discretely control volume, change programs and so much more! The first time you download the application, tutorial hints will appear to acquaint you with the various features and how to use them in each screen. The app provides the following features:

- *Concierge Opt-in*

If you have any questions, require assistance, or would like to learn more about your Earlens® Contact Hearing Solution the Earlens® Concierge is here to support you! This remote service is free to you and available during normal business hours. When you first open the Earlens® Control app, you will be asked if you would like to enroll in the concierge program. We will ask that you provide for your name, phone number, and email address so that we can contact you in the event we have important product updates or alert you when a new Apple iOS version is available.

- *Change Processor Volume*

The Processor volume level can be changed in the **Home** screen.

1. To change the master volume for both Processors, slide your finger along the volume bar to adjust the volume of both Processors. Slide left to decreases volume; slide right increases the volume.
2. To change the volume of each Processor independently, tap on the double-slider icon and then slide your finger along the volume bar to adjust the volume. Slide left to decreases volume; slide right increases the volume.
3. To mute the Processors, select the Mute icon.

NOTE: Using the volume bar in the App will adjust only the hearing aid microphones, not the streaming volume. To adjust a streamed input, use the volume controls on the Apple device.

- *Customize Sound with Bass and Treble Adjustments*

You can adjust the master bass and treble settings in the EQ screen of the Earlens® Control app to enhance listening in different environments or for audio streamed inputs.

1. Select **EQ** on the bottom navigation bar.
2. Slide your finger along the bass and/or treble bar to adjust the settings of both Processors.
3. The application will remember your settings on a per program basis.

- *Change Programs*

Up to 4 programs can be enabled in the Processor. These programs can be changed in the app in the Home screen.

1. Select **Home** on the bottom navigation bar.
2. Depending on the number of Programs stored in the Processor, active circular icons will display numbers 1-4. Under each icon, the name of the program will display.
3. Tap on the desired program. The active program will display in orange.

- *Live Mic*

Users can turn the Apple device into a remote microphone that can be used as an assistive device. This feature is designed to be helpful in challenging listening environments such as noisy restaurants.

1. Select **More** on the bottom navigation bar.
2. Press the **Live Mic** option.
3. Tap on **Start Live Mic** icon. When enabled, the icon will turn from blue to orange.
4. Within the Streaming screen, you can adjust the hearing aid microphone volume relative to the incoming streamed Live Mic audio to enhance your listening experience.

5. To stop the live stream, tap on **Start Live Mic**, it will turn back to blue.

- *Support*

The Support tab offers Earlens® contact information to receive assistance. You can also find links to MFi support videos featured on our website and troubleshooting support from this screen.

- *Additional App Features*

- Set oiling reminders

An important step to maintaining the Earlens® Contact Hearing Solution involves applying one pump of mineral, to each ear, every other day. To help remind you, a configurable notification can be enabled in the Earlens® Control app.

1. Select **More** on the bottom navigation bar.
2. Select **Settings**.
3. Enable **Mineral Oil Reminder**.
4. Tap on **Repeat** and select **Custom**.
5. At the top of the screen, tap on the arrow in the upper left next to “New Event” screen and select **Add**.

- Demo Mode

A demo mode can be enabled to allow users to get acquainted with the Earlens® Control without having active devices connected. To activate:

1. Select **More** on the bottom of the navigation bar.
2. Select **Settings**.
3. Enable **Demo Mode**.
4. “Demo” will appear in every screen of the Mobile App when it is enabled.

- Locate Hearing Aids

The locate hearing aid functionality allows you to see the last location your Processors and Apple device were connected in the event you misplace your Processors.

1. Select **More** on the bottom of the navigation bar.
2. Select **Locate**.
3. Select **Enable**.
4. A window will pop-up, select **Allow**.

10.6 Troubleshooting Made for iPhone Connectivity

Cannot Hear Audio Stream or Control Hearing Aids Using Apple Device

If the hearing aids are paired but the user is unable to hear the audio stream or control them from their Apple device, follow these steps:

1. Prior to performing any troubleshooting steps, confirm that Bluetooth is enabled in two places on the Apple device:
 - Under Settings>Bluetooth - enabled
 - Control Center – Bluetooth icon should be blue
2. Reset the hearing aid by pressing and holding the bottom user control for 3 seconds.
3. Press and hold the top user control for 3 seconds on the hearing aid until you hear the device turn on.
4. Select **Settings > Accessibility > Hearing Devices** and tap on your hearing aids, displayed under Devices, to verify that they are paired and actively connected to your Apple device.
Note: If a pairing window pops-up, select **Pair**.
5. Forget and re-pair your hearing aids to the Apple device.
 - a. Select **Settings > Accessibility > Hearing Devices**.
 - b. Tap on your hearing aid name displayed under Devices.
 - c. Select **Forget this device**.
 - d. A window will appear, select **Forget**.

- e. Proceed with instructions for **Pairing and Connecting to Your Apple Device** (Section 10.2).
6. Turn the Apple device OFF and then back ON.

If these steps do not resolve the connectivity issues, call the EarLens® Concierge 1-844-234-5367.

Made for iPhone Tips and Tricks

- To change the volume of phone calls or audio media when streaming to your hearing aid, use the volume controls located on the Apple device.
- Bluetooth connectivity will never be perfect. However, certain actions may improve connectivity:
 - Keep the Apple device within 20 feet of the hearing aids and in line-of-sight when streaming audio.
 - The body absorbs most of the Bluetooth signal, for optimal connectivity, hold the Apple device in your hand or in an armband and do not place it in pockets.
 - Car and hearing aid Bluetooth may act unpredictably with your Apple device. Please call the EarLens® Concierge for additional support.

For more MFi connectivity information and troubleshooting help, go to www.earlens.com/connectivity or connect with the EarLens® Concierge at 1-844-234-5367

10.7 Apple Hearing Aid Control

Apple offers hearing aid controls that allow the user to interact with their hearing aids without accessing the EarLens® Control app. The Apple controls allow the user to:

- Make volume adjustments
- Change programs
- Engage the Live Listen functionality

These controls can be quickly accessed by performing a triple-click of the home button (Apple products with a home button) or by triple-click of the power button on iPhone X or newer.

11. Operating Specifications

- Certain components of the EarLens® Contact Hearing Solution, including the Processor and the Ear Tip are classified as a Type BF applied parts as described in the international standard IEC 60601-1:2005, Medical Electrical Equipment-Part 1:General Requirements for Basic Safety and Essential Performance.
- Please refer to the tables provided for more information on recommended distances for separation of the EarLens® Contact Hearing Solution.
- Expected useful life of the EarLens® Contact Hearing Solution include:
 - Processor and Charger- one year
 - Ear Tip- one year
 - Lens- one year
- The EarLens® Contact Hearing Solution is designed for continuous use.
- The Processor is not designed to prevent the ingress of water.

11.1 Power Requirements

Battery Charger Input	100-240 VAC, 50-60Hz, 0.2A
Battery Charger Output	5.0 VDC, 1.0A

11.2 Operating and Storage Conditions

Operating Conditions	5°C- 40°C 15-93% humidity 700 – 1060 hPa	Storage Conditions and Temperature Limit*	-20°C to 50°C Maximum relative humidity of 93% non-condensing.
Use conditions	Avoid high temperatures and sustained exposure to direct sunlight.	Frequency range	100 Hz to 10,000 Hz

* If the system is stored at a temperature below room temperature, allow the system to stabilize at room temperature for a minimum of 1 hour before use.

11.3 Electromagnetic Compatibility Compliance Statement

- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents.
- Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.
- The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used. The following accessories supplied with the Earlens® Contact Hearing Solution have been tested for electromagnetic emissions compliance.

List of all Cables Utilized with the Earlens® Contact Hearing Solution

Cable Type	Cable Description	Maximum Cable Length	Cable Manufacturer	Cable Model Number
USB Cable	Hi-speed 2.0 Shielded	80 inches	TrumPower	E189529

The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Earlens® Contact Hearing Solution is intended for use in the electromagnetic environment specified below. The customer or the user of the Earlens® Contact Hearing Solution should assure that it is used in such an environment.

Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The Earlens® Contact Hearing Solution uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic Earlens® Contact Hearing Solution. The Earlens® Contact Hearing Solution is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Earlens® Contact Hearing Solution is intended for use in the electromagnetic environment specified below. The customer or the user of the Earlens® Contact Hearing Solution should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Earlens® Contact Hearing Solution requires continued operation during power mains interruptions, it is recommended that the Earlens® Contact Hearing Solution be powered from an uninterruptible power supply or a battery.
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Earlens® Contact Hearing Solution is intended for use in the electromagnetic environment specified below. The customer or the user of the Earlens® Contact Hearing Solution should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			<p>Portable and mobile RF communications Earlens® Contact Hearing Solution should be used no closer to any part of the Earlens® Contact Hearing Solution, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.2\sqrt{P}$</p>

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)	3 Vrms	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Earlens® Contact Hearing Solution is used exceeds the applicable RF compliance level above, the Earlens® Contact Hearing Solution should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Earlens® Contact Hearing Solution.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended Separation Distances Between
Portable and Mobile RF Communications Earlens® Contact Hearing Solution and the Earlens® Contact Hearing Solution**

The Earlens® Contact Hearing Solution is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Earlens® Contact Hearing Solution can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications Earlens® Contact Hearing Solution (transmitters) and the Earlens® Contact Hearing Solution as recommended below, according to the maximum output power of the communications Earlens® Contact Hearing Solution.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

11.4 FCC Information

FCC ID: 2AGDU-EL2PIN

Earlens Contact Hearing Solution complies with part 15 of the FCC rules and ICES-003 of the IC 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.

CAUTION: Changes or modifications not expressly approved by Earlens Corporation for compliance could void the user's authority to operate the equipment.

NOTE: Earlens Contact Hearing Solution has been tested and found to comply with the limits for a 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 a particular installation. If this equipment does cause harmful 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.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - Consult the dealer or an experienced radio/TV technician for help.
- Earlens Contact Hearing Solution complies with part 18 of the FCC rules.

11.5 Summary of Wireless Technologies

The Earlens® Contact Hearing Solution incorporates two wireless technologies. One is an inductive link to transmit data and power from the Processor and Ear Tip to the Tympanic Lens. The second is a Bluetooth streaming link that supports Apple Made for iPhone (MFi) audio streaming for hearing aids.

Description of Inductive Link:

A proprietary inductive link which operates at a nominal range of 5 mm, transfers both the audio signal and power to the motor in the Lens via a coupled magnetic field. The Processor generates an amplitude modulated (AM) transmit signal, over a carrier frequency of 2.56 MHz. The Lens contains a receiver circuit which separates the audio signal from the carrier and drives the motor in the Lens. The short range of the coupled magnetic field due to close proximity of the Transmit coil in the Ear Tip to the Receive coil in the Lens ensures minimal possibility of an external source interfering with the Inductive Link. In case such interference happens, the patient may hear brief audio artifacts such as distortion or clicks. These artifacts will subside as the patient moves away from the interferers.

Description of Bluetooth Streaming Link:

The Earlens® Inductive System supports the Apple MFi (made for iPhone) streaming protocol for hearing aids. The Apple MFi streaming protocol operates on a Bluetooth Low Energy (BLE) 4.2 link which operates in the 2.4 GHz Industrial, Scientific, and Medical radio (ISM) wireless band. The controls during audio streaming include volume up/down, bass/treble control, program selection, remote microphone audio streaming and processor status with respect to battery state of charge. The Apple streaming protocol is secure and managed by its proprietary operating system (iOS). Security is maintained in the BLE 4.2 link through encryption and checksum validation. If packetized data contains errors the protocol allows for retry. In case of missing packets, the user

may experience audio artifacts such as brief losses of audio or audio distortion. If connection between the processor and iOS device is lost, the BLE link automatically reestablishes the connection. The MFi streaming feature is designed to operate at a maximum line of sight distance of 10 m (33 feet). For optimum sound quality, it is recommended that the Earlens® wearer keep the iOS device within 6 m (20 feet) of the processor.






Tips for Success with Earlens® MFi Connectivity












- Always turn the Processor OFF and back ON to refresh the Bluetooth advertising window prior to pairing device(s) to an Apple device.
- Pairing and connecting Earlens® Processors to an Apple device follows the same steps as other hearing aid manufacturers. Please review the MFi Quick Start Guide for details at: www.earlens.com/connectivity
- A binaural set of Processors must be programmed together in Earlens fitting software, at any fitting session, for an Apple device to continue recognizing them as a pair.
- The Earlens® Control app is available for free in the Apple App Store.
- Earlens® wearers are encouraged to call the Earlens® MFi Concierge at (844) 234-5367 if they encounter any connectivity issues or have any questions.
- Audiologists and Earlens® wearers can visit the Earlens® MFi information page at: www.earlens.com/connectivity for the latest Apple iOS and device compatibility information.


12. Glossary of Terms

TM	Tympanic Membrane (eardrum)
Lens	Tympanic Lens
EAS	Electronic Article Surveillance
AE	Adverse Event

13. Graphic Symbols Contained in Device Labeling

Symbol	Description	Reference	Symbol	Description	Reference
	Refer to instruction manual/booklet	IEC 60601-1:2005 ISO 7010-M002		Temperature limit	ISO 15223-1:2021, 5.3.7
	Separate collection for electrical and electronic equipment	WEEE Directive 2012/19/EU, Annex IX		Atmospheric pressure limitation	ISO 15223-1:2021, 5.3.9
	Keep Dry	ISO 15223-1:2021, 5.3.4	IP57	Ingress Protection Code signifying protection against dust and the effects of temporary immersion in water.	IEC 60601-1:2005 IEC 60529, 4.2
RxOnly	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)	FDA Final Rule 81 FR 38911	IP22	Ingress Protection Code signifying protection against solid foreign objects of 12.5mm Ø and greater, and protection against vertically falling water drops when enclosure tilted up to 15°.	IEC 60601-1:2005 IEC 60529, 4.2

	Humidity limitation	ISO 15223-1:2021, 5.3.8		Serial number	ISO 15223-1:2021,5.1.7
	Non-ionizing radiation	IEC 60601-1-2:2014 IEC 60417-5140 (2003-04)		Caution	ISO 15223-1:2021, 5.4.4
	Batch code	ISO 15223-1:2021, 5.1.5		MR unsafe	ASTM F2503-13
	Catalog number	ISO 15223-1:2021, 5.1.6		FCC Part 18 Declaration of Conformity	FCC Guidelines for Labeling, Part 15 and Part 18, 2014
	Date of manufacture	ISO 15223-1:2021, 5.1.3		Type BF applied part	IEC 60601-1:2005 IEC 60417-5333
	Consult Instructions for Use	ISO 15223-1:2021, 5.4.3			

 Manufacturer (Ref. ISO 15223-1:2021, 5.1.1):
Earlens Corporation
Menlo Park, CA 94025

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