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## Wireless Earlens Light-Driven Hearing Aid Patient Instructions

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## 1. Introduction

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

Rx ONLY

For hearing professional instructions, please see *Earlens Light-Driven Hearing Aid Hearing Professional Instructions*. For physician instructions, please see *Earlens Light-Driven Hearing Aid Physician Instructions*.

## 2. Wireless Earlens Light-Driven Hearing Aid Device Description

The wireless *Earlens Light-Driven Hearing Aid* uses non-visible light to send sound information to a custom-made Tympanic Lens (Lens). The Lens converts the light into vibrations that are directly applied to the eardrum and are perceived as sound (Figure 1). The Earlens Hearing Aid is composed of the following:

- Lens
- Photon™ 2 Processor
- Light Tip
- Earlens Fitting Software (ELF)
- Charger with Power Adapter
- Earlens Impression System
- Mineral Oil
- Earlens Control Application

### 2.1 Tympanic Lens (Lens)

The Lens (Figure 2) is designed to receive light signals from the Light Tip and convert the light signals into mechanical vibrations of the tympanic membrane (TM). The Lens is customized for you 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 Photon™2 Processor and Light Tip

The Processor is directly connected to the Light Tip via the cable (Figure 3). The Processor is designed to pick-up sounds via the microphones, apply signal processing and transmit the signal via the cable to the Light Tip. The Processor should be placed in the Charger for recharging every day.

The Processor 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. For additional information, please contact your hearing professional or visit [www.earlens.com/connectivity](http://www.earlens.com/connectivity).

The Light Tip is connected to the Processor via the cable and can be modified to fit by a hearing professional. The Light Tip shell features a large opening or vent, which is designed to allow the ear canal to have an open, non-occluding feel (Figure 4). The Light Tip is specifically designed to stabilize and aim the emitter at the Lens.

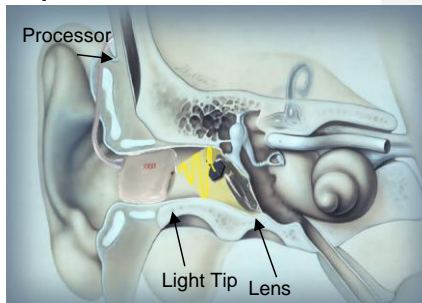


Figure 1: Earlens components schematic

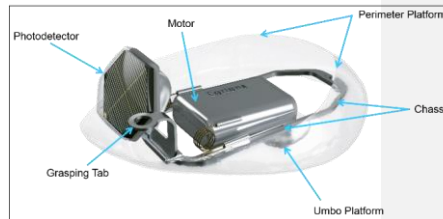


Figure 2: Lens

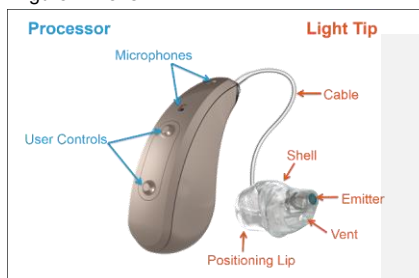


Figure 3: Processor



Figure 4: Light Tip large vent opening

### 2.3 Earlens Fitting Software (ELF)

ELF is used to program the Processor, enabling the hearing 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 5). 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 Light 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 two pumps of mineral oil to your ears daily or as directed by your physician.

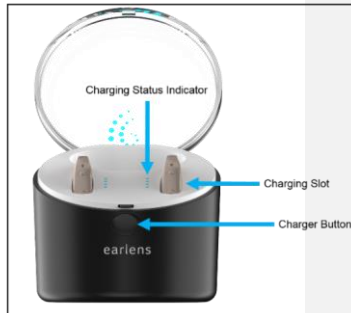


Figure 5: Earlens Charger

## 3. Indications for Use

The wireless Earlens Light-Driven Hearing Aid (a.k.a. Earlens 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 Light-Driven Hearing Aid provides the full spectrum of amplification that includes 125 Hz – 10,000 Hz. The audiometric fitting range for the Earlens Hearing Aid is shown in Figure 6.

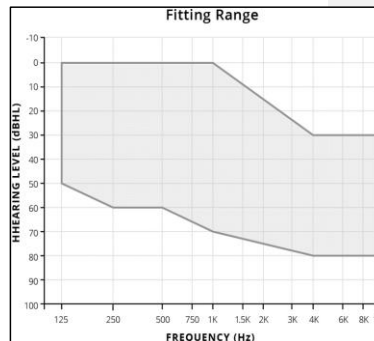


Figure 6: Earlens Fitting Range

## 5. Contraindications

The following section includes medical terminology that may be unfamiliar to you. If you have any questions, contact your physician or hearing professional. You must not have any known or active medical issues that would preclude 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, or received radiation of the head ever 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 Hearing Aid (5% were unable to anatomically accommodate the Lens).

## 6. Warnings



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

- The Earlens Hearing Aid 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 Hearing Aid in place.
- The Processor and Light Tip unit contain a Class 1 laser product. It is safe to use under normal operating conditions. The Class 1 laser light is NOT visible. Do NOT look directly into the laser or aim directly into the eyes. Should any part of the Aid become damaged, discontinue use and contact your hearing 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 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 professional.
- Do not crush, short circuit, modify or disassemble any component of the Earlens Hearing Aid. Keep all components of the Earlens Hearing Aid out of the reach of children, pets and others, to avoid risk of swallowing.
- Do not incinerate any component of the Earlens Hearing Aid 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 Hearing Aid, 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 component contains nickel that is coated with a parylene barrier. If you develop an allergic reaction, the Lens should be promptly removed.
- The Lens was 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 within the 1 year expected life.
- Only healthcare professionals trained in the fitting of hearing aids may fit the Processor and Light Tip.
- The Earlens Hearing Aid is custom designed and intended to be used only by a single patient.
- The Light Tip is designed to sit a set distance from the Lens. Sound output may deviate if the Light Tip is not inserted to the proper depth. If the sound output does deviate, you can reposition the Light 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 Light 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 Hearing Aid 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 Hearing Aid.
- Handle the components carefully and prevent hard knocks. Do not drop them as it may damage the Earlens Hearing Aid.
- 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 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 Hearing Aid. 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 professional.

## 8. Risk/Benefit

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 Hearing Aid confirmed the safety and effectiveness of the Earlens Hearing Aid 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 Hearing Aid 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 Hearing Aid 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 Hearing Aid 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 Hearing Aid at a speech level of 45 dB HL. The objective was to show that the Earlens Hearing Aid 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 7); 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 measured at 30 days post placement when compared to unaided measured prior to placement. Mean functional gain was 30.5 dB ( $p < 0.0001$ ), indicating that the Earlens Hearing Aid was able to deliver significant functional gain (Figure 8). Functional gain reached a maximum of 68 dB at 9,000-10,000 Hz.

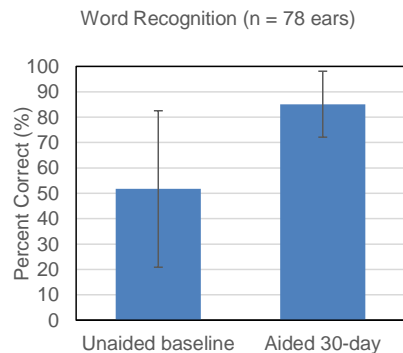


Figure 7: Word Recognition

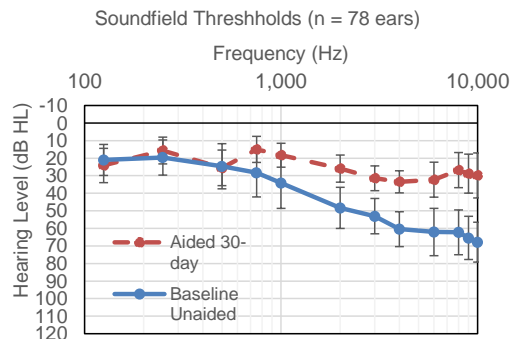


Figure 8: Soundfield thresholds

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 (swimming, bathing, 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 Aid more than overcomes the TM damping effect.

### 8.6 Summary of Extended Study

The safety and effectiveness of the Earlens Hearing Aid was monitored beyond the 4 months of the Definitive Study. In the Extended Study, 24 subjects (48 ears) chose to continue wearing the Aid after completing the Definitive study. At the conclusion of the Extended Study, 33ears 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 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 Light Tip fit and both were resolved after Light Tip modification. One subject continues to report a sensation of fullness.

Based on the results of the Definitive study, the Earlens Hearing Aid has been shown to be safe and effective in delivering the full spectrum of amplification from 125 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 weekly maintenance by application of mineral oil.

### 9.2 Daily Maintenance Oiling

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

- Apply two pumps of mineral oil to the ear canal daily 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 depressing the pump a few times into a tissue until a consistent stream of oil is observed.
  2. With head in an upright position, place the cone tip of the mineral oil dispenser fully into the ear canal opening.
  3. Dispense two pumps of oil into the ear canal by depressing the pump twice.
  4. 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.
  5. Repeat above steps for the opposite ear.
  6. After oiling, your ears may feel a little stuffy. This should subside on its own when the oil is absorbed.
  7. Re-apply oil daily. 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 Light Tip Functions

#### General Considerations

Your hearing 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 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.
- The light that comes out of the Light Tip is not visible.
- All Light Tips incorporate an indicator: a red indicator identifies the right Light Tip; a blue indicator identifies the left Light Tip.
- If the Processor becomes hot during use, promptly remove it from your ear.

#### Placing the Processors and Light Tips

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

1. Place the Processor behind the ear, it is designed to rest there comfortably.
2. Hold the Light 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 Light Tip to ensure that it has been seated in the correct position.

#### Removing the Processors and Light Tips

The Processor and Light Tip can be removed by grasping the Ear Tube between your thumb and index finger near the Light Tip and gently pulling the Light Tip 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

- Once removed from a plugged-in Charger, the Processors are ON.
- 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 professional will explain how the controls have been configured.



### Processor Volume and Program Control Button

The Processor user controls are configured by your hearing 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 9 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 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 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 checked="" 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 checked="" 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 checked="" type="radio"/> Long Press Down	Do Nothing Do Nothing Power Off Power Off

Figure 9: 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 Hearing Aid 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 Hearing Aid, 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 <b>flashing</b> light	Charger connecting to Processor
•	One solid light	Battery charging; <b>below</b> 33% charged
• •	Two solid lights	Battery charging; <b>above</b> 33% charged
• • •	Three solid lights	Battery charging; above 66% charged
• • • •	Four solid lights	Battery fully charged
☼☼☼☼	Four <b>flashing</b> 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 Hearing Aid in a clean, dry location out of direct sunlight.
- Avoid exposure to excessively high or low temperatures.
- Store the EarLens Hearing Aid 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.
- The Light Tips may collect wax on the end where the light is emitted. Although light can travel through a thin layer of wax, large pieces should be removed to ensure proper functioning of the devices. Use a soft cloth to remove wax.
- Wax may collect in the Light Tip vent. If the vent is visually obstructed, clean using a standard hearing aid vent cleaning tool. Ensure the tool is not abrasive to the material of the Light Tip.
- Do not use liquid cleaners on the Processors as these can damage the devices. The Light Tips may be cleaned with a baby wipe or other Isopropyl Alcohol (IPA) based wipe.

## 9.7 Troubleshooting

- If the Light Tip becomes separated from the cable or Processor, contact your hearing professional.
- If the Light Tip becomes stuck in your ear canal, contact your hearing professional.

### Processor Malfunctioning

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

- a. Remove the Processor from your ear and dock it into the Charger.
- b. 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**.
- c. Ensure that the Light Tips are placed properly in your ear by removing and reinserting them and checking their position in a mirror.
- d. If a Program or Volume control is enabled on your Processor, press the control to see if an alert is heard.
- e. Ensure that the Light Tip is not blocked by wax by gently wiping any debris off with a soft cloth.
- f. If, after performing all of the above steps, the Processor does not function, contact your hearing professional or the EarLens Concierge 1-844-730-5986.

### Feedback/Whistling

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

### Four Blinking Lights on the Charger

If the Charger displays 4 blinking lights, the Charger is unable to connect and charge the Processor. 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 any 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 Processor continues to blink, perform steps a-d up to 5 times. If after repeating these steps the Processor does not connect, please contact your hearing professional or the EarLens Concierge 1-844-730-5986.

## 10. Wireless Connectivity- Made for iPhone Feature

### 10.1 Device Compatibility

The Earlens Hearing Aid is compatible with the following Apple® devices that have iOS 11 or later:

iPhone®	iPad®	iPod®
iPhone XR	12.9-inch iPad Pro 2nd gen	iPod touch 6 <sup>th</sup> gen
iPhone XS Max	12.9-inch iPad Pro 1st gen	
iPhone XS	10.5-inch iPad Pro	
iPhone X	9.7-inch iPad Pro	
iPhone 8	iPad Air 2	
iPhone 8 Plus	iPad Air	
iPhone 7	iPad 5th gen	
iPhone 7 Plus	iPad mini 4	
iPhone 6s	iPad mini 3	
iPhone 6s Plus	iPad mini 2	
iPhone 6		
iPhone 6 Plus		
iPhone 5s		

Real-time updates for compatibility with newer Apple products can be found at [www.earlens.com/connectivity](http://www.earlens.com/connectivity). Some Apple products are not compatible with iOS 11 or newer. Instructions for older versions of Apple iOS are available at [www.earlens.com/connectivity](http://www.earlens.com/connectivity).

### 10.2 Pairing and Connecting an Apple Device

To connect to your Apple device with iOS 12, 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 > **General** > **Accessibility** > **MFi Hearing Devices**.
3. Ensure Bluetooth is enabled. The Apple device will start searching for your hearing aids (Figure 10).
4. Once the hearing aids are discovered, your First Name + Hearing Aid and R+L\* will display (Figure 11).
5. Tap your name.
6. A pairing request window will appear for each device. Select **Pair** (Figure 12).
7. When the hearing aids are paired and connected, you will see the word "Connected" in the main MFi Hearing Devices screen (Figure 13).

\*If you connect one hearing aid, an L or R will display and only one pairing request window will appear.

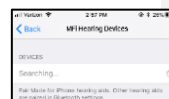


Figure 10

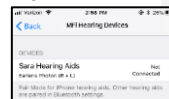


Figure 11

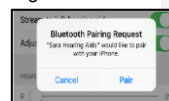


Figure 12

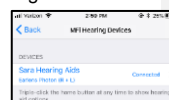


Figure 13

### 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 1-844-730-5986.


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:

1. Open the Control Center (Figure 14).
2. Press the  icon in the upper right corner of the audio card. Select your preferred audio source (Figure 15).

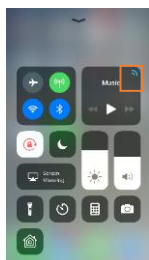


Figure 14

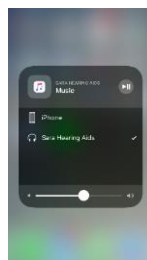



Figure 15

##### 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 16).  
Note: The source may be changed from this screen by tapping on the audio button (Figure 17).
4. Select the End icon to disconnect from the call.

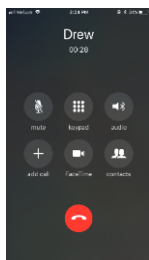


Figure 16

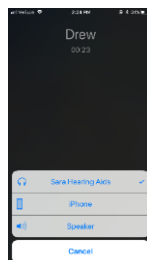


Figure 17

###### 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](http://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 Hearing Aid 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.

- 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 decrease volume; slide right to increase the volume.
- To change the volume of each Processor independently, tap on the splitter icon and then slide your finger along the volume bar to adjust the volume. Slide left to decrease volume; slide right to increase the volume.
- To mute the Processors, select the Mute icon.
- The volume bar in the app will adjust the hearing aid microphones, not the streaming volume from the Apple device. To adjust the streamed input, use the volume controls on the side of the Apple device.

- *Change Programs*

Up to 4 programs can be enabled in the Processor and are programmed by your hearing professional. 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, bars with the program name will display. To change the Processor program tap on the desired program bar. The active program will display in orange.

- *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.

- *Support*

The Support tab offers Earlens Concierge contact information, helpful videos, and links to additional resources.

- *Additional App Features*

- *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. Tap on Live Mic.
3. Tap on the Start Live Mic icon. When enabled, the icon will turn from blue to orange.
4. In the Live Mic screen, you can adjust the hearing aid microphone volume relatively to the audio stream.
5. To stop the live stream, tap on **Start Live Mic**, it will turn back to blue.

- *Set oiling reminders*

An important step to maintaining the Earlens Hearing Aid involves applying two pumps of mineral, to each ear, daily. 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 **Every Day**.

5. At the top of the screen, tap on the arrow in the upper left next to "New Event" screen and select **Add**.

o *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.

o *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 15 seconds.
3. Press the top user control on the hearing aid until you hear the device turn on.
4. Select **Settings > General > Accessibility > MFi 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 > General > Accessibility > MFi 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 1-844-730-5986.**

#### Made for iPhone Tips and Tricks

- To change the volume of phone calls or audio media when streaming to your hearing aids, use the volume controls located on the Apple device.
- Bluetooth connectivity will never be perfect. However, certain actions may improve connectivity:
  - o Keep the Apple device within 20 feet of the hearing aids and in line-of-sight when streaming audio.
  - o 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.
  - o 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](http://www.earlens.com/connectivity) or connect with the Earlens Concierge at 1-844-730-5986.

### 10.7 Apple Hearing Aid Control

Apple offers hearing aid controls that allow you to interact with your 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 Hearing Aid, including the Processor and the Light 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 Hearing Aid.
- Expected service life of the Earlens Hearing Aid include:
  - Processor and Charger- one year
  - Light Tip- one year
  - Lens- one year
- The Earlens Hearing Aid 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	100Hz to 10,000Hz

\* 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 Hearing Aid have been tested for electromagnetic emissions compliance.

**Guidance and Manufacturer's Declaration – Immunity**

The Earlens Hearing Aid has been successfully tested for use in the electromagnetic environment specified below. The customer or user of the Earlens Hearing Aid should ensure that it is used in such an environment, not to exceed conditions listed below.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±8kV Contact* ±15kV Air*	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical home, commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical home, commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds	Mains power quality should be that of a typical home, commercial or hospital environment. If the user of the Earlens Hearing Aid requires continued operation during power mains interruptions, it is recommended that the Earlens Hearing Aid be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	30 A/m*	Power frequency magnetic fields should be that of a typical home, commercial or hospital environment.

**List of all cables utilized with the Earlens Hearing Aid**

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 Hearing Aid has been successfully tested for use in the electromagnetic environment specified below. The customer or user of the Earlens Hearing Aid should ensure that it is used in such an environment, not to exceed conditions listed below.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Earlens Hearing Aid does not use RF energy for any of its functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Earlens Hearing Aid 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.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	



**Guidance and Manufacturer's Declaration – Immunity**

The Earlens Hearing Aid has been successfully tested for use in the electromagnetic environment specified below. The customer or user of the Earlens Hearing Aid should ensure that it is used in such an environment, not to exceed conditions listed below.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±8kV Contact* ±15kV Air*	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical home, commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical home, commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds	Mains power quality should be that of a typical home, commercial or hospital environment. If the user of the Earlens Hearing Aid requires continued operation during power mains interruptions, it is recommended that the Earlens Hearing Aid be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	30 A/m*	Power frequency magnetic fields should be that of a typical home, commercial or hospital environment.

\*Compliance was tested at higher levels representative of requirements for home use per IEC 60601-1-2 Edition 4:2014-02

**Guidance and Manufacturer's Declaration – Electromagnetic Immunity**

The Earlens Hearing Aid has been successfully tested for use in the electromagnetic environment specified below. The customer or user of the Earlens Hearing Aid should ensure that it is used in such an environment, not to exceed conditions listed below.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)=3Vrms & 6Vrms in ISM bands*	Portable and mobile communications equipment should be separated from the Earlens Hearing Aid by no less than the distances calculated/listed below:  D=1.2(Sqrt P) [3V Level] 150kHz to 80MHz D=2(Sqrt P) [6V Level] 150kHz to 80MHz  D=1.2(Sqrt P) 80 to 800 MHz  D=2.3(Sqrt P) 800 MHz to 2.5 GHz  where P is the max power in watts and D is the recommended separation distance in meters.  Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).  Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	(E1)=10V/m*	

\*Compliance was tested at higher levels representative of requirements for home use per IEC 60601-1-2 Edition 4:2014-02

### Recommended Separation Distances for the Earlens Hearing Aid

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

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz outside ISM bands  D=1.2(Sqrt P) (Test Level 3 V)	Separation (m) 150kHz to 80MHz in ISM and Amateur bands  D=2(Sqrt P) (Test Level 6 V)	Separation (m) 80 to 800MHz  D=1.2(Sqrt P) (Test Level 10 V/m)	Separation (m) 800MHz to 2.5GHz  D=2.3(Sqrt P) (Test Level 10 V/m)
0.01	0.12	0.2	0.12	0.23
0.1	0.38	0.63	0.38	0.73
1	1.2	2.0	1.2	2.3
10	3.7	6.3	3.8	7.3
100	12	20	12	23







#### 11.4 FCC Compliance

- FCC ID: 2AGDU-EL1; IC ID: 20825-EL1
- The Earlens Light Driven Hearing Aid complies with part 18 of the FCC rules and ICES-003 of the IC rules.












### 12. Glossary of Terms

TM	Tympanic Membrane (eardrum)
Lens	Tympanic Lens
ELF	Earlens Fitting Software
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 15223-1:2016, 5.3.7
	Separate collection for electrical and electronic equipment	WEEE Directive 2012/19/EU, Annex IX		Atmospheric pressure limitation	ISO 15223-1:2016, 5.3.9
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	IP21	International Protection Code against ingress of solid foreign objects $\geq$ 12.5mm diameter and vertically falling water drops when enclosure tilted up to 15°	IEC 60601-1:2005 IEC 60529, 4.2
	Keep Dry	ISO 15223-1:2016, 5.3.4		Serial number	ISO 15223-1:2016, 5.1.7

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	Humidity limitation	ISO 15223-1:2016, 5.3.8		Caution	ISO 15223-1:2016, 5.4.4
	Class 1 laser product	IEC 60825-1:2007, 5.2		MR unsafe	ASTM F2503-13
	Batch code	ISO 15223-1:2016, 5.1.5		FCC Part 18 Declaration of Conformity	FCC Guidelines for Labeling, Part 15 and Part 18, 2014
	Catalog number	ISO 15223-1:2016, 5.1.6	 0459	Non-ionizing radiation CE conformity marking	<a href="#">IEC 60601-1-2:2007</a> <a href="#">IEC 60417-5140 (2003-04)MDD 93/42/EEC, Annex XII</a>
	Date of manufacture	ISO 15223-1:2016, 5.1.3		Type BF applied part	IEC 60601-1:2005 IEC 60417-5333
	Non-ionizing radiation	<a href="#">IEC 60601-1-2:2007</a> <a href="#">IEC 60417-5140 (2003-04)</a>			

#### 14. Laser Certification

The Earlens Light-Driven Hearing Aid complies with 21CFR 1040.10 and 1040.11.



Manufacturer (Ref. ISO 15223-1:2016, 5.1.1):  
Earlens Corporation, Inc.  
4045A Campbell Ave.  
Menlo Park, CA 94025



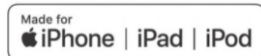
European Authorized Representative (Ref. ISO 15223-1:2016, 5.1.2):  
[Medimark@Europe-SARL](mailto:Medimark@Europe-SARL)  
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