earlens®

Earlens® Contact Hearing Solution User Manual

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Warnings

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

- Earlens 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 in place.
- Should any part of the Device 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 healthcare professional.
- Do not crush, short circuit, modify or disassemble any component of the Earlens Hearing Solution. Keep all components of the Earlens Hearing Solution out of the reach of children, pets and others, to avoid risk of swallowing.
- Do not incinerate any component of the Earlens Hearing Solution or use near an open flame. Handle waste from electronic equipment per local regulations.

Precautions

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

- This is not hearing protection. You should remove this device if you experience overly loud sounds, whether short or long lasting. if you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.
- The sound output should not be uncomfortable or painful. You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.
- You might need medical help if a piece gets stuck in your ear. If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

- 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.
- Earlens 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.
- Ear plugs or headphones can be used with the Lens in place as long as they are not over-inserted and 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 daily may result in Lens displacement.
- Do not place any component of the Earlens Hearing Solution into a microwave, or near a significant source of static electricity.

- Use only the Earlens Charger and AC wall adaptor provided. Although other adapters may look similar, they may cause damage to the Earlens Hearing Solution.
- Handle the components carefully and prevent hard knocks. Do not drop them as it may damage the Earlens Hearing Solution.
- If the Earlens Processor fails to operate or if it appears damaged, including the presense 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. 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.

Notices

- What you might expect when you start using a hearing aid. A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss. People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices. If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening — for example, noisy environments.

- Tell FDA about injuries, malfunctions, or other adverse events. To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

Welcome

Thank you for choosing the Earlens Hearing Solution. This user manual is designed to show you how to use and care for your new Earlens. We encourage you to carefully read this entire booklet including the Warnings, Precautions, and Notices sections to achieve the maximum benefit from your new hearing technology.

If you have further questions that are not answered in this manual, please contact your hearing professional or call the Earlens Concierge at 1-844-234-5367. You can always access the most up-to-date version of this user manual and the *Earlens Patient Instructions for Use (IFU)* at www.earlens.com/IFU.

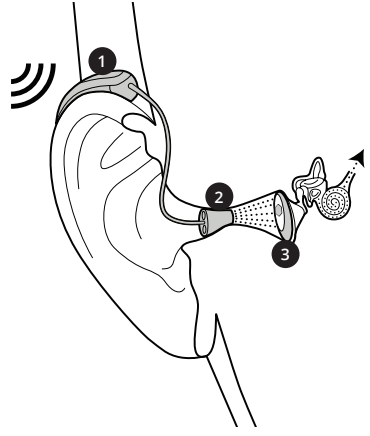
Contents

Getting to Know Your Earlens

The Earlens Hearing Solution uses a small Lens placed in your ear by a physician to activate your natural hearing system. The behind-the-ear Processor collects sound and transfers it to the Ear Tip, which converts the sound signal into an energy signal. The Lens collects energy pulses that power the Lens to vibrate and gently activate your natural hearing system.

There are important components to your Earlens that will be described in this section: the Lens, the Processor, the Ear Tip, the Charger, and mineral oil.

1. Sound enters the microphone on the Processor, which processes the audio signal based on your hearing needs.
2. The audio signal is then converted into pulses of energy that are transmitted by the Ear Tip.
3. When the energy signal reaches the Lens, it vibrates the eardrum gently at different frequencies resulting in rich, natural sound.

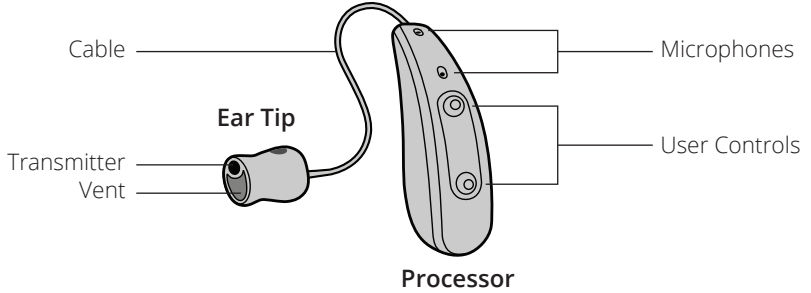


The Lens

The Lens is powered by pulses of energy that contain sound information. When the Lens detects the signal, it gently activates your natural hearing system, allowing you to hear sound. To keep your Lens functioning properly, you must apply mineral oil every other day, or as directed by your provider, and avoid placing foreign objects in your ear (such as Q-tips, bobby pins, and your fingernails).

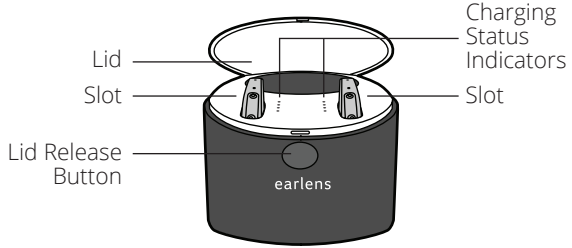
The Processor and Ear Tip

The Processor sits comfortably behind your ear. It collects and sends audio signals through the Ear Tip. Those signals are received by the Lens.

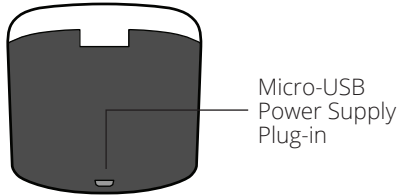


The Charger

The Charger can hold one or two devices. It features a USB-based AC wall power adapter as its power source. The Charger includes an LED indicator display to let you know the charging status of your Processor(s).



Front View of Charger



Back View of Charger

Charging Status Indicators

Charging Status Indicators		What It Means
☼	One **flashing** light	Charger connecting to Processor, it may take up to 20 seconds to connect.
●	One solid light	Battery charging and **below** 33% charged
● ●	Two solid lights	Battery charging and **above** 33% charged
● ● ●	Three solid lights	Battery charging and 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 the top user control (see page 45)
	No lights	Check that Charger is plugged in and Processors are correctly in slots

Mineral Oil

Mineral oil plays an important role in keeping the Lens in position and properly working. Apply **one** pump of mineral oil to each ear every other day, or as directed by your provider. If you forget to apply the mineral oil to your ear as advised, your Lens may stop working or fall out. In the event that you forget to oil as scheduled, apply oil as soon as possible and then resume as advised.

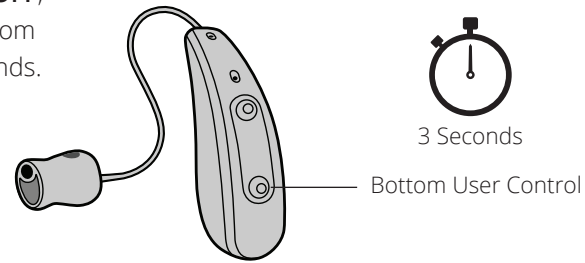
Detailed mineral oil use instructions are available in the Care and Maintenance section of this manual.

Using your Earlens Hearing Solution

Turning the Processor Off

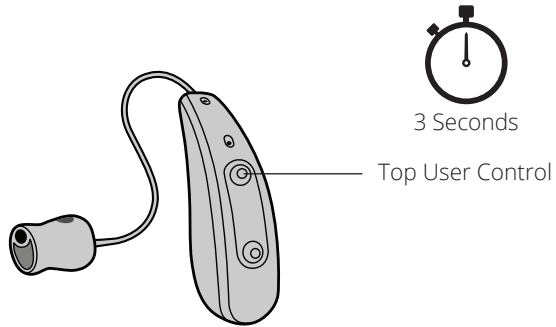
When you remove your Processor from a plugged-in Charger, it will be **ON**.

To turn the Processor **OFF**, push and hold the bottom user control for 3 seconds.



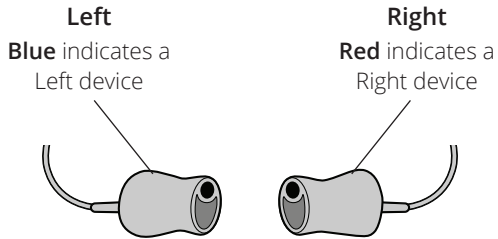
Turning the Processor On

To turn the Processor **ON**, push and hold the top user control for 3 seconds.



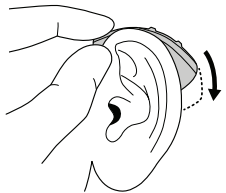
Identifying Left or Right Device

To identify a left or right device, look at the color of the indicator in the Ear Tip.



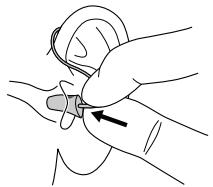
Putting on the Processor and Ear Tip

It is important that the Ear Tip is placed properly in your ear.



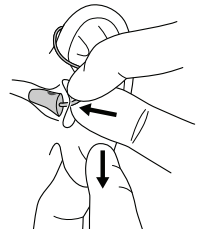
1

Place the Processor behind your ear, where it should rest comfortably.



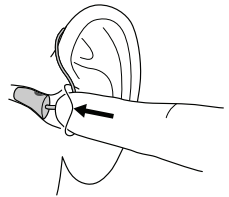
2

Hold the Ear Tip between your thumb and index finger with the colored dot pointing up and the Positioning Lip pointing toward the back of the head.



3

Slowly insert the Ear Tip into your ear canal. Gently pulling your outer ear up and back may help with insertion.

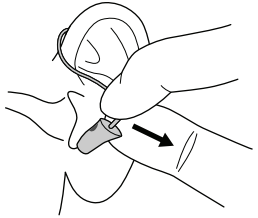


4

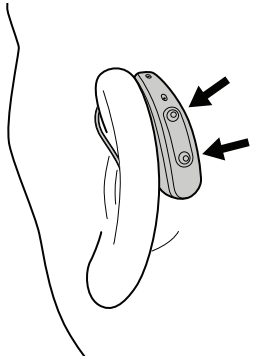
Gently push the Ear Tip into your ear canal, pushing it as far as it will comfortably go, to ensure it is seated in the correct position.

Removing the Processor and Ear Tip

To remove the Processor and Ear Tip, grasp the Cable between your thumb and index finger near the Ear Tip and gently pull it out of the ear canal.

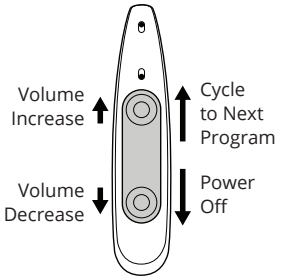


Changing Volume and Program

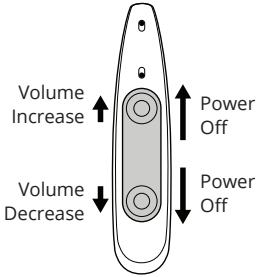


Your hearing professional can customize your user controls based on your preferences and needs. Your user controls can be set up to change volume, change programs or to change both the volume and programs. Please speak to your hearing professional about how your user control settings have been customized. The tables on the next few pages can also serve as a helpful reference.

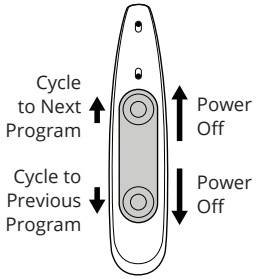
User Control Options	Action/Press			
Volume & Program	Volume Increase	=	Short Press Up	↑
	Volume Decrease	=	Short Press Down	↓
	Cycle to Next Program	=	Long Press Up (3 seconds)	↑
	Power Off	=	Long Press Down (3 seconds)	↓



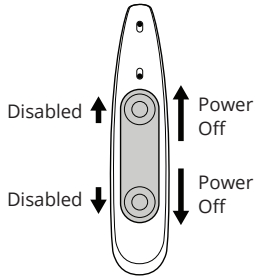
User Control Options	Action/Press			
Volume Only	Volume Increase	=	Short Press Up	↑
	Volume Decrease	=	Short Press Down	↓
	Power Off	=	Long Press Up (3 seconds)	↑
	Power Off	=	Long Press Down (3 seconds)	↓



User Control Options	Action/Press			
Program Only	Cycle to Next Program	=	Short Press Up	↑
	Cycle to Previous Program	=	Short Press Down	↓
	Power Off	=	Long Press Up (3 seconds)	↑
	Power Off	=	Long Press Down (3 seconds)	↓



User Control Options	Action/Press			
No Volume or Program Control Enabled	Disabled	=	Short Press Up	↑
	Disabled	=	Short Press Down	↓
	Power Off	=	Long Press Up (3 seconds)	↑
	Power Off	=	Long Press Down (3 seconds)	↓



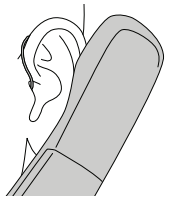
Processor Alerts

Your hearing professional can program your Processor(s) to have a number of sound alerts that indicate a specific function. The following table provides a description of each alert.

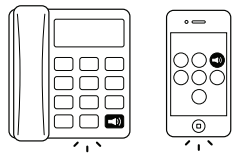
Alert Type	Description of Alert	What it Means
Power On	3 tone melody	The Processor has powered on.
Power Off	4 descending tone melody	The Processor has powered off.
Battery	6 tone melody OR a voice alert that states "Battery"	The battery is low and the Processor will shut off in either 15 or 60 minutes.
Volume Change	1 quick beep	The volume has increased/decreased.
Default Volume Level	2 quick beeps	The volume is at the default programmed level.
Min/Max Volume	3 quick beeps	You are at the minimum or maximum limits of your volume control.
Program Change	P1 = 1 beep P2 = 2 beeps P3 = 3 beeps P4 = 4 beeps OR voice alerts that say the name of the program	The program has changed.

Telephone and Cellphone Use

There are a few ways you can try to use your phone with your Earlens.

1. 

   Hold the upper portion of the phone over the microphones on your Processor, with the mouthpiece pointed towards your mouth.

2. 

   If available, use the speaker phone feature on your phone.

3. Earlens features Made for iPhone compatibility. This feature allows you to take phone calls and stream media from your Apple device directly to your Processor(s). For the latest iOS and Apple device compatibility information, please go to www.earlens.com/connectivity.

With the Made for iPhone feature, you can connect your Earlens Hearing Solution to your Apple device. This connection, along with the Earlens Control App, allows you to easily and discretely change your hearing aid programs and volume. You can also take phone calls and stream media from your iPhone, iPad, and iPod touch directly to your hearing aids.

Pairing and Connecting your Apple Device

To pair your hearing aids to your Apple device, follow these steps:

1. Turn your hearing aids off and back on.
2. On your Apple device, tap the **Settings** icon > **Accessibility** > **Hearing Devices.**
3. Ensure Bluetooth is enabled. The Apple device will start searching for your hearing aids (Fig.1).
4. Once your hearing aids are discovered, your ***First Name + Hearing Aids*** and ***R+L*** will display*
5. Tap on your name.
6. A pairing request window will appear for each device. Select **Pair*** (Fig.3).
7. When your hearing aids are paired and connected, you will see the word "Connected" (Fig.4) in the main Hearing Devices screen.

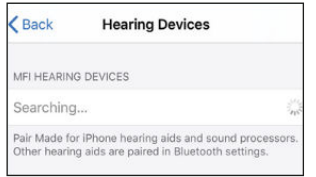


Figure 1. Searching for hearing aids

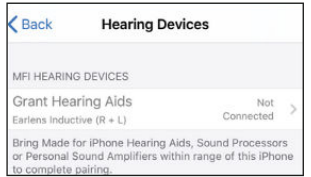


Figure 2. Hearing aids discovered

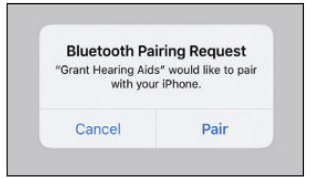


Figure 3. Pairing request window

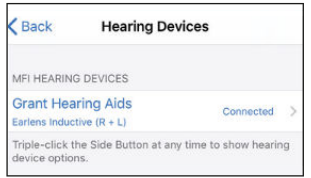


Figure 4. Hearing aids paired and connected

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

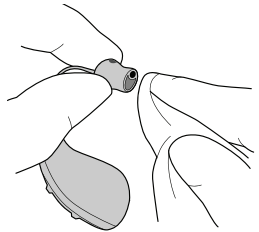
Charging and Battery Life

The Processor battery will last an average of 20 hours. It takes 4 hours in the Charger to completely recharge a fully depleted Processor battery. We highly recommend charging your Processor(s) in a dry and low-humidity location.

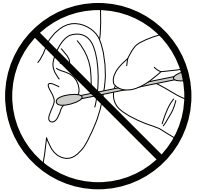
1. To charge, place the Processor and Ear Tip into the Charger.
2. Wait until the indicator light turns solid to ensure the Processor is successfully charging.
3. If four indicator lights flash, the Processor is not charging. Remove the Processor from the Charger, place it back into the charging slot and immediately press the top user control button. If the indicator lights continue to flash, refer to page 45 before contacting your hearing professional.

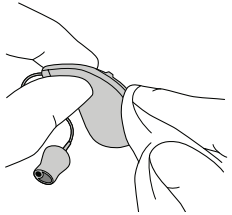
Cleaning and Maintenance

Daily Care



1. Check that there is no wax or debris on the Ear Tip. If wax or debris is present, use a soft cloth, a baby wipe, or other Isopropyl Alcohol (IPA) based wipes to remove.
2. If there is a wax or debris in the Ear Tip vent or on the end of the transmitter, use a soft-bristle toothbrush, a pipe-cleaner or a hearing aid cleaning tool to gently clear the debris. Only perform cleaning when the device is off of the ear and **do not** use a sharp brush or tool when cleaning the Ear Tip.





3. If you notice wax on the Ear Tip, use a soft cloth to wipe the bowl of your ear. Never insert foreign objects into the ear canal, such as Q-tips, bobby pins or your fingernails even to remove earwax. Insertion of foreign objects could result in pain, may damage your ear and may cause damage to the Lens.
4. If you need to have ear wax removed, or your ear canal cleaned, contact your ENT physician.
5. Wipe the Processor with a soft cloth if you notice any moisture or debris.
6. Never use chemicals on the Processor or Ear Tip.
7. Use a soft cloth to wipe the Charger when necessary.
8. When applying hair products, lotions, or gels, first remove the Processors from behind your ear. After application, ensure your hands are clean before repositioning your Processors.

Oiling Instructions

Oiling is required to keep the Lens in place and functioning properly. Apply **one** pump of mineral oil to each ear every other day, or as directed by your provider.

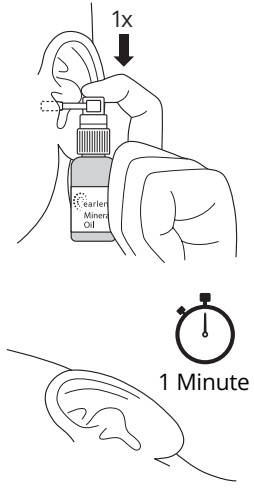
Follow the instructions provided by your physician if he or she asks you to oil on a different schedule. If you have difficulty applying the mineral oil, consider having another person assist you.

We recommend you oil your ears at bedtime, after you have removed your devices for the day. After you oil, you may notice a slight decrease in your hearing, which is temporary.

- After oiling, your ears may feel a little stuffy. This feeling should subside on its own as the oil is absorbed.
- It is recommended that you reapply mineral oil after you go swimming, take a bath or enjoy any other activity that causes your ear canals to fill with water.
- Use only the mineral oil and container provided and/or recommended by your hearing provider or Earlens.

1

Before each use, prepare the mineral oil dispenser by turning the nozzle until it can fit comfortably into your ear.



2 With your head in an upright position, place the cone tip of the dispenser fully into the ear canal opening. Dispense **one pump** of oil into the ear canal by depressing the pump.

3 Remove the dispenser from the ear and tilt your head to the side. Allow oil to run down to the eardrum by keeping your head tilted for **approximately one minute.** You may hear or feel the oil when it reaches the eardrum.

4 Repeat on the opposite ear.

Note: Upon first use, prime the dispenser until oil is dispensed.

Avoiding Moisture & Heat

Moisture and heat can damage your Earlens. You can avoid this by taking these steps:

- Do not leave your devices in extreme heat.
- Do not wear your processor(s) in heavy rain, steam baths or showers.
- Do not dry your devices in a microwave or with any other heat source.
- Take off your processor(s) when applying hairspray, perfume, aftershave, insect repellent or any other harsh chemical as it can damage your device.
- If there is moisture on any component, wipe it off.
- Store the Earlens Hearing Solution in a clean, dry location out of direct sunlight.
- Store the Earlens Processor and Ear Tip in the Charger when not in use.

Warranty

Your Earlens Hearing Solution is covered by a warranty. Please talk to your hearing provider about the details of your warranty. You can register your Earlens online at: www.earlens.com/register

Warranty Period

Start Date: _____

End Date: _____

Troubleshooting

Issue	Possible Causes	Possible Remedy
No sound	Battery is not charged.	Charge the Processor until at least 2 solid lights appear. If 2 or more solid lights appear, the battery is not the issue. Contact your hearing professional.
Not loud enough	The Ear Tip is improperly inserted.	Remove and re-insert the Ear Tip and check the position in a mirror if possible.
	Volume is set too low.	If your device features volume user control functionality, increase the volume. If you still require more volume, contact your hearing professional.
Damage to Ear Tip or Cable	Wear and tear.	Contact your hearing professional.
Sound distorted/ not clear	Battery is low.	Charge the Processor until at least 2 solid lights appear.
	Hearing aid is damaged.	Contact your hearing professional.
	Hearing aid setting is not optimal.	Contact your hearing professional.
Charger is flashing 4 lights	Something is wrong with the Charger or Processor.	Remove the Processor from the Charger, re-insert the device into the charging slot and immediately press the top user control. It may take the Processor up to 20 seconds to connect to the Charger. Repeat removal and insertion up to 5 times. If the lights continue to flash, contact your hearing professional or call the Earlens Concierge at 1-844-234-5367.

Issue	Possible Causes	Possible Remedy
Whistling (feedback)	The Ear Tip is not properly inserted.	Remove and re-insert the Ear Tip and check the position in a mirror if possible. If the issue persists, contact your hearing professional.

Technical Information

- 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, 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.

Power Requirements

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

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.

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.
RF emissions CISPR 11	Class B	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.
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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
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	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. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 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	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
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 (MHz)[a]	Service[a]	Modulation[b]	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine[c]	2	0.3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
1720 1845 1970	1700 –1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 –5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

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.

FCC Information

FCC ID: 2AGDU-EL2PIN

Earlens® Contact Hearing Solution complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

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.

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.

Clinical Study Information

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.

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.

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.

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 Occuring	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

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 5); 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 6). Functional gain reached a maximum of 68 dB at 9,000-10,000 Hz.

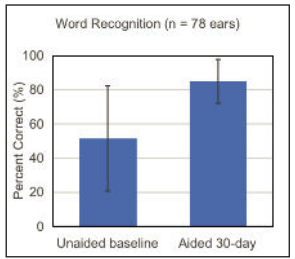


Figure 5. Word Recognition

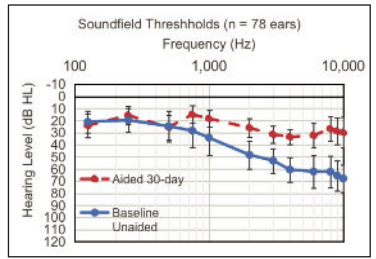


Figure 6. Sound field thresholds

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.

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.

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.

Device Labeling Symbols

Refer to Instruction Manual

Date of Manufacture

MR Unsafe

Rx Only — By Prescription Only

SN — Serial Number

REF — Catalog Code

IP22 — Ingress Protection Code

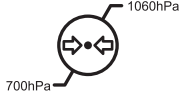
IP57 — Ingress Protection Code

LOT — Batch Code

Humidity Limitation

Non-Ionizing Radiation

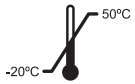
Product is a Type BF Applied Part



Atmospheric Pressure Limitation

FCC Approved Equipment

Caution



Storage Temperature Limit

Keep Dry

"Made for iPod," "Made for iPhone," and "Made for iPad" mean that an electronic accessory has been designed to connect specifically to iPod, iPhone, or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPod, iPhone, or iPad may affect wireless performance.

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