



Contact Hearing Solution User Manual
Earlens[®] Hearing Aid User Manual





Earlens(R) Contact Hearing Solution User Manual

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 ~~Hearing Aid~~. We encourage you to carefully read this entire booklet including the Warnings and Precautions 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 1-844-730-5986. You **can** always access the most up-to-date version of the *Earlens ~~Hearing Aid~~ Patient Instructions for Use (IFU)* at www.earlens.com/IFU. The IFU contains results from Earlens ~~Hearing Aid~~ clinical studies and information regarding safe and effective EMC use.

Contents

| | | | |
|---|----|-----------------------------------|----|
| Getting to Know Your Earlens Hearing Aid | 4 | Telephone and Cellphone Use | 24 |
| The Lens | 6 | Charging and Battery Life | 26 |
| The Processor and Ear Tip | 7 | Cleaning and Maintenance | 27 |
| The Charger | 8 | Daily Care | 27 |
| Mineral Oil | 10 | Oiling Instructions | 29 |
| Using your Earlens Hearing Aid | 11 | Avoiding Moisture & Heat | 32 |
| Turning the Processor Off | 11 | Warranty | 33 |
| Turning the Processor On | 12 | Troubleshooting | 34 |
| Identifying Left or Right Device | 13 | Warnings | 37 |
| Putting on the Processor and Ear Tip | 14 | Precautions | 39 |
| Removing the Processor and Ear Tip | 16 | Technical Information | 43 |
| Changing Volume and Program | 17 | Device Labeling Symbols | 44 |
| Processor Alerts | 22 | | |

Getting to Know Your Earlens ~~Hearing Aid~~

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 ~~a rapidly pulsed energy pulses that power the Lens to vibrate and gently activate your natural hearing system.~~

There are important components to your Earlens ~~Hearing Aid~~ that will be described in this section: the Lens, the Processor, the Ear Tip, the Charger and mineral oil. ~~The components that you will interact with include the Processor, Ear Tip, 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.

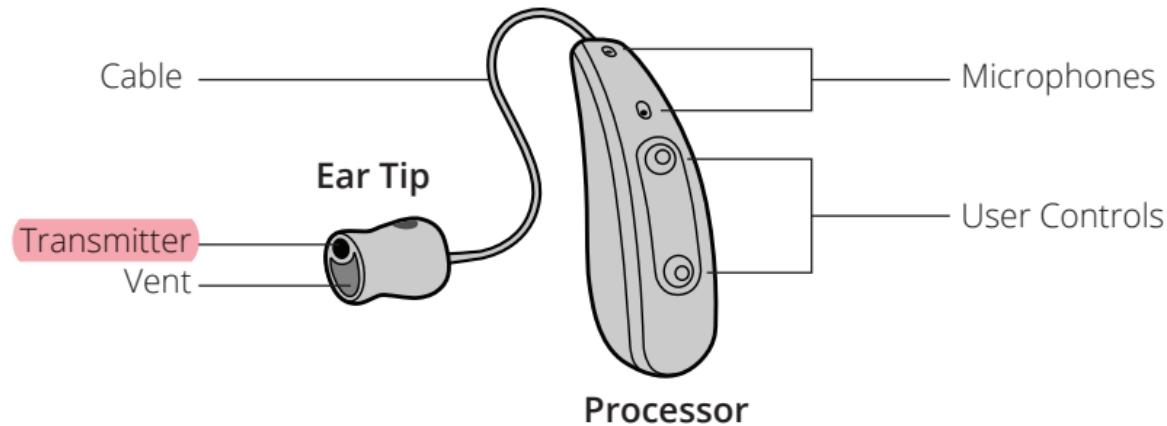


The Lens

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 once to twice daily, or as directed by your provider, and avoid placing foreign objects in your ear (such as Q-tips, bobby pins, and your fingernails).

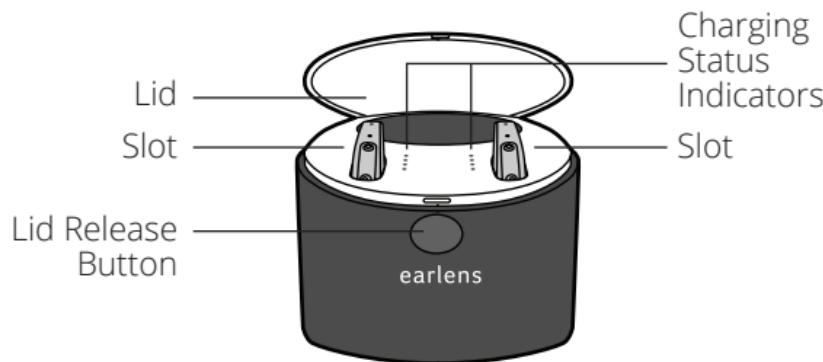
The Processor and Ear Tip

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

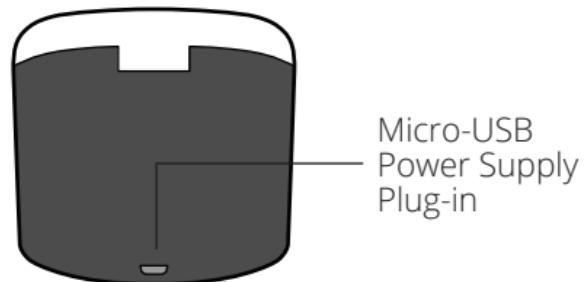


The Charger

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).

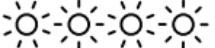


Front View of Charger



Back View of Charger

Charging Status Indicators

| Charging Status Indicators | What It Means |
|---|---|
|  | One flashing light Charger connecting to Processor |
|  | 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 top user control |
| | 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 daily, 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.

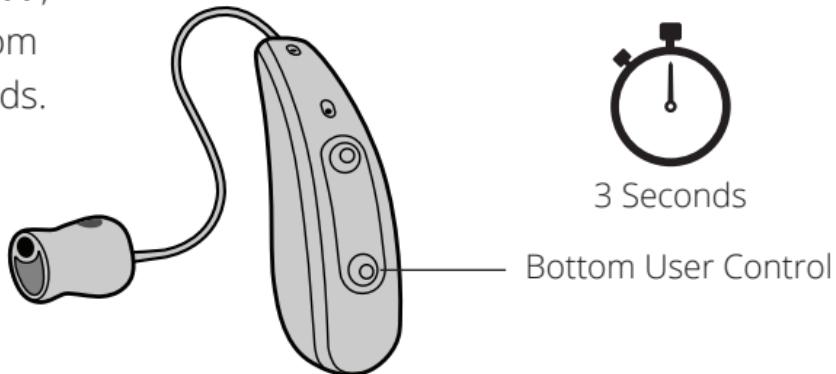


Using your Earlens Hearing Solution

Turning the Processor Off

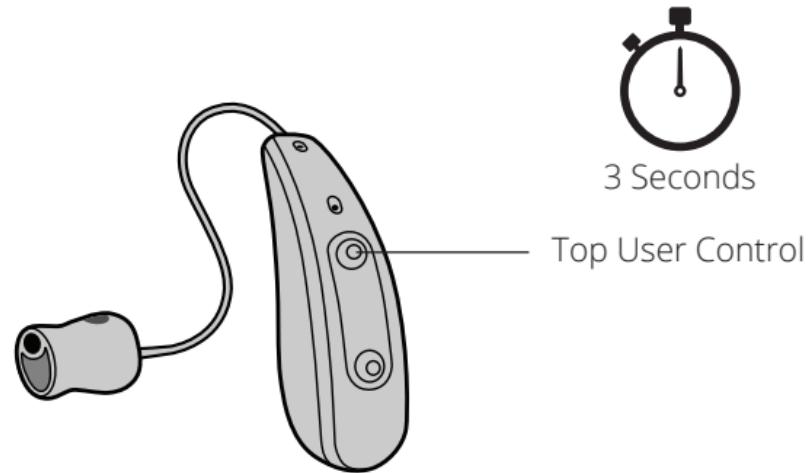
When you remove your Processor from a plugged-in Charger, it will be **ON**.

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



Turning the Processor On

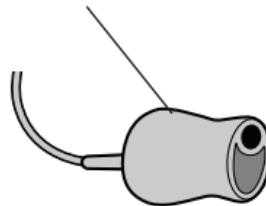
To turn the Processor **ON**, push and hold the top user control for 3 seconds.



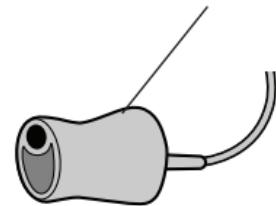
Identifying Left or Right Device

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

Left
Blue indicates a
Left device

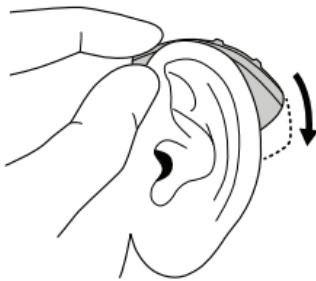


Right
Red indicates a
Right device



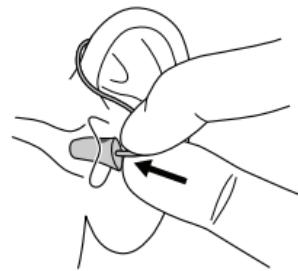
Putting on the Processor and Ear Tip

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



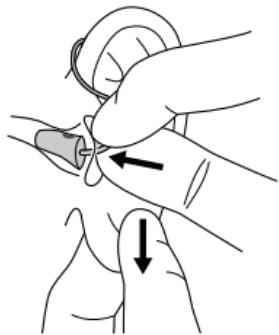
1

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



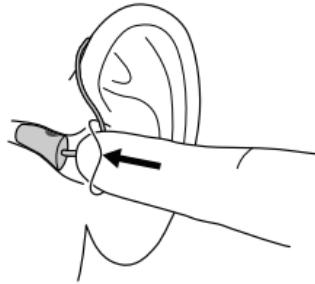
2

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.

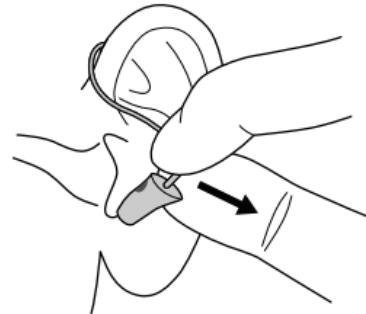


4

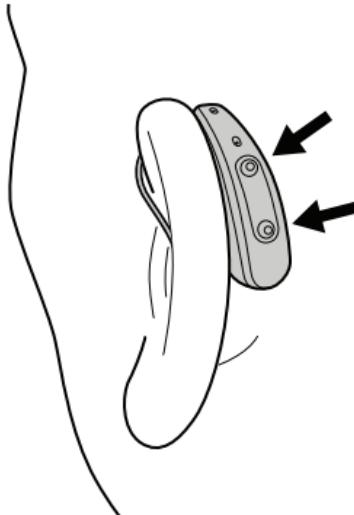
Gently push the Ear Tip into your ear canal, pushing it as far as it will comfortably go, to ensure it is seated in the correct position.

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.

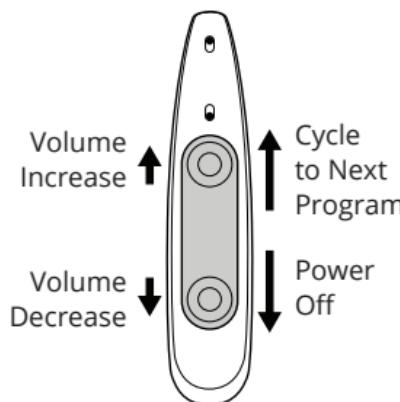


Changing Volume and Program

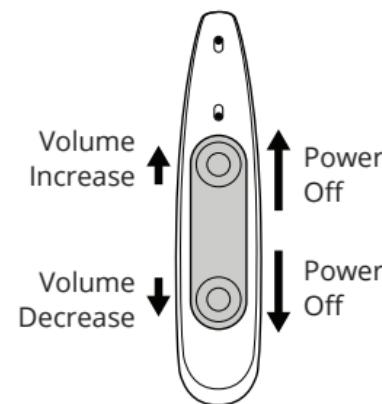


Your hearing professional can customize your user controls based on your preferences and needs. Your user controls can be set up to change volume, change programs or to change both the volume *and* programs. Please speak to your hearing professional how your user control settings have been customized.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

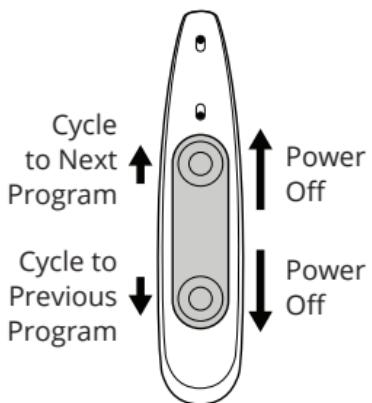
| User Control Options | Action/Press |
|----------------------|---|
| Volume & Program | Volume Increase = Short Press Up  |
| | Volume Decrease = Short Press Down  |
| | Cycle to Next Program = Long Press Up (3 seconds)  |
| | Power Off = Long Press Down (3 seconds)  |



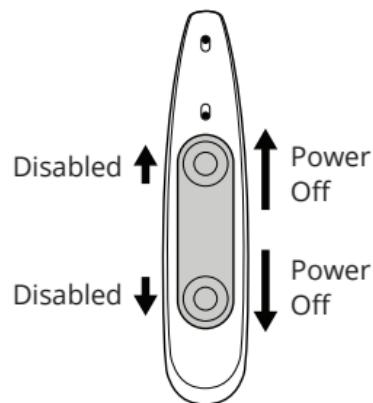
| User Control Options | Action/Press |
|----------------------|---|
| Volume Only | Volume Increase = Short Press Up ↑ |
| | Volume Decrease = Short Press Down ↓ |
| | Power Off = Long Press Up (3 seconds) ↑ |
| | Power Off = Long Press Down (3 seconds) ↓ |



| 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.

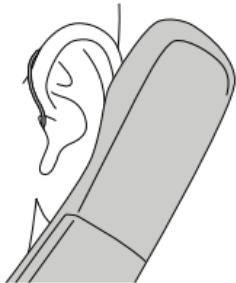
| Alert Type | Description of Alert | What it Means |
|-------------------|--|--|
| Power On | 3 tone melody | The Processor has powered on. |
| Power Off | 4 descending tone melody | The Processor has powered off. |
| Battery | 6 tone melody OR a voice alert that states "Battery" | The battery is low and the Processor will shut off in either 15 or 60 minutes. |

| Alert Type | Description of Alert | What it Means |
|-----------------------------|---|--|
| 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

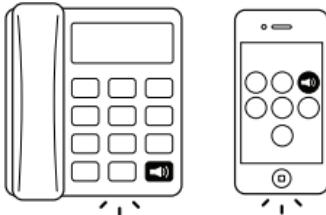
There are a few ways you can try to use your phone with your Earlens ~~Hearing Aid~~.

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

~~The~~ Earlens Hearing Aid 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.

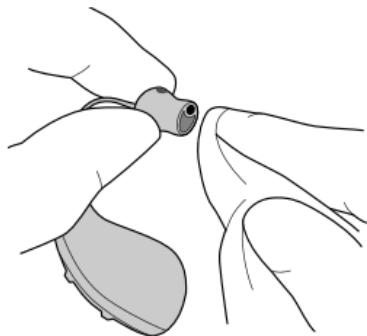
Charging and Battery Life

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.

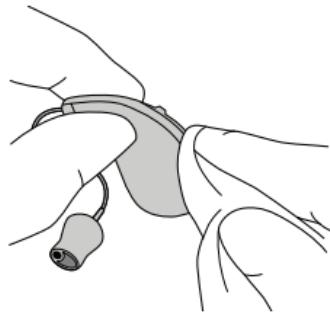
- 1 To charge, place the Processor and Ear Tip into the Charger.
- 2 Wait until the indicator light turns solid to ensure the Processor is successfully charging.
- 3 If four indicator lights flash, the Processor is not charging. Remove the Processor from the Charger, **place it back into** the charging slot and immediately press of the top user control **button**. If the indicator lights continue to flash, contact 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 wax or debris in the Ear Tip vent or covering the emitter, 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, such as Q-tips, bobby pins or your fingernails. Insertion of foreign objects could result in pain, may damage your ear and may cause damage to the Lens.
- 4 Wipe the Processor with a soft cloth if you notice any moisture or debris.
- 5 Never use chemicals on the Processor or Ear Tip.
- 6 Use a soft cloth to wipe the Charger when necessary.

Oiling Instructions

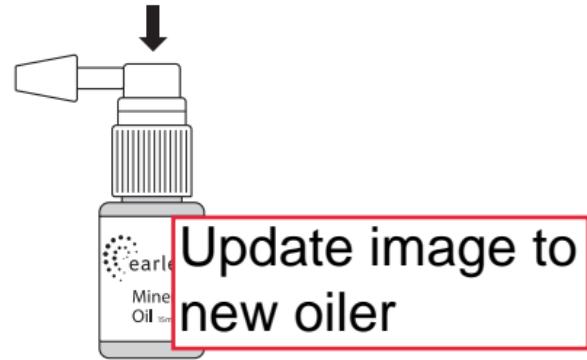
Oiling is required to keep the Lens in place and functioning properly. Apply one pump of mineral oil daily, or as directed by your provider, to your ear canal.

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.

Instructions for Oiling:

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 by depressing the pump until a constant stream is observed.



- 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 **one to two minutes**. You may hear or feel the oil when it reaches the eardrum.
- 4 Repeat on the opposite ear.

Avoiding Moisture & Heat

Moisture and heat can damage your Earlens ~~Hearing Aid~~. 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.

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 ~~Hearing Aid~~ 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. |

| Issue | Possible Causes | Possible Remedy |
|-------------------------------------|---|--|
| 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 short press the top user control. Repeat removal and insertion up to 5 times. If the lights continue to flash, contact your hearing professional or call the EarLens Concierge at 1-844-730-5986. |

| 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. |

Warnings



Before using the **Earlens(R) Contact Hearing Solution**, 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.
- 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.

- If you have known nickel sensitivity/allergy, please be aware that the Lens and Ear Tip components contain nickel that is coated with a parylene barrier. If you develop an allergic reaction, the Lens and Ear Tip should be promptly removed.
- The Lens and Ear Tip were tested for nickel leaching and found to be compliant and within the safe levels identified in European standard EN1811. Traces of oxidation (discoloration) may be visible on the Lens surface following prolonged wear. Testing indicated the oxidation was not likely to affect the structural integrity of the Lens and Ear Tip within the 1 year expected life.
- Only healthcare professionals trained in the fitting of hearing aids may fit the Processor and Ear Tip.

- The Earlens Hearing Aid is custom designed and intended to be used only by a single patient.
- The Ear Tip is designed to sit a set distance from the Lens. Sound output may deviate if the Ear Tip is not inserted to the proper depth. If the sound output does deviate, you can reposition the Ear Tip until optimal sound output is achieved.
- Earplugs or headphones can be used with the Lens in place as long as **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 twice a week 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 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 healthcare professional.

Technical Information

Earlens Hearing Aid FCC ID: 2AGDU-EL2PIN.

IC ID: 20825-EL2PIN

Device Labeling Symbols



Refer to
Instruction
Manual



Date of
Manufacture



MR Unsafe



Product is a
Type BF Part

RxOnly

By Prescription
Only



Serial Number

IP21

Ingress
Protection
Code

LOT

Batch Code

REF

Catalog Code



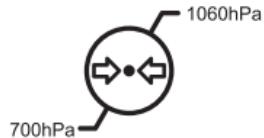
Humidity
Limitation



Non-Ionizing
Radiation



Caution



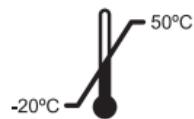
Atmospheric
Pressure
Limitation



FCC Approved
Equipment



Keep Dry



Storage
Temperature
Limit



Dispose
Electronic
Waste Properly

"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.

Apple, the logo, AirPlay, iPhone, iPad, iPod are trademarks of Apple Inc., registered in the U.S. and other countries.



This device 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.

This product does not contain any user serviceable components. Any unauthorized product changes or modifications will invalidate warranty and all applicable regulatory certifications and approvals, including authority to operate this device.

FCC Part 15 Digital Emissions Compliance We, Earlens®, declare under our sole responsibility that this product 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.

WARNING: This equipment 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 and radiates 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 the one the receiver is connected to.

Consult the dealer or an experienced radio/TV technician for help. The user may find the following booklet prepared by the Federal Communications Commission helpful: The Interference Handbook

This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402. Stock No.004-000-00345-4



Manufactured by:
**Earlens(R) Corporation,
Inc.** 4045A Campbell Ave.
Menlo Park, CA 94025 USA
+1 (844) 234-LENS
www.earlens.com



European Authorized Representative:
Medimark® Europe SARL
11, Rue Emile Zola, B.P. 2332
F-38033 Grenoble Cedex 2 – France

www.earlens.com



LBL00153vC March 2019

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