



Earlens® Contact Hearing Solution Physician Instructions

1.	Introduction	2
2.	Earlens® Contact Hearing Solution Device Description.....	2
3.	Indications for Use.....	3
4.	Fitting Range	3
5.	Contraindications.....	3
6.	Warnings	4
7.	Precautions.....	4
8.	Clinical Study Results (Information summarized from 2015 Definitive Study)	5
9.	Operating Instructions.....	7
10.	Operating Specifications.....	9
11.	FCC Information	9
12.	Glossary of Terms.....	10
13.	Graphic Symbols Contained in Device Labeling	10

1. Introduction

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

Rx ONLY

For patient instructions, please see *Earlens® Contact Hearing Solution Patient Instructions*.

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

2. Earlens® Contact Hearing Solution Device Description

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

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

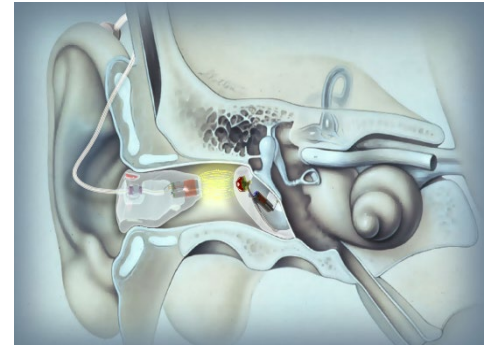


Figure 1: Earlens component schematic

2.1 Lens

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

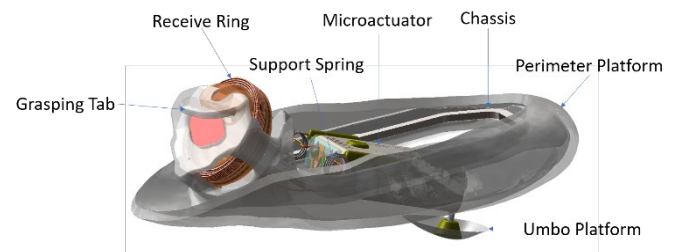


Figure 2: Lens

2.2 Processor and Ear Tip

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

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

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

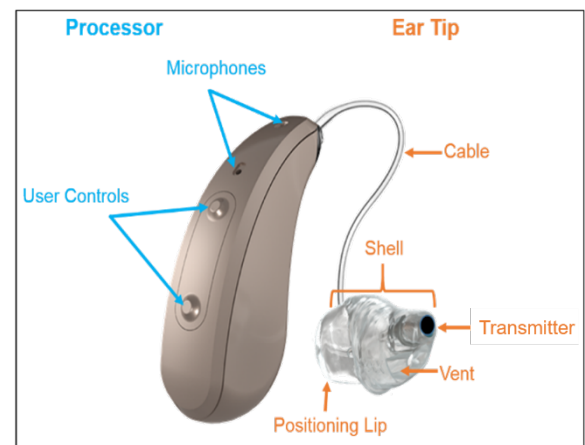


Figure 3: Processor & Ear Tip

2.3 Earlens® Fitting Software

The fitting software is used to program the Processor, enabling the hearing healthcare professional to calibrate and program the Processor specific to the patient's needs.

2.4 Earlens® Charger and Power Adapter

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

2.5 Earlens® Impression System

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

2.6 Mineral Oil

White mineral oil (food grade) is used to lubricate the eardrum to keep the Lens in place and functioning properly. To maintain the devices, it is recommended that patients apply one pump of mineral oil to their ears every other day or as recommended by their physician.

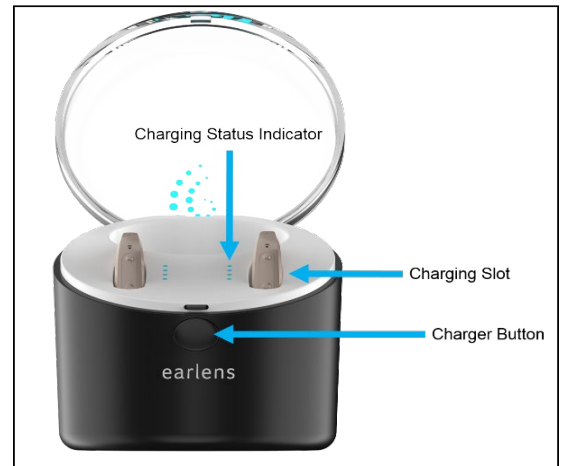


Figure 4: Earlens Charger

3. Indications for Use

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

4. Fitting Range

The Earlens® Contact Hearing Solution provides the full spectrum of amplification that includes 125 Hz – 10,000 Hz. The audiometric fitting range is shown in Figure 5.

5. Contraindications

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

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

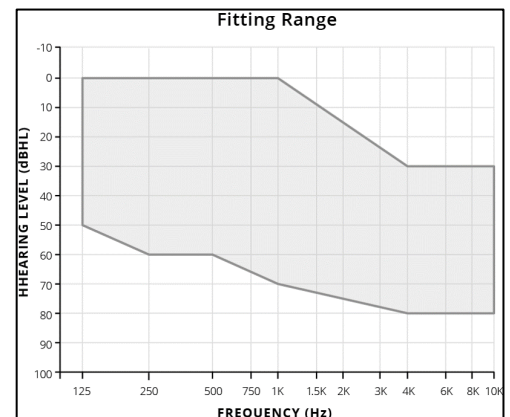


Figure 5: Earlens Fitting Range

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

6. Warnings



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

- The Earlens® Contact Hearing Solution is considered MRI 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.**
- The patient should not use therapeutic or medical diathermy using electromagnetic radiation (magnetic induction coils or microwave) from the shoulders up with Earlens® Contact Hearing Solution in place.
- Should any part of the Aid become damaged, the patient should discontinue use and contact their hearing healthcare professional.
- If the patient experiences discomfort or pain in their ear, they should contact their ENT physician immediately. Only physicians trained in Ear, Nose & Throat procedures should place or remove the Lens.
- The patient should not insert foreign objects into the 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.
- The patient should contact their hearing healthcare professional if they experience discharge from the ear or persistent discomfort or any other problems.
- Should the Processor become unusually warm or hot, the patient should promptly remove it, discontinue use, and contact their hearing healthcare professional.
- Do not crush, short circuit, modify, or disassemble any component of the Earlens® Contact Hearing Solution. Keep all components of the Earlens® Contact Hearing Solution out of the reach of children, pets, and others, to avoid risk of swallowing.
- Do not incinerate any component of the Earlens® Contact Hearing Solution or use near open flame. Handle waste from electronic equipment per local regulations.

7. Precautions



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

- Individuals with known nickel sensitivity/allergy should be informed that the Lens and Ear Tip components contain nickel that is coated with a parylene barrier. If an allergic reaction develops, 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 hearing healthcare professionals trained in the fitting of hearing aids may fit the Earlens® Processor and Ear Tip.
- The Earlens® Contact Hearing Solution is custom designed and intended to be used for 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, the patient can reposition the Ear Tip until optimal sound output is achieved.
- Earplugs or headphones can be used with the Lens in place as long as care is taken not to over-insert them and they do not protrude deeply into the ear canal.

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

8. Clinical Study Results (Information summarized from 2015 Definitive Study)

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 the 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. The subjects were seen across three clinical sites with the largest enrollment at Site 1 (Site 1= 21, Site 2=15 and Site 3=12). 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. The objective was to identify any change in baseline hearing after four months of device usage using a four-frequency threshold average criterion (500, 1000, 2000, and 4000 Hz, referred to as PTA4). A determination of clinically non-significant hearing threshold change was made if calculated PTA4 hearing change of the subject population was less than 10 dB. 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 for

either ear at any frequency. In addition, no serious device or procedure-related adverse events were reported during the trial. There were 31 adverse events 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 and effectiveness outcomes were not impacted. The subject continued use throughout the study period of four months. Table 1 presents 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

Effectiveness Outcomes

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

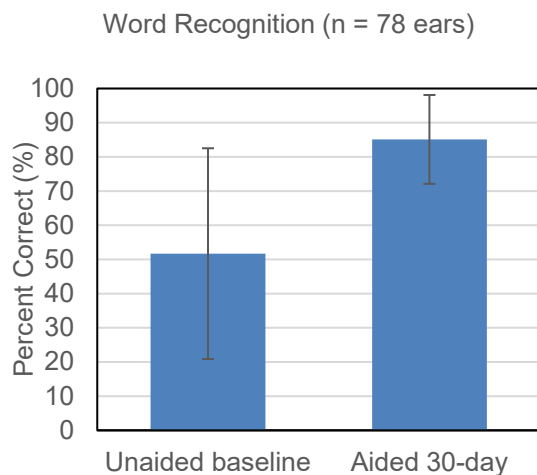


Figure 6: Word Recognition

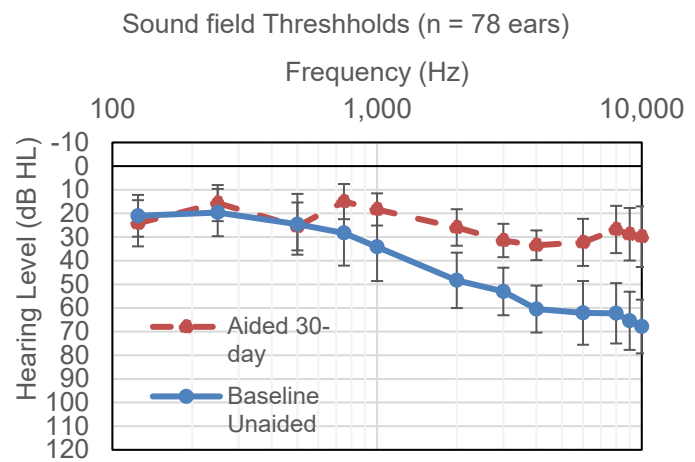


Figure 7: Sound field thresholds

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

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) 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.

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

9. Operating Instructions

9.1. Ear Canal Impression

Before making the ear canal impression using the Earlens® Impression System, please read and follow the precautions and procedures found in the Earlens® Sitting Hybrid Impression Instructions for Use.

9.2. Lens Placement

- a. Visually inspect the Lens packaging. DO NOT use if there is any visible damage.
- b. Explain to the patient that the ear will be inspected and cleaned, then lubricated with oil (which may cause some sensations of stuffiness), and the device will be inserted. Instruct the patient to remain still during the procedure.
- c. With the patient in the supine position, use a binocular microscope to inspect the external auditory canal and the tympanic membrane and determine if there are any contraindications for Lens placement.
- d. Remove all cerumen and epithelial debris from the ear canal, anterior sulcus and tympanic membrane using the usual office instrumentation and small cotton swabs with mineral oil. If there is any bleeding or development of contraindications as a result of cleaning of the ear canal, do not place Lens.
- e. Lubricate the ear canal and TM with mineral oil.

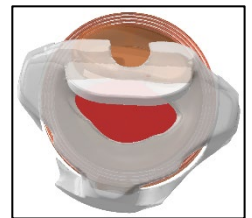


Figure 8: Right Lens

- f. Read the package label to confirm that the device is for the correct patient and ear. The right device is identified by a red dot located in the center, underneath the Grasping Tab (Figure 8). The left device is identified by a blue dot located in the center, underneath the Grasping Tab (Figure 9).
- g. Grasp the Lens at the Grasping Tab (Figure 2) using smooth alligator forceps.
- h. Using alligator forceps, gently advance the Lens through a thin bladed nasal speculum to the medial region of the ear canal.
- i. Then, using an aural speculum and curved pick, gently advance the Lens onto the TM and position it such that the Perimeter Platform is congruent with the anatomical contours of the patient's anatomical counterparts. At this point the Umbo platform will be in direct contact with the TM.
- j. Once satisfactory positioning is achieved, remove the speculum.

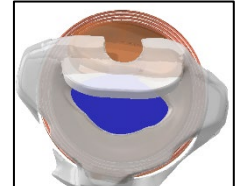


Figure 9: Left Lens

9.3. Lens Removal

- a. Explain to the patient that the ear will be inspected and cleaned, lubricated with mineral oil (which may cause some sensations of stuffiness), and the device will be gently removed. Instruct the patient to remain still during the procedure.
- b. With the patient in the supine position use a binocular microscope to inspect the external auditory canal and the TM, and determine the position of the device and the location of the grasping tab.
- c. Lubricate the ear canal with mineral oil.
- d. Using a right angle hook, use the Grasping Tab to capture the device to be removed and slowly deliver it into the lateral canal. Withdraw the speculum, and use the curved pick to remove the Lens.
- e. Inspect the external auditory canal and the TM.

9.4. Cleaning and Preparing the Lens for Reinsertion

If a Lens is removed the device and canal must be cleaned prior to reinsertion of the device.

- a. Remove the Lens per the *Lens Removal* instructions and carefully place and submerge the device in a dish of mineral oil for soaking.
- b. Thoroughly clean the ear canal, anterior sulcus and TM using cotton swabs, mineral oil and suction as needed. Remove any debris, including epithelial tissue that may have built up in the anterior sulcus or on the TM.
 - l. Hydrogen peroxide solution can be used to loosen hard epithelium or cerumen adhered to the TM or anterior sulcus. Before placement of the Lens ensure all of the hydrogen peroxide is completely suctioned out, and the applied area is cleaned with mineral oil, to avoid device contact with the hydrogen peroxide solution.
- c. Inspect the umbo of the TM and the area where the Perimeter Platform of the Lens was resting to ensure it is free of debris or epithelial tissue.
- d. Following the ear canal cleaning carefully inspect the Lens to ensure it is free of debris and is not damaged. Replacing a Lens that is not free of debris or is damaged may cause the device to displace.
- e. Proceed with device placement per the *Lens Placement* (Section 9.2) operating instructions.

9.5. Troubleshooting

The expected life for the Lens is one year. The Lens is expected to exhibit the same failure modes regardless of the duration of wear. The Lens can become displaced from the tympanic membrane, blocked by debris or degrade over time. This may cause the sound output of the EarLens® Contact Hearing Solution to cease, become reduced or become intermittent. Perform the following troubleshooting steps to assess Lens function:

- a. Inspect the ear canal and Lens. If the Lens is blocked by debris, carefully clean the ear canal. If removal or reinsertion is required, follow *Lens Removal* and *Cleaning and Preparing Lens for Reinsertion* instructions above.
- b. Inspect the position of the Lens on ear. If the perimeter platform does not appear to be in contact with the wall of the ear canal, the Lens may be displaced.

- l. In the event of displacement of the Lens, remove the device per *Lens Removal* instructions and replace following the *Cleaning and Preparing Lens for Reinsertion* operating instructions.
- c. Inspect the appearance of the Lens on ear. If the Lens appears damaged or abnormal, remove using the *Lens Removal* instructions and contact EarLens.
- d. If there is a suspected performance issue with the Lens that otherwise appears fine visually (e.g. significant elevation of system Calibration), remove the device per *Lens Removal* instructions and replace following the *Cleaning and Preparing Lens for Reinsertion* operating instructions. Once Lens is replaced assess if the suspected performance issue is resolved (e.g. system Calibration is no longer elevated).

If after performing the troubleshooting steps listed above, the Lens still does not function, remove it using the *Lens Removal* operating instructions and contact EarLens.

9.6. Care & Maintenance

- a. Store the EarLens® Contact Hearing Solution in a clean, dry location out of direct sunlight.
- b. The expected life of the Lens is one year. As for any patient with a hearing assist device, it is recommended that the patient return annually to their hearing healthcare professional(s) to monitor their audiologic and otologic status.

10. Operating Specifications

- For technical details about the EarLens® Contact Hearing Solution and compliance to applicable standards, please consult the Hearing healthcare professional Instructions for Use.
- Certain components of the EarLens® Contact Hearing Solution, including the Processor and the Ear Tip are classified as a Type BF applied parts as described in the international standard IEC 60601-1:2005, Medical Electrical Equipment-Part 1:General Requirements for Basic Safety and Essential Performance.
- 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.

10.1 Power Requirements

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

10.2 Operating and Storage Conditions

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

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

11. FCC Information

FCC ID: 2AGDU-EL2PIN; IC ID: 20825-EL2PIN

Earlens Contact Hearing Solution complies with part 15 of the FCC rules and ICES-003 of the IC rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

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






NOTE: Earlens Contact Hearing Solution has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:












- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
 - Earlens Contact Hearing Solution complies with part 18 of the FCC rules.

12. Glossary of Terms

TM	Tympanic Membrane
Lens	Tympanic Lens
EAS	Electronic Article Surveillance
AE	Adverse Event

13. Graphic Symbols Contained in Device Labeling

Symbol	Description	Reference	Symbol	Description	Reference
	Refer to instruction manual/booklet	IEC 60601-1:2005 ISO 7010-M002		Temperature limit	ISO 15223-1:2016, 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
	Keep Dry	ISO 15223-1:2016, 5.3.4	IP22	Ingress Protection Code signifying protection against solid foreign objects	IEC 60601-1:2005 IEC 60529, 4.2

				of 12.5mm \varnothing and greater, and protection against vertically falling water drops when enclosure tilted up to 15°.	
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	IP57	Ingress Protection Code signifying protection against dust and the effects of temporary immersion in water.	IEC 60601-1:2005 IEC 60529, 4.2
	Humidity limitation	ISO 15223-1:2016, 5.3.8		Serial number	ISO 15223-1:2016, 5.1.7
	Non-ionizing radiation	IEC 60601-1-2:2014 IEC 60417-5140 (2003-04)		Caution	ISO 15223-1:2016, 5.4.4
	Batch code	ISO 15223-1:2016, 5.1.5		MR unsafe	ASTM F2503-13
	Catalog number	ISO 15223-1:2016, 5.1.6		FCC Part 18 Declaration of Conformity	FCC Guidelines for Labeling, Part 15 and Part 18, 2014
	Date of manufacture	ISO 15223-1:2016, 5.1.3		Type BF applied part	IEC 60601-1:2005 IEC 60417-5333
	CE conformity marking	MDD 93/42/EEC, Annex XII			



Manufacturer (Ref. ISO 15223-1:2016, 5.1.1):
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