



Wireless Earlens Light-Driven Hearing Aid Physician Instructions

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1. Introduction

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

Rx ONLY

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

2. Wireless Earlens Light-Driven Hearing Aid Device Description

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

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

2.1. Tympanic Lens

The Lens (Figure 2) is designed to receive light signals from the Light Tip and convert the light signals into mechanical vibrations of the tympanic membrane (TM). The Lens is customized for each patient and is placed in to position by a trained physician. It is placed at the end of the ear canal on the skin around the TM.

2.2. Photon™2 Processor and Light Tip

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

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

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

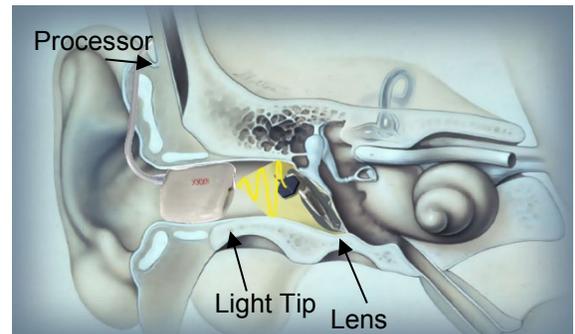


Figure 1: Earlens component schematic

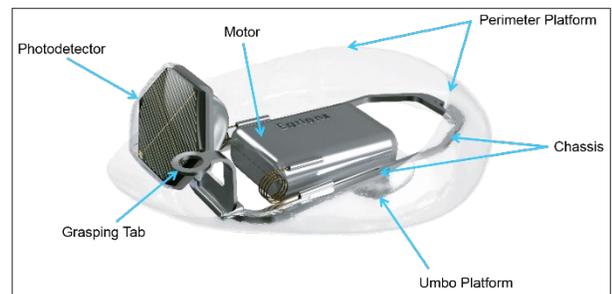


Figure 2: Lens

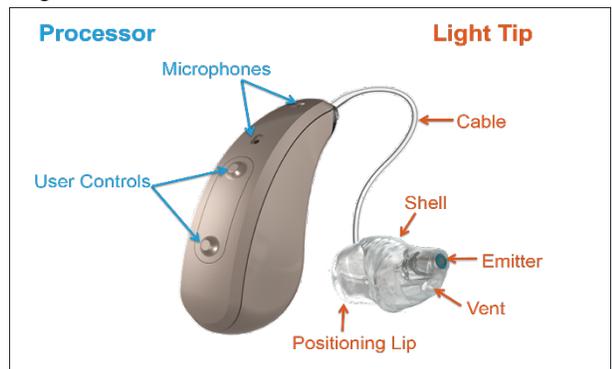


Figure 3: Processor & Light Tip



Figure 4: Light Tip large vent opening

2.3. Earlens Fitting Software (ELF)

ELF is used to program the Processor, enabling the hearing professional to calibrate and program the Processor specific to the patient's needs.

2.4. Earlens Charger and Power Adaptor

The Charger is designed to recharge the Processors (Figure 5). When connected to the wall power adaptor, the Charger houses and charges either one or two Processors simultaneously. An AC wall power adaptor is included.

2.5. Earlens Impression System

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

2.6. Mineral Oil

White mineral oil (food grade) is used to lubricate the eardrum to keep the Lens in place and functioning properly. To maintain the devices, it is recommended that patients apply two pumps of mineral oil to their ears daily.

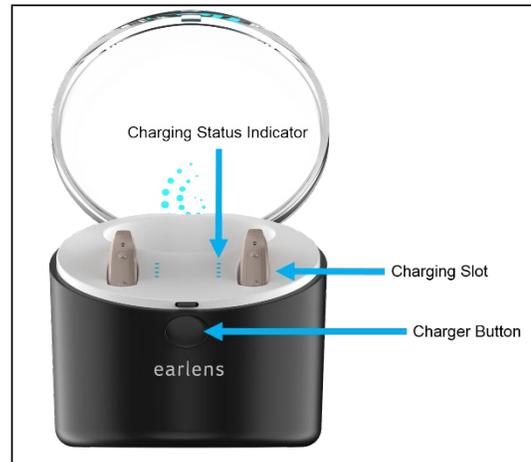


Figure 5: Earlens Charger

3. Indications for Use

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

4. Fitting Range

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

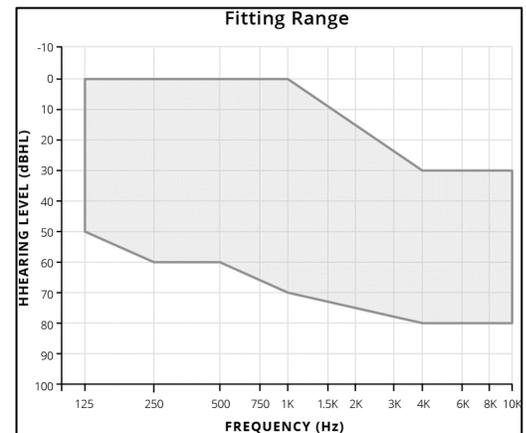


Figure 6: Earlens Fitting Range

5. Contraindications

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

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

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

6. Warnings



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

- The Earlens Hearing Aid is considered MR unsafe. The Lens should be removed prior to an MRI exam or MRI exposure. **Only physicians trained in Ear, Nose & Throat procedures should place or remove the Lens.**
- The patient should not use therapeutic or medical diathermy using electromagnetic radiation (magnetic induction coils or microwave) from the shoulders up with Earlens Hearing Aid in place.
- The Processor and Light Tip unit contain a Class 1 laser product. It is safe to use under normal operating conditions. The Class 1 laser light is NOT visible. Do NOT look directly into the laser or aim directly into the eyes. Should any part of the Earlens Hearing Aid become damaged, the patient should discontinue use and contact their hearing 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 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 professional.
- Do not crush, short circuit, modify or disassemble any component of the Earlens Hearing Aid. Keep all components of the Earlens Hearing Aid out of the reach of children, pets and others, to avoid risk of swallowing.
- Do not incinerate any component of the Earlens Hearing Aid or use near open flame. Handle waste from electronic equipment per local regulations.



7. Precautions



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

- Individuals with known nickel sensitivity/allergy should be informed that the Lens component contains nickel that is coated with a parylene barrier. If an allergic reaction develops, the Lens should be promptly removed.
- The Lens was tested for nickel leaching and found to be compliant and within the safe levels identified in European standard EN1811. Traces of oxidation (discoloration) may be visible on the Lens surface following prolonged wear. Testing indicated the oxidation was not likely to affect the structural integrity of the Lens within the 1 year expected life.
- Only hearing healthcare professionals trained in the fitting of hearing aids may fit the Earlens Processor and Light Tip.
- The Earlens Hearing Aid is custom designed and intended to be used for a single patient.
- The Light Tip is designed to sit a set distance from the Lens. Sound output may deviate if the Light Tip is not inserted to the proper depth. If the sound output does deviate, the patient can reposition the Light Tip until optimal sound output is achieved.
- Earplugs or headphones can be used with the Lens in place as long as care is taken not to over-insert them and they do not protrude deeply into the ear canal.
- 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 greater risk for ear canal abrasions, either from the ear impression procedure or from Light Tip use.
- The patient should avoid getting the Processor wet, as it may damage the device. The patient must remove the Processor 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 Hearing Aid into a microwave, or near a significant source of static electricity.
- Use only the Earlens Charger and AC wall adapter provided. Although other adapters may look similar, they may cause damage to the Earlens Hearing Aid.
- Handle the components carefully and prevent hard knocks. Do not drop them as it may damage the Earlens Hearing Aid.
- If the Earlens Processor fails to operate or if it appears damaged, including the presence of battery leakage or swelling, the patient should promptly remove the Processor, discontinue use and contact their 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 the patient perceives unexpected noise or interference in the presence of the Earlens Hearing Aids, 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 professional.

8. Clinical Study Results

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

8.1. Study Demographics

The average age of the study population was 69 years with a gender ratio of 60% for males and 40% for females. 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.

8.2. Safety Outcomes

The primary safety endpoint was intended to demonstrate that use of the Earlens Hearing Aid did not result in a change in residual hearing function. The objective was to identify any change in baseline hearing after four months of device usage using a four frequency threshold criteria (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 Aid 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

8.3. Effectiveness Outcomes

The primary efficacy endpoint was intended to demonstrate device effectiveness by improving speech recognition using the Northwestern Auditory Test No.6 (NU-6) test of word recognition with the Earlens Hearing Aid at a speech level of 45 dB HL. The objective was to show that the Earlens Hearing Aid provides a statistically significant improvement in mean aided word recognition at 30 days post placement when compared to the baseline unaided condition measured prior to placement. The average baseline unaided score was 52% and the average aided score was 85% (Figure 7); this improvement was statistically significant ($p < 0.0001$). A secondary measure of device effectiveness was defined as more than 10 dB improvement (functional gain) in thresholds over the range of frequencies from 2,000 to 10,000 Hz for aided measured at 30 days post placement when compared to unaided measured prior to placement. Mean functional gain was 30.5 dB ($p < 0.0001$), indicating that the Earlens Hearing Aid was able to deliver significant functional gain (Figure 8). Functional gain reached a maximum of 68 dB at 9-10 kHz.

Word Recognition (n = 78 ears)

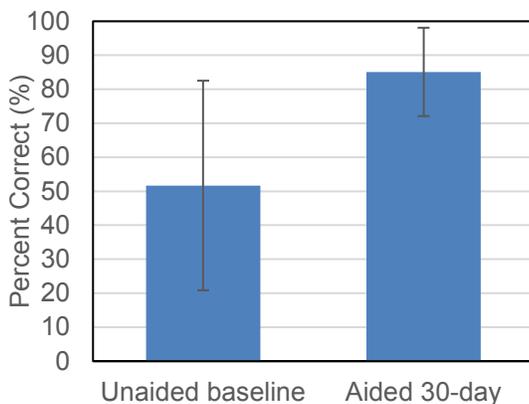


Figure 7: Word Recognition

Sound-field Thresholds (n = 78 ears)

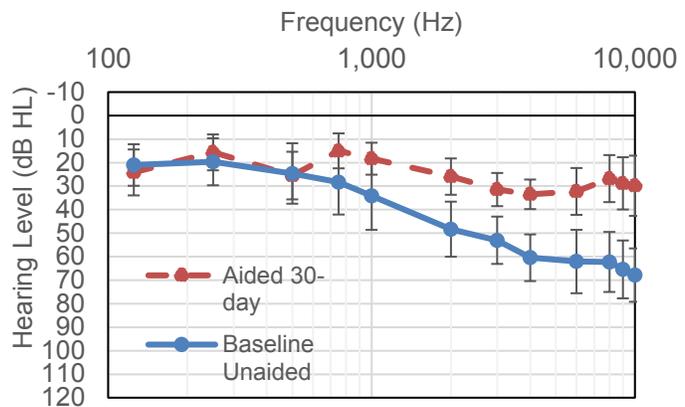


Figure 8: Sound-field thresholds

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

(standard deviation = 14%). 92% of subjects completing the study (35 out of 38) perceived a clinically significant improvement for Earlens relative to unaided as measured by APHAB.

8.4. Temporary TM Damping

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

8.5. Summary of Extended Study

The safety and effectiveness of the Earlens Hearing Aid was monitored beyond the 4 months of the Definitive Study. In the Extended Study, 24 subjects (48 ears) opted to continue wearing the Earlens Hearing Aid 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 AEs were experienced by 8 subjects in 10 ears. All events were temporary and resolved. Nine of 11 AEs were related to ear cleaning pre-impression (3 AEs), the impression procedure (4 AEs), or the inspection process pre-impression (2 AE). Two of the related AEs were attributed to Light Tip fit and both were resolved after Light Tip modification. One subject continues to report a sensation of fullness.

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

9. Operating Instructions

9.1. 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 Impression System 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.
- f. Read the package label to confirm that the device is for the correct patient and ear (left or right). On the shipping mold, a right Lens is identified by a red dot and a left by a blue dot.

- g. The Lens also includes an indicator for a right or left device which, is dependent on the Lens design. There are two possible designs you may encounter:
- o **Grasping Tab left/right of Photodetector (Figure 9):** When facing the Photodetector, the Grasping Tab for a right Lens is located on the right side and the Grasping Tab for the left Lens is located on the left side.
 - o **Grasping Tab centered below Photodetector (Figure 10):** When facing the Photodetector, the Grasping Tab is located below and centered. A right Lens will have a red dot located on the right side and a left Lens will have a blue dot located on the left side.
- h. Grasp the Lens at the Grasping Tab (Figure 2) using smooth alligator forceps.
- i. Using alligator forceps, gently advance the Lens through a thin bladed nasal speculum to the medial region of the ear canal.
- j. 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.
- k. Once satisfactory positioning is achieved, remove the speculum.

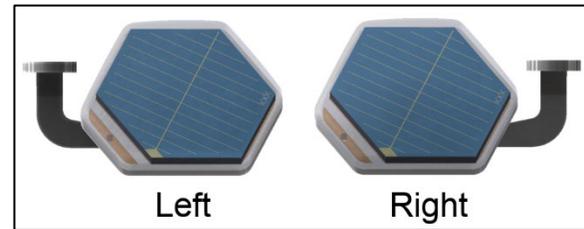


Figure 9: Grasping Tab Left/Right of Photodetector

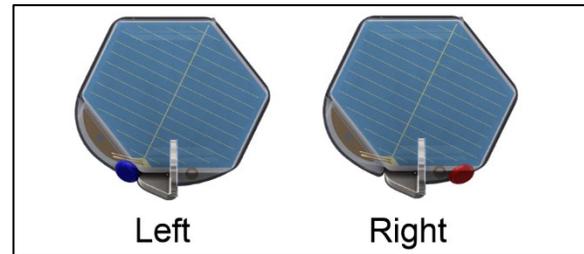


Figure 10: Grasping Tab Centered Below Photodetector

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 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. After soaking, grasp the Lens at the Grasping Tab using alligator forceps under visual magnification. Carefully suction any debris remaining from the Perimeter Platform and/or Photodetector.

- I. Avoid directly contacting the support springs and Umbo Platform while cleaning the Lens.
- II. Holding the Grasping Tab of the Lens with the alligator forceps prevents the Lens from being suctioned up, dropped to the floor or experiencing undue pressure on the Umbo Platform. It also aids to control the suction to the Lens.
- e. Following the cleaning carefully inspect the Lens to ensure it is free of debris and is not damaged.
 - I. Replacing a Lens that is not free of debris or is damaged may cause the device to displace.
- f. Proceed with device placement per the instructions outlined in Section 9.2.

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 Hearing Aid 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.
 - I. 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 Light 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 Light 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 Hearing Aid 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 professional(s) to monitor their audiologic and otologic status.

10. Operating Specifications

- For technical details about the EarLens Light Driven Hearing Aid and compliance to applicable standards, please consult the Hearing Professional Instructions for Use.
- Certain components of the EarLens Hearing Aid, including the Processor and the Light Tip are classified as a Type BF applied parts as described in the international standard IEC 60601-1:2005, Medical Electrical Equipment-Part 1:General Requirements for Basic Safety and Essential Performance.
- Expected service life of the EarLens Hearing Aid include:
 - Processor and Charger- one year
 - Light Tip- one year
 - Lens- one year
- The EarLens Hearing Aid is designed for continuous use.

- The Processor is not designed to prevent the ingress of water.

10.1 Power Requirements

Battery Charger Input	100-240 VAC, 50-60Hz, 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	100Hz to 10,000Hz

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

11. Glossary of Terms

TM	Tympanic Membrane
Lens	Tympanic Lens
ELF	Earlens Fitting Software
EAS	Electronic Article Surveillance
AE	Adverse Event

12. 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	IP21	International Protection Code against ingress of solid foreign objects \geq 12.5mm diameter and vertically falling water drops when enclosure tilted up to 15°	IEC 60601-1:2005 IEC 60529, 4.2
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		Serial number	ISO 15223-1:2016, 5.1.7

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

13. Laser Certification

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



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