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## **Earlens® Contact Hearing Solution Hearing Professional Instructions**

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<b>1.</b>	<b>Introduction .....</b>	<b>2</b>
<b>2.</b>	<b>Earlens® Contact Hearing Solution Device Description.....</b>	<b>2</b>
<b>3.</b>	<b>Indications for Use.....</b>	<b>3</b>
<b>4.</b>	<b>Fitting Range .....</b>	<b>3</b>
<b>5.</b>	<b>Contraindications.....</b>	<b>3</b>
<b>6.</b>	<b>Warnings .....</b>	<b>4</b>
<b>7.</b>	<b>Precautions.....</b>	<b>4</b>
<b>8.</b>	<b>Clinical Study Results .....</b>	<b>5</b>
<b>9.</b>	<b>Operating Instructions.....</b>	<b>7</b>
<b>10.</b>	<b>Wireless Connectivity- Made for iPhone Feature .....</b>	<b>31</b>
<b>11.</b>	<b>Operating Specifications.....</b>	<b>36</b>
<b>12.</b>	<b>Glossary of Terms.....</b>	<b>43</b>
<b>13.</b>	<b>Graphic Symbols Contained in Device Labeling .....</b>	<b>43</b>

## 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 encoded sound information from a Processor and Ear Tip to a receiving coil antenna on a Tympanic Lens (Lens). The Earlens® Contact Hearing Solution includes the following components:

- Lens
- Processor
- Ear 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 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.

### 2.2. Processor and Ear Tip

The Processor features microphones, a digital signal processor, and a rechargeable battery. The Ear Tip connects directly into 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 and then 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](http://www.earlens.com/connectivity).

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

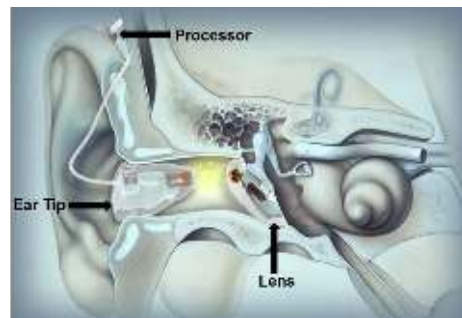


Figure 1. Earlens component schematic

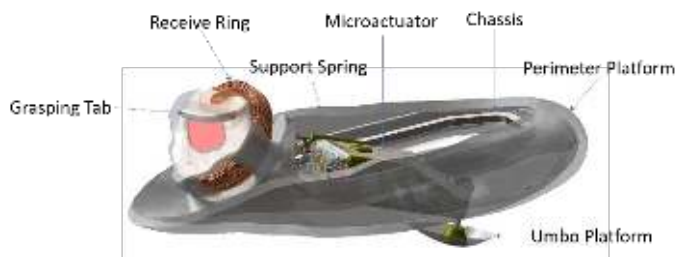


Figure 2. Tympanic Lens



Figure 3. Earlens Processor and Ear Tip

### 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 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 direct by the physician.

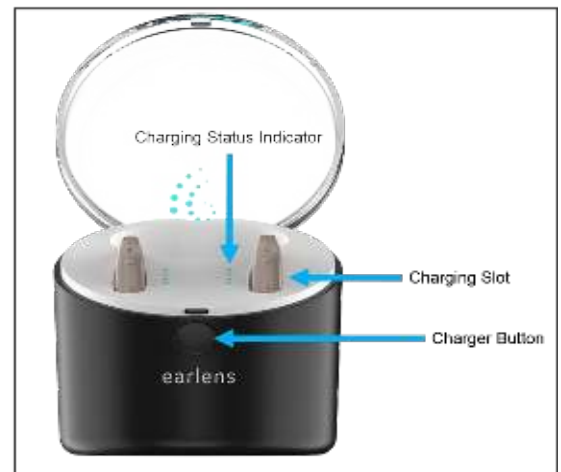


Figure 4. Earlens Charger

## 3. Indications for Use

The Earlens® Contact 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® Contact Hearing Solution provides the full spectrum of amplification, providing access to speech signals across a frequency range from 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 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.

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).

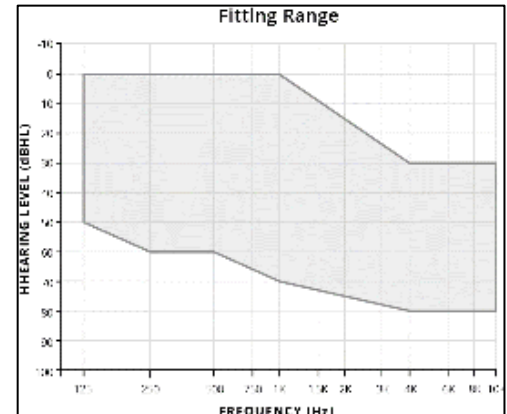


Figure 5. Earlens audiometric fitting range

## 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 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® 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 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 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 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 professional.

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

The Definitive Clinical Study of the EarLens® Light-Driven Hearing Aid confirmed the safety and effectiveness of the EarLens® Light-Driven 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® 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.

### **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® 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.

Table 1. Adverse events across study period

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

### 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® 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.

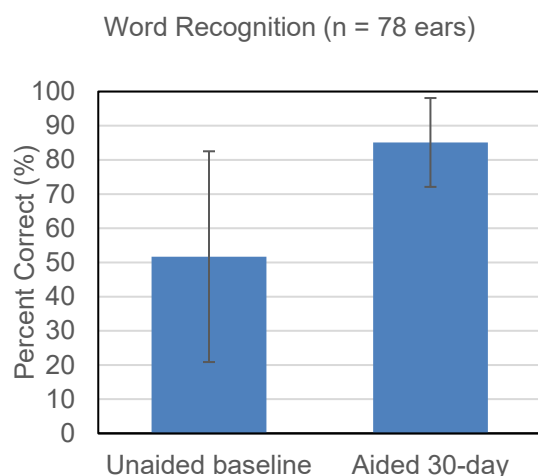


Figure 6. Word Recognition Performance

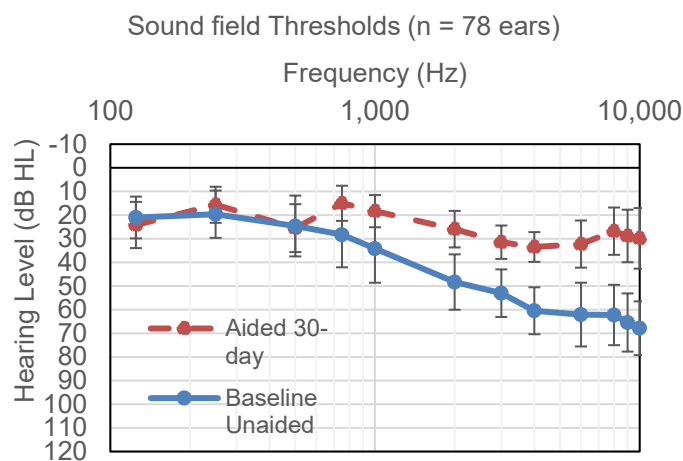


Figure 7. Sound field thresholds

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.

#### **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 (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.

#### **8.5. 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.

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. Processor and Ear Tip Fitting Procedure**

Earlens provides Processors and customized Ear Tips for each patient. The Ear Tip is designed to fit deeply into the patient's ear canal, like an IIC or CIC. It is very important that it is placed properly and fits well to ensure consistent sound amplification. Physical modifications of the Ear Tip shell or cable may be necessary to achieve improved comfort/fit. All Ear Tips include a colored indicator, red for the right and blue for the left.

#### **Placement of the Processor and Ear Tip**

- a. Place the Processor behind the patient's ear.
- b. Hold the Ear Tip between your thumb and index finger and gently insert it into the ear canal.
- c. The Ear Tip should be aimed down the length of the ear canal towards the Lens.
- d. Once fully inserted, the Ear Tip should fit snugly but be comfortable for the patient.
- e. If necessary, physical modifications of the Ear Tip shell or the shape of the cable may be necessary to achieve improved comfort or fit.

### **9.2. Programming the Processor with the ELF Software**

#### **ELF Software Requirements**

To install ELF your computer must meet the following requirements:

- OS: Windows 7/8/8.1/10
- Processor: 2 gigahertz (GHz) or faster
- RAM: 4 gigabyte (GB)
- Hard Drive Space: 5 gigabyte (GB)
- Noah 4.8 or later must be installed
- HI-PRO 2 software must be installed
- Noahlink Wireless programmer version 2.19 or later
- Internet connection

## Navigating ELF

- **Top Tool Bar (Figure 9)**

- File: allows the user to exit the software.
- Tools:
  - FG Mode: Enables Functional Gain Mode and opens the sound field threshold entry (see page 24 for more information).
  - Import ELF files: Allows the clinician or Earlens Customer Care to import ELF fitting files.
  - Update Charger Firmware: Initiates a Charger firmware updates when one is available. Note: Processor firmware updates can be initiated, when available, in the Start screen when Processors are connected to ELF.
  - Reset Processor(s): “Refreshes” the Processor in the event that it is on but unable to communicate with ELF software.
  - Factory Restore: Restores a Processor to manufacturer’s default settings, erasing all fitting and datalog information from the Processor.
  - Check HI-PRO2 Connectivity: Checks the communication status between the HI-PRO2 programming interface and ELF fitting software.
  - Check Earlens Cloud: Checks the connection between the ELF server and your fitting computer. Having an active connection will ensure that you receive the latest software updates and lets Earlens know in real time when a patient has been activated.
  - Update ELF Software: Initiates an ELF software update when one is available.
- Help:
  - Help: Additional functionality coming soon.
  - About: Provides information regarding the ELF software version and if an update is available.

- **Status Bar (Figure 8)**

- Battery indicator: Provides the current percentage of battery life measured for a Processor when a mouse pointer hovers over the icon.



Processor has a charge



Processor does not have a charge

- Connection status icons: Displays the current connection status of the Processor to ELF when using wired fitting.



Processor not connected



Processor connected

- Bluetooth signal strength: Displays the current strength of Bluetooth connectivity from the Noahlink Wireless to the Processor.



Strong signal connectivity



Weaker signal connectivity



No signal connectivity


- Mute/Unmute: Allows for the Processor to be muted/unmuted during programming.



**Mute** – When displayed, indicates device is not muted





 **Unmute** – When displayed, indicates device is muted

- ELF to Earlens cloud connection status: When there is an active connection between ELF and the Earlens® cloud, no icon appears in the Status Bar.



**ELF and Earlens cloud are not connected** on your fitting computer

- Program: When selected, the settings displayed in ELF, will be programmed to the Processor.

### • ELF Fitting Screens

- **Start:** Detect Processors, start a fitting session and access Simulation mode (Figure 9).

Select Wired to start a session with the Hi-Pro 2

Select Simulation to simulate software without live Processors

Select Connect after finding Processors and selecting

Select Find Processor(s) to detect Processors

Start Fitting to begin session

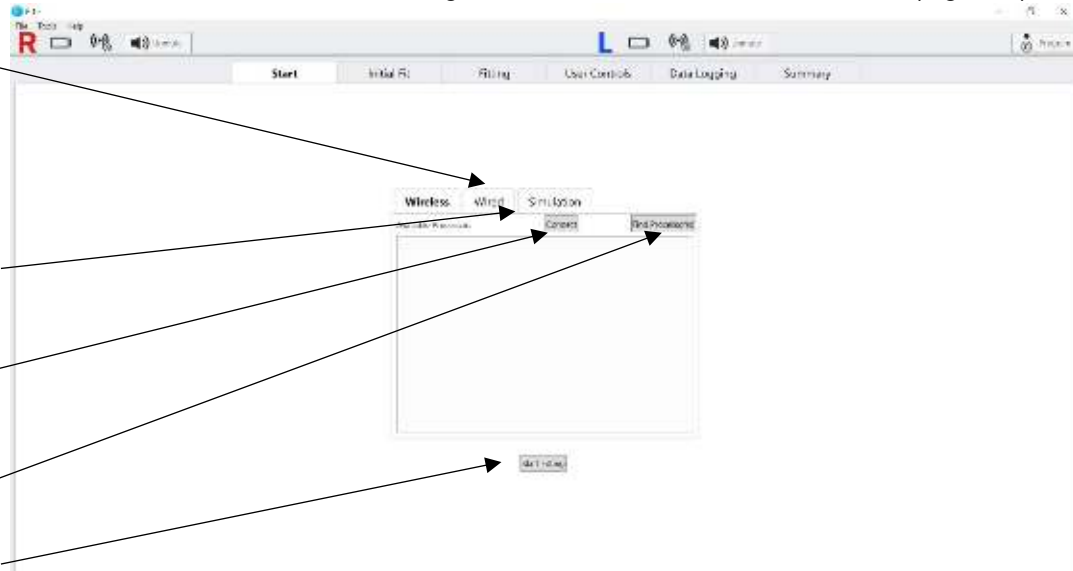


Figure 9. ELF Start screen

- **Initial Fit:** Enter 10 kHz audiometric data point (when available; if not available, ELF will predict 10kHz threshold based on slope and severity of hearing loss), measure and view calibration settings, run

Select to begin Calibration Measure

Run Feedback Measurement

View Earlens® and/or conventional aided sound field thresholds

10 kHz threshold entry (blue box)

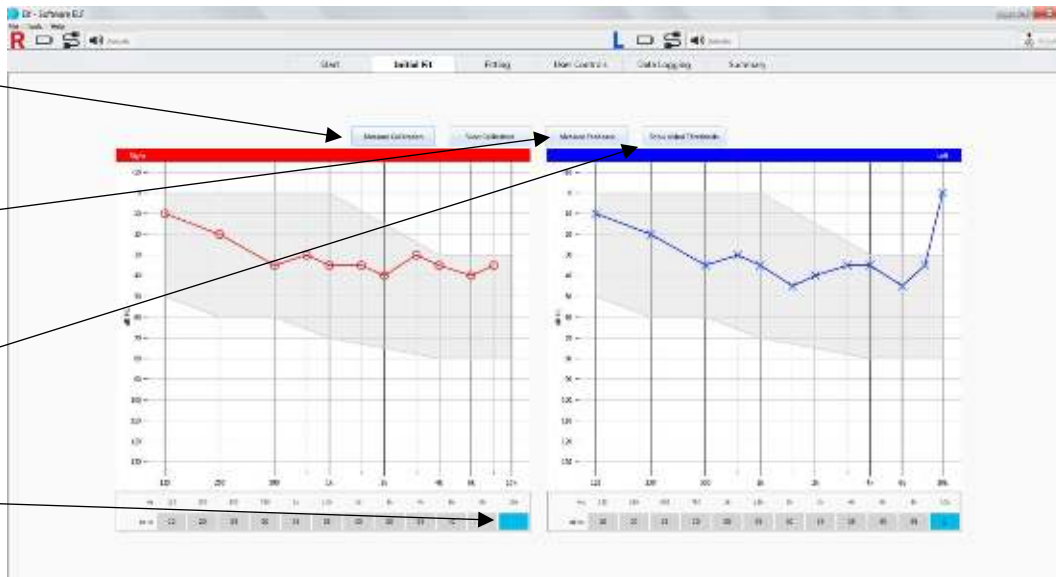


Figure 10. Initial Fit screen

feedback measurement and display aided threshold data (Figure 10).

- **Fitting:** Fine-tune the frequency response of the Processor (Figure 11), access automatic or manual acclimatization (Figure 12) and modify feature settings (Figure 13).

Select and/or change program

Change display (Output or Gain)

Copy program

Binaural programming link

Increase or decrease gain

Fitting Data Tab

Acclimatization Tab

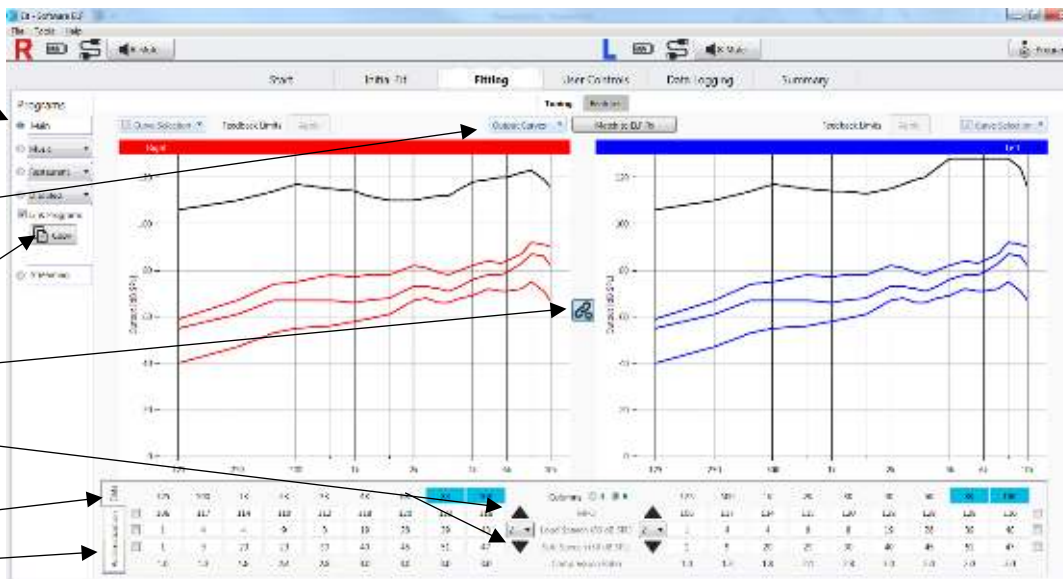


Figure 11. Fitting screen: Fine Tuning data tab

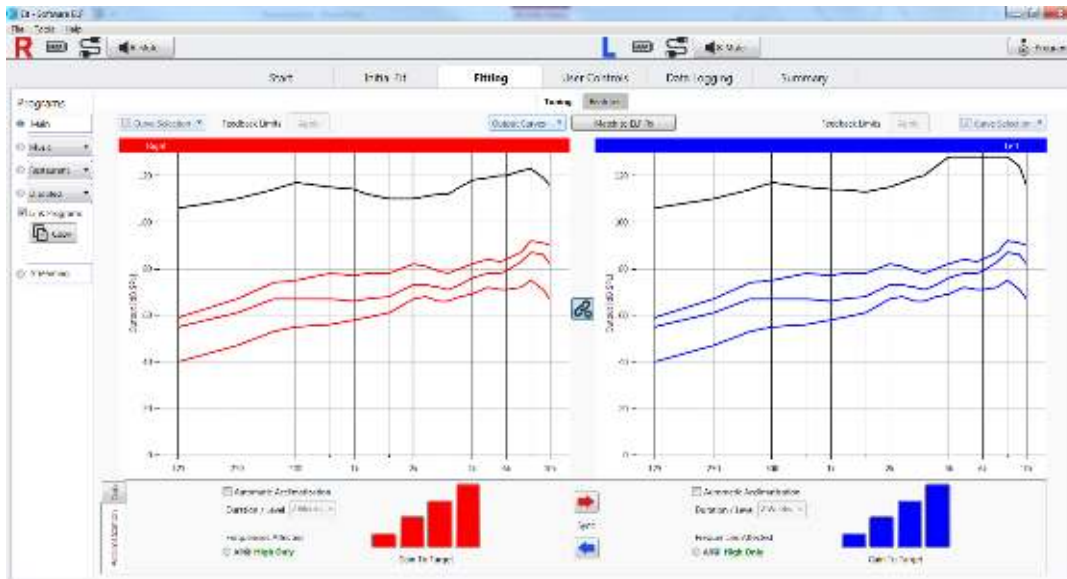


Figure 12. Fitting screen: Fine Tuning Acclimatization tab

Via drop down menu adjust noise reduction feature settings, directional microphone modes and feedback cancellation settings

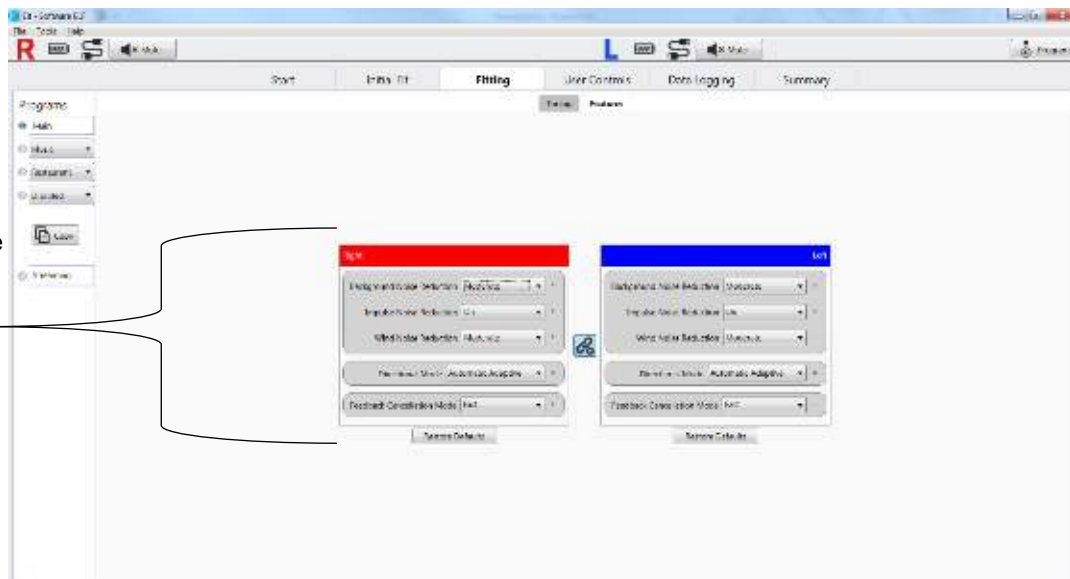


Figure 13. Fitting screen: Features

- **User Controls:** Set the user control configuration on the Processor, customize alert settings and enable Volume Learning (Figure 14).

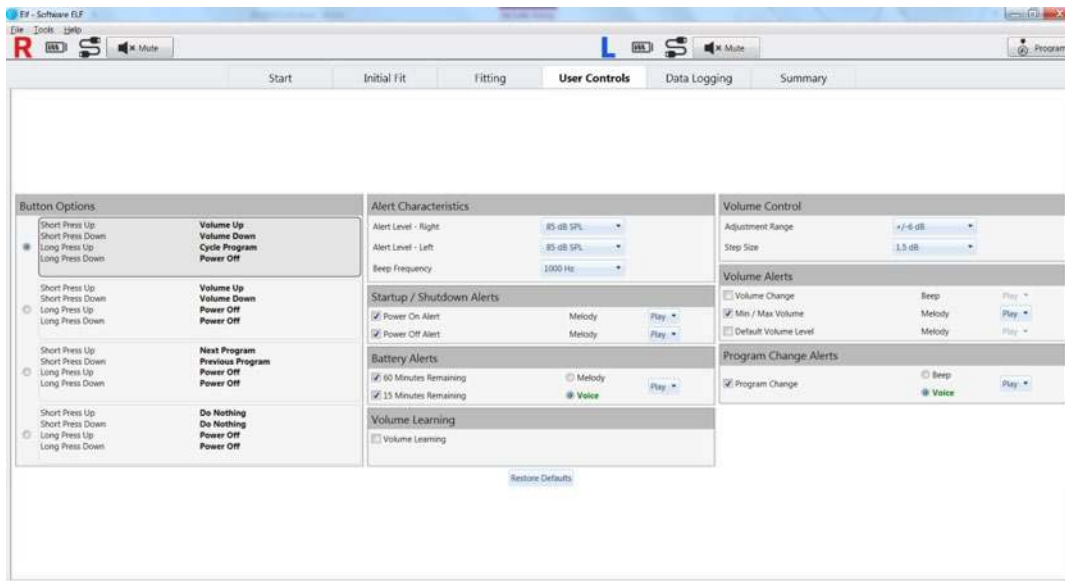


Figure 14. User Controls screen

- **Data Logging:** View patient usage data (Figure 15).  
Note: “Read Processor” option must be selected to obtain data logging information.

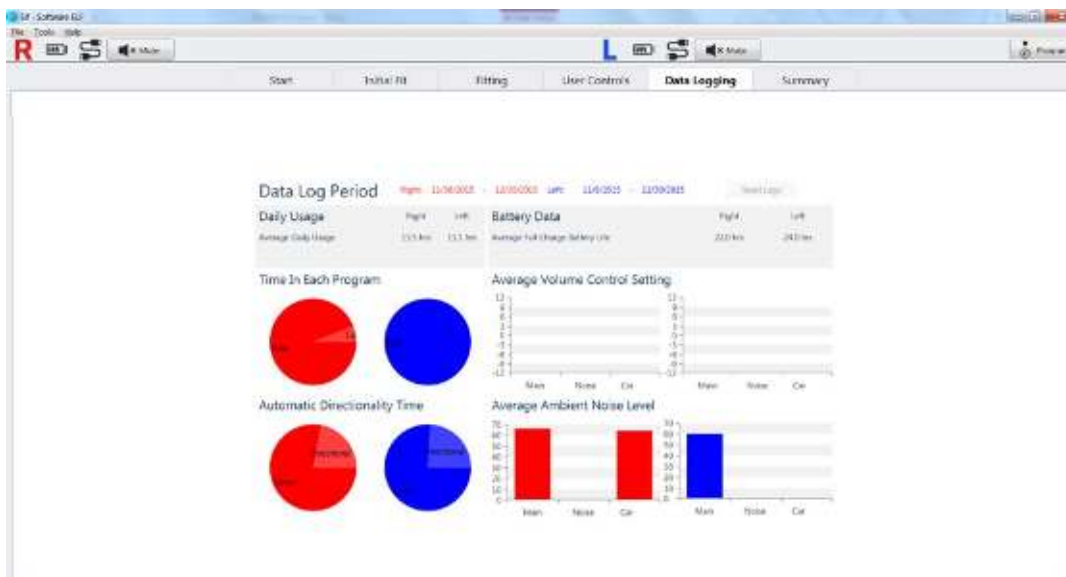


Figure 15. Data Logging screen

- **Summary:** View the summary of the fitting session, enter session notes, print Patient Instructions, and print Audiologist Report (Figure 16).
-



Figure 16. Summary screen

## Processor Features in ELF

Feature	Description	Options
Background Noise Reduction	Intended to reduce background noise without reducing speech levels.	Off, mild, moderate, strong
Impulse Noise Reduction	Designed to reduce gain in the presence of sudden, loud noises.	Off, On
Wind Reduction	Designed to reduce the noise produced when wind is detected over the Processor microphones.	Off, mild, moderate, strong
Directional Mode	<p>The behavior of the microphones for a given program.</p> <ul style="list-style-type: none"> <li>- It is recommended that both Processors be set to the same microphone mode</li> <li>- Every program features recommended defaults that may be modified</li> </ul>	<ul style="list-style-type: none"> <li>• Omni- amplifies sound equally from all directions</li> <li>• Fixed- sounds coming from the front are amplified and sounds from the back are attenuated</li> <li>• Automatic adaptive- designed to actively switch from omnidirectional to directional when speech is detected in the presence of noise, and steer the microphone null toward the loudest noise source</li> <li>• Automatic fixed- automatically switches from Omni to Fixed mode when noise is detected</li> </ul>
Feedback Cancellation	Intended to prevent squealing of the Processors caused by feedback.	<ul style="list-style-type: none"> <li>• Off, Slow, Fast</li> </ul>
<p>Acclimatization:</p> <p><i>Automatic</i></p> <p><i>Manual</i></p>	<p>Provides gradual increases to gain settings over a defined period of time.</p> <p>Allows professionals to manually manage gain settings for quick global tuning adjustments.</p>	<p>When enabled, the following parameters can be set:</p> <ul style="list-style-type: none"> <li>• Duration: the amount of time it takes to progress from one level to the next. Options include 1, 2, 3 and 4 weeks</li> <li>• Starting Level: 70, 80, 90% from the targeted response</li> <li>• Frequency range affected: acclimatization can occur for the entire frequency response or for the frequencies only (&gt;5kHz)</li> <li>• Gain to Target off-sets options include 70, 80, 90 and 100%</li> <li>• Frequency range affected: acclimatization can occur for the entire frequency response or for the frequencies only (&gt;5kHz)</li> </ul>
Volume Learning	The Processor tracks and remembers volume control changes made by the patient and gradually changes the preferred volume level over time.	Off (default), On

## Pre-Programming Tips

- We highly recommend that Processors have at least a 33% charge (2 LEDs or more displayed in the Charger) for programming.
- Obtain current audiometric threshold information for the patient. Though it is not required, we recommend obtaining thresholds at 125 and 10 kHz.
- A quiet room is highly recommended for Earlens® fittings especially for Calibration and feedback measurement.

## First Fit Steps

The following instructions describe the steps necessary to complete a bilateral first fit of the Earlens® Contact Hearing Solution. Please note that a fitting may be completed monaurally. To program a Processor for a single ear, perform the steps described, but only connect one Processor. Fitting/programming of processors can be completed via wired or wireless programming as described below. Note that if re-fitting or adjusting an existing patient who has not previously been fit wirelessly via the Noahlink Wireless Programmer, it may be necessary to first upgrade the processor firmware via the wired (Hi-Pro 2) programmer connection.



Figure 17. Processor set-up

### 1. Connect to Processors: Wired

To perform wired programming, a Hi-Pro 2 must be used with cables provided by Earlens.

- a. Turn the Processors on by pressing and holding the top user control for 3 seconds.
- b. Remove the Processor cover to expose the programming port (see Figure 38 a & b for removal instructions).
- c. Connect the Processors to the HI-PRO 2, using programming cables (Figure 17).
- d. Open Noah and select the patient's file.  
Note: Make sure you have entered 250, 500, 1000, 2000, 4000 and 8000 Hz audiometric thresholds in the Noah Audiogram Module.
- e. Open ELF.  
Note: You must select a patient file for ELF to open.
- f. The "Start" screen will open.
- g. In the "Wired" tab, click "Detect" to connect the Processors.

### 2. Connect to Processors: Wireless

To perform wireless programming, a Noahlink Wireless Programmer with firmware version 2.19 or newer will be needed. The programmer should be plugged directly into a USB port on the computer. USB hubs should be avoided.

- a. If processors have been previously paired with the patient's iOS device, turn off Bluetooth on the Smartphone/iPad prior to proceeding.
- b. Place the Processors into the Charger to ensure the device charge status is reflected as having at least 2 LED lights illuminated, ensuring sufficient battery charge to complete the fitting.
- c. Remove the Processors from the Charger and place them on the desk in front of you within 10 feet (3m) of your Noahlink Wireless Programmer.
- d. Click "Find Processor(s)".
- e. Your patient's Processors will be listed by name in the available Processor box. For new patients or processors, you will see the serial numbers of the Processors.
- f. Click the check box for the device(s) you would like to program and confirm serial number assignment to the appropriate ear(s) by playing tones if desired.
- g. Click "Connect".

### 3. Start Fitting

- a. Once the devices are connected, select "Start Fitting" to begin the fitting session (Figure 18).

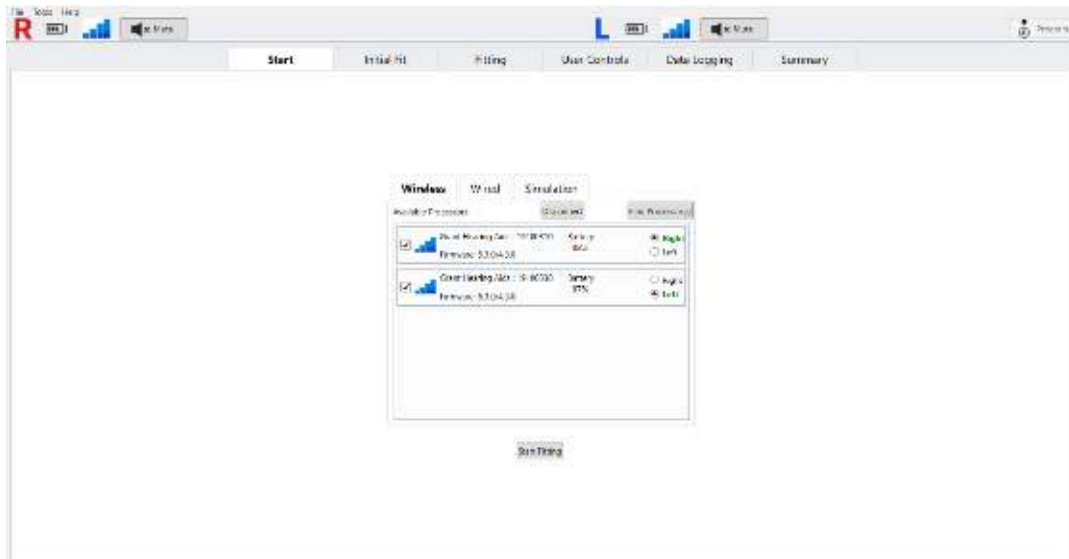


Figure 18. Connect Processors in Start screen

- b. A pop-window will appear asking “What would you like to do?” Select “Start Session.” (Figure 19). Do not attempt to “Read Processors” with new devices.



Figure 19. "What would you like to do?" pop-up window

### IMPORTANT

- “Read Processor” reads current device settings including acclimatization and data log information. This option is highly recommended for follow-up fitting sessions. If no settings are programmed to the Processor, ELF will automatically open to the “Initial Fit” screen to perform calibration measurements.
- Start Session- is required for a first-time fitting. When selected for a follow-up fitting session, ELF will retrieve the most recent or selected fitting session from Noah.
- Cancel- will return to the Start screen.

- c. A Fitting Data Status window will appear (Figure 20). Select “Ok” and ELF will open to the Initial Fit screen and enter Calibration Mode.

Note: To program the Processors, audiometric thresholds and Calibration measurements must be completed.

4. Enter the 10 kHz audiometric threshold for the right and/or left ear into the blue boxes, if available. If this frequency was not tested, ELF will estimate the 10kHz threshold based on the slope and severity of hearing loss at adjacent frequencies.

### 5. Calibration

Unlike an acoustic hearing aid which uses sound pressure waves to move the eardrum, Earlens transmits mechanical sound vibrations through direct contact between the Lens and TM. To calculate the equivalent



Figure 20. Fitting Data Status window



sound pressure level output (dB SPL) with this mechanism, an in-situ calibration procedure must be performed in ELF to program the Processor. During calibration, tones are presented at the standard audiometric frequencies at a known dB level via the Processor. The in-situ thresholds are compared to the audiometric thresholds to properly scale the output of the Processor. The result is the on-screen output and gain curves accurately reflect the in-ear response as the relationship between the patient's unique hearing loss and the mechanical coupling of the Lens to the TM is accounted for by the calibration step.

To perform Calibration, complete the following steps:

- a. Select "Calibration" in the Initial Fit screen.
- b. The Calibration pop-up window will appear (Figure 21).
- c. Find the patient's threshold at each frequency by presenting tones of increasing intensity until the patient is just able to detect the signal. Standard audiometric threshold seeking practices are recommended for this process. Tones can be presented in two ways:
  - On Click: Selecting the "Play tone" button or by pressing the space bar. Use the keyboard up and down arrow or the mouse to select the level and then use the same techniques you would to obtain audiometric thresholds. Once you have obtained a threshold, press enter or click "Store" to save the data.
  - Mouse Over: Hover over the dot representing the level you would like to present to the patient. Press enter or click "Store" to save the data.

Note: the difference between each level is approximately 5 dB.

- d. Obtain thresholds at every frequency for both ears. To select a different frequency, use either the left and right arrow on the keyboard or click of the mouse.
- e. Select "Close" to complete calibration. To clear stored threshold data, select "Clear All" or "Clear" for each ear individually.

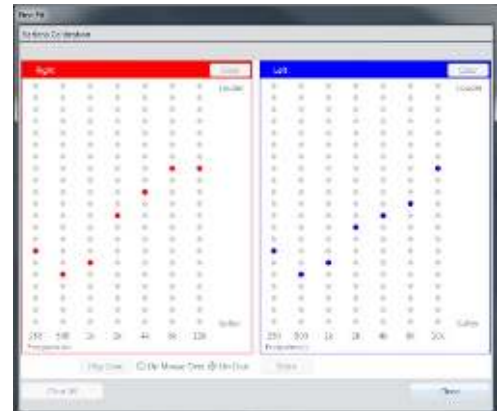


Figure 21. Calibration window

## 6. Feedback Measurement Utility

To perform the feedback measurement, you must first complete calibration. You will be prompted immediately after calibration to run the feedback measurement, which is recommended. If you do not want to perform the feedback measurement, you can initiate the measurement at a later time by selecting "Measure Feedback" in the Initial Fit screen.

- Prior to performing feedback measurement, ensure that all noise sources in the fitting room are minimized. The patient should be instructed to remain quiet and still during the measurement.
- ELF will measure the maximum gain before feedback by presenting a stimulus at a known level and measuring the response level and phase at the microphone. Results can be viewed in the Tuning tab, in the Fitting screen, by selecting the Gain Display option (Figure 22).
- Once measured, the software will automatically open to the Fitting screen.
- If the maximum stable gain interacts with the gain prescription, gain limits will be automatically applied to the Current Fit Response to prevent feedback (Figure 23).
- Gain can be increased beyond the feedback limits but may result in the patient experiencing audible feedback. A warning icon will appear when feedback potential exists on a per ear and program basis. When this occurs, select "Apply" to apply the feedback limits to the frequency response (Figure 24).

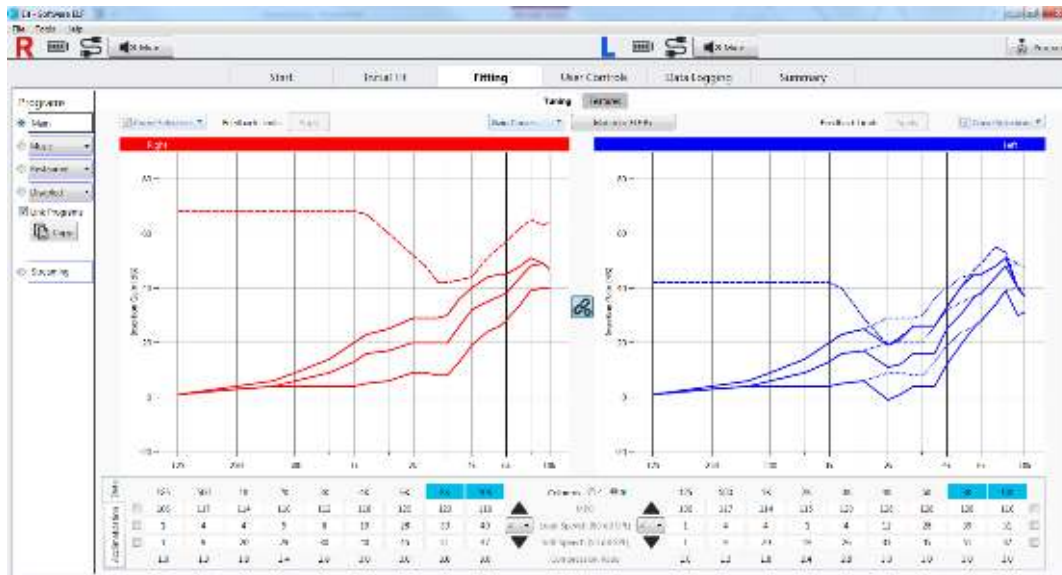


Figure 22. Fine Tuning: Gain Curves displaying maximum stable gain data and feedback limits applied for the left ear

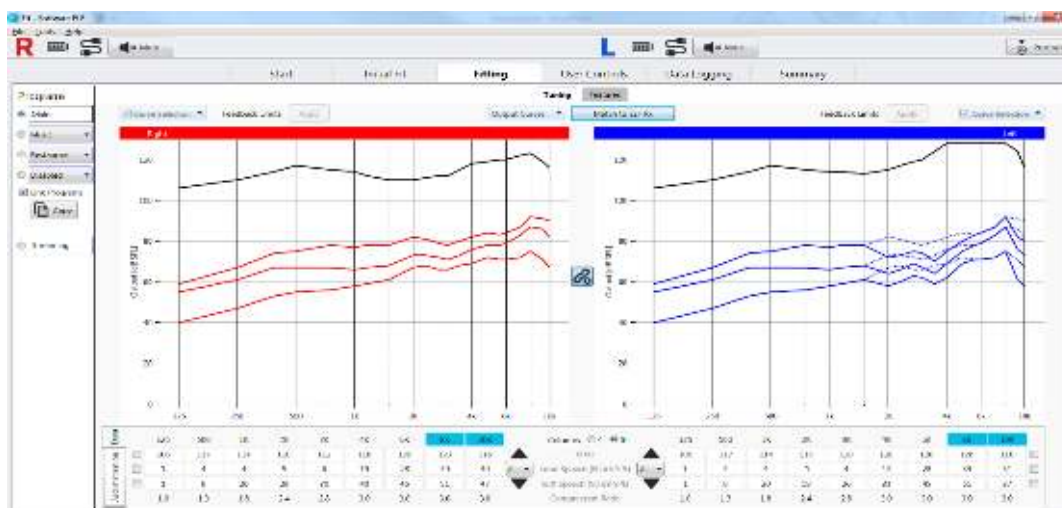


Figure 23. Fine Tuning: Output Curves displaying feedback limits applied for the left ear

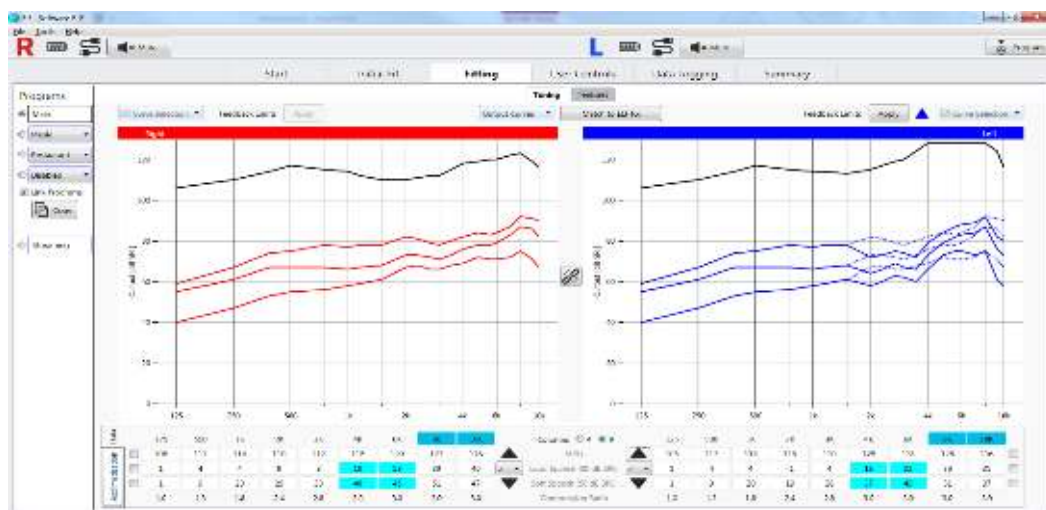


Figure 24. Fine Tuning: Output Curve displaying feedback potential for the left ear

## 7. Fine Tuning

Like any hearing instrument, the Earlens® Contact Hearing Solution can be customized to the patient's needs. To change gain settings, click on individual band(s) or check the box next to the desired speech input curve to select all bands. Use the up or down arrow to increase or decrease gain settings in 1, 2, or 3 dB increments. You can also click and drag the mouse to select more than one frequency and input level.

At the prescribed gain settings (ELF Rx), we encourage you to check the following:

- a. Do you or the patient hear feedback?
  - If yes, reduce the gain for soft speech in the region where the feedback is occurring until it subsides.
- b. Is speech uncomfortably loud for the patient?
  - If yes, reduce the gain until it is at a comfortable level.
- c. Ask the patient how their own voice sounds.
  - "Louder"- counsel the patient that this is a very common report after initial placement of the Lens. They will likely adjust after a few days of use.
  - "Muffled"- counsel the patient that this is generally due to the application of mineral oil during placement and typically subsides.

## 8. Enable Automatic Acclimatization (recommended settings)

- New Hearing Aid User- Select 70% gain with an acclimatization of 1 level per week **for all frequencies**.
- Experienced User- Select 70% gain with an acclimatization rate of 1 level per week for **high frequencies**.

Note: when automatic acclimatization is enabled, the acclimatization curve (solid orange line) is based off of the Current Fit response curve and the Gain to Target value selected. This ensures that any gain changes made prior to enabling acclimatization are accounted for once the automatic acclimatization has concluded.

#### 9. *Configure User Controls and Alerts*

- A variety of options are available for the Processor user controls, to personalize to the patient's needs. Available functions include:
  - Volume changes
  - Program changes
- Configurable user alerts are available for:
  - Alert level per ear
  - Turning the Processor on/off
  - Battery notifications
  - Volume changes
  - Program changes
- Checking the box next to each alert type enables or disables each individual alert.
- Select "Play" to demo any alert.
- Alert levels are configurable by ear to address perceived volume imbalance.

#### 10. *Print Patient Instructions*

Go to the Summary screen and click on Print Patient Instructions to obtain a copy of the Patient's program(s), user control settings and helpful care and maintenance reminders.

Note: An Audiologist Report is also available for print from the Summary screen.

#### 11. *Program Processors*

**All changes made in the ELF software will temporarily be transmitted to the device. To permanently program the device, you must select "Program" in the ELF Status Bar or by following step 11.**

#### 12. *Exit ELF*

When you "x" out of ELF or select File>Exit, a pop-up Window will appear asking you to "Save to Noah" and "Program Processor" (Figure 25). If you have already programmed the devices and have not made any changes, you can uncheck "Program Processor." Once you select "OK" the ELF fitting file will save to Noah and ELF will close. If using wired fitting, follow steps 13-15 below



Figure 25. Exit ELF pop-up window

#### 13. *Wait for the ELF software window to close, then physically disconnect the Processors from the programming cables.*

#### 14. *Place the CS45 adhesive port cover over the programming port.*

#### 15. *Put the case cover on both Processors (see Figure 39).*

## Additional ELF Features

- **Firmware Update**

When a firmware update is available for Processors, a pop-up notification will appear once you have detected devices in the Start Screen (Figure 26). We recommend updating the firmware when prompted to ensure the device has the most up to date features and performance enhancements. Firmware updates take no more than 5 minutes. Currently, firmware can be updated via a wired connection to the HiPro 2 Programmer.

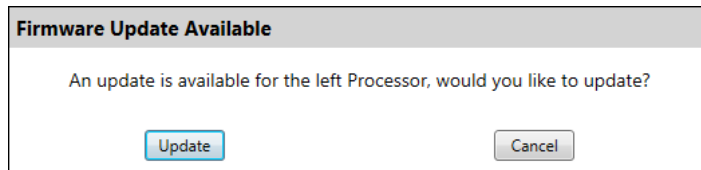


Figure 26. Firmware Update Notification

In the event you would like to update the firmware at another time, return to the Start Screen and click on "Update Available" (Figure 27) to initiate the firmware update.

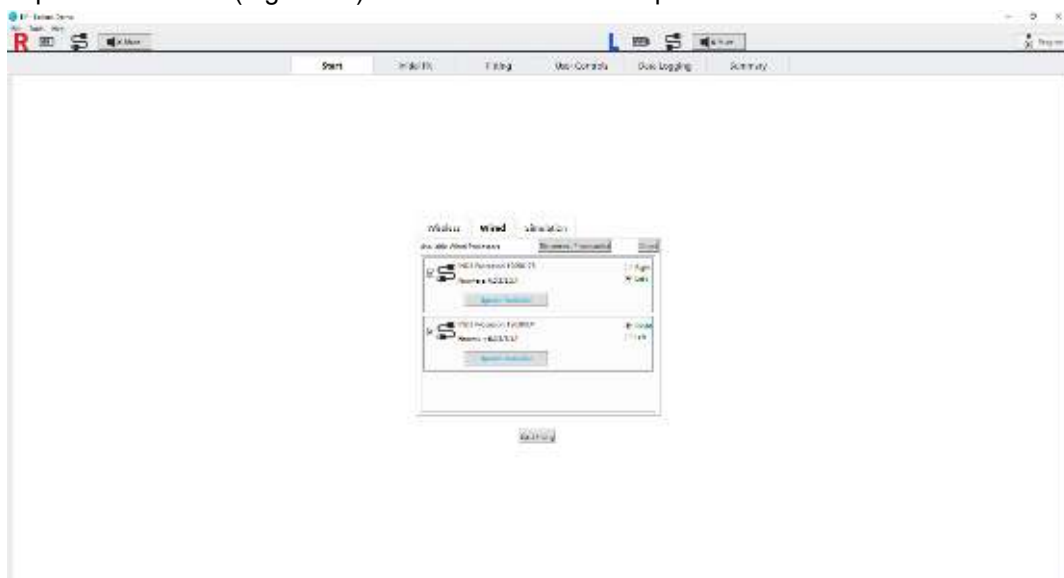


Figure 27. Firmware Update

- *Simulation Mode*

ELF offers a simulation mode in the “Start” screen that can be used when Processors are not actively connected to the software (Figure 28). Once in Simulation mode, any screen can be accessed, and adjustments can be made as if devices were actively connected.

**NOTE:** the feedback measurement functionality is disabled in Simulation mode.

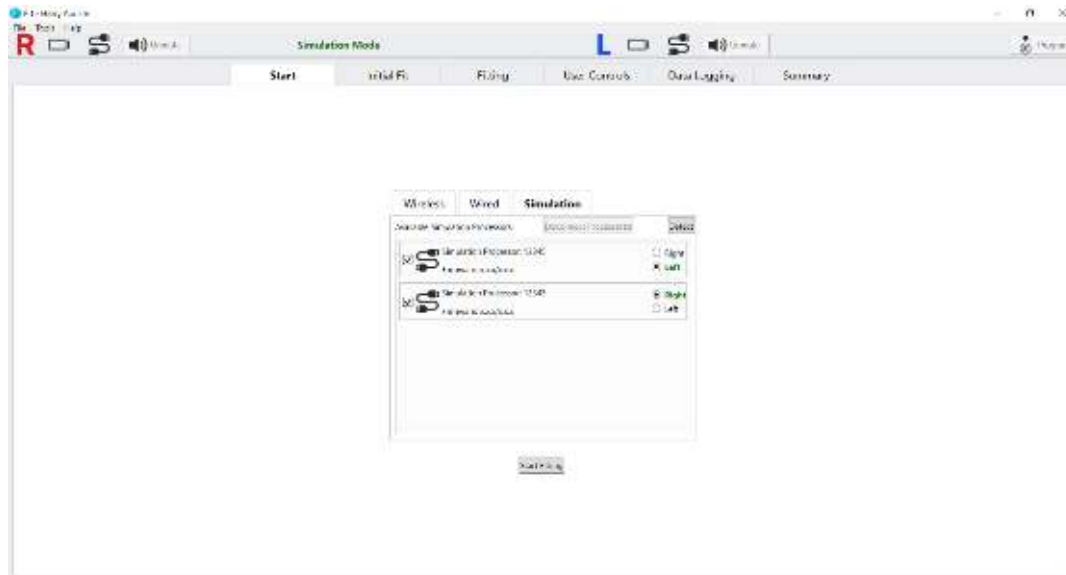


Figure 28. Simulation

- *Streaming Program*

The streaming program (Figure 29) is designed to optimize sound quality for non-acoustic streamed audio input from a compatible Apple device (see Section 10 for more details). The streaming program is not part of the standard program rotation, rather it is automatically enabled whenever streaming starts with no action required of the patient. The frequency response is determined by the patient's audiometric thresholds but can be further fine-tuned.

To ensure optimal sound quality when streaming, the hearing aid microphones are set to turn OFF during an active audio stream. For increased environmental awareness while streaming, the default microphone settings can be changed by accessing the Features Tab from the streaming memory fitting screen (Figure 30). The microphones can be activated with no attenuation (On), or with the microphone sound attenuated by -3 dB, -6 dB, -9 dB and Off. The patient also has the ability to adjust the hearing aid microphones via the Apple native controls and Earlens® Control app.

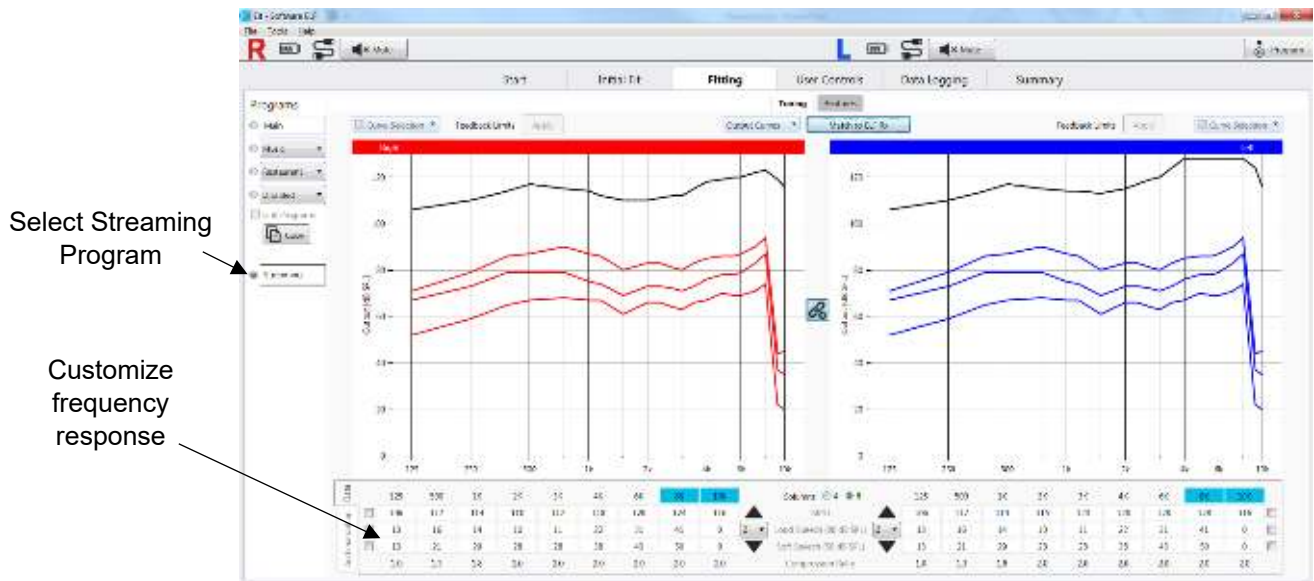


Figure 29. Streaming program fine tuning

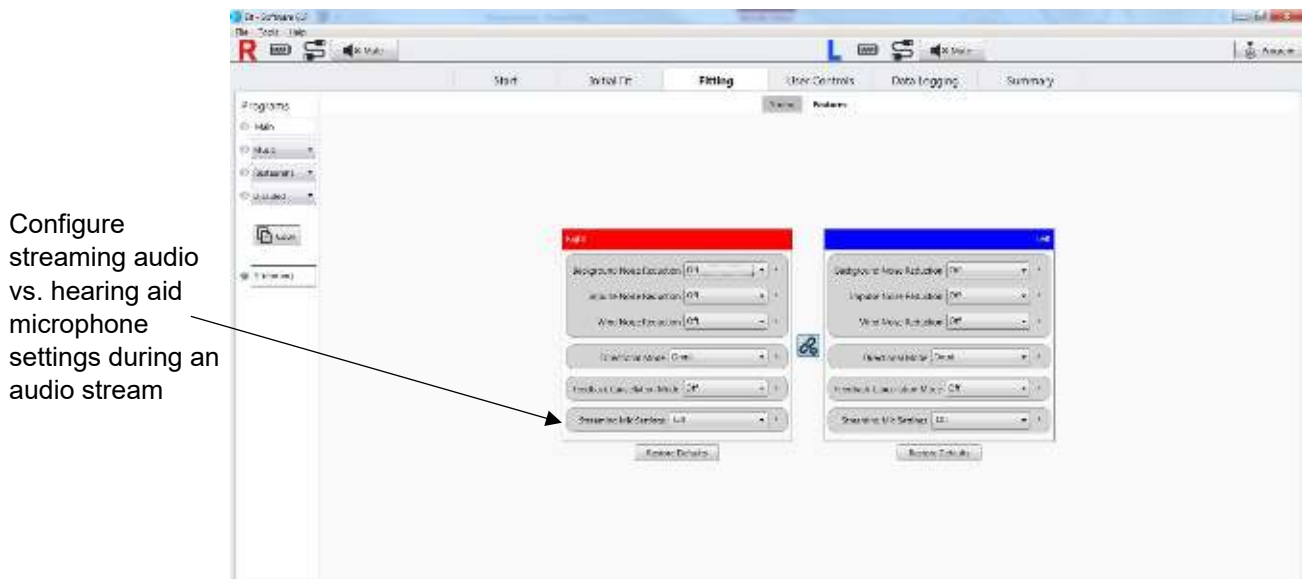


Figure 30. Streaming program feature settings

- Data Logging**

The data log feature in ELF provides a summary of a patient's device use. Data captured includes average daily use, time spent in each program, battery life data, time spent in a directional or omni-modes and average ambient noise level per program. The data log can be reset (Figure 31).



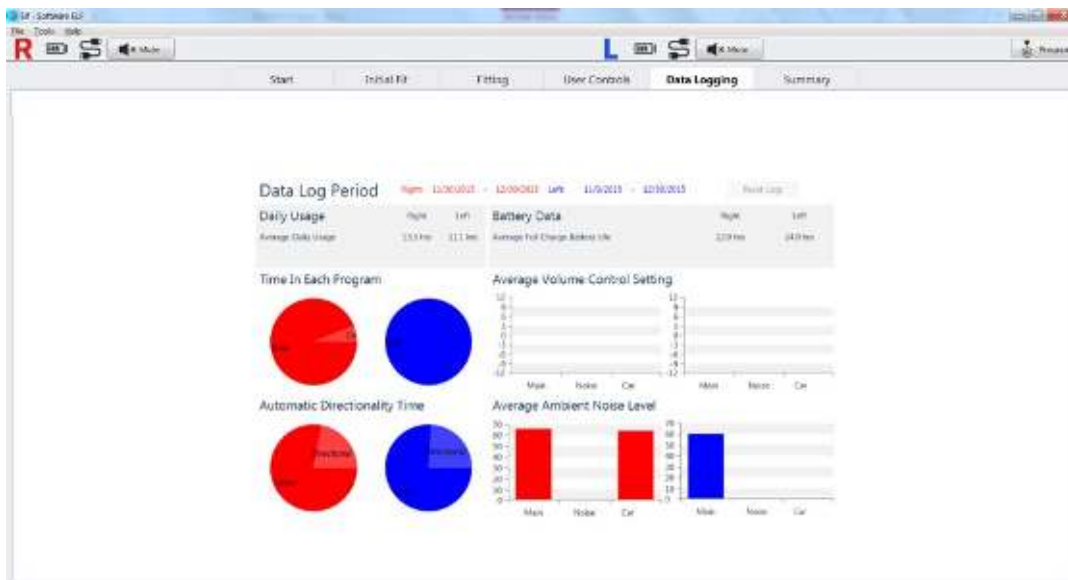


Figure 31. Data Log screen

- **Functional Gain (FG) Mode**
  - What is FG Mode? FG mode temporarily deactivates noise reduction and expansion features to permit accurate measurement of aided thresholds in the sound field.
  - Why perform aided sound field threshold testing? Because Earlens does not provide acoustic amplification, verification of audibility cannot be performed using probe microphone equipment. FG mode allows for in-situ confirmation of the enhancement of broad-spectrum audibility provided by the Earlens® System by streamlining device settings to achieve useful test data in a matter of minutes.
  - When to use it: FG Mode is intended for use during aided threshold testing in the sound field. By comparing aided and unaided thresholds, you can derive a measure of the aided gain achieved with the Earlens® System in response to soft inputs. This gain is representative of the gain applied at the compression threshold after fine-tuning to the needs of the patient.
  - How it works: FG mode minimizes the potential impact of various signal processing strategies on the audibility of the test stimulus. When in this mode, expansion, noise reduction algorithms and directional microphones are disabled. With these settings, the gain prescribed for that individual's hearing level for soft speech inputs in each channel is applied.
  - What can you learn from FG testing? FG measures are intended to provide an indication of low-level audibility across the full frequency range of the Earlens® system. By performing sound field threshold testing with narrow band noise stimuli in aided and unaided conditions, it is possible to generate an aided audiogram, clearly illustrating the benefit of amplification.



- Steps to perform FG:

- Connect the Processors.
- Instruct the patient that their Earlens® Contact Hearing Solutions will be set to a special test mode that will allow you to measure the improvement in hearing due to the Earlens® Contact Hearing Solution. They may hear an increase in the noise floor as expansion is disabled.
- Select “FG Mode” under Tools in the Tool Bar.
- A pop-up window will open and display the patient's audiometric values and space to enter aided threshold data (Figure 32).
- If using wired programming disconnect the HI-PRO 2 cables from the Processors, making sure to leave the FG Mode window open in ELF.
- Situate the patient in the appropriate test location in the calibrated test booth sound field, facing the target speaker.
- Each ear should be independently tested. For the non-test ear, remove the Processor and plug the ear with a foam insert/plug.
- Instruct the patient to raise their hand or press the response button when they are able to detect the test stimulus, even if the sound is very soft.
- Make sure your sound field has been calibrated for narrow-band noise stimuli, a backup alternative test stimulus is pulsed warble tones.
- Present pulsed, narrow band noise stimuli, using your usual threshold seeking procedure. Mark the aided threshold at each test frequency.
- Switch to the other ear and repeat the threshold test.
- Once testing is completed, reconnect the Processor(s) to the HI-PRO cables if applicable.
- Exit FG mode by selecting “Exit Functional Gain Mode.” **Do not leave the Processor in functional gain mode.**
- Close the ELF software and save to both Noah and the processor(s) after completing the testing to ensure that patient settings are saved to the processors and aided threshold test data is save to the Noah database.

**Audiologist Name**

**Functional Gain Mode**

Functional Gain Mode allows for aided threshold seeking without noise floor from the advanced features of the system. The table below displays the patient's unaided thresholds that can be used as a reference during functional gain testing.

	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right	20	20	25	25	30	40	40	50	60	60	70	70
Left	20	20	25	25	30	40	40	50	60	60	70	70

**Conventional Hearing Aid Aided Thresholds**

Hearing Aid Brand / Series

	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right												
Left												

**Earlens Aided Thresholds**

	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right												
Left												

Exit Functional Gain Mode

Figure 32. FG Mode Window

- Illustrate the Earlens® Benefit with Sound Field Threshold Entry**  
ELF allows you to enter aided threshold data for Earlens and conventional hearing aid devices to illustrate the Earlens® benefit. Note: You do not need to be actively connected to Processors to open FG Mode and enter threshold data.

- Open the FG Mode via Tools, in the Tool Bar.
- Manually enter aided audiometric threshold data (Figure 33).
- View data in Initial Fit screen, by clicking on “Show Aided Thresholds” (Figure 34). Aided thresholds for Earlens are represented by the letter ‘E’, while conventional hearing aid thresholds are represented by the letter ‘C’ at each test frequency.

**Audiologist Name** Michele

**Functional Gain Mode**

Functional Gain Mode allows for aided threshold seeking without noise floor from the advanced features of the system. The table below displays the patient's unaided thresholds that can be used as a reference during functional gain testing.

	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right	20	20	25	25	30	40	40	50	60	60	70	70
Left	20	20	25	25	30	40	40	50	60	60	70	70

**Conventional Hearing Aid Aided Thresholds**

Hearing Aid Brand / Series: Manulac, Inc. - White-Bang Hearing Aid

	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right	20	20	25	25	30	40	40	50	60	60	70	70
Left	20	20	25	25	30	40	40	50	60	60	70	70

**Earlens Aided Thresholds**

	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right	20	20	25	25	30	40	40	50	60	60	70	70
Left	20	20	25	25	30	40	40	50	60	60	70	70

Exit Functional Gain Mode

Figure 33. FG Mode window: Sound field threshold entry

- d. View or print the data by going to the Summary screen and selecting “Print Patient Instructions” (Figure 35).

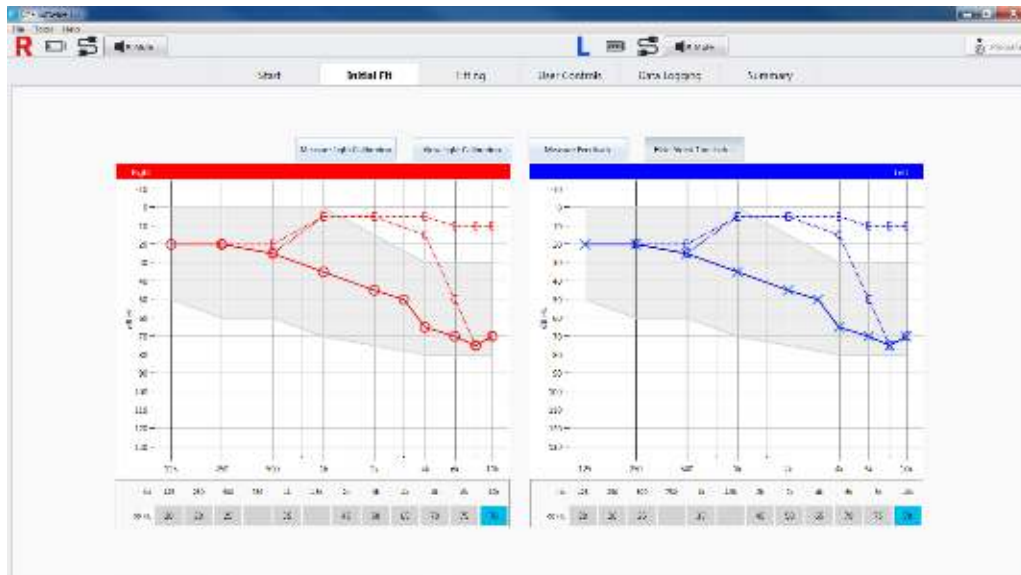


Figure 34. Initial Fit screen: Show Aided Thresholds

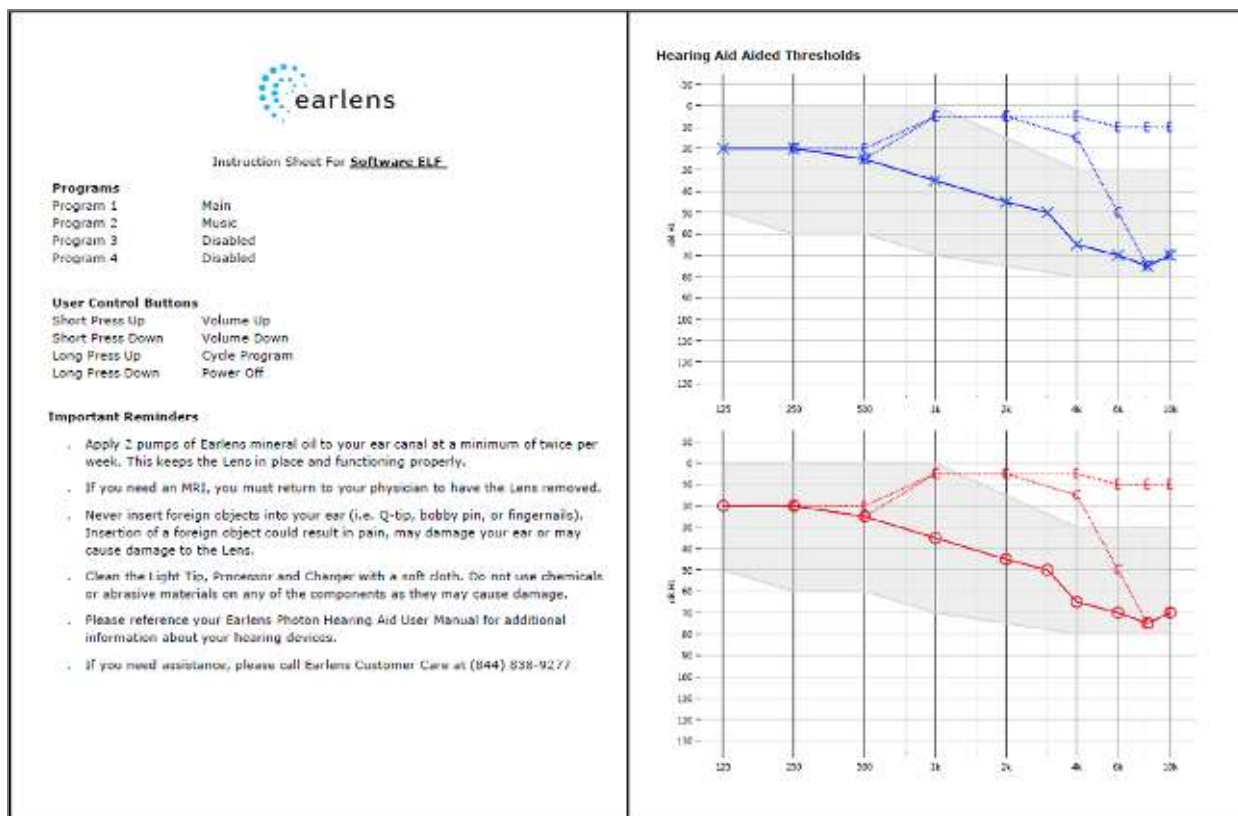


Figure 35. Patient Instruction printout

- **Enable, Disable and Copy Program(s)**

- Use the Programs menu to enable and disable different programs. The Main program represents the primary program and cannot be removed.
- The default program selections are 1.) Main, 2.) Music, 3.) Restaurant, 4.) Car. Except for Main, programs can be changed or disabled.
- Pre-defined program types are available and include: Main, Music, Restaurant, Car, Quiet, Noise, Party, Outside, TV and Streaming.
- Selecting “Disabled” will disable that program slot.
- Programs can be swapped and copied from one to another using the Copy Program(s) menu featured in the Tuning tab (Figure 36).

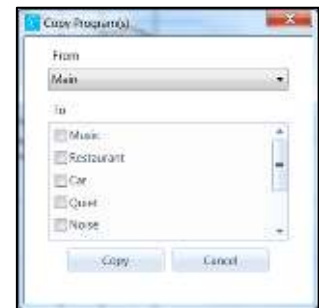


Figure 36. Copy programs

Note: Duplicate programs cannot be programmed to the Processors. A pop-up alert will appear if a duplicate program is selected.

- **Match to ELF Rx:** Resets the fitting response back to ELF calculated fitting targets (ELF Rx). In the Fitting screen under the Tuning tab, click “Match to ELF Rx.” If “Link Programs” is enabled, all programs will be reset to ELF Rx; if “Link Programs” is disabled, only the active program will be reset to ELF Rx.
- **Apply Feedback Limits:** When selected, this feature limits the prescribed gain to a value less than the measured maximum stable gain before feedback for both, left, right or neither ear(s).
- **Restore Defaults:** Resets all features to recommended defaults. This feature can be located in the Fitting screen under the Features tab. Selecting “Restore Defaults” will not impact the fitting response of the Processors.

### 9.3. Connection and disconnection of the Ear Tip from the Processor

To disconnect the Ear Tip from the Processor:

- Hold the Processor in one hand and with the other hand place your index finger under the cable where it connects to the Processor with the thumb on top of the cable (Figure 37).
- Pull the cable straight out of the Processor.

To connect the Ear Tip to the Processor:

- Insert the Ear Tip connector straight into the Processor until a click is felt.

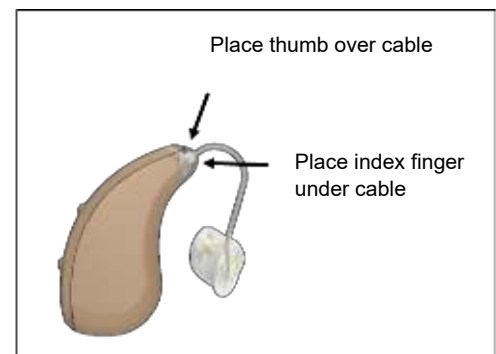


Figure 37. Ear Tip Removal

#### 9.4. Removal and Replacement of Processor Case Cover

The Processor cover can be removed and replaced for the purpose of wired programming or to replace the attached microphone screens if fouled or damaged.

- a. Using your fingernail or flat tweezers, unsnap the cover on each side of the user controls. The location of the snaps is marked "X" in Figure 38b.
- b. Gently lift the cover straight back.

To replace the cover (Figure 39):

- a. Beginning at the top of the Processor near the cable connector, insert the case cover tab into the opening.
- b. Working along the side seams, snap each side in place between the two user controls buttons.
- c. Latch the bottom of the case cover into place on the Processor housing.

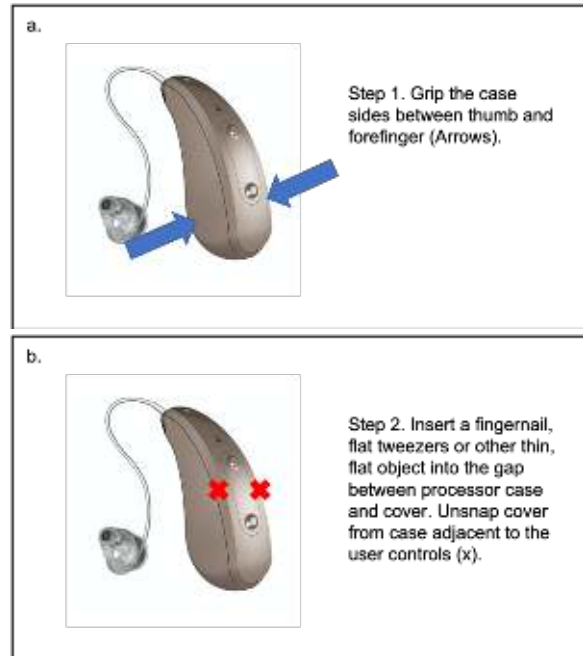


Figure 38. Processor cover removal

#### 9.5. Maintenance Oiling of the Tympanic Lens

**It is recommended that the patient apply one pump of mineral oil to the ear canal every other day or as directed by the physician, to maintain the Lens.** The oil lubricates the eardrum to keep the Lens in place and functioning properly. Patients should only use the oil and container provided and/or recommended by EarLens.

##### Instructions for Oiling

Inform the patient about applying oil and describe the following steps:

- a. Prepare the mineral oil dispenser by rotating the nozzle until it is at a right angle.
- b. Depress the pump until a consistent stream of oil is observed.
- c. With their head in an upright position, place the tip of the mineral oil dispenser into the ear canal opening.
- d. Dispense one pump of oil into the ear canal by depressing the pump.
- e. Remove the dispenser from the ear and tilt head to the side so that the oiled ear is uppermost. Allow the oil to run down to the eardrum by keeping the head tilted for approximately 1 minute. The patient may hear or feel the oil as it touches and wets the eardrum.
- f. Repeat for the opposite ear.
- g. After oiling, the ears may feel a little stuffy. This should subside on its own as the oil is absorbed under the lens and excess drains from the ear canal.

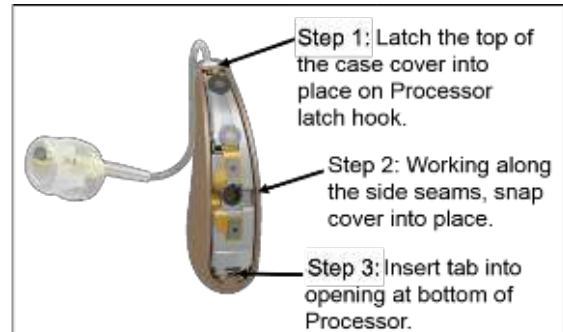


Figure 39. Processor case cover replacement

## 9.6. Processor Functions

### Battery Life

- The Processor battery is intended to provide a minimum runtime of 16 hours and an average runtime of 20 hours on a full charge. When depleted, the Processor battery requires 4 hours in the Charger to fully recharge. Processors should be charged every day.
- Low Battery Alerts:
  - The low battery User Alert can be configured in the ELF software in the User Controls screen.
  - The low battery warning alert is 3 beeps that can be set to sound 60 minutes and/or 15 minutes before the device will shut off.
  - An optional voice-prompt low battery warning can be selected in the User Controls screen.

### Turning Processors On and Off

When a Processor is removed from a plugged in Charger, it is automatically powered ON.

- To power OFF: press and hold the bottom control button for 3 seconds.
- To power ON: press and hold the top Processor control button for 3 seconds.

### Processor User Controls

- The Processor user controls can be programmed in the User Control screen in ELF.
- Each Processor features two controls that can be configured to have separate functions via a short or long press.
  - Short press = press of less than 3 seconds.
  - Long press = press and hold of 3 seconds or more.
- It is recommended that user controls are configured with the same functionality within a binaural set of Processors.

### Processor Serial Number







Should troubleshooting be necessary, Earlens may require the Processor serial number. The number is located on the inner curve of the Processor.

## 9.7. Earlens® Charger

The Earlens® Charger is designed to charge the Processors.

- The AC wall adapter (included) is used to plug the Charger into the wall outlet. Do not plug the Charger into an outlet that is difficult to access.
- The Charger can house and charge two Processors at the same time when connected to the wall power adapter.
- Do not use any other Charger or AC wall adapter with the Earlens® Contact Hearing Solution or use the Earlens® Charger to charge any other devices. Using the incorrect Charger or AC wall adapter could damage the charger or processor(s).
- The LED lights on the front of the Charger indicate the charge status for each Processor. When the Processor is first placed in the Charger a single light will blink for up to 20 seconds while the Processor and Charger are communicating. Table 2 details what each indicator light means.

Table 2. Charger indicator status

Charging Status Indicators		What It Means
	One <b>flashing</b> light	Charger connecting to Processor, it may take up to 20 seconds to connect
	One solid light	Battery charging; <b>below</b> 33% charged
	Two solid lights	Battery charging; <b>above</b> 33% charged
	Three solid lights	Battery charging; above 66% charged
	Four solid lights	Battery fully charged
	Four <b>flashing</b> lights	Processor not charging; remove from Charger, re-insert into charging slot and immediately press top user control
	No lights	Check that Charger is plugged in and Processors are correctly in slots

## 9.8. Care & Maintenance

### Storage

- Store the Earlens® Contact Hearing Solution in a clean, dry location out of direct sunlight when not in use. Avoid exposure to excessively high or low temperatures.
- Store the Processor and Ear Tip in the Earlens® Charger when not in use. The Earlens® Charger is designed to protect the Ear Tip and charge the device.

### Processor Battery Maintenance

- The Processors should be docked in the Charger when not in use or stored in a clean, dry place.
- It is recommended that Processors be charged overnight.

### Cleaning

- The Processors and Charger can be cleaned with a soft cloth to remove debris or accumulated ear wax. Do not use liquid cleaners as these can damage the devices
- A soft cloth, a baby wipe or Isopropyl Alcohol (IPA) based wipes may be used to remove wax from the Ear Tips. If wax accumulates in the vent, use a standard hearing aid cleaning tool to gently remove it. Do not use an abrasive tool.

### Troubleshooting

- **No Sound Output-** If the patient reports that the Processor has no output or sound, perform the following troubleshooting activities:
  - a. Check the battery status of the Processor. If only one LED displays, charge until at least 2 LEDs display. If the Earlens® Charger blinks 4 lights after the Processors are placed:
    - i. Remove the Processor.
    - ii. Re-dock the Processor in the charging slot and immediately press the top user control.
    - iii. If 1 light becomes solid, the Processor battery is very low and should not be used until at least 2 lights display.
    - iv. If the Charger continues to blink 4 lights, perform steps a-d in section *Four Blinking Lights on the Charger* below, up to 5 times. If after repeating these steps the Processor does not connect to the charger, please contact Earlens.
  - b. Check placement of Ear Tip in the ear canal by removing and reinserting and checking the position.
  - c. Press the Program change control (if enabled) to see if an alert is heard.



- **Feedback-** If the patient is experiencing feedback, check the position and insertion of the Ear Tip. Check feedback measurement data in the Gain Curves display located in the Tuning tab in ELF to determine if the patient's gain settings may exceed the stable gain measured during the Feedback Measurement. If the stable gain limit is exceeded, it may be necessary to apply gain adjustments to prevent feedback. If feedback persists after making changes to the fitting, contact Earlens to discuss Ear Tip remake options.
- **Four Blinking Lights on the Charger** - If the Charger displays 4 blinking lights, the Charger is unable to connect to and charge the Processor. This may occur because the Processor is turned off or because the battery is fully depleted. To commence charging, perform the following steps:
  - a. Remove the Processor from the Charger.
  - b. Re-dock the Processor into the charging slot.
  - c. While 1 light is flashing, quickly press the top user control.
  - d. If 1 light becomes solid, the Processor battery is very low and should not be used until at least 2 lights display.
  - e. If the Charger continues to blink 4 lights, remove the processor from the charger and replace. Allow the charger to search for the processor until four blinking lights are displayed.
  - f. Repeat step a-e 4-5 times, allowing the charger to search until four blinking lights are displayed each time.
  - g. Finally, remove the processor from the charger and replace, then press the top button for three seconds while the single light is flashing. The processor should connect to the charger and display one solid light.
  - h. Allow the processor to charge for at least four hours.
  - i. If the Processor does not connect, please contact Earlens.

## 10. Wireless Connectivity- Made for iPhone Feature

### 10.1 Device Compatibility

The Earlens® Contact Hearing Solution is compatible with the following Apple® devices that have iOS 12 or later:

<i>iPhone®</i>	<i>iPad®</i>	<i>iPod®</i>
iPhone 11	12.9-inch iPad Pro	iPod Touch 7 <sup>th</sup> gen
iPhone 11 Pro	11-inch iPad Pro	iPod Touch 6 <sup>th</sup> gen
iPhone 11 Pro Max	10.5-inch iPad Pro	
iPhone XR	10.2 iPad 7 <sup>th</sup> gen	
iPhone XS Max	9.7-inch iPad Pro	
iPhone XS	iPad Air 3 <sup>rd</sup> gen	
iPhone X	iPad Air 2	
iPhone 8	iPad Air	
iPhone 8 Plus	iPad 5 <sup>th</sup> gen	
iPhone 7	iPad mini 5 <sup>th</sup> gen	
iPhone 7 Plus	iPad mini 4	
iPhone 6s	iPad mini 3	
iPhone 6s Plus	iPad mini 2	
iPhone 6		
iPhone 6 Plus		
iPhone SE		
iPhone 5S		

Real-time updates for compatibility with newer Apple products can be found at [www.earlens.com/connectivity](http://www.earlens.com/connectivity). Some Apple products are not compatible with iOS 13 or newer. Instructions for older versions of Apple iOS are available at [www.earlens.com/connectivity](http://www.earlens.com/connectivity).

## 0.2 Pairing and Connecting an Apple Device

To connect to your Apple device with iOS 13, you must first pair it to your hearing aids.

1. Ensure that Bluetooth is enabled on the Apple device.
2. Turn the hearing aids off and back on.
3. On the Apple device, tap on the **Settings** icon > **Accessibility** > **Hearing Devices**
4. The Apple device will start searching for your hearing aids (Figure 40).
5. Once the hearing aids are discovered, the First Name + Hearing Aid and R+L\* will display (Figure 41).
6. Tap on the name of the detected devices.
7. A Bluetooth pairing request window will appear for each device. Select **Pair** (Figure 42).
8. When the hearing aids are paired and connected, you will see the word "Connected" in the main Hearing Devices screen (Figure 43).

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



Figure 40.



Figure 41.



Figure 42.



Figure 43.

## 10.3 Reconnecting to an Apple Device

When the hearing aids are placed into a plugged in Charger, they will turn off, which will temporarily disconnect them from the Apple device. Once removed from the Charger, the hearing aids will automatically turn on and re-connect to the Apple device. This behavior is also true when you turn the Processors off/on via the user controls on the Processor. If the hearing aids do not automatically connect to the Apple device, see section 10.6 for further instructions or call the Earlens® Concierge at 1-844-234-5367.

Please note, when updating to new versions of iOS, the hearing aids may lose their pairing to the Apple device requiring the patient to un-pair and re-pair them.


## 10.4 Streaming Audio

Patients can directly stream audio from an Apple device to their hearing aids. Once paired and connected, audio will automatically route from the Apple device to their hearing aids.

### Streaming Audio Media


In the event the audio stream does not automatically route to the hearing aids or the user would like to change it, perform the following steps:



1. Open the Control Center (Figure 44).
2. Press the  icon in the upper right corner of the audio card (see orange box) to select the preferred audio source (Figure 45).

## Streaming Phone Calls

### Outgoing Call

1. Select the Phone icon .
2. Select the contact name to call or dial a phone number to initiate the call.
3. Once the phone begins to ring, the source display will indicate that the Processors are the active audio source (Figure 46).

**Note:** The source may be changed from this screen by tapping on the audio button (Figure 47).

4. Select the End icon to disconnect from the call.

### Incoming Call

1. The iPhone will indicate the arrival of an incoming call.  
**Note:** If the call is received while streaming media, the stream will be interrupted by the call. Once the call is ended, the stream will resume.
2. Select the Accept or Decline icons on the iPhone.
3. Select the End icon to disconnect.



Figure 44.



Figure 45.

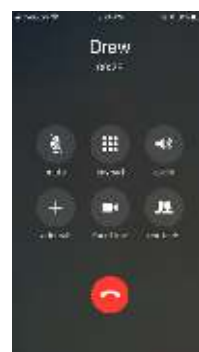


Figure 46.

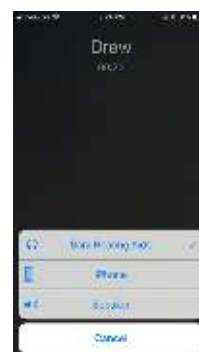



Figure 47.

## 10.5 Earlens® Control Mobile Application

### Download the Earlens® Control App

Patients must have an iTunes account to download the Earlens® Control mobile application. To set up an iTunes account go to [www.itunes.com](http://www.itunes.com).

1. Select the App Store icon  on the Apple device.
2. In the search field, type "Earlens Control".
3. Click *Get*, then *Install*.
4. A window may appear requesting an Apple Password or Touch ID in order to proceed.

### Earlens® Control App Features

The Earlens® Control app allows patients to seamlessly interact with their hearing aids to quickly and discretely control volume, change programs and so much more! The first time the application is opened, tutorial hints will appear to acquaint them with the various features and how to use them in each screen. The app provides the following features:

- **Concierge Opt-in**  
If your patient has any questions, requires assistance, or would like to learn more about their Earlens® Contact Hearing Solution, the Earlens® Concierge is available. This remote service is free to the patient and available during normal business hours. When the user first opens the Earlens® Control app, a prompt will appear asking them if they'd like to enroll in the program. We will ask for their name, phone number, and email address so that we can contact them in the event that Earlens has important product updates or to alert them when a new Apple iOS version is available.
- **Change Processor Volume**  
The Processor volume level can be changed in the **Home** screen.

- To change the master volume for both Processors, slide your finger along the volume bar to adjust the volume of both Processors. Slide left to decreases volume; slide right increases the volume.
- To change the volume of each Processor independently, tap on the double-slider icon and then slide your finger along the volume bar to adjust the volume. Slide left to decreases volume; slide right increases the volume.
- To mute the Processors, select the Mute icon.

**NOTE:** Using the volume bar in the App will adjust only the hearing aid microphones, not the streaming volume. To adjust a streamed input, use the volume controls on the Apple device.

- *Customize Sound with Bass and Treble Adjustments*

Adjust the master bass and treble settings in the EQ screen of the Earlens® Control app to enhance listening in different environments or for audio streamed inputs.

1. Select **EQ** on the bottom navigation bar.
2. Slide your finger along the bass and/or treble bar to adjust the settings of both Processors.
3. The application will remember your settings on a per program basis.

- *Change Programs*

Up to 4 programs can be enabled in the Processor via ELF. The user can select the desired program through the Home screen in the app.

1. Select **Home** on the bottom navigation bar.
2. Depending on the number of Programs stored in the Processor, 1-4 blue ovals will be displayed. The names of the programs will be displayed inside the ovals.
3. Tap on the oval with the desired program name. The active program will display in orange.

- *Live Mic*

Users can turn the Apple device into a remote microphone that can be used as an assistive device. This feature is designed to be helpful in challenging listening environments such as noisy restaurants.

1. Select **"More"** on the bottom navigation bar.
2. Press the **"Live Mic"** Option
3. Tap on the **"Start Live Mic"** icon. When enabled, the icon will change from blue to orange.
4. Within the **Live Mic** screen, you can adjust the hearing aid microphone volume relative to the incoming streamed Live Mic audio to enhance your listening experience.
5. To stop the live mic, tap on **"Stop"**. The **Live Mic** icon will turn back to blue and the audio stream will stop.

- *Support*

The Support tab offers Earlens® contact information to facilitate the user in receiving assistance. You can also find links to MFi support videos featured on our website and troubleshooting support from this screen.

- *Additional App Features*

- Set oiling reminders

An important step to maintaining the Earlens® Contact Hearing Solution involves applying one pump of mineral oil to each ear, every other day or as recommended by their physician. A configurable notification can be enabled in the Earlens® Control app.

1. Select **More** on the bottom navigation bar.
2. Select **Settings**.
3. Enable **Mineral Oil Reminder**.
4. Tap on **Repeat** and select **Custom**.
5. At the top of the screen, tap on the arrow in the upper left next to "New Event" screen and select **Add**.

- Demo Mode  
A demo mode can be enabled to allow users to get acquainted with the Earlens® Control app without having active devices connected. To activate:
  1. Select **More** on the bottom of the navigation bar.
  2. Select **Settings**.
  3. Enable **Demo Mode**.
  4. "Demo" will appear in every screen of the Mobile App when it is enabled.
- Locate Hearing Aids  
The locate hearing aid functionality allows you to see the last location that your Processors and Apple device were connected. This may be helpful in the event that you misplace your Processors.
  1. Select **More** on the bottom of the navigation bar.
  2. Select **Locate**.
  3. Select **Enable**.
  4. A window will pop-up, select **Allow**.

## 10.6 Troubleshooting Made for iPhone Connectivity

### Cannot Hear Audio Stream or Control Hearing Aids Using Apple Device

If the hearing aids are paired but the user is unable to hear the audio stream or control them from their Apple device, follow these steps:

1. Prior to performing any troubleshooting steps, confirm that Bluetooth is enabled on the Apple device:
  - a. Earlens Under Settings>Bluetooth - enabled
  - b. Control Center – Bluetooth icon should be blue
2. Reset the hearing aid by pressing and holding the bottom user control for 3 seconds.
3. Press and hold the top user control on the hearing aid for 3 seconds until you hear the device turn on.
4. Select **Settings > Accessibility > Hearing Devices** and tap on your hearing aids, displayed under Devices, to verify that they are paired and actively connected to your Apple device.  
Note: If a pairing window pops-up, select **Pair**.
5. Forget and re-pair your hearing aids to the Apple device.
  - a. Select **Settings > Accessibility > Hearing Devices**.
  - b. Tap on your hearing aid name displayed under Devices.
  - c. Select **Forget this device**.
  - d. A window will appear, select **Forget**.
  - e. Proceed with instructions for **Pairing and Connecting to Your Apple Device** (Section 10.2).
6. Turn the Apple device OFF and then back ON.

**If these steps do not resolve the connectivity issues, call the Earlens® Concierge 1-844-234-5367.**

### Made for iPhone Tips and Tricks

- To change the volume of phone calls or audio media when streaming to the hearing aid, use the volume controls located on the Apple device.
- Bluetooth connectivity will never be perfect. However, certain actions may improve connectivity:
  - Keep the Apple device within 20 feet of the hearing aids and in line-of-sight when streaming audio.
  - The body absorbs most of the Bluetooth signal, for optimal connectivity, hold the Apple device in your hand or in an armband and do not place it in pockets.
  - Car and hearing aid Bluetooth may act unpredictably with an Apple device. Please call the Earlens® Concierge for additional support.

For more MFi connectivity information and troubleshooting help, go to [www.earlens.com/connectivity](http://www.earlens.com/connectivity) or connect with the Earlens® Concierge at 1-844-234-5367.

## 10.7 Apple Hearing Aid Control

Apple offers hearing aid controls in iOS that allow the user to interact with their hearing aids without accessing the Earlens® Control app. The Apple controls allow the user to:

- Make volume adjustments
- Change programs
- Engage the Live Listen functionality

## 11. Operating Specifications

- 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.
- 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 features an IP57 rating.

### 11.1. Approximate Dimensions and Weight

Component	Dimensions	Weight
Lens	15 x 5 x 10mm	135mg
Processor	37 x 18 x 8.6mm	5g
Charger	81.5 x 68.5 x 77mm	177g

### 11.2. Power Requirements

Battery Charger Input	100-240 VAC, 50-60 Hz, 0.2 A
Battery Charger Output	5.0 VDC, 0.6 A

### 11.3. 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 10,000 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.

#### 11.4. 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	Mains power quality should be that of a typical commercial or hospital environment.

		±2 kV common mode	
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.

### 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
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.  <b>Recommended separation distance</b> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ 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 <sup>a</sup> , should be less than the compliance level in each frequency range. <sup>b</sup>

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.

<sup>a</sup> 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.

<sup>b</sup> 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 = 1.2vP	80 MHz to 800 MHz d = 1.2vP	800 MHz to 2.7 GHz d = 2.3vP
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 <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM <sup>c)</sup> ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18 Hz	2	0.3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28
1845						
1970						



2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
5500						
5785						

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.

### 11.5. FCC Compliance

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.

### 11.6. 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.

### *Description of Inductive Link:*

A proprietary inductive link which operates at a nominal range of 5 mm, transfers both the audio signal and power to the motor in the Lens via a coupled magnetic field. The Processor generates an amplitude modulated (AM) transmit signal, over a carrier frequency of 2.56 MHz. The Lens contains a receiver circuit which separates the audio signal from the carrier and drives the motor in the Lens. The short range of the coupled magnetic field due to close proximity of the Transmit coil in the Ear Tip to the Receive coil in the Lens, ensures minimal possibility of an external source interfering with the Inductive Link. In the event that such interference happens, the patient may hear brief audio artifacts such as distortion or clicks. These artifacts will subside as the patient moves away from the interferers.

### *Description of Bluetooth Streaming Link:*

The Earlens® Inductive System supports the Apple MFi (made for iPhone) streaming protocol for hearing aids. The Apple MFi streaming protocol operates on a Bluetooth Low Energy (BLE) 4.2 link which operates in the 2.4 GHz Industrial, Scientific, and Medical radio (ISM) wireless band. The controls during audio streaming include volume up/down, bass/treble control, program selection, remote microphone audio streaming and processor status with respect to battery state of charge. The Apple streaming protocol is secure and managed by its proprietary operating system (iOS). Security is maintained in the BLE 4.2 link through encryption and checksum validation. If packetized data contains errors the protocol allows for retry. In case of missing packets, the user may experience audio artifacts such as brief losses of audio or audio distortion. If connection between the processor and iOS device is lost, the BLE link automatically reestablishes the connection. The MFi streaming feature is designed to operate at a maximum line of sight distance of 10 m (33 feet). For optimum sound quality, it is recommended that the Earlens® wearer keep the iOS device within 6 m (20 feet) of the processor.

To optimize streaming sound quality for MFi users, the following steps in ELF are recommended for the Audiologist:

- Enable the Streaming program in one of the programming slots.
- The ELF software automatically applies default settings to the streaming program. Specifically,
  - Gain is reduced in the 8-10 kHz region as the Apple audio streaming codec does not transmit audio data in this frequency range.
  - Processor signal processing features are defaulted to 'off' to maximize streamed sound quality.
  - The bass response is increased to optimize sound quality for streamed music.
- To adjust the system response to the preferences of the user, un-check the "Link Programs" box.
  - In the Streaming Tuning screen:
  - Adjust gain and frequency response per the verbal feedback of the patient.
















### *Tips for Success with Earlens® MFi Connectivity*

- Always turn the Processor OFF and back ON to refresh the Bluetooth advertising window prior to pairing device(s) to an Apple device.
- Pairing and connecting Earlens® Processors to an Apple device follows the same steps as other hearing aid manufacturers. Please review the MFi Quick Start Guide for details at: [www.earlens.com/connectivity](http://www.earlens.com/connectivity)
- A binaural set of Processors must be programmed together in ELF, at any fitting session, for an Apple device to continue recognizing them as a pair.
- The Earlens® Control app is available for free in the Apple App Store.
- Earlens® wearers are encouraged to call the Earlens® Concierge at (844) 234-5367 if they encounter any connectivity issues or have any questions.
- Audiologists and Earlens® wearers can visit the Earlens® MFi information page at: [www.earlens.com/connectivity](http://www.earlens.com/connectivity) for the latest Apple iOS and device compatibility information.

## 12. Glossary of Terms

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

## 13. Graphic Symbols Contained in Device Labeling

Symbol	Description	Reference	Symbol	Description	Reference
	Refer to instruction manual	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 of 12.5mm Ø and greater, and protection against 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	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 code	ISO 15223-1:2016, 5.1.6		FCC Part 18 Declaration of Conformity	FCC Guidelines for Labeling, Part 18, 2014
	Date of manufacture	ISO 15223-1:2016, 5.1.3		Type BF applied part	IEC 60601-1:2005 IEC 60417-5333



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