



Wireless Earlens Light-Driven Hearing Aid Hearing Professional Instructions

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1. Introduction

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

Rx ONLY

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

For physician instructions, please see *Earlens Light-Driven Hearing Aid Physician Instructions*.

2. Wireless Earlens Light-Driven Hearing Aid Device Description

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

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

2.1. Tympanic Lens

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

2.2. Photon™ 2 Processor and Light Tip

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

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

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

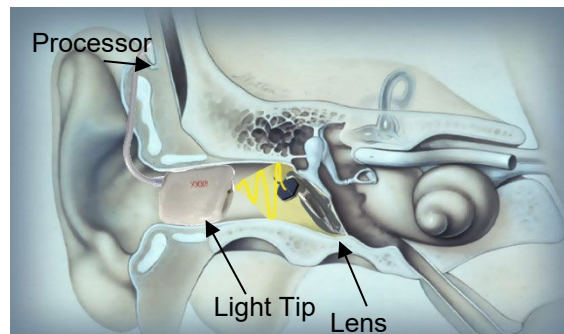


Figure 1: Earlens component schematic

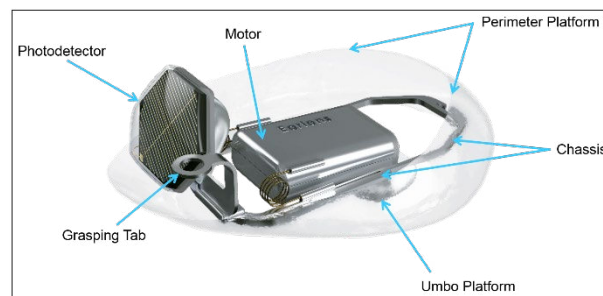


Figure 2: Lens

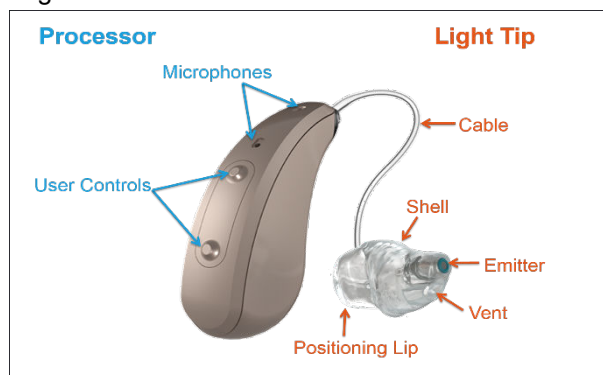


Figure 3: Processor & Light Tip



Figure 4: Light Tip large vent opening

2.3. Earlens Fitting Software (ELF)

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

2.4. Earlens Charger and Power Adapter

The Charger is designed to recharge the Processor (Figure 5). 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 Light Tip.

2.6. Mineral Oil

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

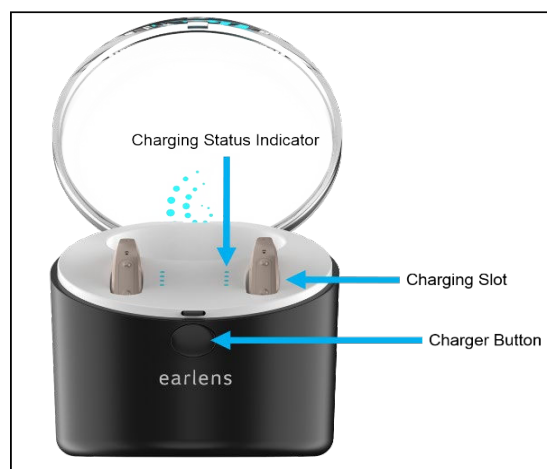


Figure 5: Earlens Charger

3. Indications for Use

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

4. Fitting Range

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

5. Contraindications

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

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

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

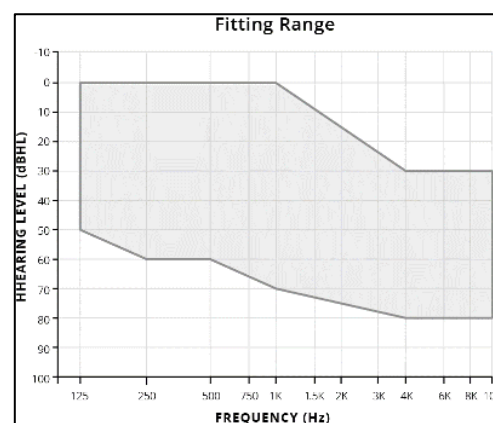


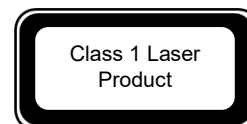
Figure 6: Earlens Fitting Range

6. Warnings



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

- The Earlens Hearing Aid is considered MR unsafe. The Lens should be removed prior to an MRI exam or MRI exposure. **Only physicians trained in Ear, Nose & Throat procedures should place or remove the Lens.**
- The patient should not use therapeutic or medical diathermy using electromagnetic radiation (magnetic induction coils or microwave) from the shoulders up with Earlens Hearing Aid in place.
- The Processor and Light Tip unit contain a Class 1 laser product. It is safe to use under normal operating conditions. The Class 1 laser light is NOT visible. Do NOT look directly into the laser or aim directly into the eyes. Should any part of the Aid become damaged, the patient should discontinue use and contact their hearing professional.
- If the patient experiences discomfort or pain in their ear, they should contact their ENT physician immediately. Only physicians trained in Ear, Nose & Throat procedures should place or remove the Lens.
- The patient should not insert foreign objects into the ear, such as Q-tips, bobby pins or fingernails. Insertion of foreign objects could result in pain and damage to the ear, damage to the Lens or cause it to operate improperly.
- The patient should contact their hearing professional if they experience discharge from the ear or persistent discomfort or any other problems.
- Should the Processor become unusually warm or hot, the patient should promptly remove it, discontinue use and contact their hearing professional.
- Do not crush, short circuit, modify or disassemble any component of the Earlens Hearing Aid. Keep all components of the Earlens Hearing Aid out of the reach of children, pets and others, to avoid risk of swallowing.
- Do not incinerate any component of the Earlens Hearing Aid or use near open flame. Handle waste from electronic equipment per local regulations.



7. Precautions



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

- Individuals with known nickel sensitivity/allergy should be informed that the Lens component contains nickel that is coated with a parylene barrier. If an allergic reaction develops, the Lens should be promptly removed.
- The Earlens Lens was tested for nickel leaching and found to be compliant and within the safe levels identified in European standard EN1811. Traces of oxidation (discoloration) may be visible on the Lens surface following prolonged wear. Testing indicated the oxidation was not likely to affect the structural integrity of the Lens within the 1 year expected life.
- Only hearing professionals trained in the fitting of hearing aids may fit the Earlens Processor and Light Tip.
- The Earlens Hearing Aid is custom designed and intended to be used for a single patient.
- The Light Tip is designed to sit a set distance from the Lens. Sound output may deviate if the Light Tip is not inserted to the proper depth. If the sound output does deviate, the patient can reposition the Light Tip until optimal sound output is achieved.
- Earplugs or headphones can be used with the Lens in place as long as care is taken not to over-insert them and they do not protrude deeply into the ear canal.
- The patient may shower, bathe or swim with the Lens in place. Ear plugs may be used to prevent water from entering the ears so long as care is taken to not over-insert them. Removing water from ears may be more difficult with the Lens in place.

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

8. Clinical Study Results

The Definitive Clinical Study of the Earlens Light-Driven Hearing Aid confirmed the safety and effectiveness of the Earlens 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 Hearing Aid 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 Hearing Aid did not result in a change in residual hearing function. The objective was to identify any change in baseline hearing after four months of device usage using a four frequency threshold criteria (500, 1000, 2000, and 4000 Hz, referred to as PTA4). A determination of clinically non-significant hearing threshold change was made if calculated PTA4 hearing change of the subject population was less than 10 dB. After wearing the Lens for 4 months, no decrease in hearing sensitivity of more than 10 dB was observed. A secondary safety endpoint assessed any decrease in hearing sensitivity of >10 dB by subject per ear at each test frequency. After four months of use no subjects exhibited a decrease of >10 dB for either ear at any frequency. In addition, no serious device or procedure-related adverse events were reported during the trial. There were 31 adverse events reported in 20 subjects for 22 ears. All but one of the adverse events were temporary and resolved. One subject report of a 'fullness' sensation when wearing the Earlens Hearing Aid did not change during the trial and effectiveness outcomes were not impacted. The subject

continued use throughout the study period of four months. Table 1 presents the adverse events by type, frequency of occurrence and resolution status at the conclusion of the study.

Adverse Event Category	Number Occurring	Serious AE	Status
Abrasion/blood blister in ear canal	17	No	Resolved
Ear discomfort/pain	5	No	Resolved
Inflammation/granulation tissue on tympanic membrane	3	No	Resolved
Abrasion/blood blister on tympanic membrane	2	No	Resolved
Ear tip-related: ear canal swelling, itching, etc.	2	No	Resolved
Pain upon eructation & valsalva	1	No	Resolved
Sensation of fullness	1	No	Ongoing

Table 1: Adverse events across study period

8.3. Effectiveness Outcomes

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

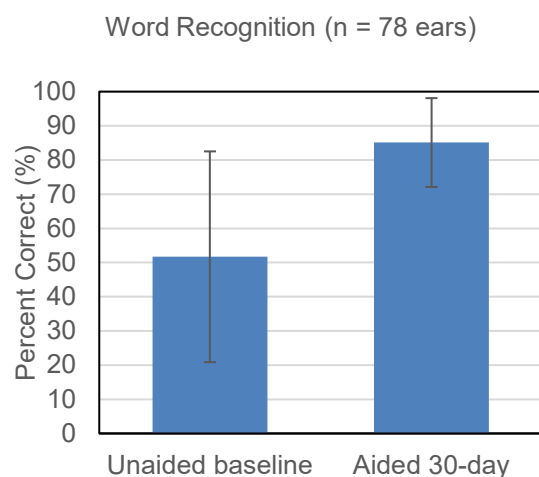


Figure 7: Word Recognition

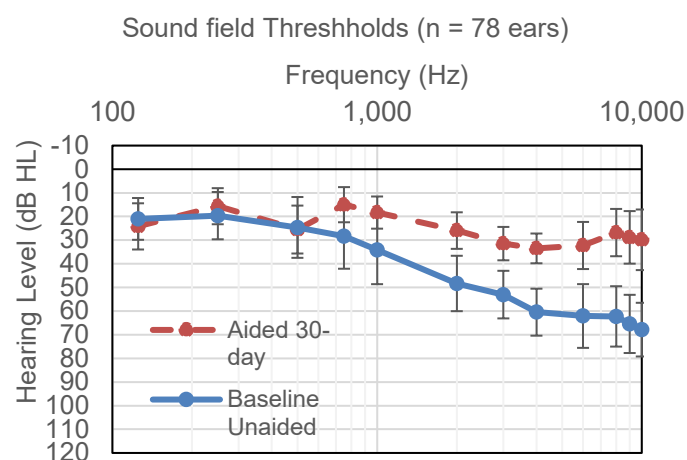


Figure 8: Sound field thresholds

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

8.4. Temporary TM Damping

The Lens is designed to remain in place even when the Processor is not worn. When the Processor is removed (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 Hearing Aid more than overcomes the TM damping effect.

8.5. Summary of Extended Study

The safety and effectiveness of the Earlens Hearing Aid was monitored beyond the 4 months of the Definitive Study. In the Extended Study, 24 subjects (48 ears) opted to continue wearing the Earlens Hearing Aid after completing the Definitive study. At the conclusion of the Extended Study, 33 ears had at least 12 months of cumulative Lens wear with no change in unaided air conduction hearing thresholds under earphones. Of the 24 active subjects in the Extended Wear Study, 11 related adverse events (AEs) were experienced by 8 subjects in 10 ears. All events were temporary and resolved. Nine of 11 AEs were related to ear cleaning pre-impression (3 AEs), the impression procedure (4 AEs), or the inspection process pre-impression (2 AE). Two of the related AEs were attributed to Light Tip fit and both were resolved after Light Tip modification. One subject continues to report a sensation of fullness.

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

9. Operating Instructions

9.1. Processor and Light Tip Fitting Procedure

Earlens provides Processors and customized Light Tips for each patient. The Light 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 Light Tip shell or cable may be necessary to achieve improved comfort/fit. All Light Tips include an indicator, red for the right and blue for the left.

Placement of the Processor and Light Tip

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

Note: Modify with caution, be careful not to damage or alter the orientation of the embedded emitter.

9.2. Programming the Processor with 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 gigabytes (GB)
- Noah 4.6 or later must be installed
- HI-PRO 2 software must be installed
- 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 22 for more information).
 - Import ELF files: Allows 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. Please see Section 11 for additional information about Processor firmware updates.
 - 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 manufacture default settings, erasing all fitting and data log information from the Processor.
 - 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 9)**





- Battery indicator: Hover over the battery icon to see the current percentage of battery life measured for a connected Processor
- Connection status icons: Displays the current connection status of the Processor to ELF.
 -  Processor not connected
 -  Processor connected
- 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
- Program: When selected, the settings displayed in ELF will be programmed to the Processor.
You must program the Processor(s) to store fitting session data.



Figure 9: Navigating ELF

- **ELF Fitting Screens**

- **Start:** Detect Processors, start a fitting session and access Simulation mode (Figure 10).

Select Simulation to simulate software without live Processors

Select Detect to connect Processors

Start Fitting to begin session

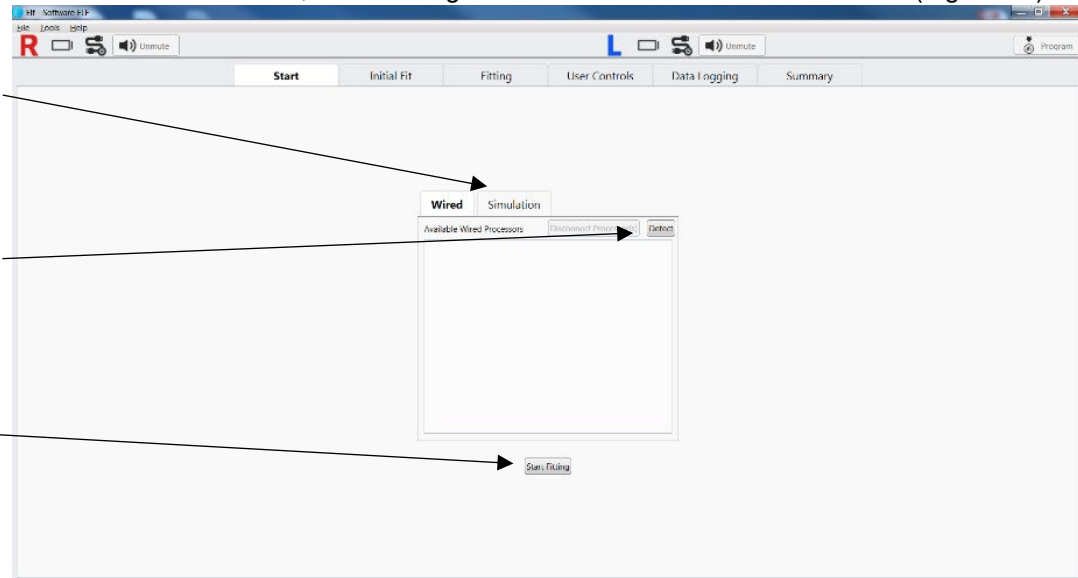


Figure 10: Start screen

- **Initial Fit:** Enter 10 kHz audiometric data point (when available), measure and view light calibration settings, run feedback measurement and display aided threshold data (Figure 11).

Select to begin Measure Light Calibration

Run Feedback Measurement

View Earlens and/or conventional aided sound field thresholds

10 kHz threshold entry (blue box)

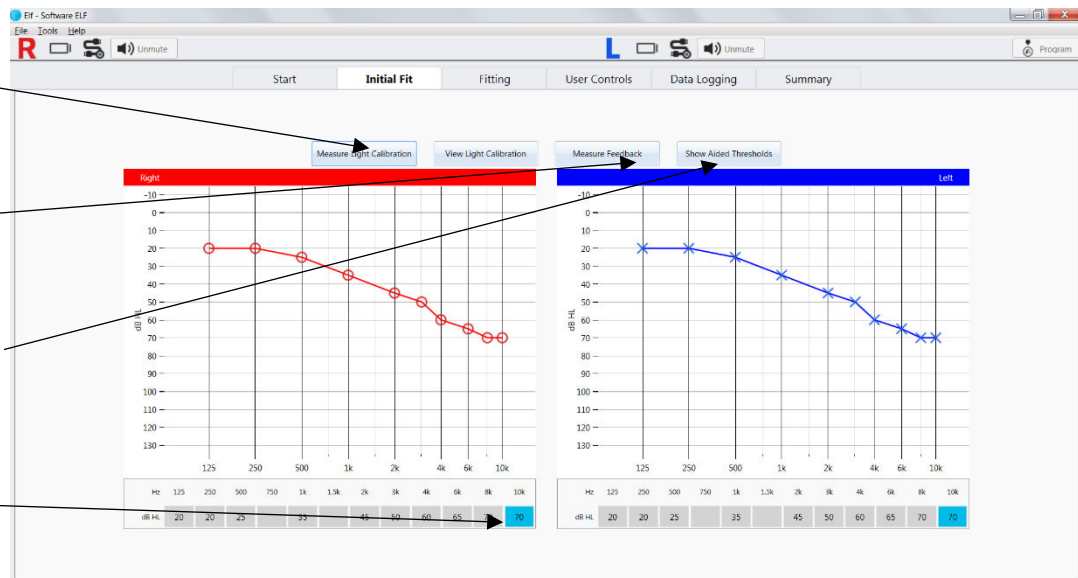


Figure 11: Initial Fit screen

- **Fitting:** Fine-tune the frequency response of the Processor (Figure 12), access automatic or manual acclimatization (Figure 13) and modify feature settings (Figure 14).

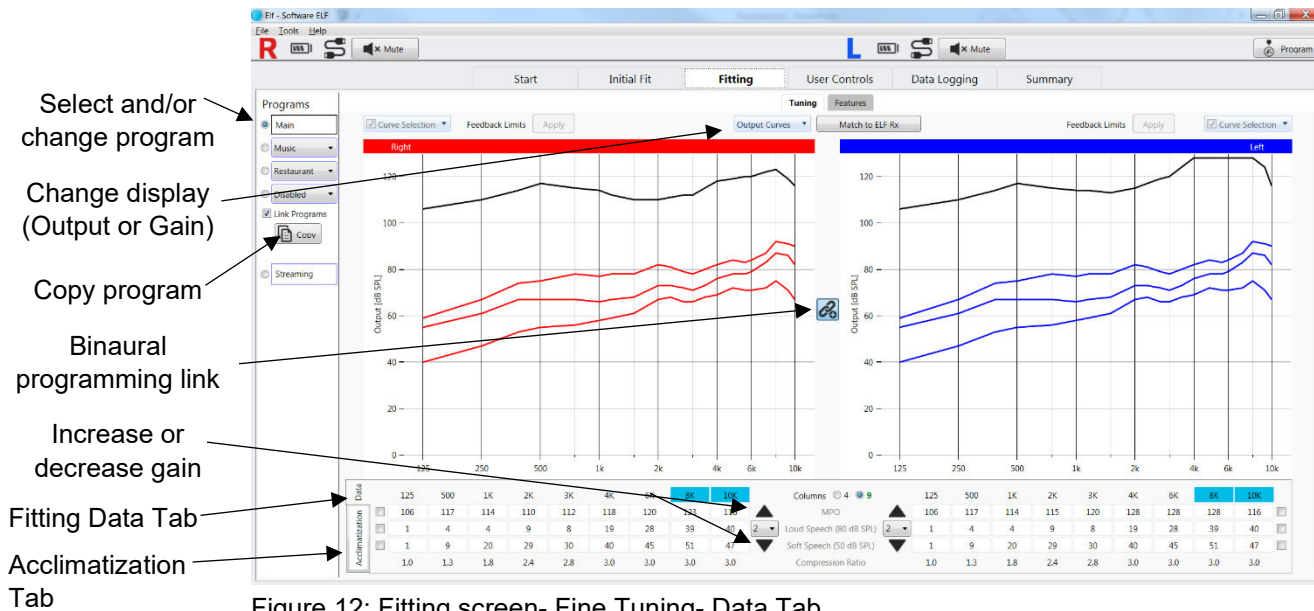


Figure 12: Fitting screen- Fine Tuning- Data Tab

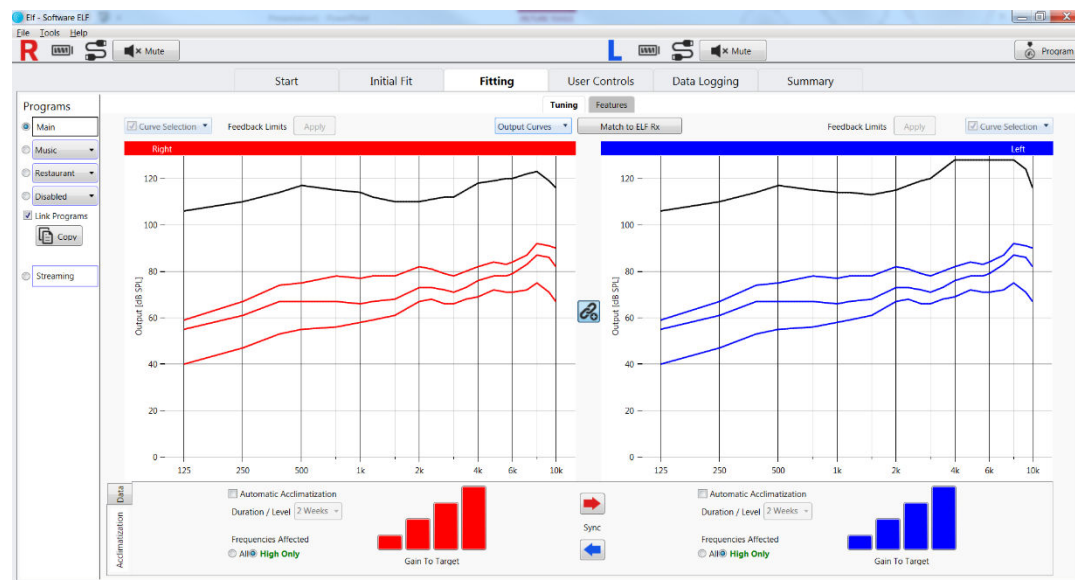


Figure 13: Fitting screen- Fine Tuning- Acclimatization tab

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

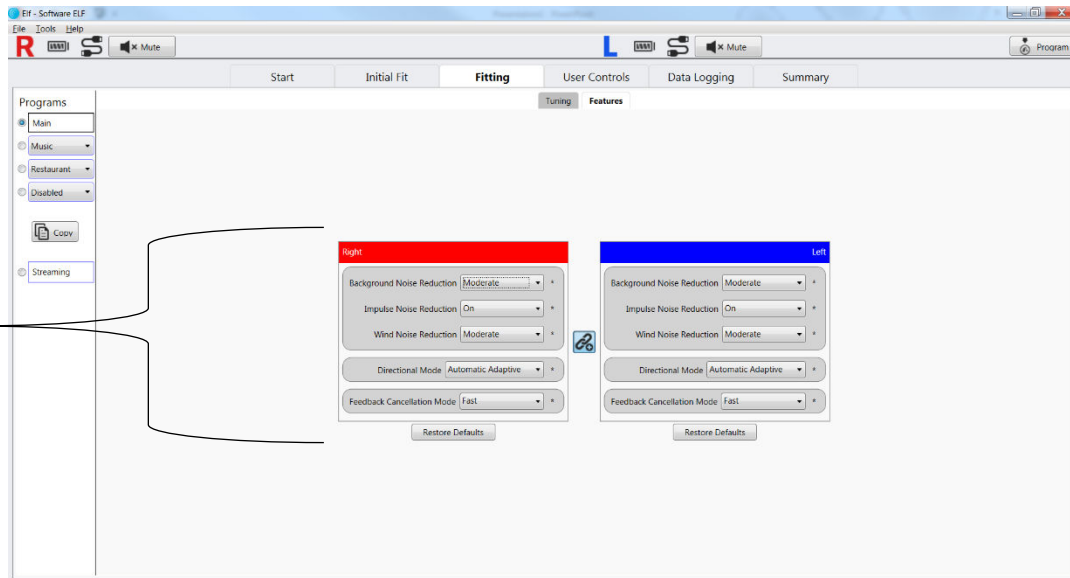


Figure 14: Fitting screen- Features

- *User Controls*: Set the user control configuration on the Processor, customize alert settings and enable Volume Learning (Figure 15).

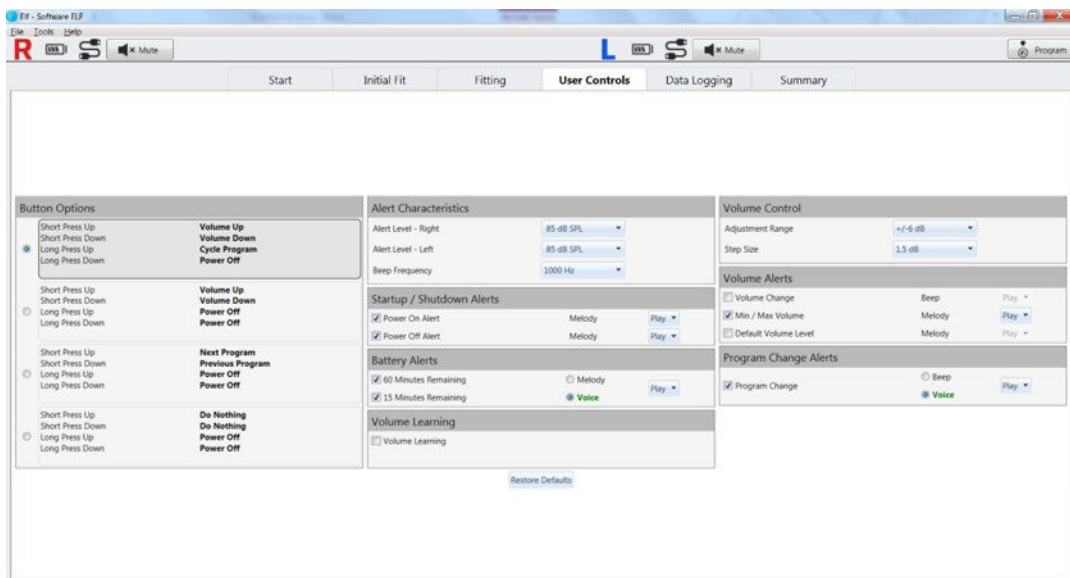


Figure 15: User Controls screen

- **Data Logging:** View patient usage data (Figure 16).
Note: “Read Processor” option must be selected to obtain data logging information.

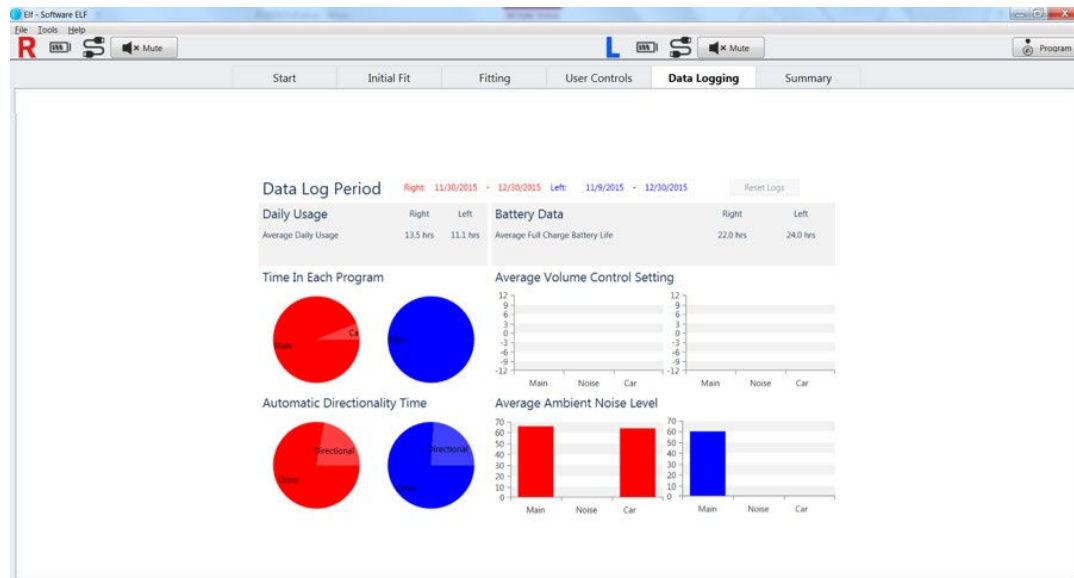


Figure 16. Data Logging screen

- **Summary:** View the summary of the fitting session, enter session notes, print Patient Instructions, and print Audiologist Report (Figure 17).

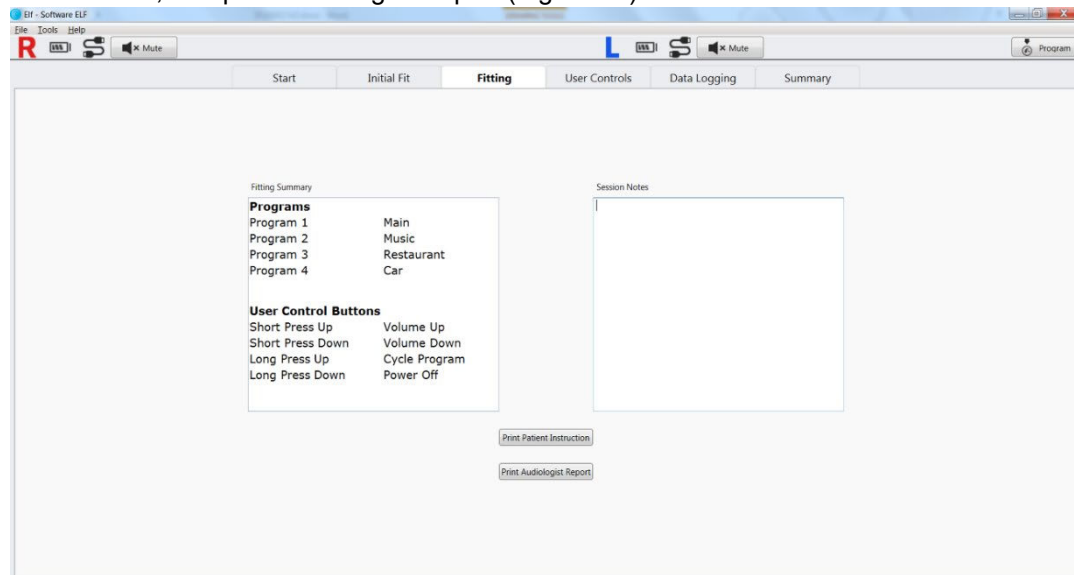


Figure 17: Summary screen

- **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"> - It is recommended that both Processors be set to the same microphone mode - Every program features recommended defaults that may be modified 	<ul style="list-style-type: none"> • Omni- amplifies sound equally from all directions • Fixed- sounds coming from the front are amplified and sounds from the back are attenuated • Automatic adaptive- designed to actively steer the microphones away from the loudest noise source • Automatic fixed- automatically switches from Omni to Fixed mode when noise is detected
Feedback Cancellation	Intended to prevent squealing of the Processors caused by feedback.	<ul style="list-style-type: none"> • Off, Slow, Fast
<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"> • Duration: the amount of time it takes to progress from one level to the next. Options include 1, 2, 3 and 4 weeks • Starting Level: 70, 80, 90% from the targeted response • Frequency range affected: acclimatization can occur for the entire frequency response or for the frequencies only (>5kHz) <ul style="list-style-type: none"> • Gain to Target off-sets options include 70, 80, 90 and 100% • Frequency range affected: acclimatization can occur for the entire frequency response or for the frequencies only (>5kHz)
Volume Learning	The Processor tracks and remembers volume control changes made by the patient and gradually changes the preferred volume level over time.	<ul style="list-style-type: none"> • 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 Light Calibration and feedback measurement.

First Fit Steps

The following instructions describe the steps necessary to complete a bilateral first fit of the Earlens Hearing Aid. 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.

1. Connect to Processors

To perform programming, a HI-PRO 2 must be used with cables provided by Earlens.

- a. Turn the Processors on by pressing and holding any user control for 3 seconds.
- b. Remove the Processor cover to expose the programming port (see Figure 37 a&b for removal instructions).
- c. Connect the Processors to the HI-PRO 2, using programming cables (Figure 18).
- 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.
- f. The "Start" screen will open.
- g. In the "Wired" tab, click "Detect" to connect the Processors.

Note: You must select a patient file for ELF to open.

2. Start Fitting

- a. Once the devices are detected, select "Start Fitting" to begin the fitting session (Figure 19).

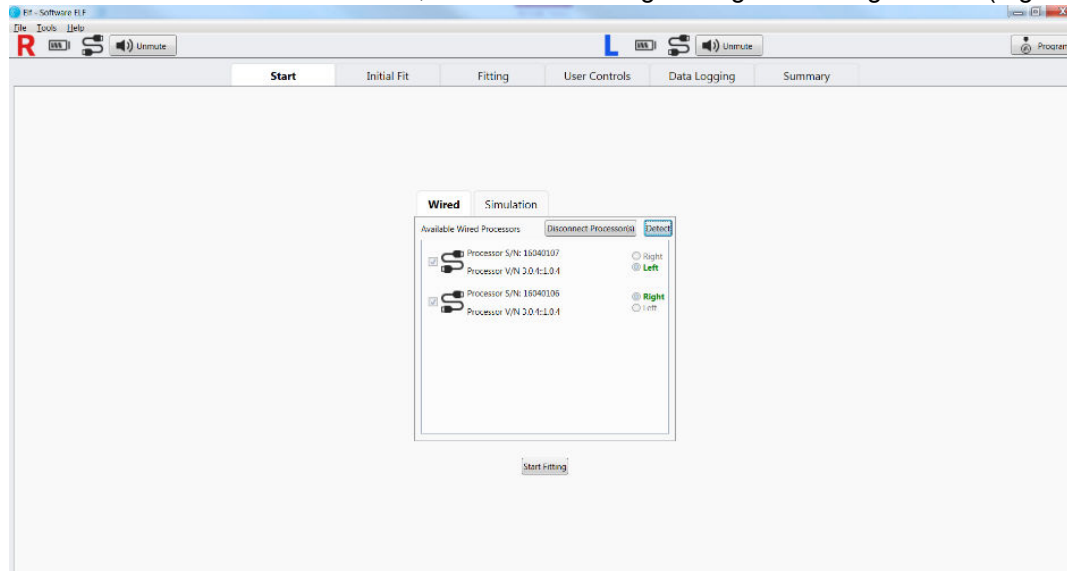


Figure 19: Detected Processors in Start screen

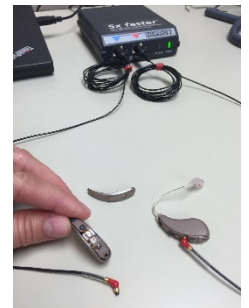


Figure 18: Processor set-up

- b. A pop-window will appear asking “What would you like to do?” Select “Start Session.” (Figure 20).

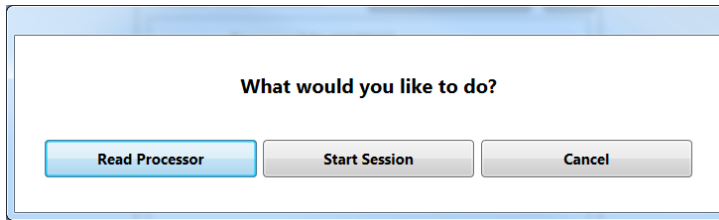


Figure 20: What would you like to do? pop-up window

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: Recommended for a first time fitting. When selected for a follow-up fitting session, it 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 21). Select “Ok” and ELF will open to the Initial Fit screen and enter Calibration Mode.
Note: To program the Processors, audiometric thresholds and Light Calibration measurements must be completed.

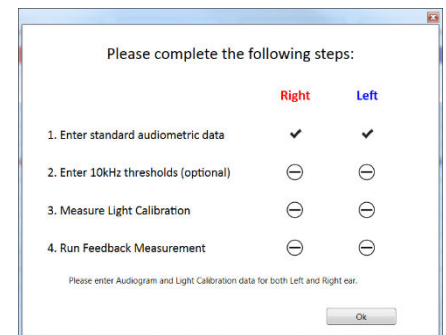


Figure 21: Fitting Data Status window

3. Enter the 10 kHz audiometric threshold for the right and/or left ear into the blue boxes, if available.
4. Measure Light Calibration.

Light Calibration is an in-situ measurement that determines how much light is needed to produce enough sound to reach the patient’s auditory threshold. This measurement is unique to each patient and must be completed in order to program the Processor. To measure Light Calibration complete the following steps:

- a. Select “Measure Light Calibration” in the Initial Fit screen.
- b. A Light Calibration pop-up window will appear (Figure 22).
- c. Find the patient’s threshold at each frequency by presenting a tone. Tones can be presented in two ways:
 - On Click: With this option you can play the tone by clicking on “Play tone” or by pressing the space bar. Use the keyboard up and down arrow or the mouse to select the light 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 level you would like to present to the patient. Press enter or click “Store” to save the data.
- 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 light calibration. To clear stored threshold data, select “Clear All” or “Clear” for each ear individually.

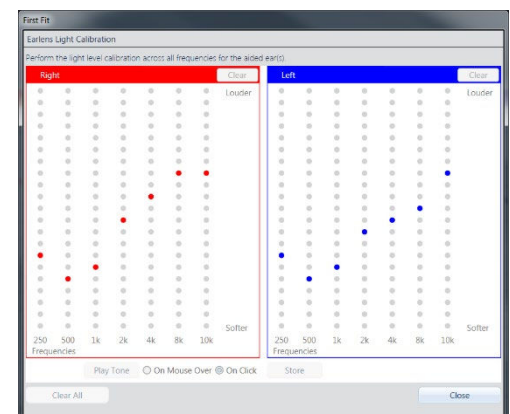


Figure 22: Light Calibration window

5. Measure Feedback

- Prior to performing feedback measurement, ensure all noise sources in the fitting room are reduced.
- Following Light Calibration, a pop-up will prompt you to measure feedback. We highly recommend performing the measurement. Maximum stable gain results can be viewed in the Tuning tab, in the Fitting screen, by selecting the Gain Display option (Figure 23).
- Once measured, the software will automatically open to the Fitting screen.
- If the maximum stable gain interacts with the gain prescription, feedback limits will automatically be applied to the Current Fit Response (Figure 24).
- Gain can be increased beyond the feedback limits but may result in the patient experiencing audible feedback. An 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 25).

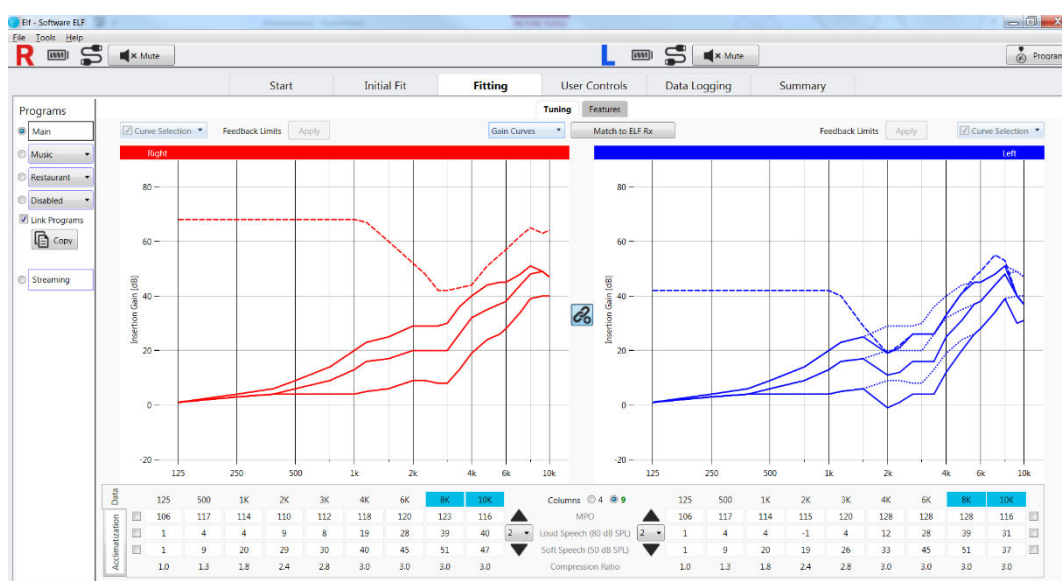


Figure 23: Fine Tuning- Gain Curves displaying maximum stable gain data and feedback limits applied for the left ear

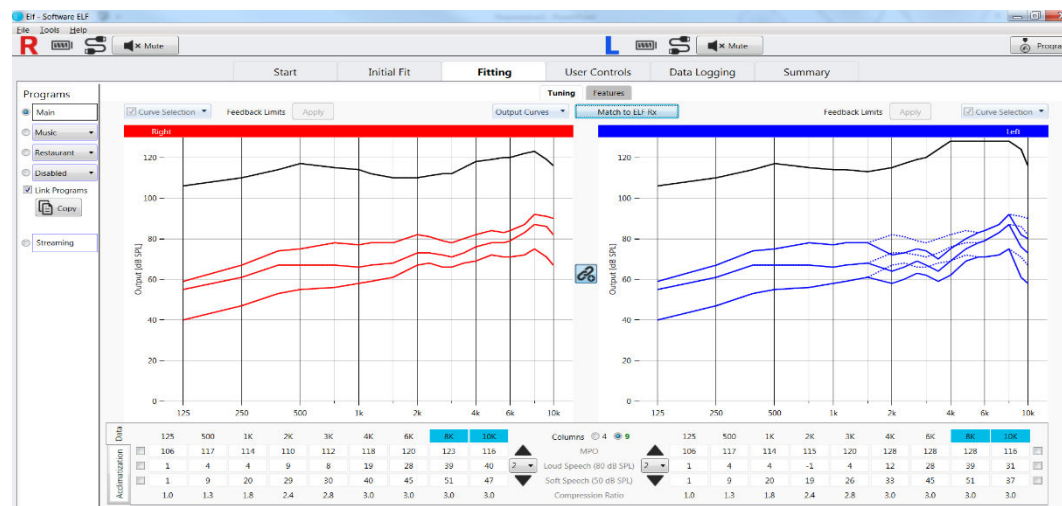


Figure 24: Fine Tuning- Output Curves displaying feedback limits applied for the left ear

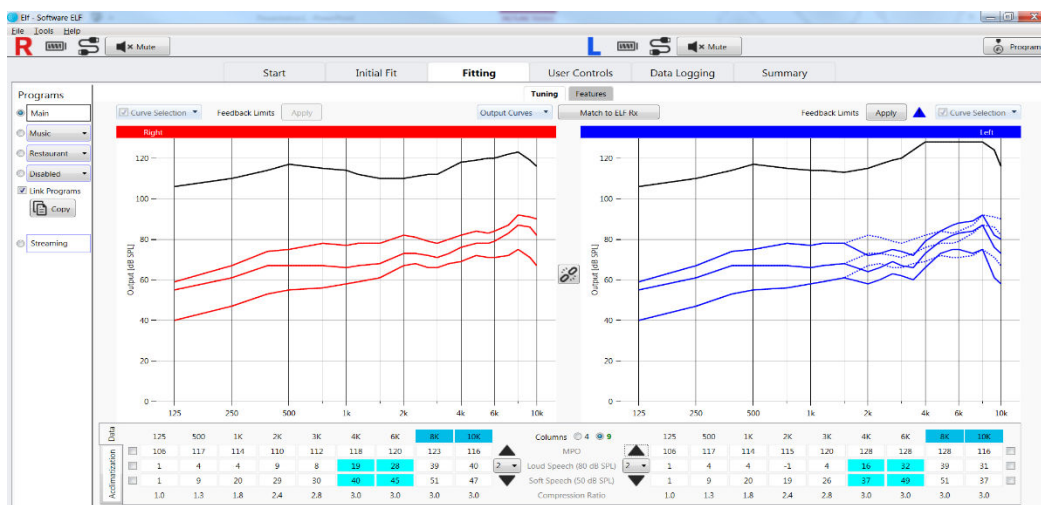


Figure 25: Fine Tuning- Output Curve displaying feedback potential for the left ear

6. Fine Tuning

Like any hearing instrument, the Earlens Hearing Aid can be customized to any 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:

- Do you or the patient hear feedback?
 - If yes, reduce the gain in the region where the feedback is occurring until it subsides.
- Is speech uncomfortably loud for the patient?
 - If yes, reduce the gain until it is at a comfortable level.
- 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.

7. 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.

8. *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 an alert type enables the alert.
- Select "Play" to demo any alert.
- Due to alignment variability and Light Calibration differences between ears, some patients may report that alert levels are uneven. Alert levels are configurable by ear to address perceived volume imbalance.

9. *Print Patient Instructions*

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

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

10. *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.

11. *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 26). 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.

12. *Physically disconnect the Processors from the programming cables.*

13. *Place the CS45 adhesive port cover over the programming port.*

14. *Put the case cover on both Processors (see Figure 40).*



Figure 26: Exit ELF pop-up window

Additional ELF Features

- **Firmware Update**

When a Processor firmware update is available, a pop-up notification will appear in the Start Screen once the Processor is detected (Figure 27). 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. In the event you would like to update the firmware at another time, return to the Start Screen and click on “Update Available” to initiate the firmware update.

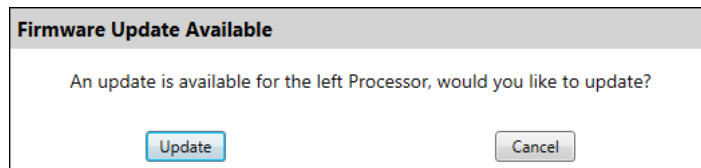


Figure 27: Firmware Update Notification

- **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.

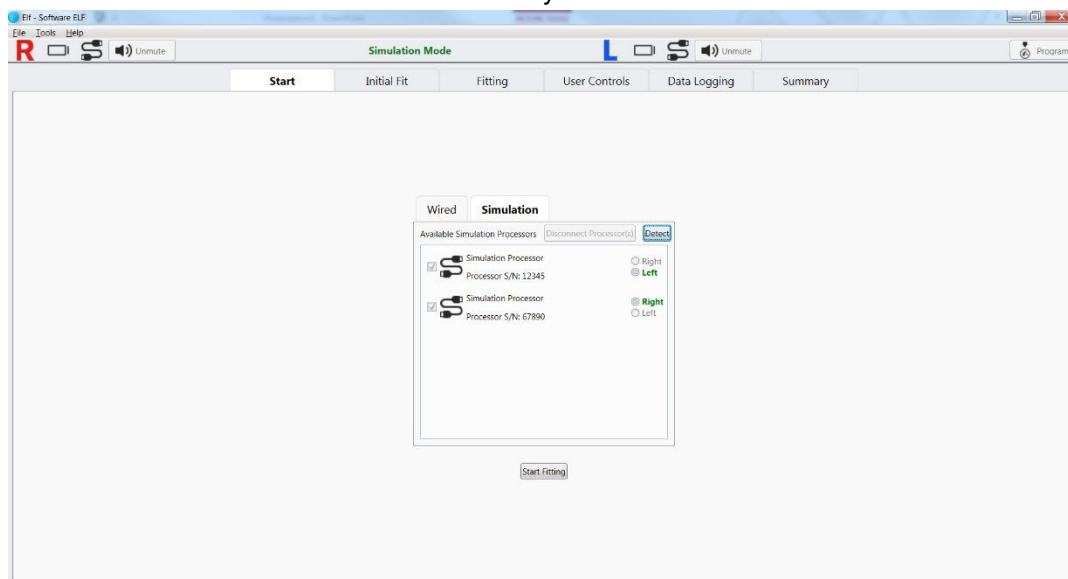
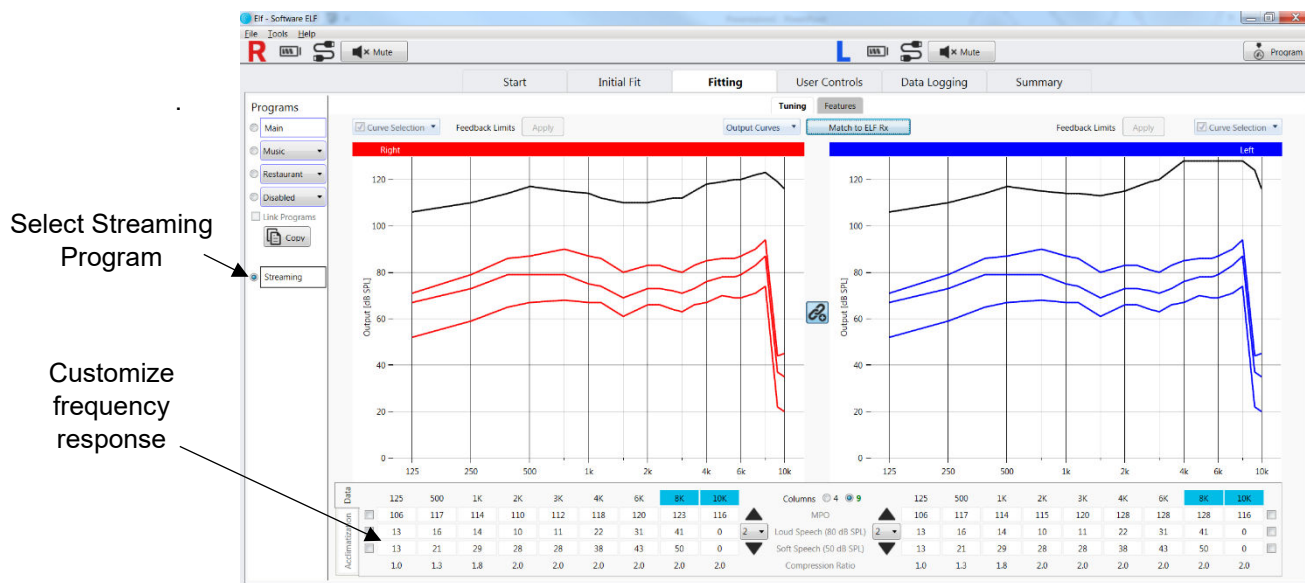


Figure 28: Simulation

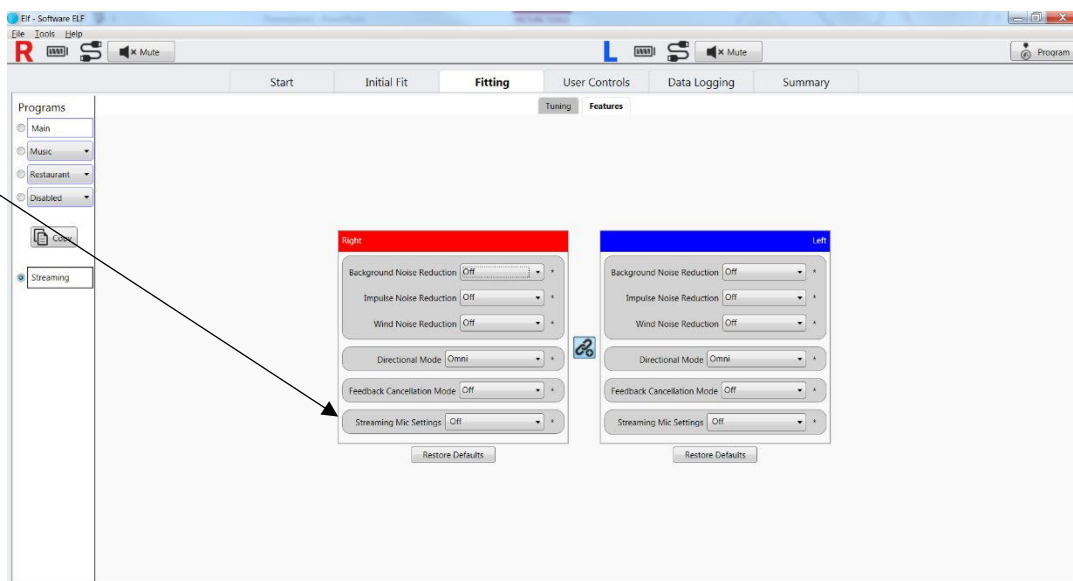
- **Streaming Program**

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 interaction by 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. The defaults settings can be changed by going to the Features Tab (Figure 30). Options include: On, -3, -6, -9 and Off. The patient also has the ability to adjust the hearing aid microphones via the Apple native controls and Earlens Control app.



Configure streaming audio vs. hearing aid microphone settings during an audio stream



- **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).

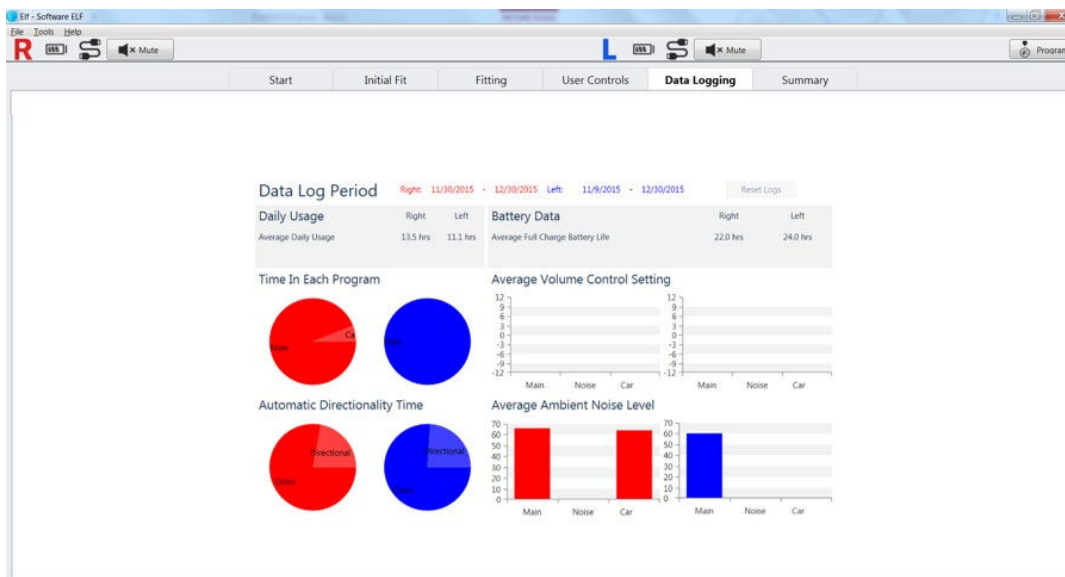


Figure 31: Data Logging Screen

- **Functional Gain (FG) Mode**

- What is 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: It 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 gain produced by 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 you can 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:
 - a. Connect the Processors.
 - b. Instruct the patient that their Earlens Hearing Aids will be set to a special test mode that will allow you to measure the improvement in hearing due to the Earlens Hearing Aid. They may hear an increase in the noise floor as expansion is disabled.
 - c. Select "FG Mode" under Tools in the Tool Bar.
 - d. A pop-up window will open and display the patient's audiometric values and space to enter aided threshold data (Figure 32).

- e. Disconnect the HI-PRO 2 cables from the Processors, making sure to leave the FG Mode open in ELF.
 - f. Situate the patient in the appropriate test location in the calibrated test booth sound field, facing the target speaker.
 - g. Each ear should be independently tested. For the non-test ear, remove the Processor and plug the ear with a foam insert/plug.
 - h. 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.
 - i. Make sure your soundfield has been calibrated for narrow-band noise stimuli, a backup alternative test stimuli is pulsed warble tones.
 - j. Present pulsed, narrow band noise stimuli, using your usual threshold seeking procedure. Mark the aided threshold at each test frequency.
 - k. Switch to the other ear, and repeat.
 - l. Once testing is completed, reconnect the Processor(s) to the HI-PRO cables.
 - m. Exit FG mode by selecting "Exit Functional Gain Mode." **Do not leave the Processor in functional gain mode.**
 - n. Make sure you save the program after completing the testing to ensure the aided thresholds are saved.
- *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.

- a. Open the FG Mode via Tools, in the Tool Bar.
- b. Manually enter aided audiometric threshold data (Figure 33).
- c. View data in Initial Fit screen, by clicking on "Show Aided Thresholds" (Figure 34).
- d. View or print the data by going to the Summary screen and selecting "Print Patient Instructions" (Figure 35).

Functional Gain Mode
Functional Gain Mode allows for aided threshold testing without interference 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.

	Hz	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right	dB HL	20	20	25		35		45	50	60	65	70	70
Left	dB HL	20	20	25		35		45	50	60	65	70	70

Conventional Hearing Aid Aided Thresholds

Hearing Aid Brand / Series

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

Earlens Aided Thresholds

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

Exit Functional Gain Mode

Figure 32: FG Mode Window

Functional Gain Mode
Functional Gain Mode allows for aided threshold testing without interference 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.

	Hz	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right	dB HL	20	20	25		35		45	50	60	65	70	70
Left	dB HL	20	20	25		35		45	50	60	65	70	70

Conventional Hearing Aid Aided Thresholds

Hearing Aid Brand / Series Manufacturer- Whiz-Bang Hearing Aid

	Hz	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right	dB HL	20	20			15		15		35	55	70	70
Left	dB HL	20	20			15		15		35	55	70	70

Earlens Aided Thresholds

	Hz	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k	10k
Right	dB HL		15	15		10		10		15	20	20	20
Left	dB HL		15	15		10		10		15	20	20	20

Exit Functional Gain Mode

Figure 33: FG Mode window- Sound Field Threshold Entry

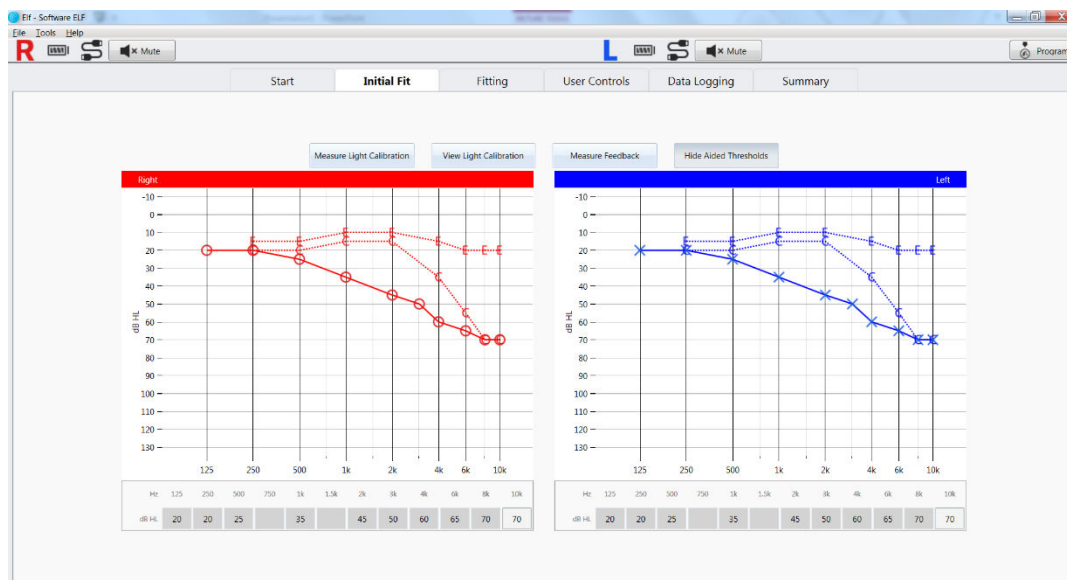



Figure 34: Initial Fit screen- Show Aided Thresholds



Instruction Sheet For **Software ELF**

Programs

Program 1	Main
Program 2	Music
Program 3	Restaurant
Program 4	Car

User Control Buttons

Short Press Up	Volume Up
Short Press Down	Volume Down
Long Press Up	Cycle Program
Long Press Down	Power Off

Important Reminders

- Apply 1 dose (pump) of Earlens mineral oil to your ear canal at a minimum of once per week. This keeps the Lens in place and functioning properly.
- If you need an MRI, you must return to your physician to have the Lens removed.
- Never insert foreign objects into your ear (i.e. Q-tip, bobby pin, or fingernails). Insertion of a foreign object could result in pain, may damage your ear or may cause damage to the Lens.
- Clean the Light Tip, Processor and Charger with a soft cloth. Do not use chemicals or abrasive materials on any of the components as they may cause damage.
- Please reference your Earlens Photon Hearing Aid User Manual for additional information about your hearing devices.
- If you need assistance, please call Earlens Customer Care at 1 (844) 234-5367

Hearing Aid Aided Thresholds

Figure 35: Patient Instruction print-out

- **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.
- Main is the only program that defaults on for a first fit. All other program slots are disabled and can be configured based on the patient's needs.
- Pre-defined programs are available and include: Music, Restaurant, Car, Quiet, Noise, Party, Outside, and TV.
- Programs can be swapped and copied from one to another using the Copy Program(s) menu featured in the Tuning tab (Figure 36).

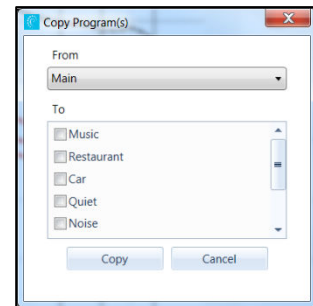


Figure 36: Copy Programs

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 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, it limits the prescribed gain to a value less than the measured maximum gain before feedback for both, left, right or neither. After Measuring Feedback, if feedback potential is detected, feedback limits will automatically be applied.
- **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. Removal and Insertion of the Light Tip from the Processor

To remove the Light Tip from the Processor:

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

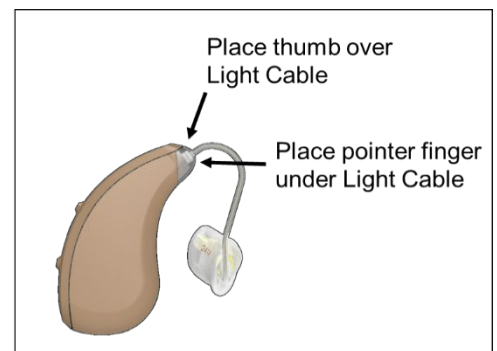


Figure 37 Light Tip Removal

To insert the Light Tip in the Processor:

- Insert the Light Tip connector straight into the Processor.

9.4. Removal and Replacement of Processor Case Cover

The Processor cover needs to be removed for Light Tip insertion, programming, and for replacement.

- Gently pinch the top and bottom of the Processor. This will create a small gap between the cover and Processor near the user controls (Figure 38a).
- 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.
- Gently lift the cover straight back.

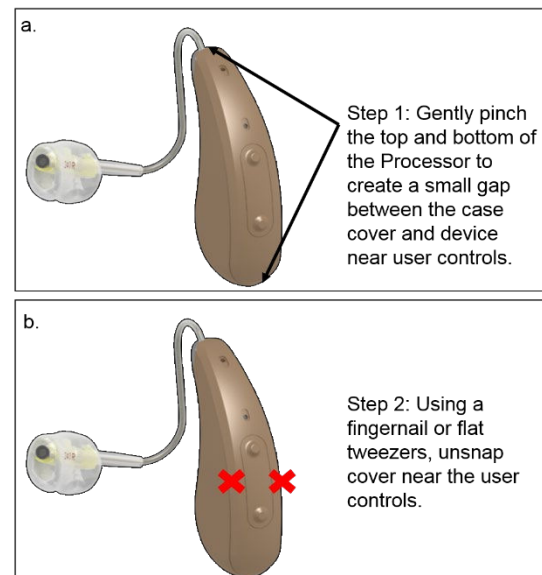


Figure 38 a & b: Processor case cover removal

To replace the cover (Figure 39):

- a. Beginning at the bottom of the Processor, 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 top of the case cover into place on the Processor housing.

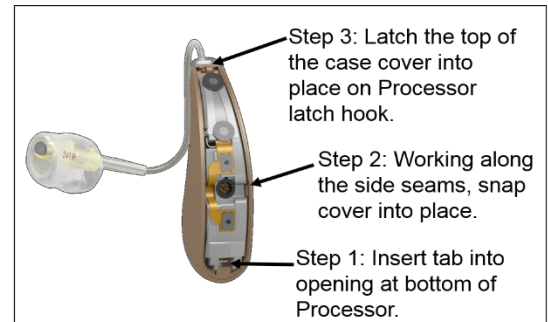


Figure 39: Processor case cover replacement

9.5. Maintenance Oiling of the Tympanic Lens

It is recommended that the patient apply 2 pumps of mineral oil to the ear canal daily 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 depressing the pump a few times into a tissue until a consistent stream of oil is observed.
- b. With their head in an upright position, place the cone tip of the mineral oil dispenser fully into the ear canal opening.
- c. Dispense two pumps of oil into the ear canal by depressing the pump twice.
- d. Remove the dispenser from the ear and tilt head to the side. 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.
- e. Repeat for the opposite ear.
- f. After oiling, the ears may feel a little stuffy. This should subside on its own when the oil is absorbed.

Additional Information and Considerations

- It is recommended that the patient reapply oil should they go swimming or do an activity that causes the ear canals to fill with water.
- Applying mineral oil at night may reduce the damping effect of oil.
- Regular application of mineral oil will help reduce the presence of ear wax.
- Patients should take care not to overfill their ear canals with oil as this may dampen their hearing temporarily.

9.6. Processor Functions

Battery Life

- The Processor battery life lasts a minimum of 16 hours and an average of 20 hours on a full charge. When depleted, the Processor 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.

Turning Processors On and Off

When a Processor is removed from a plugged in Charger, it is 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 set up the same for 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/belly 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 Hearing Aid, or use the Earlens Charger to charge any other devices. Using the incorrect Charger or AC wall adapter can damage the devices.
- 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 3 seconds while the Processor and Charger are communicating. Table 2 details what each indicator light means.







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

Table 2: Charger indicator status

9.8. Care & Maintenance

Storage

- Store the Earlens Hearing Aid in a clean, dry location out of direct sunlight. Avoid exposure to excessively high or low temperatures.

- Store the Processor and Light Tip in the Earlens Charger. The Earlens Charger is designed to protect the Light 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.
- The Light Tips may collect wax on the end where the light is emitted. Although light can travel through a thin layer of wax, large pieces should be removed to ensure proper functioning of the devices. Use a soft cloth, a baby wipe or Isopropyl Alcohol (IPA) based wipes to remove wax.
- If wax accumulates in the Light Tip vent, use a standard hearing aid cleaning tool to gently remove it. Do not use an abrasive tool.
- Do not use liquid cleaners on the Processors as these can damage the devices. The Light Tips may be cleaned with a baby wipe or other Isopropyl Alcohol (IPA) based wipes.

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.
 - 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 Processor continues to blink, perform steps a-d up to 5 times. If after repeating these steps the Processor does not connect, please contact Earlens Customer Care.
 - b. Shine the Light Tip on the Light Detector Card. If you do not see a red dot, contact Earlens Customer Care.
 - c. Check placement of Light Tip in the ear canal by removing and reinserting and checking the position.
 - d. Press the Program change control (if enabled) to see if an alert is heard. If the alert is not heard, contact Earlens Customer Care.
 - e. If the alert is heard but soft, refer the patient to the ENT physician.
 - If it is determined that the Lens is damaged, contact Earlens customer service.
 - If the Lens is malfunctioning, the ENT physician may reposition the Lens, remove and reinsert the Lens or remove the Lens.
- **Feedback-** If the patient is experiencing feedback, check the position, insertion and alignment of the Light Tip. Check feedback measurement data in the Gain Curves display located in the Tuning tab in ELF to determine if there is a potential for feedback with the patient's fitting. If feedback continues, contact Earlens to discuss Light Tip remake options.
- **Four Blinking Lights on the Charger -** If the Charger displays 4 blinking lights, the Charger is unable to connect and charge the Processor. This may occur because the Processor is in Deep Sleep Mode or because the battery is fully depleted. 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 any 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 Processor continues to blink, perform steps a-d up to 5 times. If after repeating these steps the Processor does not connect, please contact Earlens.

10. Wireless Connectivity- Made for iPhone Feature

10.1 Device Compatibility

The Earlens Hearing Aid is compatible with the following Apple® devices that have iOS 11 or later:

<i>iPhone®</i>	<i>iPad®</i>	<i>iPod®</i>
iPhone XR	12.9-inch iPad Pro 2nd gen	iPod touch 6 th gen
iPhone XS Max	12.9-inch iPad Pro 1st gen	
iPhone XS	10.5-inch iPad Pro	
iPhone X	9.7-inch iPad Pro	
iPhone 8	iPad Air 2	
iPhone 8 Plus	iPad Air	
iPhone 7	iPad 5th gen	
iPhone 7 Plus	iPad mini 4	
iPhone 6s	iPad mini 3	
iPhone 6s Plus	iPad mini 2	
iPhone 6		
iPhone 6 Plus		
iPhone 5s		

Real-time updates for compatibility with newer Apple products can be found at www.earlens.com/connectivity. Some Apple products are not compatible with iOS 11 or newer. Instructions for older versions of Apple iOS are available at www.earlens.com/connectivity.

10.2 Pairing and Connecting an Apple Device

To pair the hearing aids to the Apple device with iOS 12, follow these steps:

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

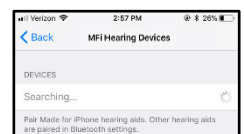


Figure 40

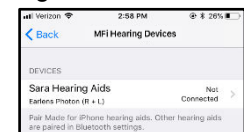


Figure 41

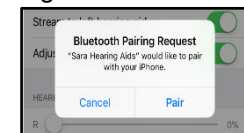


Figure 42

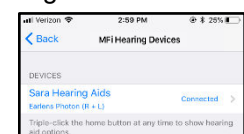


Figure 43

10.3 Reconnecting to an Apple Device

When 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 users 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 1-844-730-5986.


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 Apple Control Center (Figure 44).
2. Tap 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.

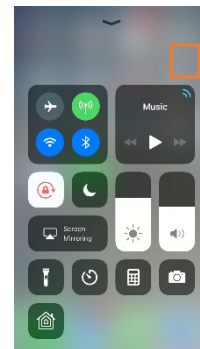


Figure 44

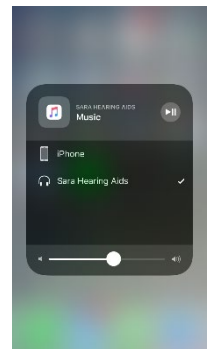


Figure 45

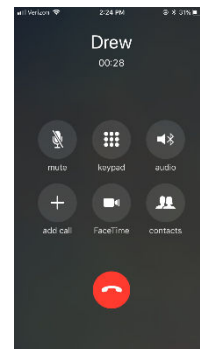


Figure 46

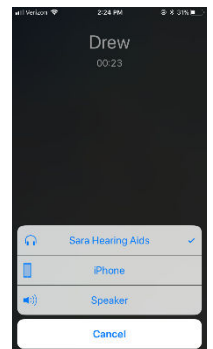


Figure 47

10.5 Earlens Control Mobile Application

Download the Earlens Control App

Users must have an iTunes account to download the Earlens Control mobile application. To set up an account go to www.itunes.com.

1. Open the App Store 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, users must enter 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 much more! The first time the application is downloaded, tutorial hints will appear to acquaint the user with the app. The following features are available in the app:

- *Concierge Opt-in*

If your patient has any questions, requires assistance, or would like to learn more about their Earlens Hearing Aid the Earlens Concierge is available. This remote service is free to the patient and available during normal business hours. When they first open 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 we have important product updates or 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 decrease volume; slide right to increase the volume.
- To change the volume of each Processor independently, tap on the splitter icon and slide your finger along the volume bar to adjust the volume. Slide left to decrease volume; slide right increase the volume.
- To mute the Processors, select the Mute icon.
- Using the volume bar in the app will adjust the hearing aid microphones, not the streaming volume from the Apple device. To adjust the streamed input, use the volume controls on the side of the Apple device.

- *Change Programs*

Up to 4 programs can be enabled in the Processor. These programs can be changed in the app in the **Home** screen.

1. Select **Home** on the bottom navigation bar.

Depending on the number of programs stored in the Processor, bars with the program name will display. To change the Processor program tap on the desired program bar. The active program will display in orange.

- *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 settings on a per program basis.

- *Support*

The Support tab offers Earlens Concierge contact information, helpful videos, and links to additional resources.

- *Additional App Features*

- *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. Tap on Live Mic.
3. Tap on the **Start Live Mic** icon. When enabled, the icon will turn from blue to orange.

4. In the Live Mic screen, you can adjust the hearing aid microphone volume relative to the audio stream.
 5. To stop the live stream, tap on **Start Live Mic**, it will turn back to blue.
- *Set Oiling Reminders*
An important step to maintaining the Earlens Hearing Aid involves applying two pumps of mineral, to each ear, daily. 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 **Every Day**.
 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 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 your Processors and Apple device were connected in the event 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 in two places on the Apple device:
 - a. 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 15 seconds.
3. Press the top user control on the hearing aid until the patient hears the device turn on.
4. Select **Settings > General > Accessibility > MFi Hearing Devices** and tap on the hearing aids, displayed under Devices, to verify that they are paired and actively connected to the Apple device.
Note: If a pairing window pops-up, select **Pair**.
5. Forget and re-pair the hearing aids to the Apple device.
 - a. Select **Settings > General > Accessibility > MFi Hearing Devices**.
 - b. Tap on the 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 an 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 1-844-730-5986.

Made for iPhone Tips and Tricks

- To change the volume of phone calls or audio media when streaming to the hearing aids, 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, we recommend holding the Apple device in the hand or in an armband and do not place it in pockets.
 - Car and hearing aid Bluetooth may act unpredictably with the Apple device. Please call the Earlens Concierge for additional support.

For more MFi connectivity information and troubleshooting help, go to www.earlens.com/connectivity or connect with the Earlens Concierge at 1-844-730-5986.

10.7 Apple Hearing Aid Control

Apple offers hearing aid controls 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

These controls can be quickly accessed by performing a triple-click of the home button (Apple products with a home button) or by triple-click of the power button on iPhone X or newer.

11. Operating Specifications

- Certain components of the Earlens Hearing Aid, including the Processor and the Light Tip are classified as a Type BF applied parts as described in the international standard IEC 60601-1:2005, Medical Electrical Equipment-Part 1:General Requirements for Basic Safety and Essential Performance.
- Please refer to the tables provided for more information on recommended distances for separation of the Earlens Hearing Aid.
- Expected service life of the Earlens Hearing Aid include:
 - Processor and Charger- one year
 - Light Tip- one year
 - Lens- one year
- The Earlens Hearing Aid is designed for continuous use.
- The Processor 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, 50-60Hz, 0.2A
Battery Charger Output	5.0 VDC, 0.6A

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 10,000Hz

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

11.4. 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 Hearing Aid have been tested for electromagnetic emissions compliance.

List of all cables utilized with the Earlens Hearing Aid				
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 Hearing Aid has been successfully tested for use in the electromagnetic environment specified below. The customer or user of the Earlens Hearing Aid should ensure that it is used in such an environment, not to exceed conditions listed below.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Earlens Hearing Aid does not use RF energy for any of its functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Earlens Hearing Aid 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.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Immunity			
The Earlens Hearing Aid has been successfully tested for use in the electromagnetic environment specified below. The customer or user of the Earlens Hearing Aid should ensure that it is used in such an environment, not to exceed conditions listed below.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±8kV Contact* ±15kV Air*	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the R/H should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical home, commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical home, commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical home, commercial or hospital environment. If the user of the Earlens Hearing Aid requires continued operation during power mains interruptions, it is recommended that the Earlens Hearing Aid be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	30 A/m*	Power frequency magnetic fields should be that of a typical home, commercial or hospital environment.

*Compliance was tested at higher levels representative of requirements for home use per IEC 60601-1-2
Edition 4:2014-02

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Earlens Hearing Aid has been successfully tested for use in the electromagnetic environment specified below. The customer or user of the Earlens Hearing Aid should ensure that it is used in such an environment, not to exceed conditions listed below.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)=3Vrms & 6Vrms in ISM bands*	Portable and mobile communications equipment should be separated from the Earlens Hearing Aid by no less than the distances calculated/listed below: $D=1.2(\text{Sqrt } P)$ [3V Level] 150kHz to 80MHz $D=2(\text{Sqrt } P)$ [6V Level] 150kHz to 80MHz $D=1.2(\text{Sqrt } P)$ 80 to 800 MHz $D=2.3(\text{Sqrt } P)$ 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	(E1)=10V/m*	

*Compliance was tested at higher levels representative of requirements for home use per IEC 60601-1-2 Edition 4:2014-02

Recommended Separation Distances for the Earlens Hearing Aid				
The Earlens Hearing Aid is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Earlens Hearing Aid can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Earlens Hearing Aid as recommended below, according to the maximum output power of the communications equipment.				
Max Output Power (Watts)	Separation (m) 150kHz to 80MHz outside ISM bands $D=1.2(\text{Sqrt } P)$ (Test Level 3 V)	Separation (m) 150kHz to 80MHz in ISM and Amateur bands $D=2(\text{Sqrt } P)$ (Test Level 6 V)	Separation (m) 80MHz to 800MHz $D=1.2(\text{Sqrt } P)$ (Test Level 10 V/m)	Separation (m) 800MHz to 2.5GHz $D=2.3(\text{Sqrt } P)$ (Test Level 10 V/m)
0.01	0.12	0.2	0.12	0.23
0.1	0.38	0.63	0.38	0.73
1	1.2	2.0	1.2	2.3
10	3.7	6.3	3.8	7.3
100	12	20	12	23















11.5. FCC Compliance

- FCC ID: 2AGDU-EL1; IC ID: 20825-EL1
- The Earlens Light Driven Hearing Aid complies with part 18 of the FCC rules and ICES-003 of the IC rules.

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	IP21	International Protection Code against ingress of solid foreign objects $\geq 12.5\text{mm}$ diameter and vertically falling water drops when enclosure tilted up to 15°	IEC 60601-1:2005 IEC 60529, 4.2
RxOnly	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)	FDA Final Rule 81 FR 38911		Serial number	ISO 15223-1:2016, 5.1.7
	Humidity limitation	ISO 15223-1:2016, 5.3.8		Caution	ISO 15223-1:2016, 5.4.4
	Class 1 laser product	IEC 60825-1:2007, 5.2		MR unsafe	ASTM F2503-13
	Batch code	ISO 15223-1:2016, 5.1.5		FCC Part 18 Declaration of Conformity	FCC Guidelines for Labeling, Part 18, 2014
	Catalog code	ISO 15223-1:2016, 5.1.6		Non-ionizing radiation	IEC 60601-1-2:2007 IEC 60417-5140 (2003-04)

	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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14. Laser Certification

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



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