



Earlens® Contact Hearing Solution Hearing Healthcare Professional Instructions for Earlens® Fidelity™

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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 Fidelity™ software
- 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 is then received by the Lens.

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

www.earlens.com/connectivity.

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

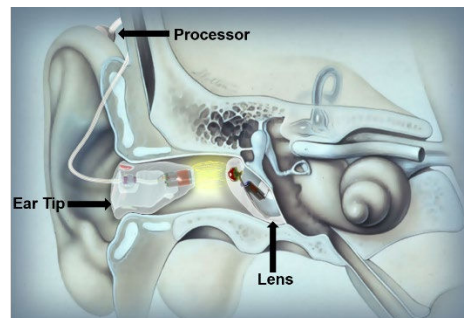


Figure 1. Earlens component schematic

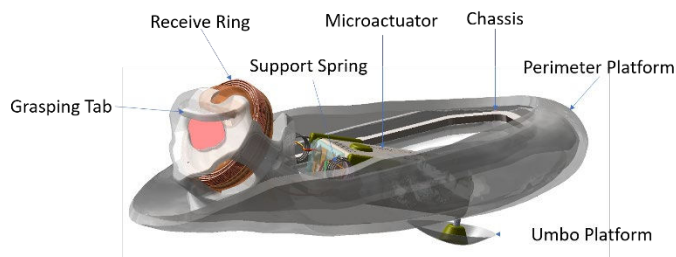


Figure 2. Tympanic Lens

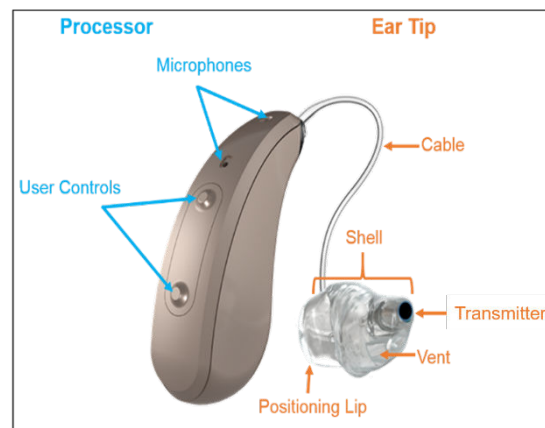


Figure 3. Earlens Processor and Ear Tip

2.3. *Earlens Fidelity™ software*

Earlens Fidelity™ software is used to program the Processor, enabling the hearing healthcare professional to calibrate and program the Processor specific to the patient's hearing 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 lens on eardrum, it is recommended that patients apply one pump of mineral oil to their ears every other day or as directed by the physician.

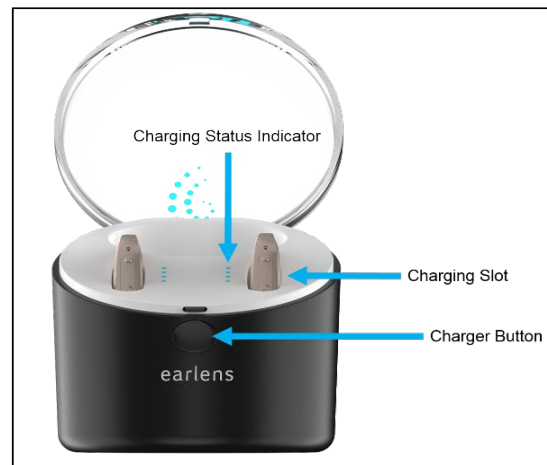


Figure 4. Earlens Charger

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 them from having a hearing device, including:

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

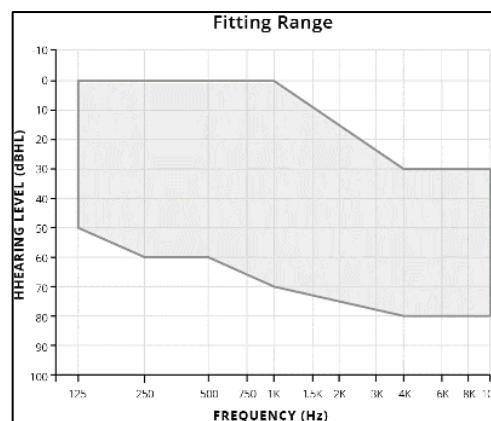


Figure 5. Earlens audiometric fitting range

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

6. Warnings



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

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

7. Precautions



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

- This is not hearing protection. The patient should remove this device (Processors and Ear Tips) if they experience overly loud sounds, whether short or long lasting. If the patient is in a loud place, they should use the right kind of hearing protection instead of wearing this device. In general, if the patient would use ear plugs in a loud place, they should remove this device (Processors and Ear Tips) and use ear plugs.
- The sound output should not be uncomfortable or painful. The patient should turn down the volume or remove the device (Processors and Ear Tips) if the sound output is uncomfortably loud or painful. If the patient consistently needs to turn the volume down, the device may need to be further adjusted.
- The patient might need medical help if a piece gets stuck in the ear. If any part of the hearing aid, like the Ear Tip, gets stuck in the patient's ear, and they can't easily remove it with fingers, they should get medical help as soon as they can. The patient should not try to use tweezers or cotton swabs because they can push the part farther into the patient's ear, injuring the eardrum or ear canal, possibly seriously.
- Individuals with known nickel sensitivity/allergy should be informed that the Lens and Ear Tip components contain nickel that is coated with a parylene barrier. If an allergic reaction develops, the Lens and Ear Tip should be promptly removed.
- The Lens and Ear Tip were tested for nickel leaching and found to be compliant and within the

safe levels identified in European standard EN1811. Traces of oxidation (discoloration) may be visible on the Lens surface following prolonged wear. Testing indicated the oxidation was not likely to affect the structural integrity of the Lens and Ear Tip within the 1 year expected life.

- Only hearing healthcare professionals trained in the fitting of hearing aids may fit the Earlens® Processor and Ear Tip.
- The Earlens® Contact Hearing Solution is custom designed and intended to be used for a single patient.
- The Ear Tip is designed to sit a set distance from the Lens. Sound output may deviate if the Ear Tip is not inserted to the proper depth. If the sound output does deviate, the patient can reposition the Ear Tip until optimal sound output is achieved.
- Earplugs or headphones can be used with the Lens in place as long as care is taken not to over-insert them and they do not protrude deeply into the ear canal.
- The patient may shower, bathe, or swim with the Lens in place. Ear plugs may be used to prevent water from entering the ears so long as care is taken to not over-insert them. Removing water from ears may be more difficult with the Lens in place.
- If the patient has small or unusually shaped ear canals, they may be at a greater risk for ear canal abrasions, either from the ear impression procedure or from Ear Tip use.
- The patient should avoid getting the Processor wet, as it may damage the device. The patient must remove the Processor and Ear Tip prior to showering, swimming, or bathing.
- The patient may experience a reduction in their hearing levels when the Lens is in place, but the Processor is not activated.
- Do not direct streams of liquid (i.e., isopropyl alcohol, hydrogen peroxide, DeBrox®) into ears, as this may cause the Lens to become dislodged or cause damage to the device.
- Failure to oil the ear canal may result in Lens displacement.
- Do not place any component of the Earlens® Contact Hearing Solution into a microwave, or near a significant source of static electricity.
- Use only the Earlens® Charger and AC wall adapter provided. Although other adapters may look similar, they may cause damage to the Earlens® Contact Hearing Solution.
- Handle the components carefully and prevent hard knocks. Do not drop them as it may damage the Earlens® Contact Hearing Solution.
- If the Earlens® Processor fails to operate or if it appears damaged, including the presence of battery leakage or swelling, the patient should promptly remove the Processor, discontinue use and contact their hearing healthcare professional.
- Only clean the Processor with a soft cloth. Do not use chemicals (i.e., hairspray) in close proximity or to clean the Processor.
- Keep Charger cord out of reach of individuals who may be at risk of strangulation.
- Electromagnetic fields produced by other electrical equipment such as cell phones, metal detectors, microwaves, RFID systems and commercial theft detection systems (also known as electronic article surveillance [EAS]) may interfere with the Earlens® Contact Hearing Solution. In the event that the patient perceives unexpected noise or interference in the presence of the Earlens® Contact Hearing Solution, move away from the source to mitigate the potential interference. If the patient has further concerns, they should remove the Processors and contact their hearing healthcare professional.

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

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

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.

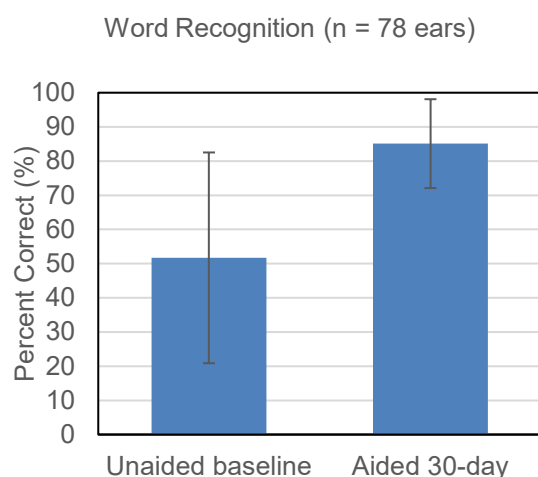


Figure 6. Word Recognition Performance

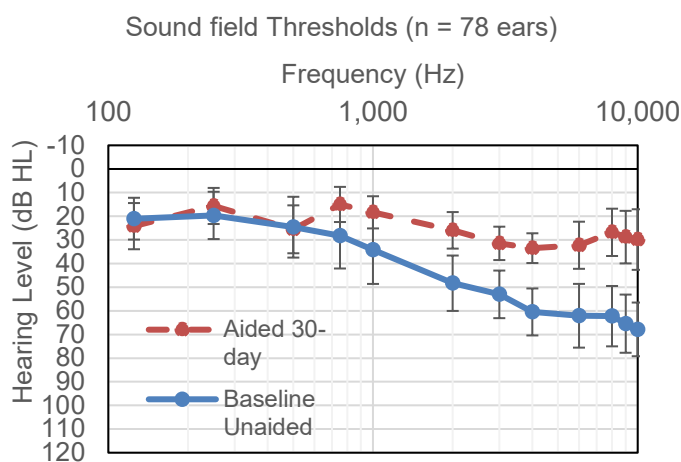


Figure 7. Sound field thresholds

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.

Based 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. Ear Tips with replaceable cables have a letter designating the length of the cable. Size 'A' is the shortest length and the cable sizes increment by 2 mm.

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. Evaluate cable length for appropriate fit and exchange with a different size cable, if needed.
- f. 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 Earlens Fidelity™ software

Earlens Fidelity™ software Requirements

To install Earlens Fidelity™ your computer must meet the following requirements:

- OS: Windows 7 (SP1) / 8 / 8.1 / 10 (Anniversary Update version 1607 or later)
- Processor: 2 gigahertz (GHz) or faster
- RAM: 4 gigabyte (GB) or higher
- Hard Drive Space: 5 gigabyte (GB) or more
- Noah 4.8 or later must be installed
- Hi-Pro 2 programmer with Hi-Pro 2 driver software installed for wired fitting
- Noahlink Wireless programmer version 2.19 or later for wireless fitting
- Internet connection

Navigating Earlens Fidelity™ software

- **Navigation Bar** (Figure 8)

- The Navigation Bar allows the hearing healthcare professional to navigate to different parts of the software. The following options are visible from top to bottom of the bar. The functionality of each screen is briefly described below.
- *Patient Name*: Patient name is displayed on the top of the navigation bar and is matched with the name entered in Noah.
- *Device connection*: Allows the hearing healthcare professional to connect Processor(s) through wireless, wired, or simulation mode.
- *Pre-fitting*: This option contains the Audiogram, Calibration, and Feedback Manager.
 - Audiogram: Imports audiogram entered in Noah and depicts it with Earlens® fitting range. This screen allows the hearing healthcare professional to enter 10 kHz hearing thresholds (if measured).
 - Calibration: Allows the hearing healthcare professional to run calibration for the devices connected in the Device Connection screen.
 - Feedback Manager: Allows the hearing healthcare professional to measure and manage feedback.
- *Fitting*: Allows the hearing healthcare professional to access the Tuning and Features options.
 - Tuning: Allows the hearing healthcare professional to change gains, maximum power output (MPO), and add programs as needed.
 - Features: Allows the hearing healthcare professional to change features (noise reduction, directionality, feedback canceller, acoustic coloring) and optimize fittings.
- *Device*: Allows the hearing healthcare professional to access device settings and data logging.
 - Settings: Allows the hearing healthcare professional to change user controls, alerts, and volume control settings.
 - Data Logging: Allows for the hearing healthcare professional to see time spent in each program, ambient noise level, volume control setting, automatic directionality, and stream time.
- *Summary*: Presents session summary to the hearing healthcare professional.
- *Tools*: Allows the hearing healthcare professional to access Fitting Tools and Device Tools.
 - Counseling Tools: allows the hearing healthcare professional to enter up to 5 specific listening situations where the patient would like to see an improvement and track change in listening with the Earlens devices.
 - Fitting Tools: contains Functional Gain Mode, Audiogram and Real World Sounds, and Import Fitting File options.
 - **Functional Gain Mode**: Enables Functional Gain Mode and opens the sound field threshold entry.
 - **Audiogram and Real World Sounds**: Allows the hearing healthcare professional to view aided thresholds for Earlens® and conventional hearing aids (if entered) along with the patient's unaided hearing thresholds. The hearing healthcare professional can also choose to superimpose the speech banana and images of real world sounds on the audiogram for counselling.
 - **Import Fitting File**: Allows the hearing healthcare professional to import prior fitting files.

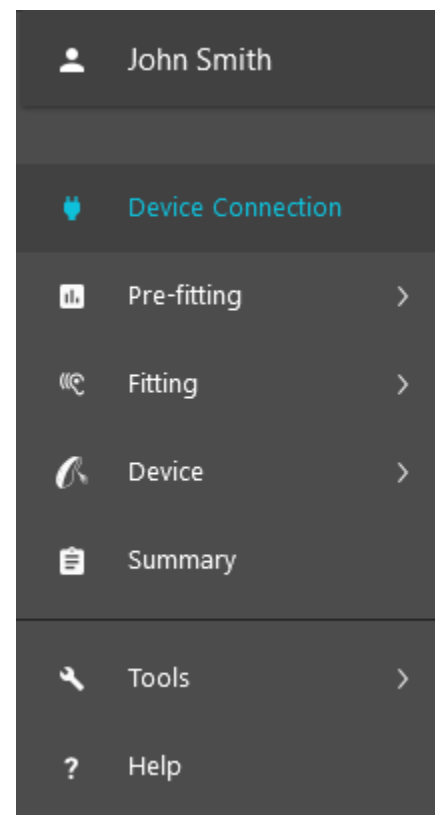


Figure 8: Navigation Bar

Device Tools: contains reset processor, factory restore, and check cloud access options.

- **Reset Processor**: Power cycles the Processor while preserving previously saved fitting data.
- **Factory Restore**: Restores a Processor to manufacturer's default settings, erasing all fitting and data log information from the Processor.
- **Check Cloud Access**: Checks the connection between the Earlens® 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 fit.

- **Help**: Opens Earlens Fidelity™ troubleshooting guidelines in a separate window.
- **Settings**: Provides information regarding the Earlens Fidelity™ software version and provides a notification when an update is available. Release highlights for the current Fidelity version are available under 'Learn more about the last update'. Information about the clinic (address, phone number, account number) can also be viewed here.

- **Information Bar** (Figure 9)

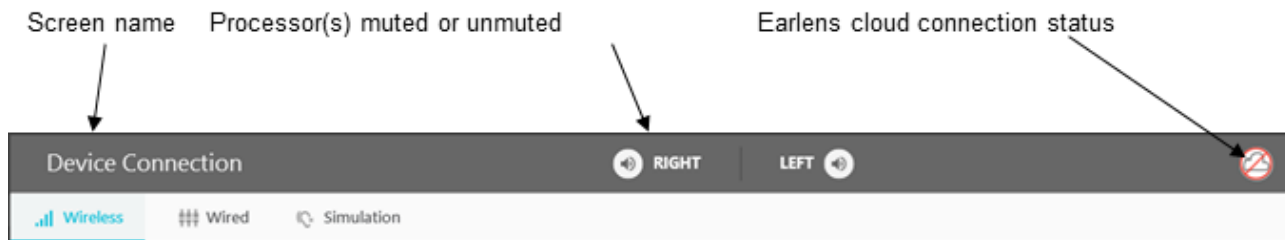


Figure 9: Information Bar

- **Screen name**: This field displays the name of the tab currently in use by the hearing healthcare professional. This field is updated when the hearing healthcare professional navigates through different screens.
- **Processor(s) muted or unmuted**: Speaker icon can be clicked to toggle the connected Processor between mute/unmute status. The icon changes when clicked, to display current status.



When displayed, indicates Processor is not muted



When displayed, indicates Processor is muted

- **Earlens Fidelity™ software to Earlens® cloud connection status**:



Earlens Fidelity™ software and Earlens® cloud are connected on your fitting computer.



Earlens Fidelity™ software and Earlens® cloud are not connected on your fitting computer

- **Device Status Bar** (Figure 10)



Figure 10: Device Status Bar

- Connection status icons: Displays the current connection status of the Processor to the Earlens Fidelity™ software. No icon will appear if a Processor is not connected.



Processor connected through wireless mode with strong Bluetooth connectivity



Processor connected through wireless mode with weak Bluetooth connectivity



Processor connected through wired mode



Simulated Processor connected

- Battery indicator: Provides the current percentage of battery life measured for a Processor



Percentage of remaining charge

Earlens Fidelity™ software navigation tabs

- **Device Connection:** Detect Processors, start a fitting session, and access Simulation mode (Figure 11).

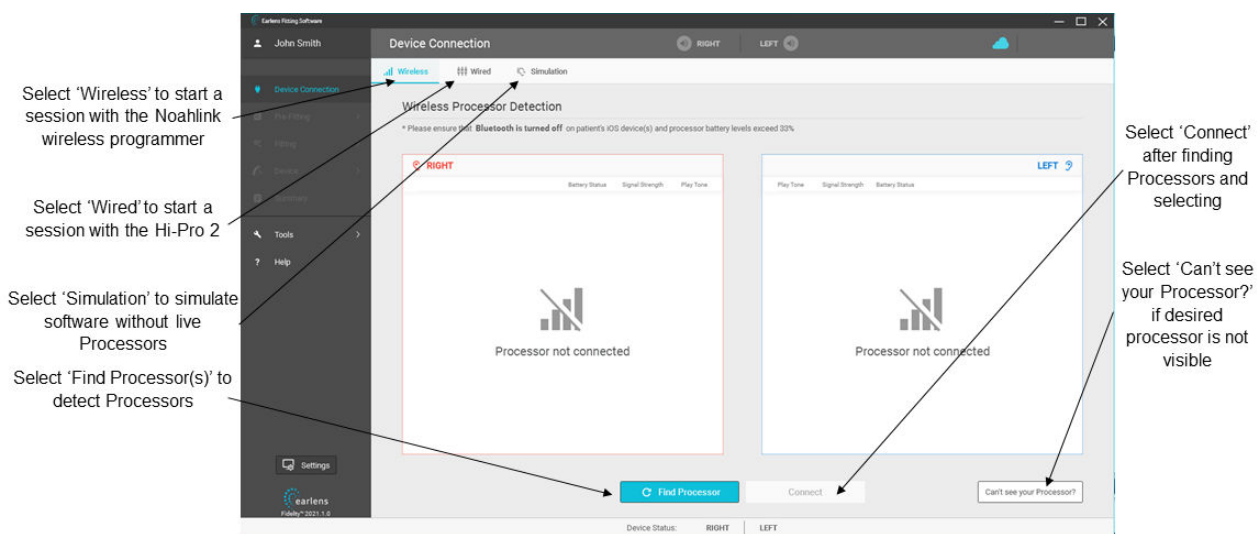


Figure 11: Device Connection screen

- **Audiogram:**
 - Enter the 10 kHz threshold, when available (Figure 12). If not available, Earlens Fidelity™ software will predict the 10kHz threshold based on the in-situ calibration results (Figure 13).

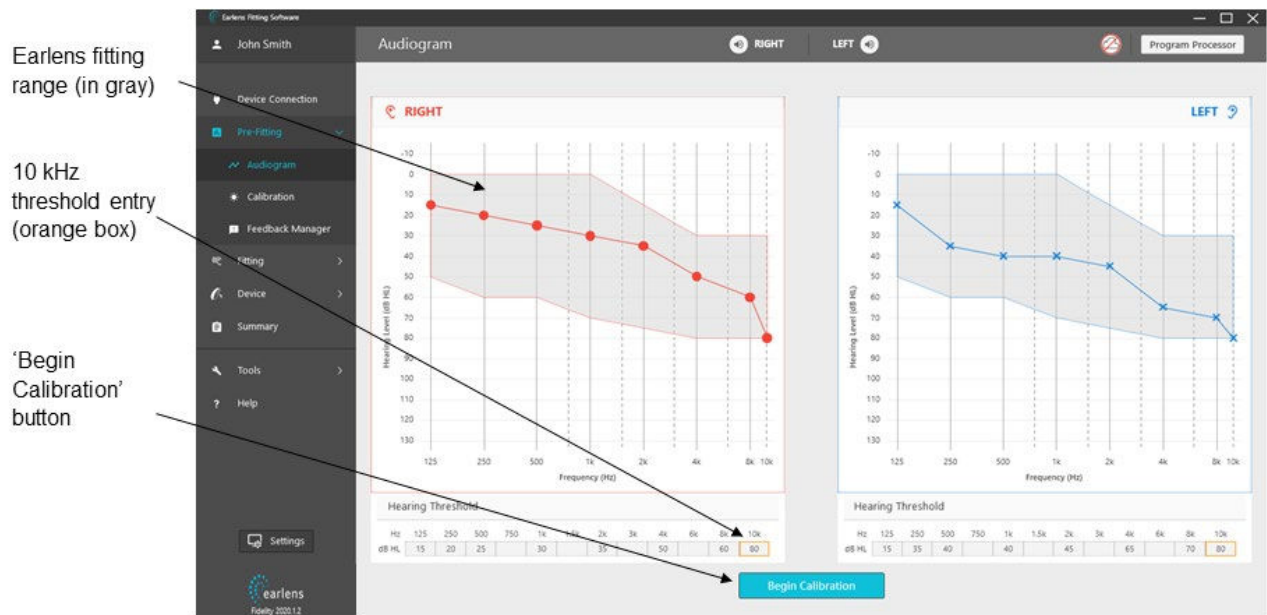


Figure 12: Audiogram screen

- **Calibration:** Measure in-situ calibration by presenting tones at different frequencies. You can also use 'Previous Calibration' toggle button to view up to two previously stored calibrations (if available) (Figure 13). Gray shaded area shows calibration guidance range which is the expected range of calibration for a given audiogram.

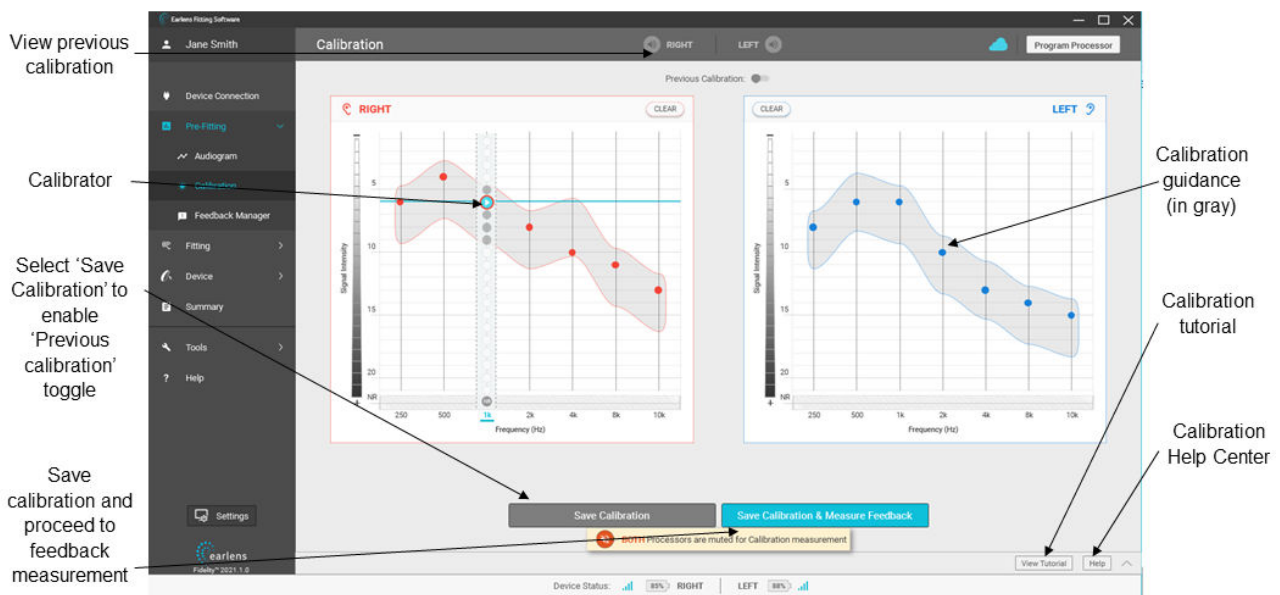


Figure 13: Calibration screen

- **Feedback Manager:** Present signal to measure feedback limits (Figure 14).

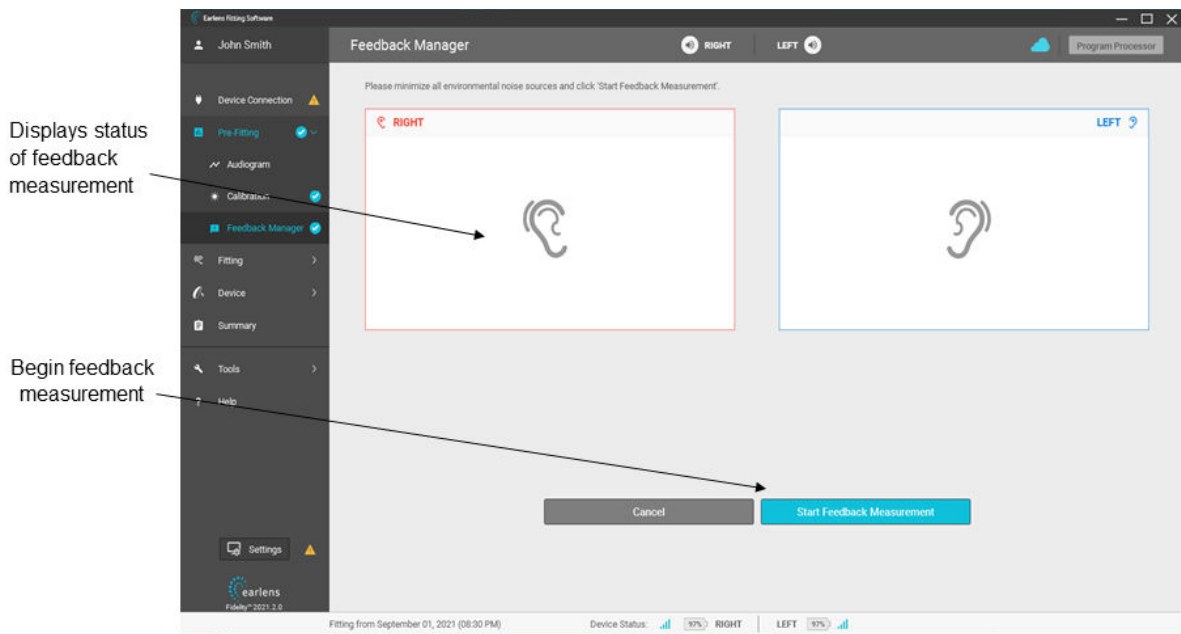


Figure 14: Feedback Manager screen

- **Tuning:** Fine-tune the frequency response of the Processor (Figure 15) and access automatic or manual acclimatization (Figure 16).

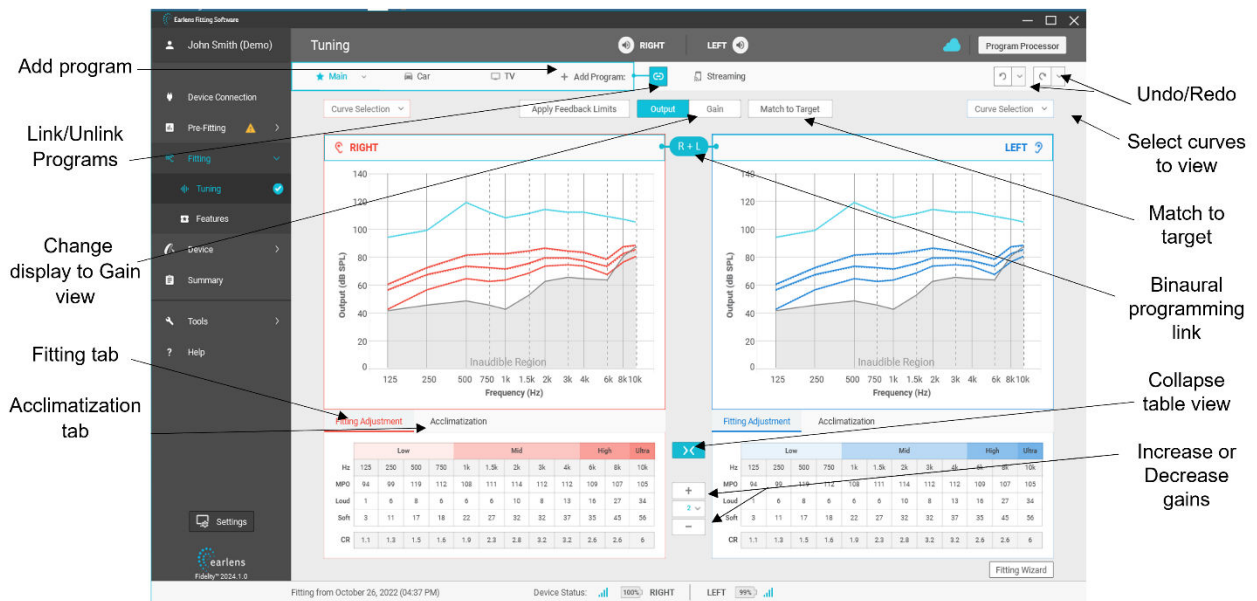


Figure 15: Tuning screen: Output view

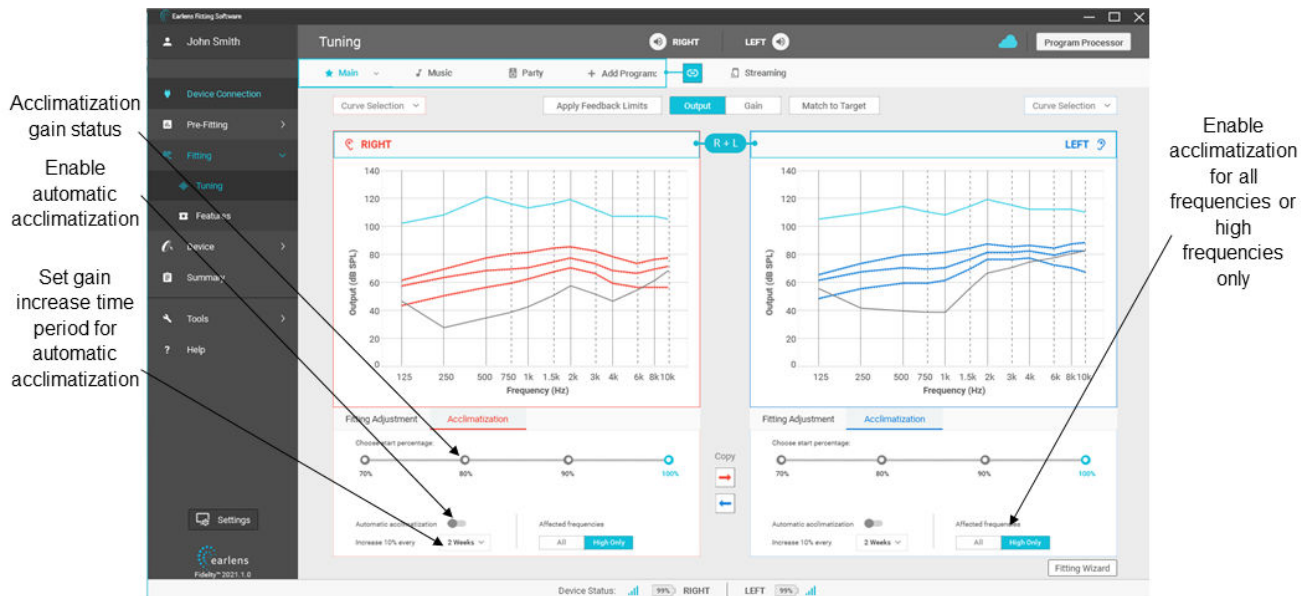


Figure 16: Tuning screen: Acclimatization tab

- **Features:** Modify feature settings (Figure 17).

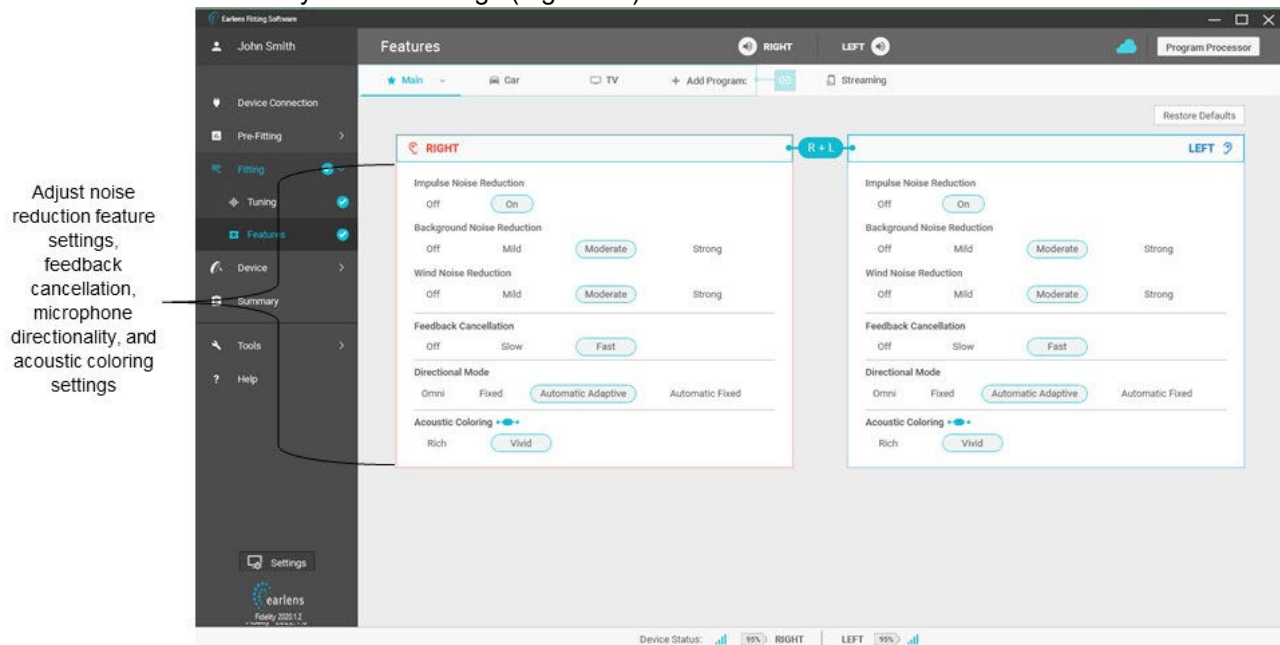


Figure 17: Features screen

- **Device Settings:** Set the User Control configuration on the Processor, customize Alert Settings, and change Volume Control settings (Figure 18).

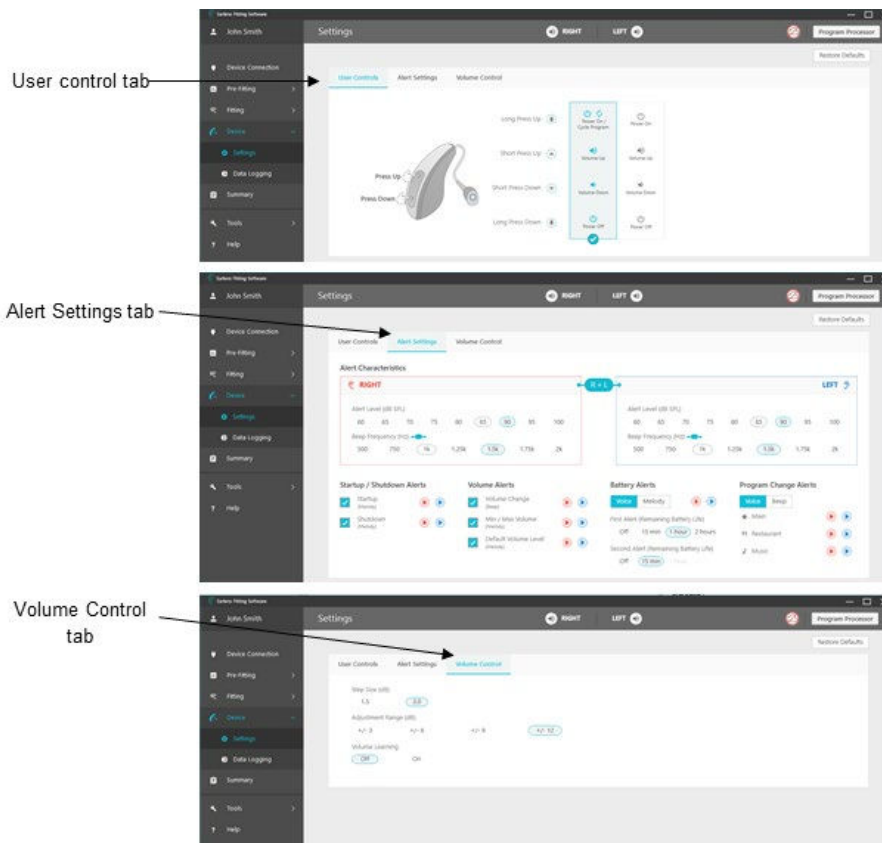


Figure 18: Device Settings: user control, alert settings, and volume control tabs.

- **Data Logging:** View patient usage data (Figure 19).
Note: "Read Processor" option must be selected to obtain data logging information.

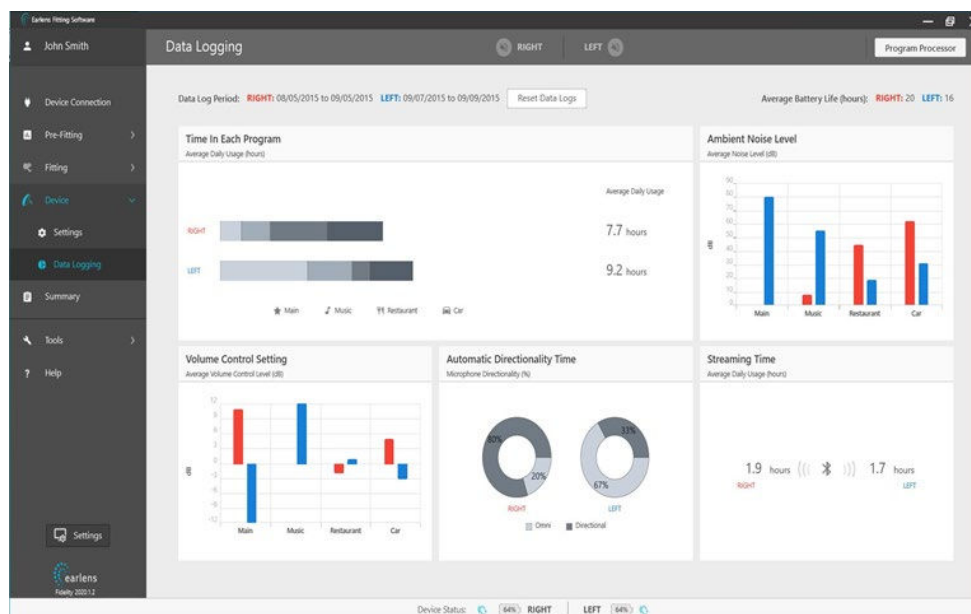


Figure 19. Data Logging screen

- **Summary:** View the summary of the fitting session, enter session notes, print patient instructions, and print audiologist report (Figure 20).

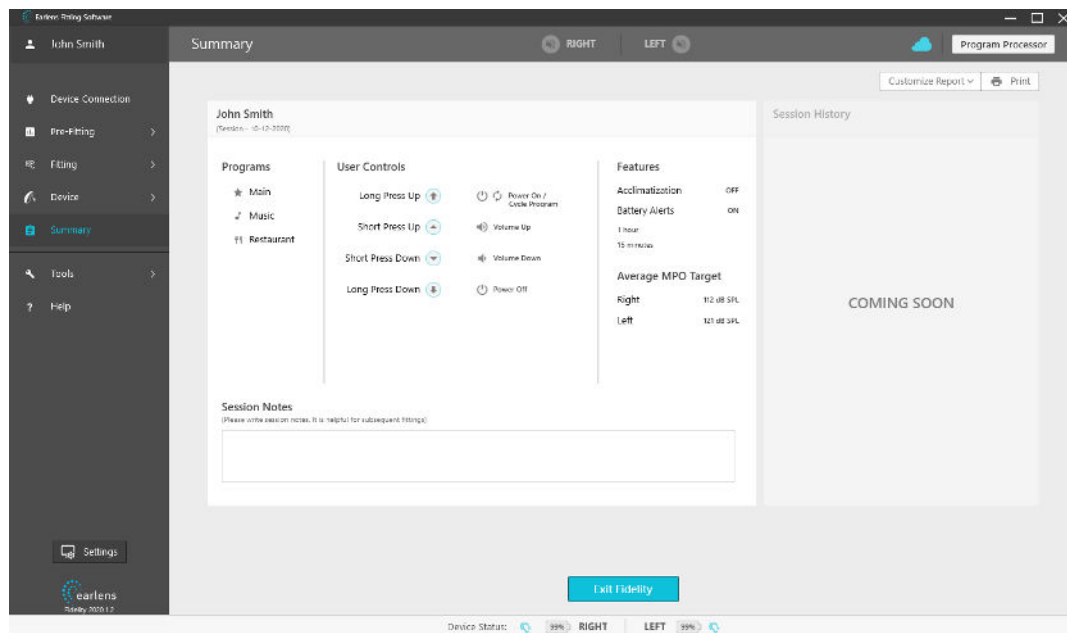


Figure 20. Summary screen

Processor features in Earlens Fidelity™ software

| Feature | Description | Options |
|----------------------------|--|---|
| Background Noise Reduction | Intended to reduce background noise without reducing speech levels. It is recommended that both Processors be set to the same noise reduction strength. | 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 | The behavior of the microphones for a given program. <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 switch from omnidirectional to directional when speech is detected in the presence of noise, and steer the microphone null toward 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 |

| | | |
|---|--|---|
| Acoustic Coloring | Designed to let the hearing healthcare professional choose compressor time constant settings | <ul style="list-style-type: none"> • Rich: Slow release time to optimize listening to music or listening in larger rooms • Vivid: Fast release time to optimize listening in dynamic environments |
| Acclimatization: <i>Automatic</i> <i>Manual</i> | Provides gradual increases to gain settings over a defined period of time. Allows professionals to manually manage gain settings for quick global tuning adjustments. | When enabled, the following parameters can be set: <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) • 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. | Off (default), On |

Pre-Programming tips

- It is recommended that the 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, it is recommended to obtain thresholds at 125 and 10 kHz.
- A quiet room is highly recommended for Earlens® fittings especially for Calibration and feedback measurement.

First Fit with Earlens Fidelity™ software

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.

1. 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 that the Processor 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. 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 Earlens Fidelity™ software.
Note: You must select a patient file for Earlens Fidelity™ to open.
- f. The “Device Connection” screen will open (Figure 11).
- g. Click “Find Processor(s)”.
- h. 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.
- i. Drag and drop the listed Processor(s) to the desired ear. Select both Processors to link ears. You can confirm serial number assignment to the appropriate ear(s) by playing tones if desired (Figure 21).
- j. Click “Connect” (Figure 21).

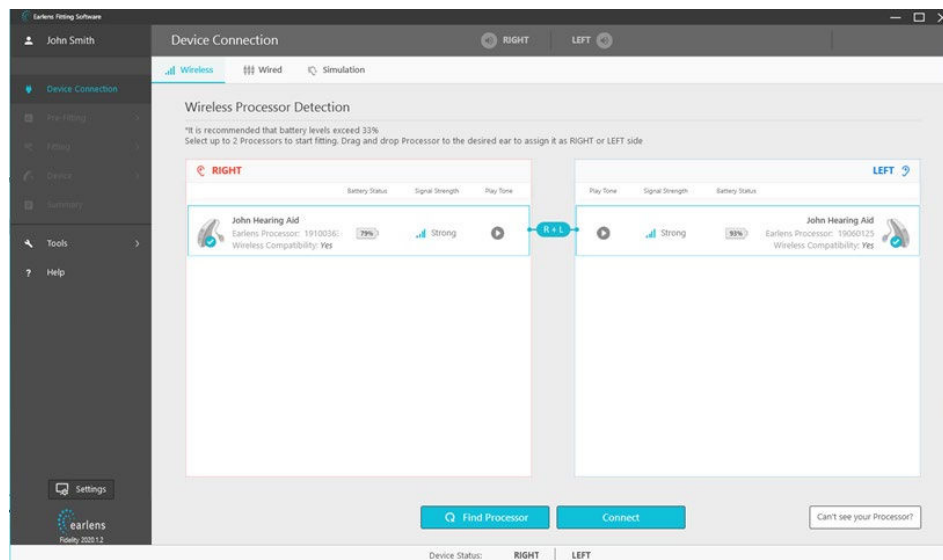


Figure 21: Device Connection screen: wireless

2. Connect to Processors: Wired

To perform wired programming, a Hi-Pro 2 must be used with cables provided by Earlens. Turn the Processors on by pressing and holding the top user control for 3 seconds.

- a. Remove the Processor cover to expose the programming port (see Figure 45 a & b for removal instructions).
- b. Connect the Processors to the HI-PRO 2, using programming cables (Figure 22).
- c. 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.
- d. Open Earlens Fidelity™ software.
Note: You must select a patient file for Earlens Fidelity™ to open.
- e. The “Device Connection” screen will open (Figure 11).
- f. In the “Wired” tab, click “Connect” to connect the Processors.

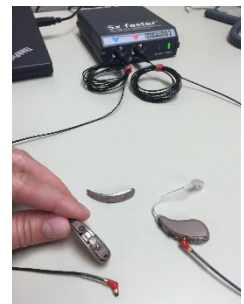


Figure 22: Processor set-up

3. Begin Fitting

- a. Once the Processor(s) are connected, you will see details of the connected Processor(s) on the screen. Select “Continue” to begin the fitting session (Figure 23). You can also input replaceable cable size for future reference (optional feature).

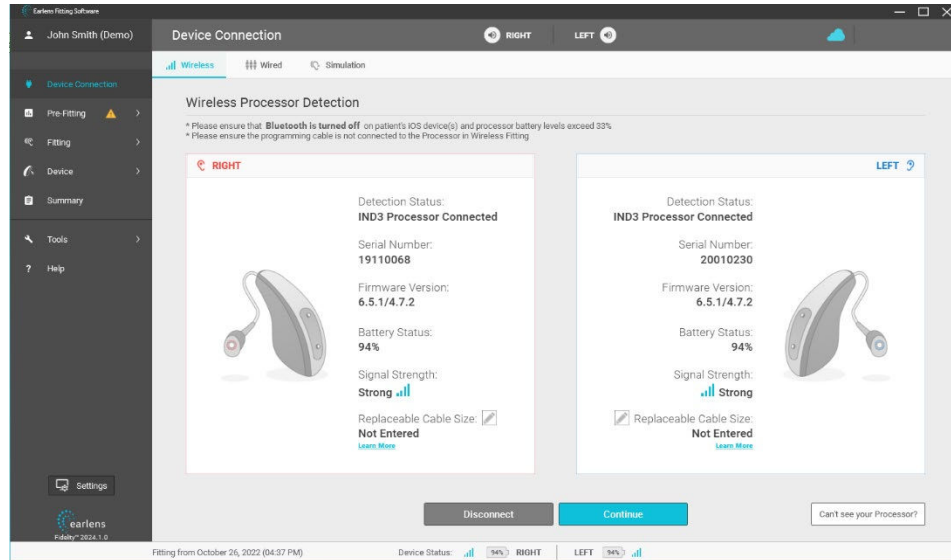


Figure 23. Device connection screen: details of connected processors

- b. Select 'Start Session' to begin fitting (Figure 24). Do not attempt to 'Read Processors' with new Processors.

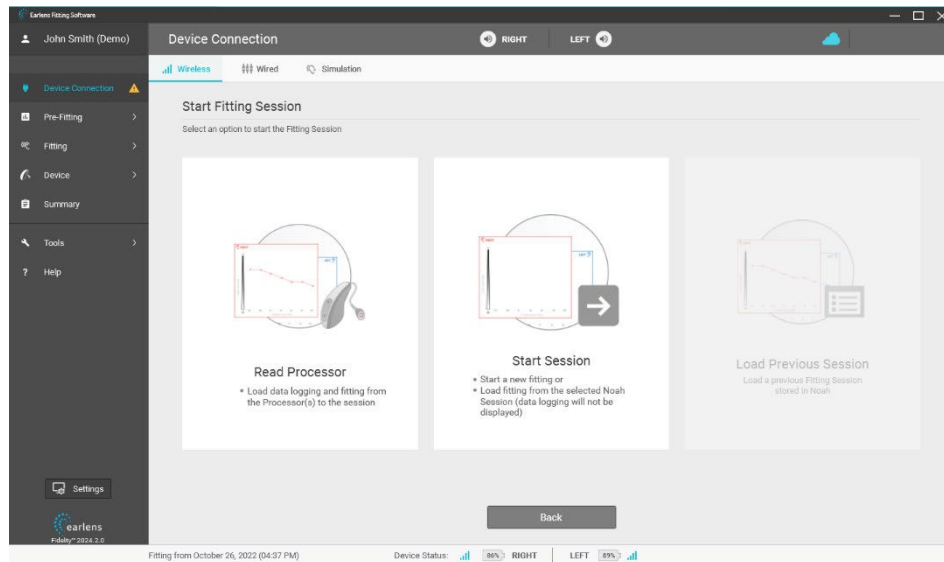


Figure 24: Device connection screen: session options

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, Earlens Fidelity™ software will inform the hearing healthcare professional that the Processor cannot be read. 'Start Session' option should be chosen instead.

- 'Start Session' is required for a first-time fitting. When selected for a follow-up fitting session, Earlens Fidelity™ software will retrieve the most recent or selected fitting session from Noah. Datalogging will not be displayed.

- A Fitting Data Status window will appear (Figure 25). Select "Ok" and Earlens Fidelity™ software will open to the Audiogram screen.

4. Enter thresholds for 10 kHz

Enter the 10 kHz audiometric threshold for the right and/or left ear into the orange boxes, if available (Figure 12). If this frequency was not tested, Earlens Fidelity™ software will estimate the 10kHz threshold based on the slope and severity of hearing loss at adjacent frequencies. Note: To program the Processors, audiometric thresholds and Calibration measurements must be completed.

| | RIGHT | LEFT |
|-------------------------------------|-------|------|
| 1. Enter standard audiometric data | ✓ | ✓ |
| 2. Enter 10KHz threshold (optional) | X | X |
| 3. Measure Calibration | X | X |
| 4. Run Headstock Manager | X | X |

Please complete calibration data.

OK

Figure 25. Fitting Data Status window

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 tympanic membrane. To calculate the equivalent sound pressure level output (dB SPL) with this mechanism, an in-situ calibration procedure must be performed in Earlens Fidelity™ software 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:

- Select "Calibration" under Pre-Fitting in the navigation bar to view the Calibration screen (Figure 13).
- 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. You can practice how to use the calibrator by clicking the 'View Tutorial' button. Calibration Help Center can be accessed using the 'Help' button. The Help Center lists answers to frequently asked questions about calibration (Figure 13). Tones can be presented in two ways:

- Keyboard: Selecting the "Play tone" (blue) button on the calibrator by pressing the space bar (Figure 26). 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 to save the data.
- Mouse: Hover over the dot representing the level you would like to present to the patient. Left click using the mouse to play the tone and click "Save" to save the data.

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

- 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. Gray shaded area shows calibration guidance range which is the expected range of calibration for a given audiogram.

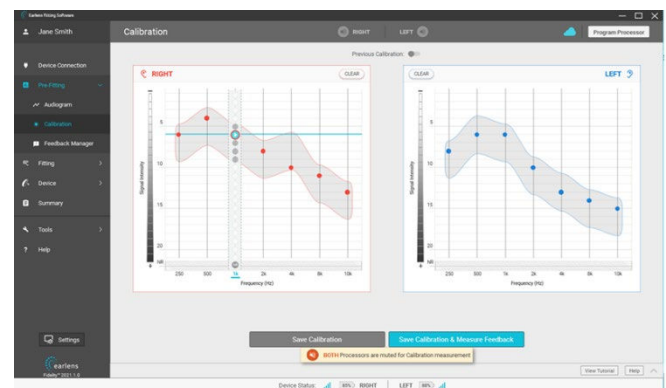


Figure 26: Calibration screen

- d. Select “Save Calibration” to complete calibration and view data. Alternatively, you can select ‘Save Calibration & Measure Feedback’ to proceed to feedback measurement. To clear stored threshold data, select “Clear” for each ear individually.

6. Feedback Manager

To perform the feedback measurement, you must first complete calibration. It is highly recommended that the feedback manager be repeated each time that calibration is measured. If you do not want to perform the feedback measurement, you can initiate the measurement at a later time by selecting “Feedback Manager” under Pre-Fitting in the Navigation Bar.

- 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. You will see a notification to re-run feedback measurement when Earlens Fidelity™ software detects high levels of environmental noise.
- Earlens Fidelity™ software 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 screen by selecting the Gain Display option (Figure 15).
- Once measured, the software will automatically open to the Tuning screen (Figure 15).
- 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 27 & Figure 28).
- 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 29).

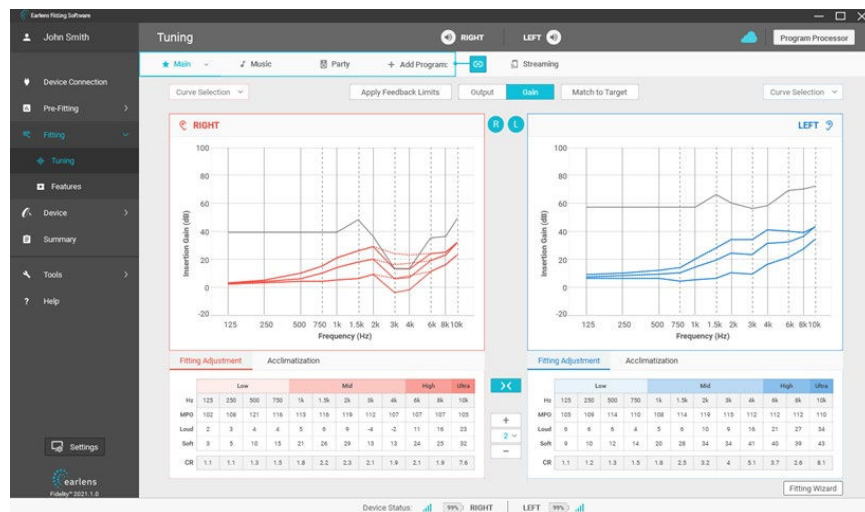


Figure 27: Tuning screen: Gain Curves displaying maximum stable gain data and feedback limits applied for the right ear

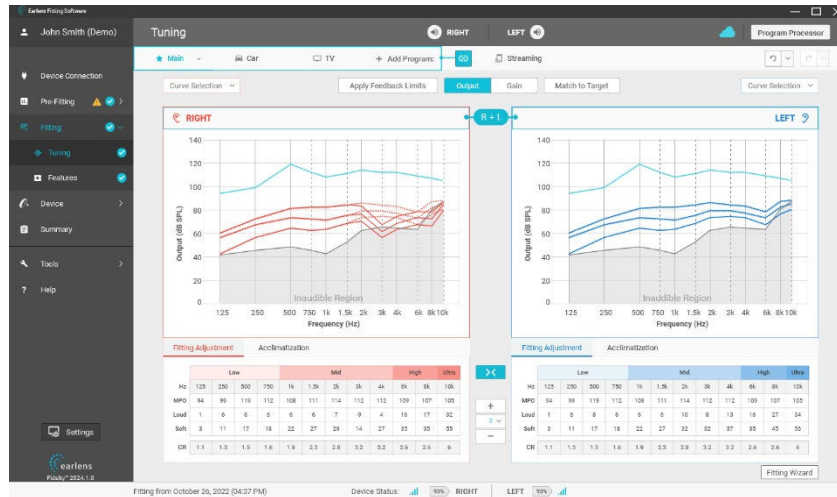


Figure 28. Tuning screen: Output Curves displaying feedback limits applied for the right ear

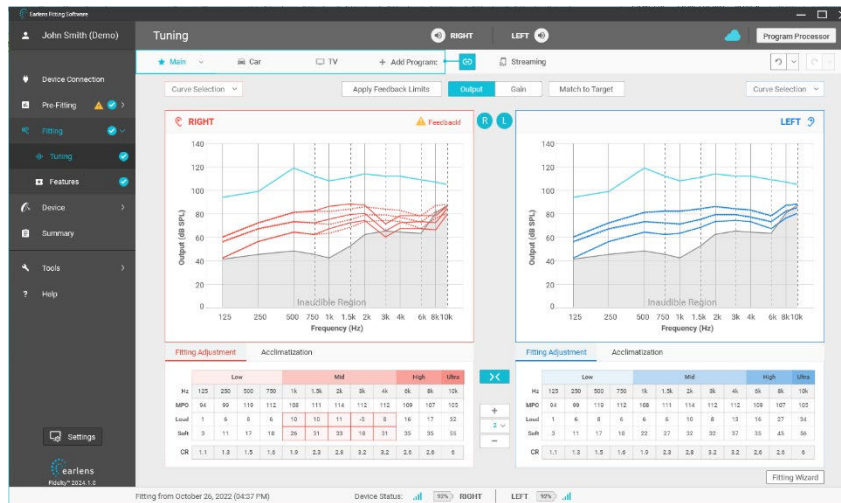


Figure 29. Tuning screen: Output Curve displaying feedback potential for the right ear

7. Fine Tuning

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. You can undo up to 5 actions on the Tuning screen and the Features screen. Undo actions on the Tuning screen include gain changes, program configuration, feedback limits, and acclimatization settings. On the Features screen, settings for noise reduction (impulse, background, wind), feedback cancellation, directional mode, and acoustic coloring can be undone. Dropdown buttons next to the undo/redo buttons allow hearing healthcare professionals to see actions available for undo/redo (see Figure 15).

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

- 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.
- 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.

Fitting wizard can be accessed on the tuning screen (Figure 15) which lists common fine-tuning solutions for most commonly encountered patient reports.

8. *Enable Automatic Acclimatization (recommended settings)*

- New Hearing Aid User- Select 70% gain with an acclimatization of 10% increase per week **for all frequencies.**
- Experienced User- Select 70% gain with an acclimatization rate of 10% increase 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 each individual alert. To disable an alert, uncheck the box.
- Select the play icon to demo any alert.
- Alert levels are configurable by ear to address perceived volume imbalance.

10. *Print Patient Instructions*

To print patient instructions, first click on the “Customize Report” tab and select the data you would like to print. After selecting the data you would like to print, click the “Print” button. You can obtain a copy of the Patient’s program(s), user control settings, and helpful care and maintenance reminders.

Note: A Fitting Summary Report is also available for print from the Summary screen.

11. *Program Processors*

All changes made in the Earlens Fidelity™ software will temporarily be transmitted to the Processor. To permanently program the Processor, you must select “Program” in the Information Bar or by following steps below.

12. *Exit Earlens Fidelity™ software*

When you close out of Earlens Fidelity™ software, a pop-up window will appear asking you to “Save to Noah” and “Program Processor” (Figure 30). If you have already programmed the devices and have not made any changes, you can uncheck “Program Processor.” Once you select “Exit” the fitting file will save to Noah and Earlens Fidelity™ will close. If using wired fitting, follow steps 13-15 below.

13. *Exiting Earlens Fidelity™ Software Through Wired Programming*

Wait for the Earlens Fidelity™ software window to close, then physically disconnect the Processors from the programming cables. Put the case cover on both Processors (see Figure 46).

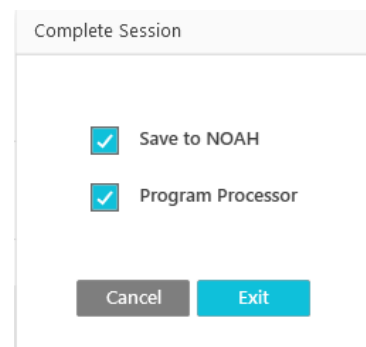


Figure 30. Exit pop-up window

Additional Earlens Fidelity™ software features

- **Firmware Update**

When a firmware update is available for the Processors, a pop-up notification will appear once you have connected the Processors in the Device Connection screen (Figure 31). We recommend updating the firmware when prompted to ensure the Processor has the most up to date features and performance enhancements. Firmware updates take less than 5 minutes. Firmware can be updated via wireless or a wired connection to the HiPro 2 Programmer.

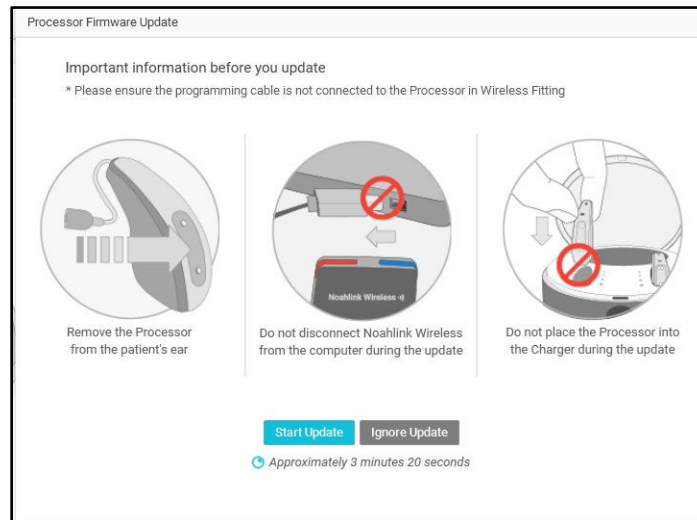


Figure 31: Firmware update pop-up

In the event you would like to update the firmware at another time, a yellow warning sign will appear next to the Device Connection tab in the navigation bar. A tool tip for updating firmware appears when the mouse pointer is hovered over this warning sign (Figure 32). Firmware can also be updated by clicking 'Update Available' button on the wireless detection screen.

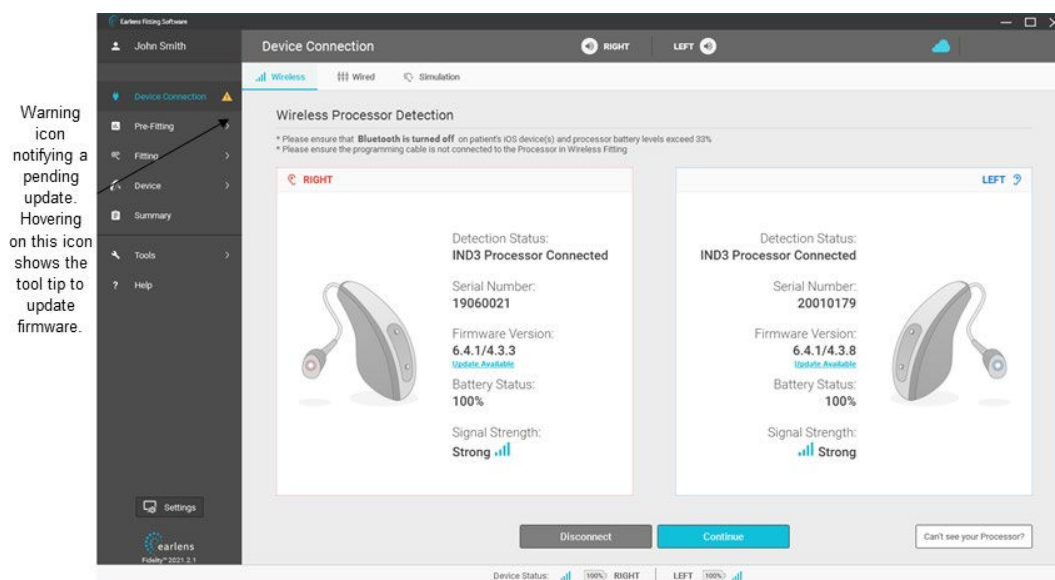


Figure 32: Device Connection screen with warning icon notifying that a firmware update is pending.

- **Simulation Mode**

Earlens Fidelity™ software offers a Simulation mode in the Device Connection screen that can be used when Processors are not actively connected to the software (Figure 33). Once in Simulation mode, any screen can be accessed, and adjustments can be made as if Processors were actively connected.

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

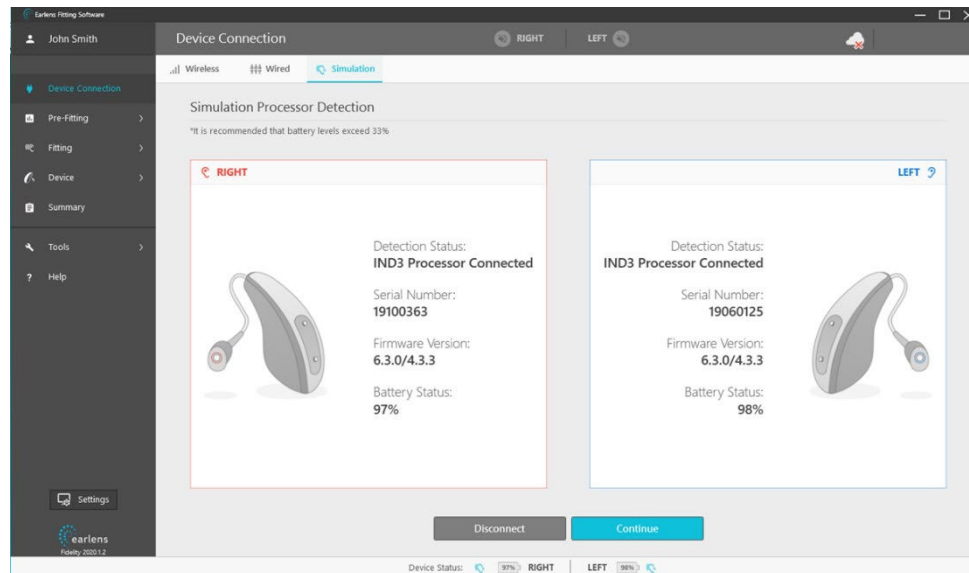


Figure 33. Simulation

- **Streaming Program**

The streaming program (Figure 34) 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 35). The microphones can be activated with no attenuation (On), or with the microphone sound attenuated by -3 dB, -6 dB, or -9 dB. The patient also has the ability to adjust the hearing aid microphones via the Apple native controls and Earlens® Control app.

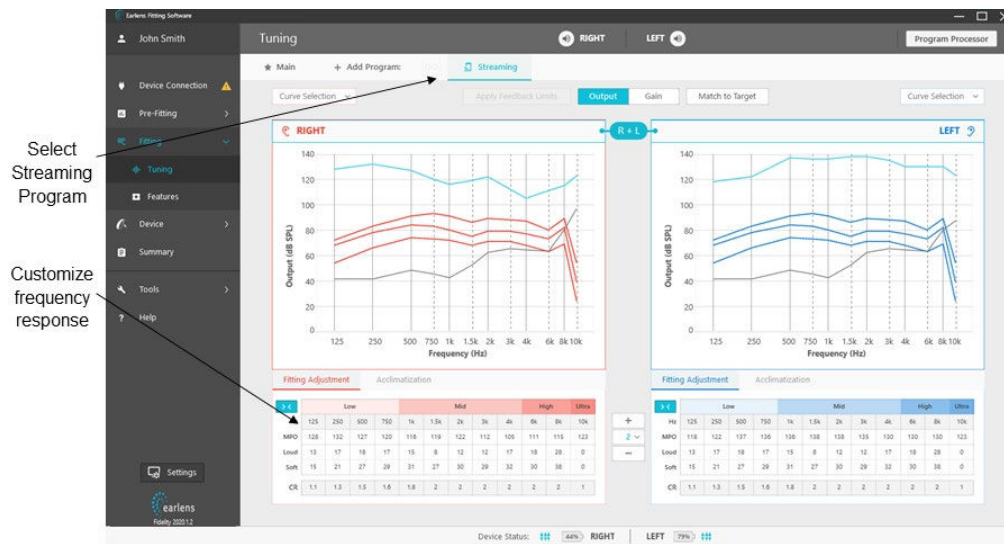


Figure 34: Streaming program in tuning view

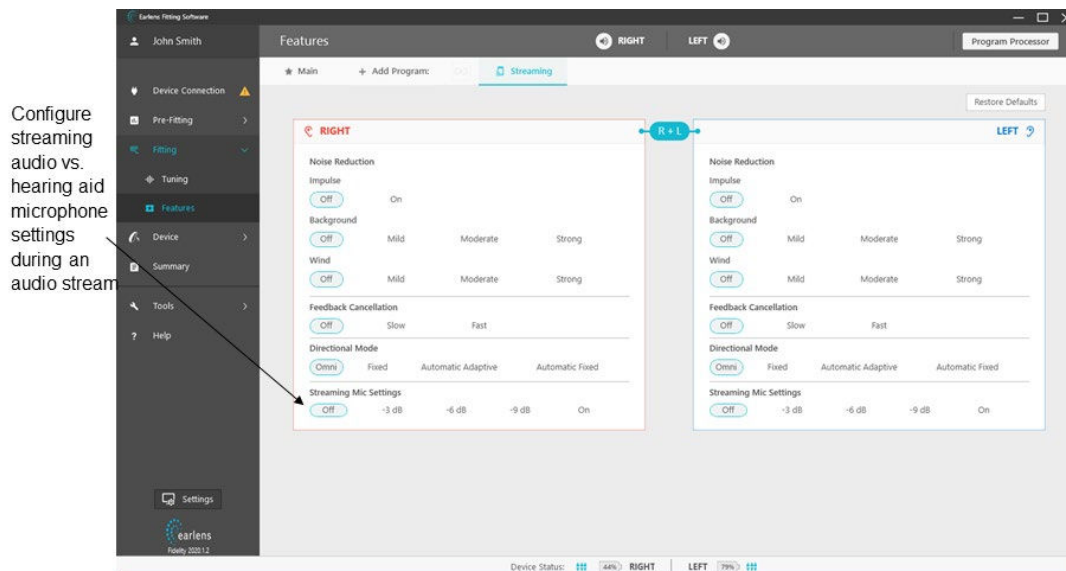


Figure 35: Streaming program feature settings

- **Data Logging**

The data log feature in Earlens Fidelity™ software 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 also be reset at any time (Figure 19).

- **Functional Gain (FG) Mode**

- What is FG Mode? Functional Gain (FG) Mode places the Earlens device into settings optimized to achieve meaningful measurements of aided hearing thresholds - disabling expansion, noise reduction, and directional microphones while maintaining compression and user's gain settings from the current program (typically tested in "Main" program gain settings.)
- Why perform aided sound field threshold testing? Although calibration effectively verifies an Earlens fitting, FG measures provide another method to verify the broad spectrum gain provided to the individual similar to other non-acoustic technologies – confirming that the individual's gain settings will result in useful audibility at suprathreshold levels. The aided audiogram is also useful as a counseling tool to objectively illustrate the benefit of Earlens amplification over an extended bandwidth.
- 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. The functional gain at each frequency should be roughly equivalent to the gain values specified in the fitting software for the gain applied to 50 dB speech, within expected variability of the measurement.
- 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. All compressor gain settings are maintained.

- **Steps to perform FG measurements**

Instruct the patient that their Earlens Processors will be set to a special test mode that will allow you to measure their hearing with the Earlens, and to respond as they would for a hearing test. They may hear a change in sound quality as certain features are disabled. Prior to conducting testing, ensure your audiometer and speaker configuration have been calibrated for sound field testing to 10 kHz with the appropriate warble tone or narrow band noise stimuli.

- Ensure Processors are connected to software and session progress is saved.
- Select "Functional Gain Mode" under Fitting Tools in the Navigation Bar.
- A pop-up window will open; this indicates Processors are now active in FG Mode.
- If using wired programming, disconnect the HI-PRO 2 cables from the Processors, making sure to leave the FG Mode window open in the Earlens Fidelity™ software.
- Situate the patient in the booth, facing the target speaker.
- Test each ear independently. For the non-test ear, remove the Processor and plug the ear with a foam insert/plug.
- Present warble tone stimuli, using a standard threshold seeking procedure. An alternate test stimulus is narrow band noise. Note the aided threshold at each test frequency to 10 kHz. Values can also be entered directly into the pop-up window (Figure 36).
- 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 "View Data" or "Exit". **Do not leave the Processor in functional gain mode.**

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 hearing thresholds that can be used for reference during aided threshold testing.

| Unaided Hearing Thresholds (dB HL) | | | | | | | | | | | | |
|------------------------------------|-----|-----|-----|-----|----|------|----|----|----|----|----|-----|
| Hz | 125 | 250 | 500 | 750 | 1k | 1.5k | 2k | 3k | 4k | 6k | 8k | 10k |
| RIGHT | 20 | 30 | 45 | | 40 | | 55 | 60 | 60 | 55 | 70 | 90 |
| LEFT | 20 | 30 | 45 | | 40 | | 55 | 60 | 60 | 55 | 70 | 80 |

| Conventional Hearing Aid Aided Thresholds (dB HL) | | | | | | | | | | | | |
|---|-----|-----|-----|-----|----|------|----|----|----|----|----|-----|
| Enter Hearing Aid Brand / Series | | | | | | | | | | | | |
| Hz | 125 | 250 | 500 | 750 | 1k | 1.5k | 2k | 3k | 4k | 6k | 8k | 10k |
| RIGHT | | | | | | | | | | | | |
| LEFT | | | | | | | | | | | | |

| Earlens Aided Thresholds (dB HL) | | | | | | | | | | | | |
|----------------------------------|-----|-----|-----|-----|----|------|----|----|----|----|----|-----|
| Hz | 125 | 250 | 500 | 750 | 1k | 1.5k | 2k | 3k | 4k | 6k | 8k | 10k |
| RIGHT | | | | | | | | | | | | |
| LEFT | | | | | | | | | | | | |

View Data Exit

Figure 36. FG Mode Window

k. After completing the testing, close the Earlens Fidelity™ software and save to both Noah and the Processor(s) to ensure that patient settings are saved to the Processors and aided threshold test data is saved to the Noah database.

- **Illustrate the Earlens® Benefit with Sound Field Threshold Entry and Speech Outcomes Data Entry**
Earlens Fidelity™ allows you to enter aided threshold data for Earlens® and conventional hearing aid devices to objectively illustrate the Earlens® benefit. Remember to tie the objective evidence of the *feature* of extended bandwidth to the resulting *advantages* of improved speech understanding and sound quality, and how these works together to *benefit* the individuals' hearing needs and goals for the Earlens technology.

Note: You do not need to be actively connected to Processors to open FG Mode and enter threshold data.

Sound Field Threshold Entry

- Open the FG Mode via Fitting Tools, in the Navigation Bar.
- Manually enter aided audiometric threshold data (Figure 37).
- You can view this data plotted on an audiogram when you select 'View Data' (Figure 37).
Alternatively, this data can be viewed anytime by navigating to Tools>> Fitting Tools>> Audiogram and Real World sounds. An audiogram with Earlens aided thresholds and conventional hearing aid thresholds (if available) is displayed (Figure 38). 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.
- Navigate to Summary on Navigation Bar to view or print the data by selecting "Print" at top right corner (Figure 20). The printout will be displayed as shown (Figure 40) and can be used to counsel and send home with the patient.

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 hearing thresholds that can be used for reference during aided threshold testing.

| Unaided Hearing Thresholds (dB HL) | | Hz | 125 | 250 | 500 | 750 | 1k | 1.5k | 2k | 3k | 4k | 6k | 8k | 10k |
|------------------------------------|--|----|-----|-----|-----|-----|----|------|----|----|----|----|----|-----|
| RIGHT | | 15 | 20 | 25 | | 30 | | 35 | | 50 | | 60 | 80 | |
| LEFT | | 15 | 35 | 40 | | 40 | | 45 | | 65 | | 70 | 80 | |

Conventional Hearing Aid Aided Thresholds (dB HL)

Air conduction Hearing Aid

| Conventional Hearing Aid Aided Thresholds (dB HL) | | Hz | 125 | 250 | 500 | 750 | 1k | 1.5k | 2k | 3k | 4k | 6k | 8k | 10k |
|---|--|----|-----|-----|-----|-----|----|------|----|----|----|----|----|-----|
| RIGHT | | 15 | 20 | 25 | | 25 | | 25 | | 35 | | 45 | 70 | |
| LEFT | | 15 | 30 | 35 | | 25 | | 25 | | 35 | | 55 | 70 | |

Earlens Aided Thresholds (dB HL)

| Earlens Aided Thresholds (dB HL) | | Hz | 125 | 250 | 500 | 750 | 1k | 1.5k | 2k | 3k | 4k | 6k | 8k | 10k |
|----------------------------------|--|----|-----|-----|-----|-----|----|------|----|----|----|----|----|-----|
| RIGHT | | 10 | 15 | 15 | | 20 | | 20 | | 25 | | 30 | 30 | |
| LEFT | | 10 | 15 | 15 | | 20 | | 25 | | 25 | | 35 | 35 | |

View Data
Exit

Figure 37: FG Mode window: Sound field threshold entry

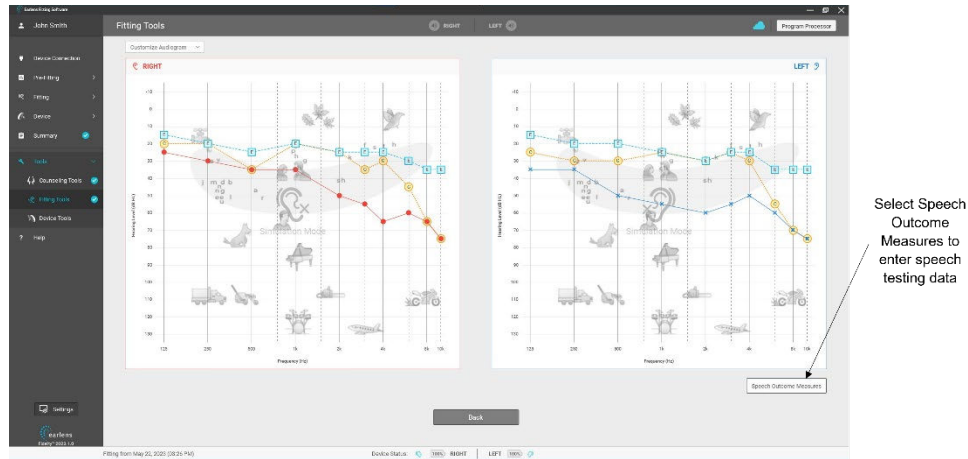


Figure 38: Audiogram and Real World sounds screen with option to enter Speech Outcome Measures data

Speech Outcomes Data Entry

You can enter data from speech intelligibility testing for unaided, conventionally aided, and Earlens aided conditions using the Speech Outcomes Measures screen (Figure 39).

- Select Speech Outcomes Measures button on Audiogram and Real Worlds sounds screen (Tools>> Fitting Tools>> Audiogram and Real World sounds, Figure 38).
- Manually enter Speech Test details such as test name, presentation level.
- Select Data Type : %, dB, or Other.
- Manually enter aided speech intelligibility testing data for ears or conditions as appropriate.
- You can also enter any other relevant test details or notes in the Notes section.
- Navigate to Summary on Navigation Bar to view or print the data by selecting “Print” at top right corner (Figure 20). The printout will be displayed as shown (Figure 40) and can be used to counsel and send home with the patient.

Speech Outcome Measures

Enter Speech Test Details

Data Type % dB Other

Enter Hearing Aids Brand / Series

| | Unaided | Conventional | Earlens |
|-----------------|---------|--------------|---------|
| RIGHT | | | |
| LEFT | | | |
| BINAURAL | | | |

Notes
Use this space to capture any additional notes

0/2000

OK

Speech Outcome Measures

NU-6 at 45 dB HL

Data Type % dB Other

XYZ Hearing Aid

| | Unaided | Conventional | Earlens |
|-----------------|---------|--------------|---------|
| RIGHT | 12 | 56 | 84 |
| LEFT | 8 | 48 | 72 |
| BINAURAL | | | |

Notes
Use this space to capture any additional notes

0/2000

OK

Figure 39: Speech Outcomes Measures screen. The left panel shows unfilled screen and right panel shows screen with data..

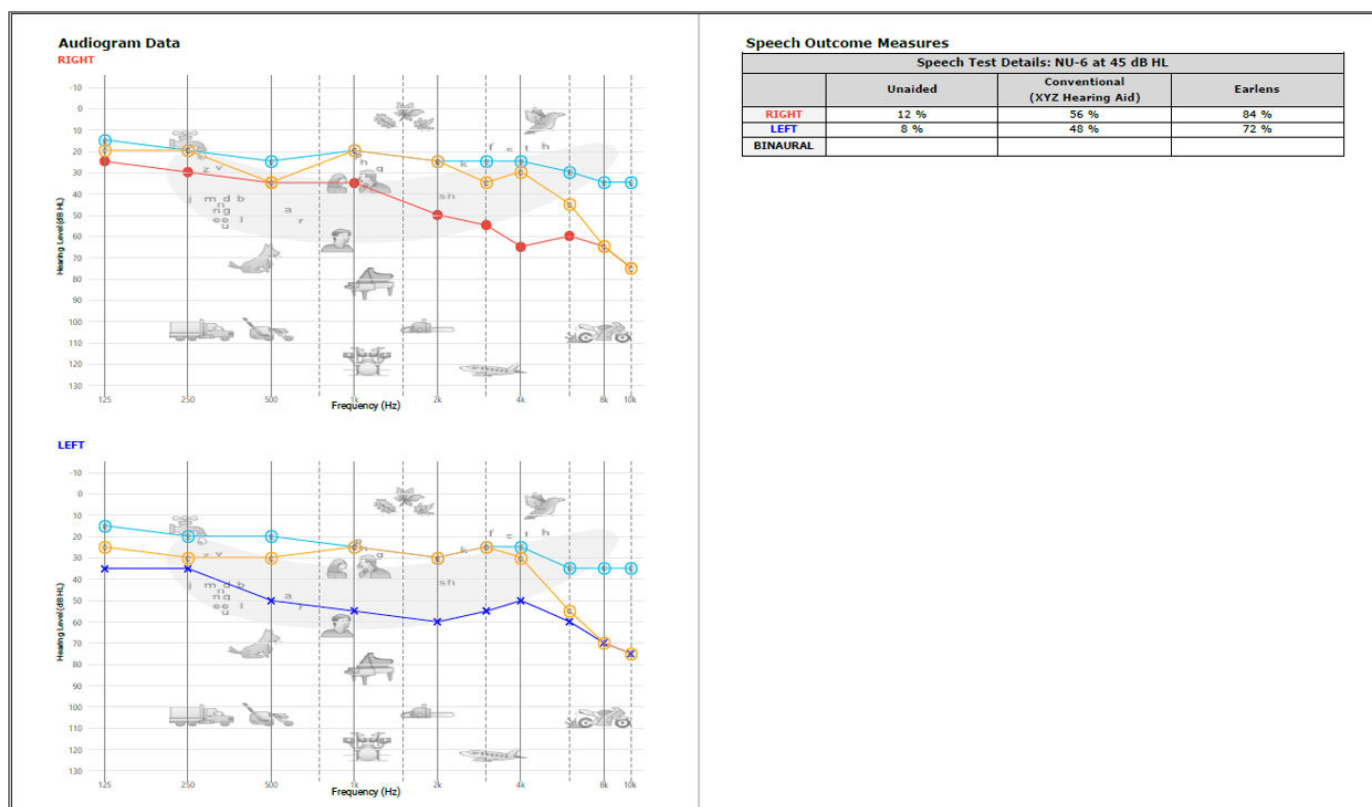


Figure 40. Patient Instruction printout

- **Enable, Disable and Copy Program(s)**
 - You can enable or disable different programs through the Tuning screen (Figure 15). The Main program represents the primary program and cannot be removed.
 - Pre-defined program types are available and include: Main, Music, Restaurant, Car, Quiet, Noise, Party, Outside, TV and Streaming.
 - Selecting "Remove" will disable that program slot.
 - Programs can be swapped and copied from one to another using the 'Copy to' option in the drop-down menu for each program slot. (Figure 41).

Note: Duplicate programs cannot be programmed to the Processors.
- **Match to Target:** Resets the fitting response back to Earlens Fidelity™ software calculated fitting targets. In the Tuning screen under the Fitting tab, click "Match to target.". The hearing healthcare professional can choose which programs should be reset to target using the dialog box.
- **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 Features screen under the Fitting tab. Selecting "Restore Defaults" will not impact the fitting response of the Processors.

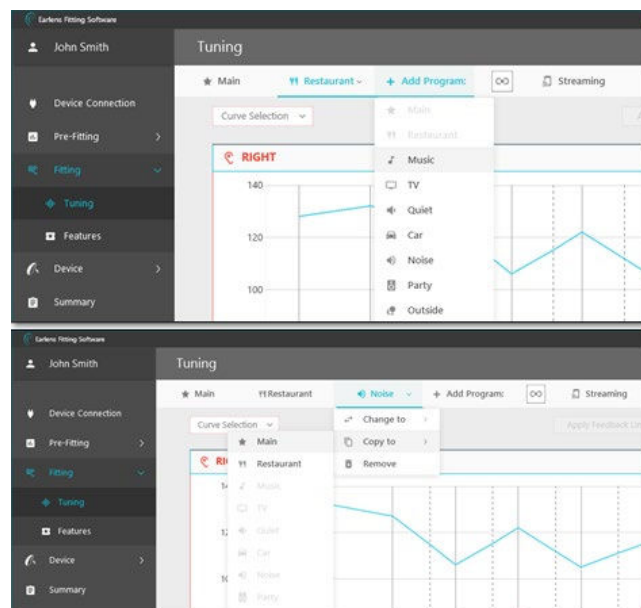


Figure 41: Add or copy programs

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

To disconnect Ear Tip cable 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 42).
- Pull the cable straight out of the Processor.

To connect Ear Tip cable to the Processor:

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

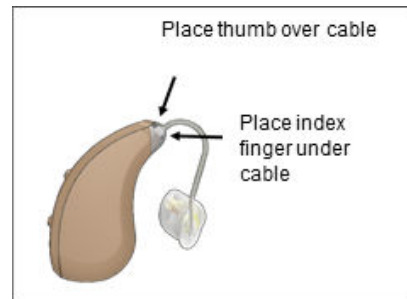


Figure 42. Cable Removal

9.4. Removal and insertion of the cable to Ear Tip Shell (for replaceable cable):

Cable Removal

- Firmly grasp the cable at the lateral opening of the shell by looping finger around the cable and pull until the coil releases from the coil pocket. Use a tissue to improve grip, if needed.
- The Ear Tip cable is designed to fit securely in the Ear Tip shell. Should cable removal be challenging:
 - Use a rocking or circular motion while pulling the cable out of shell instead of a sharp pull or tug.
 - Use insertion tool to facilitate removal, if needed. Use of other tools is not recommended.
 - Use a drop of mineral oil in coil pocket if needed to ease removal.

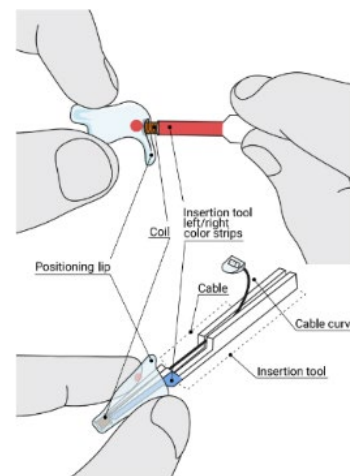


Figure 43: Cable and insertion tool positioning

Cable Insertion

- Place the cable in the insertion tool using the thumb slot to keep cable taut. The coil should be snug against the tip of the insertion tool.
- Hold the Ear Tip shell with the color dot facing vertically up. Hold insertion tool so that the matching red/blue color strip is aligned with the color dot on the Ear Tip shell (Figure 43).
- Insert the coil into the coil pocket of the shell until the coil is fully seated.
Note: The Ear Tip is designed to sit a set distance from the Lens. Sound output may deviate if the transmitter coil is not seated in the appropriate location within the shell.
- Check to make sure that the cable curvature is oriented in the same direction as the positioning lip (Figure 44). If it is not, remove the cable, reorient, and repeat the insertion step.
- The transmitter coil must be within and should not protrude beyond the medial end of the shell (Figure 44). If the coil is over-inserted, pull the cable in the lateral direction to seat the cable into the coil pocket.

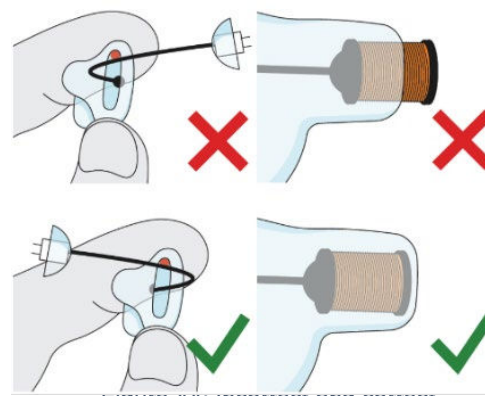


Figure 44: Incorrect and correct cable orientation (left panel) and coil positioning (right panel)

- f. Contact Earlens® Customer Care at 1-(844) 234-LENS (5367) or CustomerCare@earlens.com for additional cable sizes not included in the kit.

Note: In case a cable breaks during removal, squeeze the shell to remove damaged parts from the shell and repeat insertion steps with a new cable. In case of shell damage during fitting, contact Earlens® Customer Care at 1-(844) 234-LENS (5367) or CustomerCare@earlens.com for a replacement shell.

9.5. 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 45b.
- b. Gently lift the cover straight back.

To replace the cover (Figure 46):

- 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.

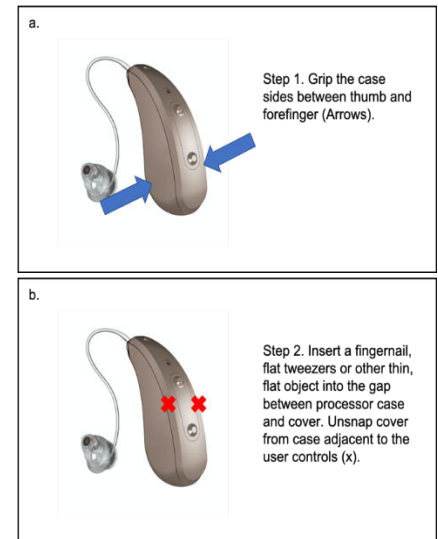


Figure 45: Processor case cover removal

9.6. 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®.

9.7. Maintenance Oiling of the Tympanic Lens

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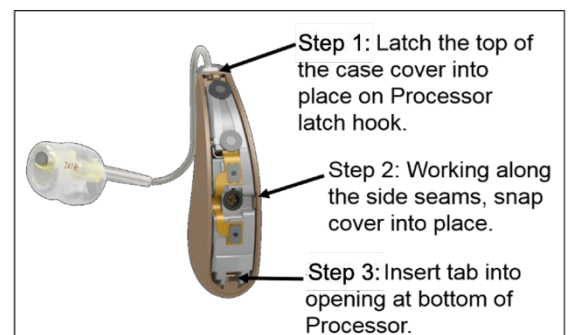


Figure 46: Processor cover replacement

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.

9.8. 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 Earlens Fidelity™ 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 Processor 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 Earlens Fidelity™ software.
- 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






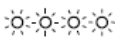
Should troubleshooting be necessary, Earlens® may require the Processor serial number. The number is located on the inner curve of the Processor.

9.9. 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 flashing light | Charger connecting to Processor, it may take up to 20 seconds to connect |
|  | 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 |

9.10. 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 Processor.

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 Fitting tab in Earlens Fidelity™ 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. This will apply a minimal charge to the battery to allow wireless connection to the charging circuit.
 - 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, after completing steps a-g as directed, please contact Earlens®.

10. Wireless Connectivity- Made for iPhone Feature

10.1. Device Compatibility

The Earlens® Contact Hearing Solution is compatible with Apple® devices that have iOS 15 or later.

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 15 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 connect to your Apple device with iOS 15, 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 47).
5. Once the hearing aids are discovered, the First Name + Hearing Aid and R+L* will display (Figure 48).
6. Tap on the name of the detected devices.
7. A Bluetooth pairing request window will appear for each device. Select **Pair** (Figure 49).
8. When the hearing aids are paired and connected, you will see the word "Connected" in the main Hearing Devices screen (Figure 50).

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

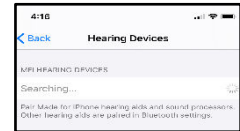


Figure 47.



Figure 48.

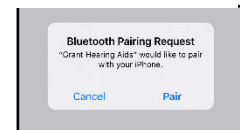


Figure 49.

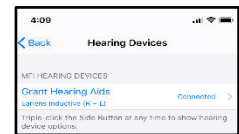


Figure 50.

10.3. Reconnecting to an Apple Device

When the Processor(s) 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. The Processor(s) will also disconnect and then reconnect when turned off and then on via the user controls on the Processor(s). If the Processor(s) 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:

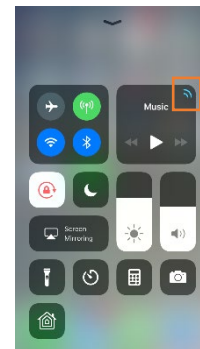


Figure 51.

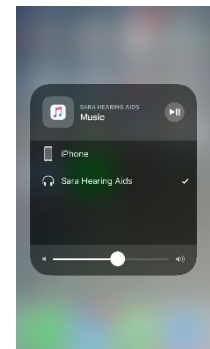




Figure 52.

1. Open the Control Center (Figure 51).
2. Press the  icon in the upper right corner of the audio card (see orange box) to select the preferred audio source (Figure 52).

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 53).

Note: The source may be changed from this screen by tapping on the audio button (Figure 54).

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.

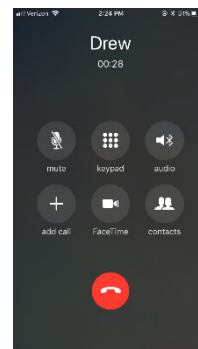


Figure 53.

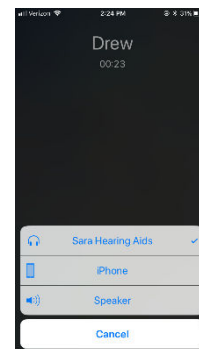



Figure 54.

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.

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 decrease 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 Earlens Fidelity™ software. 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 Processors 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. 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 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 ±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| 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. Recommended separation distance $d = 1.2\sqrt{P}$ |
| 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 ^a , should be less than the compliance level in each frequency range. ^b |

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.

^a 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.

^b 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 $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$ |
| 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 ^{a)} (MHz) | Service ^{a)} | Modulation ^{b)} | Maximum Power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
| 385 | 380 – 390 | TETRA 400 | Pulse modulation ^{b)} 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430 – 470 | GMRS 460, FRS 460 | FM ^{c)} ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 | 704 – 787 | LTE Band 13, 17 | Pulse modulation ^{b)} 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 ^{b)} 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 ^{b)} 217 Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2 400 – 2 570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, | Pulse modulation ^{b)} 217 Hz | 2 | 0.3 | 28 |

| | | | | | | |
|--|------------------|--------------------|---|-----|-----|---|
| | | LTE Band 7 | | | | |
| 5240 | 5 100 – 5 800 | WLAN 802.11 a/n | Pulse modulation ^{b)} 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;

Earlens® Contact Hearing Solution complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

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

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 Earlens Fidelity™ software are recommended for the Audiologist:

- Enable the Streaming program in one of the programming slots.
- The Earlens Fidelity™ 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 Processor(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
- A binaural set of Processors must be programmed together in Earlens Fidelity™, 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 for the latest Apple iOS and device compatibility information.

12. Glossary of Terms

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

13. Graphic Symbols Contained in Device Labeling

| Symbol | Description | Reference | Symbol | Description | Reference |
|---|---|--|---|---|--|
|  | Refer to instruction manual | IEC 60601-1:2005 ISO 7010-M002 |  | Temperature limit | ISO 15223-1:2021, 5.3.7 |
|  | Consult Instructions for Use | ISO 15223-1:2021, 5.4.3 |  | Atmospheric pressure limitation | ISO 15223-1:2021, 5.3.9 |
|  | Keep Dry | ISO 15223-1:2021, 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 15223-1:2021, 5.3.8 |  | Serial number | ISO 15223-1:2021, 5.1.7 |
|  | Non-ionizing radiation | IEC 60601-1-2:2014 IEC 60417-5140 (2003-04) |  | Caution | ISO 15223-1:2021, 5.4.4 |
|  | Batch code | ISO 15223-1:2021, 5.1.5 |  | MR unsafe | ASTM F2503-13 |
|  | Catalog code | ISO 15223-1:2021, 5.1.6 |  | FCC Part 18 Declaration of Conformity | FCC Guidelines for Labeling, Part 18, 2014 |
|  | Date of manufacture | ISO 15223-1:2021, 5.1.3 |  | Type BF applied part | IEC 60601-1:2005 IEC 60417-5333 |



Manufacturer (Ref. ISO 15223-1:2021, 5.1.1):
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