Step by step: The audiologists' guide to fitting the Inductive Earlens Contact Hearing Solution

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ML00451vA

Speaker intro

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Learning outcomes

1. Describe the clinical flow for placement and fitting of the Earlens device.
2. Describe steps for fitting and programming the Earlens device.
3. Describe the basis for the fitting prescription in Earlens fitting software
4. List three common fine-tuning steps performed by audiologists while fitting and programming an Earlens device

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Recap of candidacy and Earlens clinical flow

Audiology Online courses:

- 34073: Earlens Candidacy
- 34075: Earlens Clinic Flow

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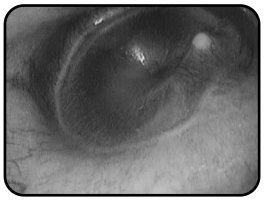
Patient candidacy evaluation



Hearing Profile

Mild to severe sensorineural hearing loss

Audibility is primary limitation

Wears hearing aids daily

Anatomy

Good visibility of the TM

Fairly open canal for Lens placement

Normal ear canal anatomy

Patient Factors

Tolerates ear cleaning

Follows directions

Accepting of new technology

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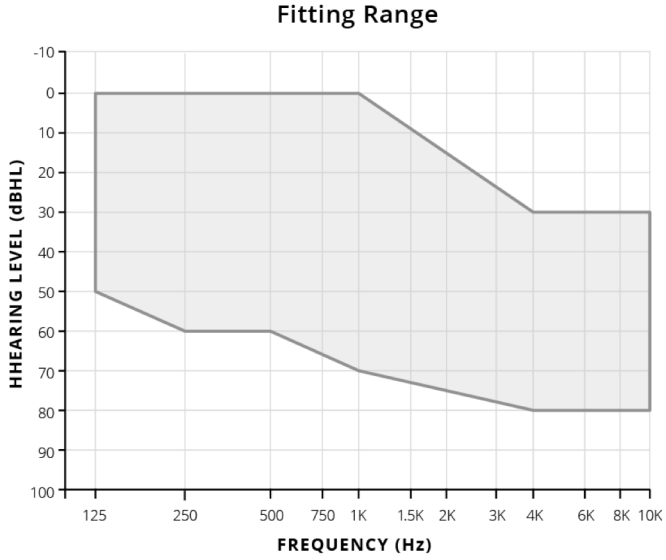
Fitting range & indications for use



18+ years of age

Mild-to-Severe **sensorineural** hearing loss

Can benefit from amplification – high WRS indicate audibility is the primary limitation to performance

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Candidacy

- No more than two primary audiometric frequencies outside the Earlens fitting range
- Unaided word recognition scores ≥ 50% at MCL
- Type A tympanogram – No significant conductive component to HL
- Compliant and able to learn new technology

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Contraindications

Hearing loss

- Rapidly Progressive Hearing Loss
- Fluctuating Hearing Loss

Outer Ear

- Restrictive ear canal anatomy
- Compromised immune system affecting tissue of pinna or ear canal

Middle ear

- >10 dB conductive component
- Abnormal tympanic membrane
- Perforated tympanic membrane
- Abnormal middle ear
- History of middle ear surgery
- Chronic and/or recurrent ear infections

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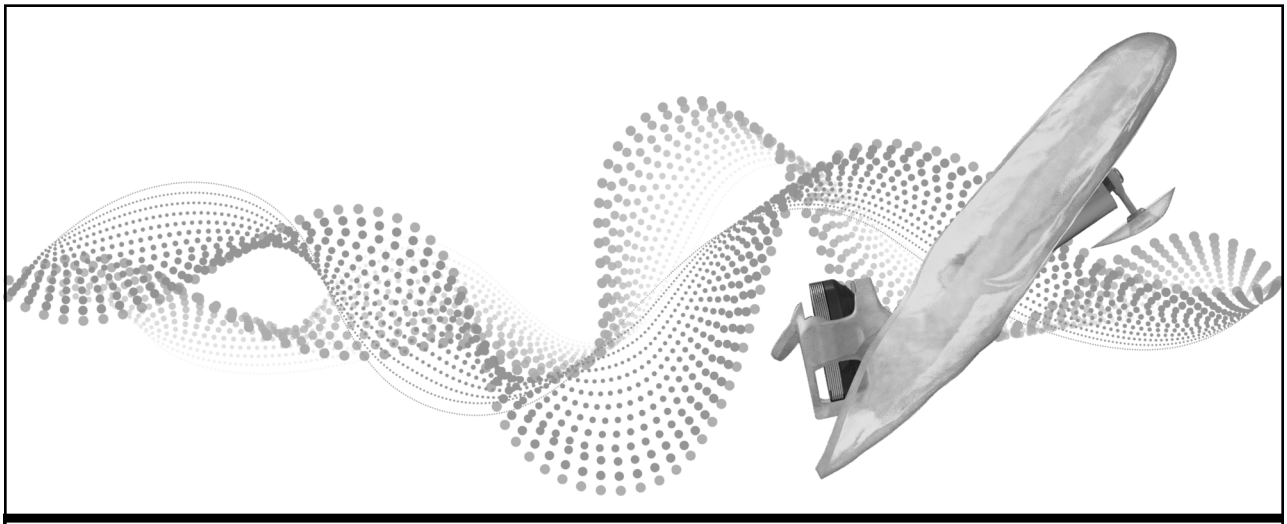
Detailed information can be found in the Hearing Professional Instructions for Use, available at Earlens.com/ifu



Parts of the Earlens Contact Hearing Solution

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Earlens Contact Hearing Solution

Tympanic Lens

Processor & Ear Tip

Charger

Earlens Control

Earlens Fitting Software (ELF)

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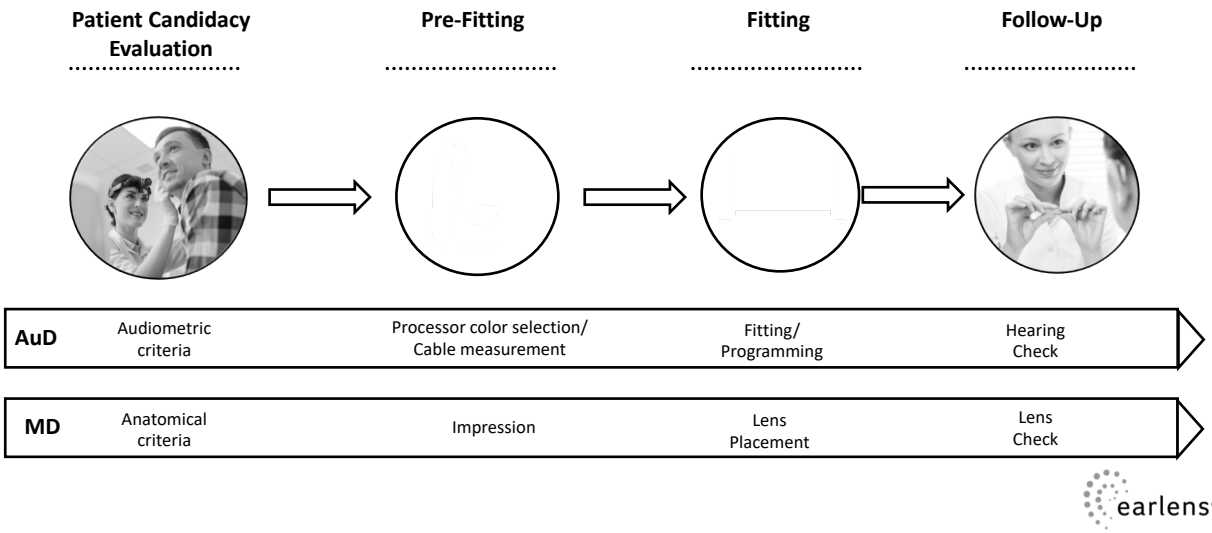
Earlens clinical flow



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MD: Impression

- Performed under a microscope
- Impression of tympanic membrane and ear canal
  - Low viscosity material for medial
  - High viscosity material for lateral
- Lens and Ear Tip modeled using the impression

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MD: Impression video

Impression Training Video

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MD: Lens Placement

- The Lens is placed into the ear canal and maneuvered into position on the TM by the ENT physician
- No anesthesia is required or recommended

Inductive Lens Placement Video

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Fitting the Earlens device

Introduction to ELF – the EarLens Fitting Software

- Noah integrated
  - Wireless programming using Noahlink OR
  - Wired programming using HI-PRO2

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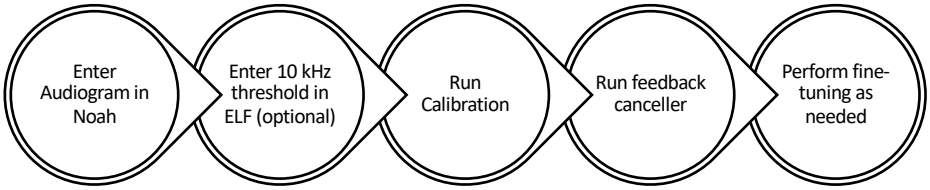
Introduction to ELF – the EarLens Fitting Software

- The ELF software allows the audiologist to program Earlens devices



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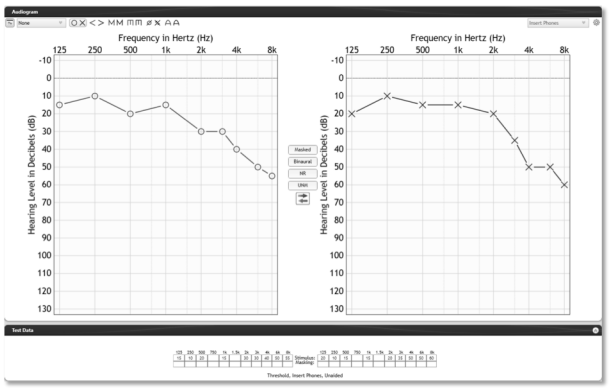
Enter the audiogram

- ELF integrated within Noah software system (does not have a standalone version)
- Create a new patient in Noah
- Enter thresholds 250 Hz to 8000 Hz
  - Enter 125 Hz (if available)



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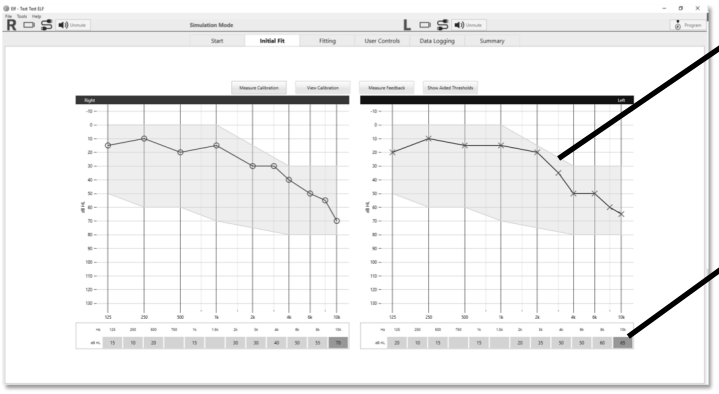
ELF initial fit screen



- Displays audiogram with Earlens fitting range (light grey) superimposed
- Imports audiogram entered in Noah Audiogram module
- 10 kHz threshold (if measured) can be added here
- Leave 10 kHz empty if not measured
- Only 10 kHz data point can be edited

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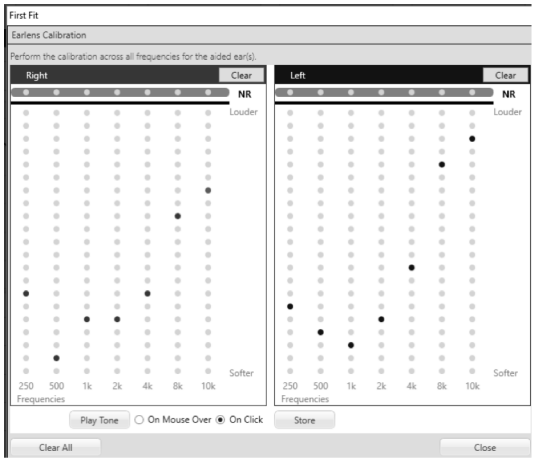
Calibration

- A required in-situ calibration procedure
- Uses Processor to obtain audiogram of hearing threshold in units of dB Full Scale (dB FS) signal output
- Must be measured at **every visit**!
- Takes about 3 minutes per ear
  - Experienced audiologist may complete both ears within 3 min.

Louder

Softer



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Why is calibration needed?

Let's assume you have an audiometer and know that using this audiometer your hearing threshold is 30 dB HL at 1000 Hz.

You would like to try out how a smartphone audiometer works

30 dB HL = ? dB HL

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Why is calibration needed?

Let's assume you have an audiometer and know that using this audiometer your hearing threshold is 30 dB HL at 1000 Hz.

You would like to try out how a smartphone audiometer works

Adjust volume control in the smartphone to make your smart phone audiometer accurate compared to your standard audiometer

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Why is calibration needed?

- Earlens uses the in-situ calibration audiogram to adjust the output level of Earlens to match the acoustic audiogram.
- Similar to manipulating the volume control of the smartphone audiometer

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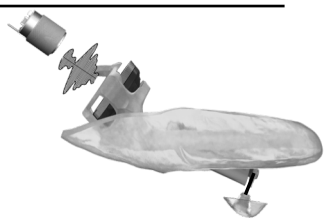
Why is calibration needed?



- Remember… Earlens does not produce sound!!
- Earlens produces low power radio signals, which the lens converts into mechanical vibrations to move the tympanic membrane
  - 0.00005 Microns – 20dB SPL
    - Diameter of a hydrogen atom
  - 1 Micron – 114dB SPL
    - 1/70th the diameter of a human hair
- Calibration is needed so the Earlens system knows how much signal is needed to produce a given amount of sound

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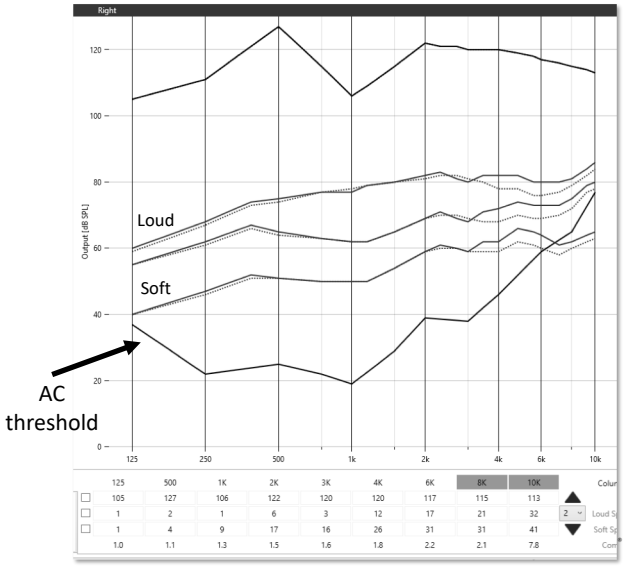
Why is calibration needed?

- An accurate audiogram and calibration are necessary because they reflect the actual expected on-ear performance of the device
- The fitting is verified and is accurate
  - Equivalent to Real Ear measurement
- When we say we are producing x dB – we really are!!



Do I need to perform calibration on everyone?

- Yes!
- Several factors affect calibration:
  - Hearing thresholds
  - Middle ear variability
  - Earlens system performance
    - Physical coupling of Lens to umbo

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When should you run calibration?

- ☑ At every visit – calibration confirms the status and functioning of the Earlens system
- ☑ When a new component is fit
- ☑ As the first step in any troubleshooting

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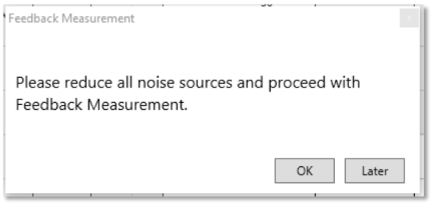
Feedback measurement

- Feedback *can* occur with Earlens
- Vibration of the eardrum produces sound!
  - Can be picked up by the mics when enough gain is applied
- ELF will automatically prompt you to run the feedback canceller every time calibration is run



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Programming and fine tuning

- ELF Rx – default gain prescription in ELF
- ELF gain targets are generated using the CAM2 fitting formula
  - Developed by Moore and Colleagues (2010)
  - Only fitting formula that prescribes gains up to 10 kHz
- Remember: ELF Rx prescribed gain is based on acoustic hearing thresholds and NOT calibration!
  - Calibration has no effect on ELF Rx

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Basis of common fitting prescriptions

Fitting formulae	Basis of gain prescription	Details
NAL-NL2	Maximizing SII while normalizing overall loudness for average speech	Tinniness/unnatural sound quality but widely used as IG can be implemented in conventional devices
DSL-5	Attempts to restore audibility for 50 dB SPL speech while keeping 80 dB SPL speech within the dynamic range	Widely used for pediatric fittings
Proprietary algorithms	Variations of NAL-NL2	Lower gains than NAL-NL2 resulting in patients asking for more gains. REM necessary, but not always run by audiologists
CAM2	Loudness equalization and normalization	Does not compromise sound quality to maximize speech intelligibility.

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ELF Rx: Based in CAM2

- Loudness Equalization + Loudness Normalization
- Equalizes *specific* loudness across the critical bands
  - Applies different gain to different critical bands to equalize loudness
- Normalizes *overall* loudness for soft and loud speech
  - The overall loudness level should be about the same as for a normal hearing person listening to soft speech or loud speech.

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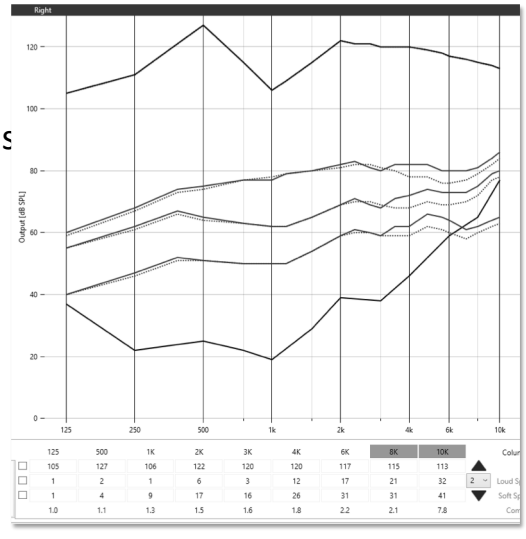
Gain handles in ELF

- Can fine-tune in 9 bands
- These control gains in 20 sub- bands (hidden)



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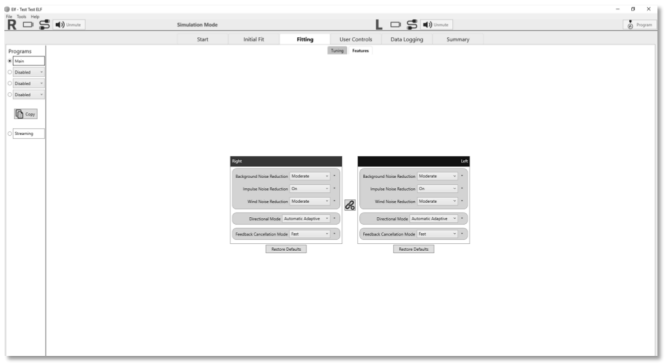
Other features in the Earlens system



Background noise reduction
- Choose strength of noise reduction from 4 options off, mild, moderate, strong

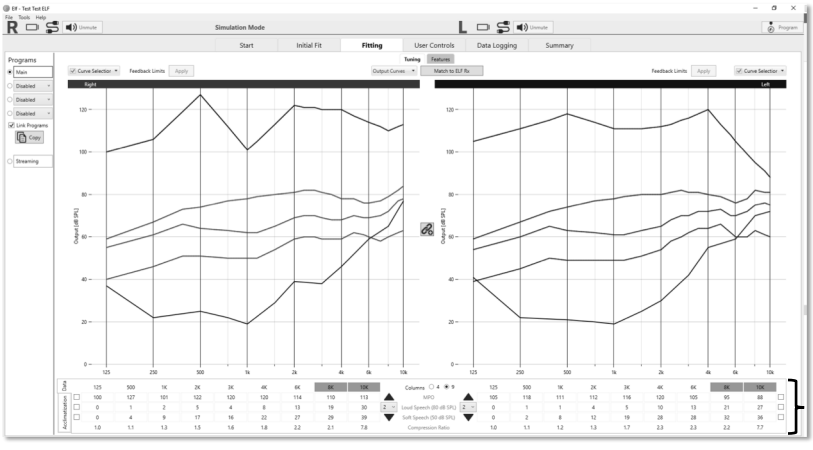
Impulse noise reduction
- For managing transient, loud sounds
- Off/On

Wind noise reduction
- Off/mild/moderate/strong

Directional mode
- Microphone setting
- 4 options – omni/fixed/automatic adaptive/automatic fixed

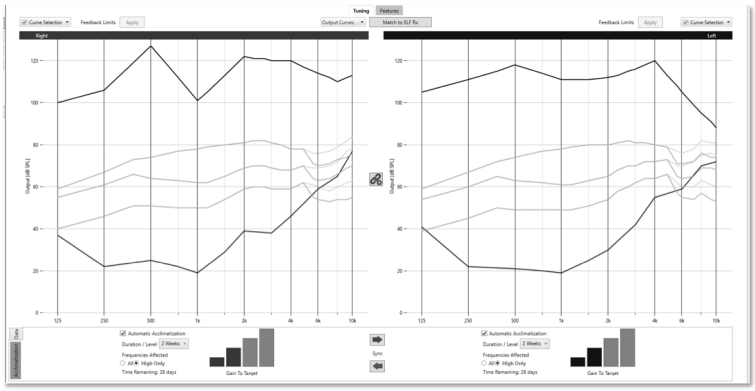
Feedback cancellation mode
- Slow/Fast/Off

Other features in the Earlens system



- Ability to add up to 4 program for a patient
- Default programs include:
  - Music
  - Restaurant
  - Car
  - Quiet
  - Noise
  - Party
  - Outside
  - TV

Other features in the Earlens system



- Acclimatization
  - Manual
  - Automatic
- Adjusts % of gain to target over a period of time
- Can enable for all frequencies or high frequencies only
- Unique approach of CAM2

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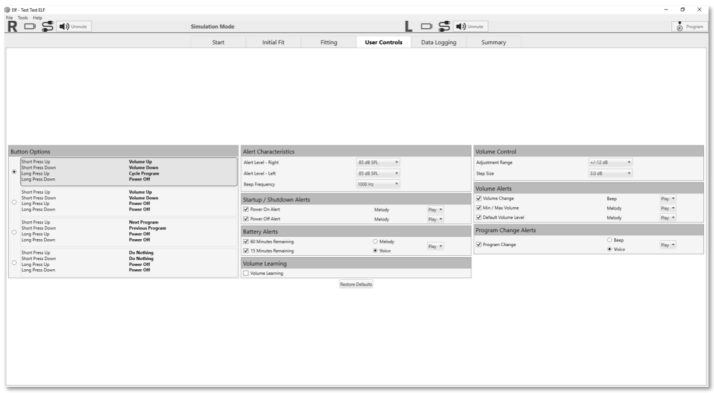
Other features in the Earlens system



- Customize buttons on the Processor
- Choose level of alerts (voice prompts)
- Can choose melody-based or voice prompts for alerts
- Enable/disable low battery warning alerts
- Change volume control range
- Change volume control step size

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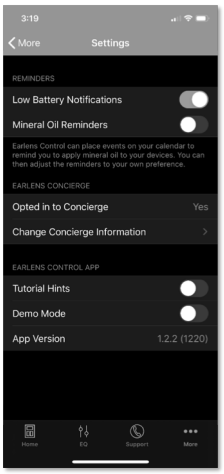
Other features in the Earlens system

- **Made For iPhone (MFi) – Earlens Control App**
  - Allows patients to change programs and volume
  - Equalizer
  - Live mic
  - Locate my Earlens
  - Reminders for oiling



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Counseling

Device use and maintenance

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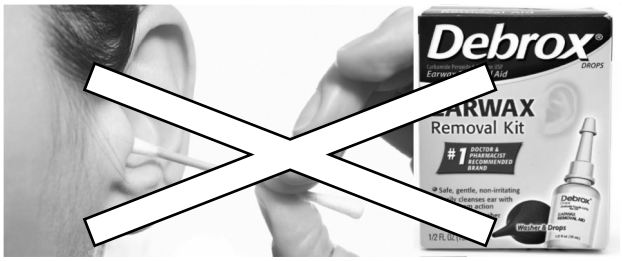
Counseling- Use & Care

- Use of device
  - Patients must oil
    - Keeps Lens in place via hydrostatic tension
    - Creates buffer area for epithelial migration
  - Review oiling regimen
  - No Q-tips or wax removal kits



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Counseling- Use & Care

- Wireless inductive charging
  1 Indicator Light = depleted/charging
- 4 hours to fully charge
- Charge status indicators
- Minimum 16 hours of battery life
  4 Indicator Lights= fully charged

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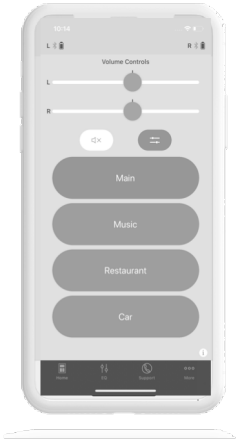
- Installation and use of Earlens Control App



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Counseling- Use & Care

With the Lens in place, patients **CAN**…

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Counseling- Use & Care

With the Lens in place, patients **CAN** use…

as long as the device is not over-inserted and does not protrude deeply into the ear canal.

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Earlens Concierge

Earlens Concierge are Customer Service associates dedicated to proactively supporting your patients through their Earlens journey

- Free up your time by reducing the number of office visits
- Focus your time on high value activities
- Increase success with Earlens by addressing patient issues immediately
- Increase patient satisfaction by troubleshooting remotely

Earlens® Concierge **1-844-234-5367**

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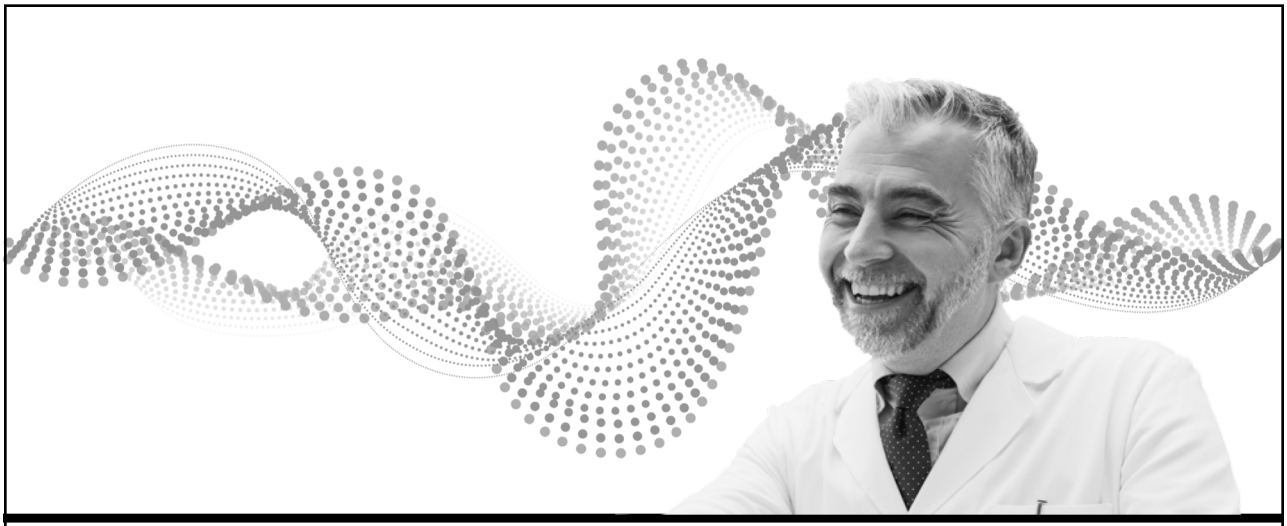

Follow-up visits

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Follow-up Checklist

1-2 Week Follow-Up

- ❑ View the lens through Otoscopy
- ❑ Evaluate Ear Tip stability, consistency and comfort
- ❑ ELF
  - ❑ Calibration
  - ❑ Fine-Tuning, if needed
- ❑ Ensure that the patient is following oiling regimen

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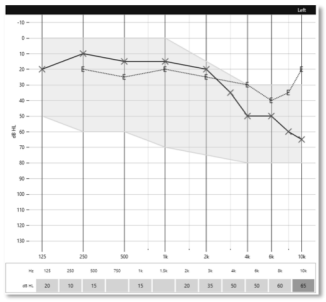
Additional measures obtained (optional)

Follow-Up Visits

- ❑ Obtain damped unaided thresholds (under earphones, no Ear Tip, Lens in place)
  - Baseline for annual exam
- ❑ Measure Aided Thresholds



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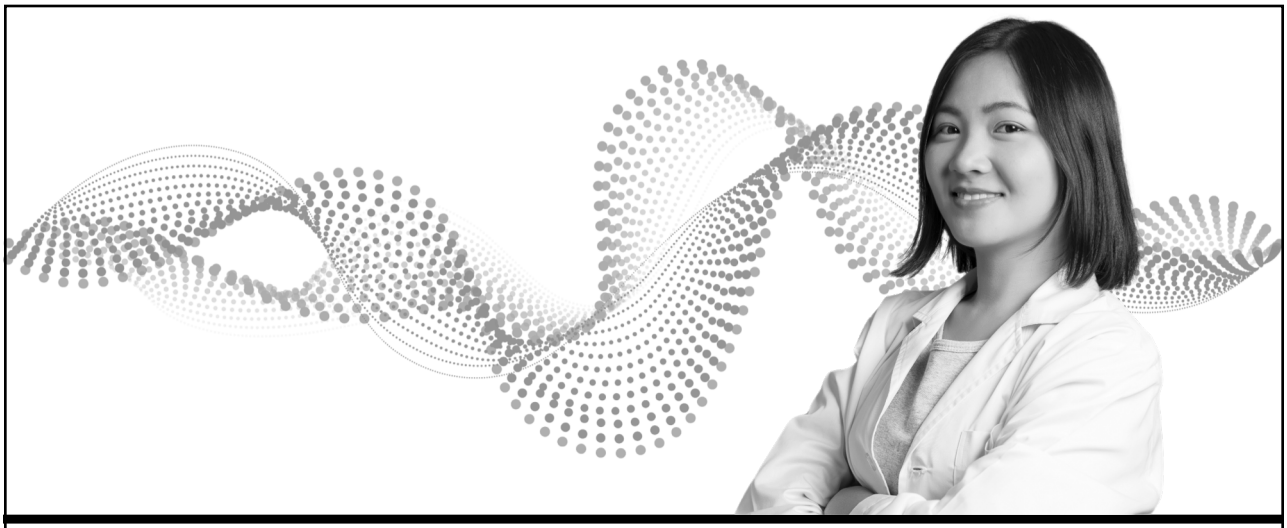

Commonly performed fine-tuning for Earlens fittings

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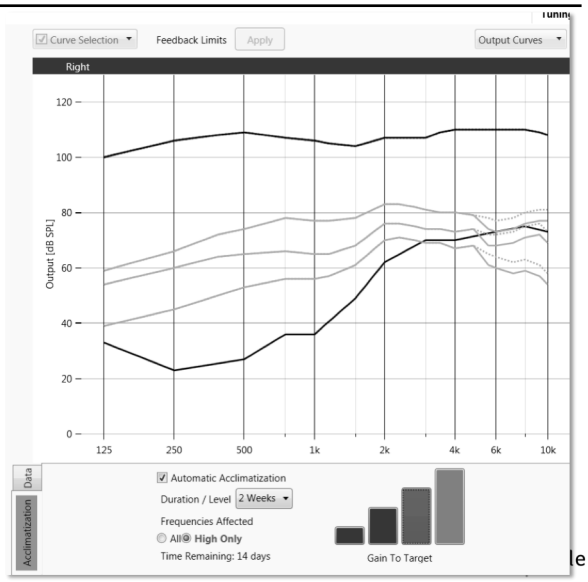
Hissiness, sharpness, or tinniness

Every new Earlens user is new to extended high frequency amplification above ~6 kHz

1. **Use the automatic acclimatization feature (highly recommend)** or reduce gain from 6kHz to take the edge off
2. If you make other fine-tuning adjustments, reconsider the adjustments made above 6kHz
   - If increased gain at other frequencies, consider decreasing gains >6kHz
   - Always keep audibility in mind



Own voice "too loud" or "in a barrel"

- Presence of Lens and oil can increase perception of own voice loudness – especially after initial placement
  - Counsel especially at first fit where excess oil is common

- Programming can also affect own voice perception
  1. Decrease gain for loud speech from 125-500 Hz
  2. Increase gains by 3-6 dB for 2-4kHz

Music sound quality optimization

- Fine-tuning
  - Increase bass
  - Turn off automatic features
    - Noise cancellation
    - Impulse noise reduction
    - Wind noise reduction
- Feedback cancellation
  - Can commonly be disabled for better sound quality of music
  - Look for >20 dB of gain margin between feedback measurement and gain for soft speech

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Summary

- Earlens placement and fitting – synergistic partnership between ENT physician and Audiologist
- Fitting of Earlens device
  - Enter hearing thresholds
  - Run Calibration
  - Perform fine-tuning
  - Activate features as needed
- Earlens – a unique addition to your practice
  - Offers a noticeably and meaningfully superior listening experience for your patients

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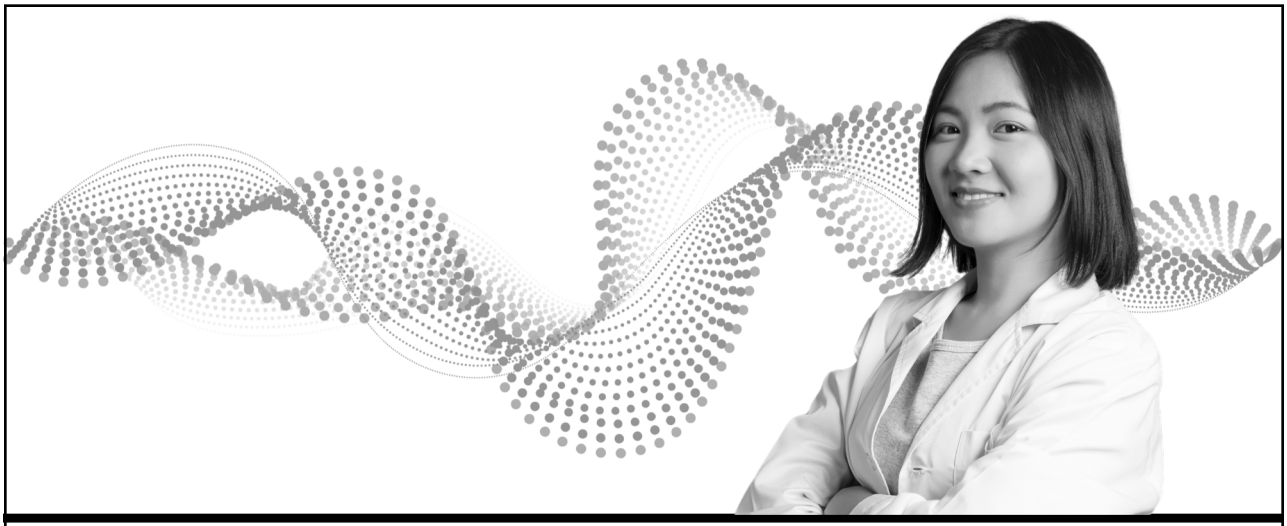

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