



Earlens® Inductive Comparator Instructions For Use

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1. Introduction

Carefully read all instructions prior to use.

2. Earlens® Inductive Comparator Description

The Earlens® Inductive Comparator (Figure 1) allows prospective users to experience the extended bandwidth and sound quality of the Earlens system and compare that listening experience to the user's own air conduction hearing aids, by listening to speech, music or other sound while wearing high-quality, circumaural headphones. The Comparator can also be used for troubleshooting purposes to listen to the Earlens Processor and Ear Tip to determine if the system is working appropriately.



Figure 1: Inductive Comparator

For the sound demonstration, the Earlens Processor and Ear Tip are placed in the integrated simulator case. (See Figure 2 below). The audiologist or hearing healthcare professional selects processor settings that would approximate those suitable for the listener's audiometric profile by choosing one of the four processor memories. The user's own hearing aid is inserted into the acoustic coupler, which captures the sound output of the hearing aid via a high-quality microphone. The user adjusts the volume of the acoustic hearing aid output to a comfortable level using the knob labeled 'Volume', then toggles the 'Source' switch to listen to the output of the Earlens demonstration system, adjusting the volume on the simulator in a similar fashion, until it is at a similar, comfortable volume.

For the listening check, the Earlens Processor and Ear Tip are placed in the simulator case and the audiologist listens to the output of the two components with the headphones.

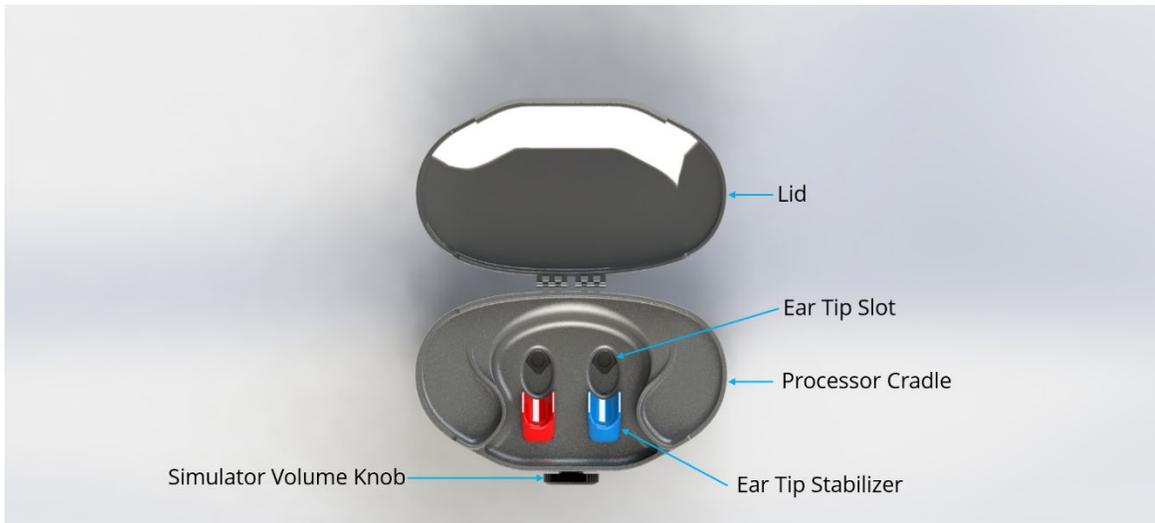


Figure 2: Simulator

3. Intended Use

The primary intended use of the Earlens Comparator is to compare the audio output of the Earlens Contact Hearing Aid and a listener's conventional acoustic hearing aid via a source toggle switch to demonstrate the Earlens sound performance to a prospective user. The secondary intended use of the Comparator is to allow clinical troubleshooting by the clinician by listening to the Earlens Processor and Ear Tip to determine whether the components are working appropriately. The Inductive Comparator is not intended to support, supplement, or augment the performance of the Earlens Contact Hearing Aid to amplify sound in the ear.

4. Warnings



Before using the Earlens Inductive Comparator, read and make sure you understand each of the following safety warnings.

- Should the device become damaged, stop use and contact Earlens Customer Care.
- Do not crush, short circuit, modify or disassemble any component of the Inductive Comparator.
- Do not incinerate any component of the Inductive Comparator or use near open flame.
- Handle waste from electronic equipment per local regulations.

5. Precautions



Before using the Earlens Inductive Comparator, read and make sure you understand each of the following safety precautions.

- Avoid getting the Inductive Comparator wet, as this may damage the device.

- Handle the Inductive Comparator carefully. Do not drop it and prevent hard knocks. This may damage the device.
- If the Inductive Comparator fails to operate or if it appears damaged, including battery leakage, or swelling of the device, stop use and contact Earlens Customer Care.
- DO NOT AUTOCLAVE.

6. Operating Instructions

Setup Prior to Use

The demo Processor provided with the Inductive Comparator package is in deep sleep mode.

- Press and hold the top user control for 3 seconds to turn the Processor on.
- Ensure that the demo Processor is charged by placing the Processor into the charger and verify that the charger displays at least 3 solid lights.
- Press the Power Button on the comparator to power on. The Power Button will illuminate green when the Comparator is powered on.
- The Comparator is powered by a 9-volt battery. If the Inductive Comparator does not power on, replace the battery.

Inductive Comparator Setup

- Place the demo Earlens Processor and Ear Tip into the left side of the Simulator mounted on top of the Comparator (indicated by the blue Ear Tip Stabilizer).
- Ensure that the Ear Tip is seated snugly into the Ear Tip Slot and the Processor microphones are facing outward seated in the Processor Cradle.
- Once the Processor and Ear Tip are in place and powered on, close the Simulator lid.

Earlens Program Selection

- Prior to selecting a program, review the listener's audiogram.
- The Demo Processor has four memories, pre-programmed for the following hearing losses.
 - Mild Sloping to Moderate
 - Flat Moderate
 - Moderate Sloping to Severe
 - Precipitously Sloping Loss
- Select the program which fits the listener's hearing loss most accurately by cycling through the programs.
- To cycle through programs, press and hold the top user control for 3 seconds. Beeps will play to indicate that the processor has entered into the corresponding memories 1-4.

Conventional Device Setup

- Remove the listener's hearing aids and clean the devices using isopropyl alcohol (IPA) before each use.
- Utilize the hearing aid which has the more severe hearing loss if the listener has an asymmetrical hearing loss.
- Insert the listener's acoustic air conduction hearing aid into the Coupler to best simulate the connection to their ear:

- If the hearing aid is an open fit receiver in canal (RIC) device, simply place the earmold deeply into the coupler.
 - If the hearing aid has a custom earmold, apply Fun-Tak putty around the earmold, position the speaker outlet or earmold tubing and vent over the acoustic coupler opening, and secure the putty down against the surface of the coupler. Do not occlude the vent with Fun-Tak.
- d. Confirm that the conventional hearing device is turned on.
 - e. Both the Earlens Processor and conventional device microphones should be facing in the same direction to ensure the most accurate comparison.

Volume Settings of Devices

- a. Insert the headphones provided in the Comparator case (Sennheiser HD-280) into the headphone jack. Note: These headphones were selected based on their frequency response and sensitivity. Substituting other headphones may result in an unpredictable or poor listener experience.
- b. As the demonstrator, place the headphones on yourself.
- c. Use the Toggle Switch to switch the Comparator's output to hearing aid (HA).
- d. Adjust the volume of the conventional device output using the Comparator's Volume Knob.
- e. Rotating the knob clockwise will raise the volume and turning the knob counterclockwise will decrease the volume.
- f. Switch the toggle to the Earlens output and adjust the volume of the Earlens Contact Hearing Solution using the Simulator Volume Knob to match the output of the conventional device.
- g. Toggle back to the HA setting and place the headphones on the listener's ears.
- h. Confirm with the listener that the volume is comfortable. If the volume is too loud or too soft, remove the headphones from the listener, place them back on the demonstrator, and adjust both conventional volume and Earlens Contact Hearing Solution volume to match.
- i. Repeat volume adjustments until the listener is comfortable with the volume.

Sound Demonstration

- a. Start the sound demo on the listener's acoustic hearing aid.
- b. Start by having a conversation with the listener or playing music for the listener.
- c. Toggle the switch back and forth between the acoustic hearing aid and the Earlens system to allow the listener to hear the difference between the Earlens Contact Hearing Solution and their conventional device.

Simulator Usage

The Simulator can be used separately from the Comparator to evaluate the sound quality of an Earlens Processor and Ear tip.

- a. To use the Simulator, insert the user's Ear Tip into the left Ear Tip Slot. (indicated by the blue Ear Tip Stabilizer).
- b. Ensure that the Processor and Comparator are both powered on.
- c. Insert the headphones into the auxiliary headphone connector on the Simulator and place on the clinician's ears.
- d. Adjust the volume of the Simulator using the Simulator volume knob until the output of the Earlens system can be clearly heard.
- e. Evaluate the sound quality of the Ear Tip and Processor using familiar and appropriate clinical troubleshooting techniques.

7. Operating Specifications

Inductive Comparator Output	Capable of producing sound from 125- 10,000Hz		
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.
Operating Conditions	18°C to 28°C 0-93% humidity	Use conditions	Avoid high temperatures and sustained exposure to direct sunlight.

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

8. Graphic Symbols Contained in Device Labeling

The following symbols appear on the Inductive Comparator

Symbol	Description	Reference	Symbol	Description	Reference
	Separate collection for electrical and electronic equipment	WEEE Directive 2012/19/EU, Annex IX		Caution	ISO 15223-1:2016, 5.4.4
	Keep Dry	ISO 15223-1:2016, 5.3.4		Batch Code	ISO 15223-1:2016, 5.1.5