



Earlens Light Pen Instructions For Use

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1. Introduction

Carefully read all instructions prior to use.

2. Earlens Light Pen Description

The Earlens Light Pen (Figure 1) is a portable, battery operated tool that features a low-level laser light source. When placed in the ear canal, the Light Pen projects a light signal into the ear canal.

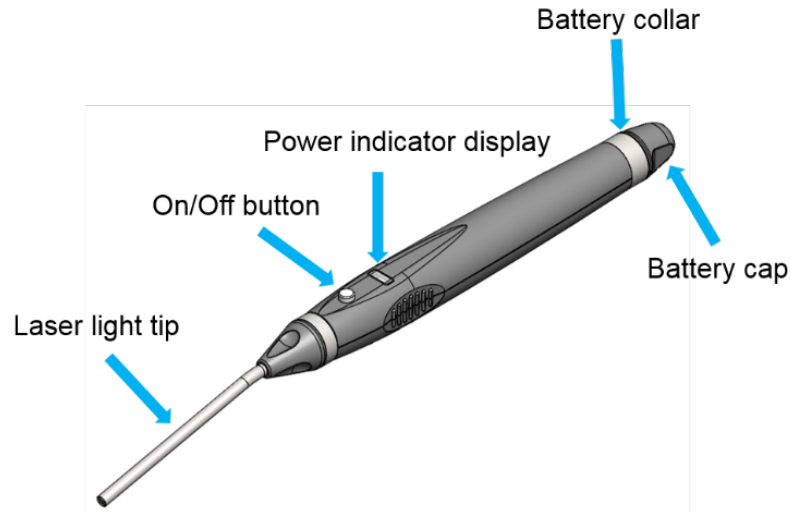


Figure 1. Light Pen components

3. Intended Use

The Light Pen is an optional tool available for the convenience of the health care professional to demonstrate the Earlens Hearing Aid sound quality experience after proper placement. The Light Pen does not affect the normal operation of the Earlens Hearing Aid to amplify sound in the ear. The Light Pen is not intended to support, supplement, or augment the performance of the Earlens Hearing Aid to amplify sound in the ear.

4. Warnings



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

- The Light Pen contains a Class 1 laser. It is safe to use under normal operating conditions. The Class 1 laser used on the Light Pen is NOT visible. DO NOT look directly into the laser or aim it directly into your eye. Should the device become damaged, stop use and contact Earlens Customer Care.
- Do not crush, short circuit, modify or disassemble any component of the Light Pen.
- Do not incinerate any component of the Light Pen or use near open flame.



- Handle waste from electronic equipment per local regulations.
- When using any instruments in the ear canal, be careful to avoid damaging the ear canal or tympanic membrane.

5. Precautions



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

- Avoid getting the Light Pen wet, as this may damage the device.
- Only individuals trained in the evaluation and placement of hearing aids should use the Light Pen.
- Handle the Light Pen carefully. Do not drop it and prevent hard knocks. These may damage the device.
- If the Light Pen 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

Please refer to the Earlens Simulator Instructions for Use to obtain additional instructions for using the Simulator and Light Pen together.

First Time Light Pen Use

When you receive the Light Pen, you must first insert the supplied AAA battery.

- Open the battery compartment by twisting the battery cap counter-clockwise until the cap comes off.
- Place the AAA battery with the positive end of the battery facing towards the laser light tip.
- Close the battery compartment, place the battery cap on the Light Pen and twist the battery cap until fully secured.

Earlens Light Pen Demonstration Instructions

- Prior to use, wipe the laser light tip with an isopropyl alcohol soaked wipe or cloth.
- Turn on the Light Pen by pressing the button. When the device is ON, the power indicator will display a blue light.
- Place the Light Pen carefully in the ear canal aiming it at the Lens and gradually advance it forward until the patient can hear the music. Ensure the Light Pen does not contact the Lens.
- Hold the Light Pen in position for 30 seconds to demonstrate the sound experience for the patient.
- Gently remove the Light Pen from the ear canal.
- Turn OFF the Light Pen by pressing any button.
- Wipe the laser light tip with an isopropyl alcohol soaked wipe or cloth.

Note- If the Light Pen is not turned off following use, it will automatically turn off after 10 minutes.

Battery Replacement

If the battery is low, the power indicator display will turn from blue to red when the Light Pen is ON.

- a. Open the battery compartment by twisting the battery cap counter-clockwise until the cap comes off.
- b. Remove the battery collar.
- c. Replace with a disposable or rechargeable AAA battery with the positive end of the battery facing towards the laser light tip.
- d. Replace the battery collar.
- e. Close the battery compartment by placing the battery cap on the Light Pen and twisting the battery cap until fully secured.













7. Operating Specifications

Light Pen Output	Capable of producing sound from 125-10,000Hz	Length of Music	30 seconds
Storage Conditions and Temperature Limit*	-20°C to 55°C Maximum relative humidity of 93% non-condensing.	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 Light Pen or packaging:

Symbol	Description	Reference	Symbol	Description	Reference
	Refer to instruction manual/booklet	IEC 60601-1:2005 ISO 7010-M002		Temperature limit	ISO 15223-1:2016, 5.3.7
	Separate collection for electrical and electronic equipment	WEEE Directive 2012/19/EU, Annex IX		Atmospheric pressure limitation	ISO 15223-1:2016, 5.3.9
	Keep Dry	ISO 15223-1:2016, 5.3.4		Caution	ISO 15223-1:2012, 5.4.4
	Class 1 laser product	IEC 60825-1:2007, 5.2		Batch code	ISO 15223-1:2016, 5.1.5
	Catalog number	ISO 15223-1:2016, 5.1.6		Date of manufacture	ISO 15223-1:2016, 5.1.3
	CE conformity marking	MDD 93/42/EEC, Annex XII		Humidity limitation	ISO 15223-1:2016, 5.3.8



Manufactured by (Ref. ISO 15223-1:2016, 5.1.1):
Earlens Corporation.
4045A Campbell Ave.
Menlo Park, CA 94025



European Authorized Representative (Ref. ISO 15223-1:2016, 5.1.2):
Medimark® Europe SARL
11, Rue Emile Zola, B.P. 2332
F-38033 Grenoble Cedex 2 – France



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