Earlens® Inductive Pen Instructions For Use

1. Introduction

Carefully read all instructions prior to use.

2. Earlens Inductive Pen Description

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

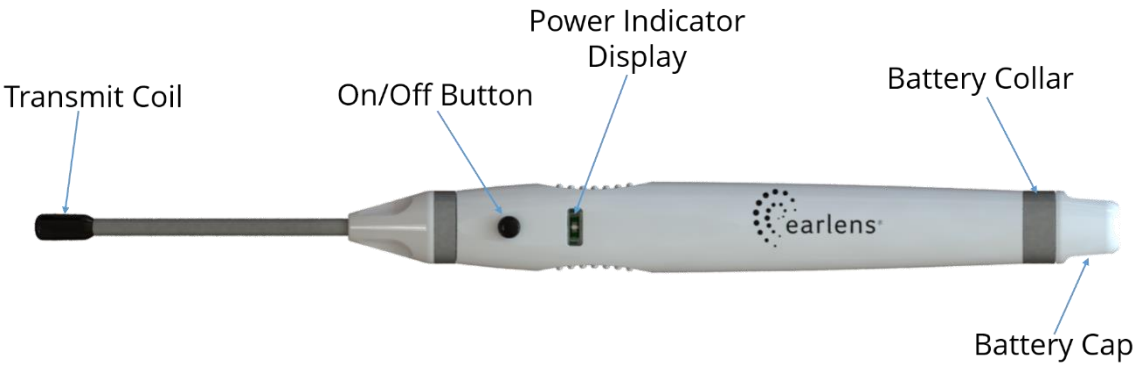

Figure 1. Inductive Pen components

3. Intended Use

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

4. Warnings

Before using the Earlens Inductive Pen, 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 Pen.
- Do not incinerate any component of the Inductive 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 Inductive Pen, read and make sure you understand each of the following safety precautions.

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

First Time Inductive Pen Use

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

a. Open the battery compartment by twisting the battery cap counter-clockwise until the cap comes off.
b. Place the AAA battery with the positive end of the battery facing towards the transmit coil tip.
c. Close the battery compartment by place the battery cap on the Inductive Pen and twisting until fully secured.
d. The LED will blink twice, indicating the battery was inserted correctly.

Earlens Inductive Pen Demonstration Instructions

a. Prior to use, wipe the Transmit Coil with an isopropyl alcohol-soaked wipe or cloth.
b. Turn on the Inductive Pen by pressing the button. When the device is ON, the power indicator will display a blue light.
c. Place the Inductive 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 Inductive Pen does not contact the Lens.
d. Hold the Inductive Pen in position for 30 seconds to demonstrate the sound experience for the patient.
e. Gently remove the Inductive Pen from the ear canal.
f. Turn OFF the Inductive Pen by pressing the On/Off button again.
g. Wipe the Transmit Coil with an isopropyl alcohol-soaked wipe or cloth.

Note – If the Inductive Pen is not turned off following use, it will automatically turn off after 5 minutes.

Battery Replacement

If the battery is low, the Power Indicator Display will turn from blue to red when the Inductive Pen is ON.

a. Open the battery compartment by twisting the battery cap counter-clockwise until the cap comes off.
b. Replace with a disposable or rechargeable AAA battery with the positive end of the battery facing towards the Transmit Coil.
c. Close the battery compartment by placing the battery cap on the Inductive Pen and twisting the battery cap until fully secured.
d. The Power Indicator Display will flash blue twice indicating proper insertion.

7. Operating Specifications

Inductive Pen Output	Capable of producing sound from 125- 10,000Hz	Length of Music	30 Seconds
Storage Conditions and Temperature Limit*	-20ºC to 50ºC 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. FCC Information

FCC ID: 2AGDU-INDPEN;

This device 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: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

9. Electromagnetic Compatibility Compliance

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® Inductive Pen have been tested for electromagnetic emissions compliance.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Earlens® Inductive Pen is intended for use in the electromagnetic environment specified below. The customer or the user of the Earlens® Inductive Pen should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The Earlens® Inductive Pen 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 A	The Earlens® Inductive Pen is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Earlens® Inductive Pen is intended for use in the electromagnetic environment specified below. The customer or the user of the Earlens® Inductive Pen 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 %.
(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® Inductive Pen is intended for use in the electromagnetic environment specified below. The customer or the user of the Earlens® Inductive Pen should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications should be used no closer to any part of the Earlens® Inductive Pen, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 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® Inductive Pen is used exceeds the applicable RF compliance level above, the Earlens® Inductive Pen should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Earlens® Inductive Pen. [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 and the Earlens® Inductive Pen	
The Earlens® Inductive Pen is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Earlens® Inductive Pen can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications (transmitters) and the Earlens® Inductive Pen as recommended below, according to the maximum output power of the communications device.	
Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter** (m)

(W)	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.7 GHz d = 2.3√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, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
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.						

10. Summary of Wireless Technologies

The Earlens® Inductive Pen incorporates only one wireless technology. This is the inductive link to transmit data and power from the Inductive Pen to the Tympanic Lens.

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 Inductive Pen 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 Inductive Pen to the Receive coil in the Lens ensures minimal possibility of an external source interfering with the Inductive Link. In case 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.

11. Graphic Symbols Contained in Device Labeling

The following symbols appear on the Inductive 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 15223-1:2016, 5.4.4
	Catalog number	ISO 15223-1:2016, 5.1.6		Date of manufacture	ISO 15223-1:2016, 5.1.3
	Batch Code	ISO 15223-1:2016, 5.1.5		Humidity limitation	ISO 15223-1:2016, 5.3.8
	Federal Communications Commission (FCC) TCB Review	FCC Guidelines for Labeling, 47 CFR Part 15		Non-ionizing radiation	IEC 60601-1-2:2014 IEC 60417-5140 (2003-04)

 Manufactured by (Ref. ISO 15223-1:2016, 5.1.1):
Earlens Corporation.
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 European Authorized Representative (Ref. ISO 15223-1:2016, 5.1.2):
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