



Earlens Photon™ 2 Processor
User Manual





Earlens Photon™ 2 Processor
User Manual

Welcome

Thank you for choosing the Earlens Light-Driven Hearing Aid. This user manual is designed to show you how to use and care for your new Earlens Hearing Aid. We encourage you to carefully read this entire booklet including the Warnings and Precautions sections to achieve the maximum benefit from your new hearing technology.

If you have further questions that are not answered in this manual, please contact your hearing professional or call the Earlens Concierge at 1-844-234-LENS. You should always access the most up-to-date version of the *Earlens Light-Driven Hearing Aid Patient Instructions for Use (IFU)* at www.earlens.com/IFU. The IFU contains detailed warnings, precautions, results from Earlens Hearing Aid clinical studies and information regarding safe and effective EMC use.

Contents

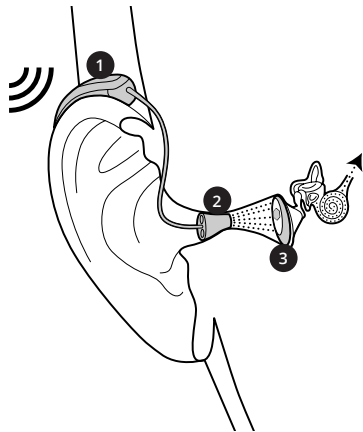
Getting to Know Your Earlens Hearing Aid	4	<i>Charging and Battery Life</i>	26
<i>The Lens</i>	6	Cleaning and Maintenance	27
<i>The Photon™ 2 Processor and Light Tip</i>	7	<i>Daily Care</i>	27
<i>The Charger</i>	8	<i>Oiling Instructions</i>	29
<i>Mineral Oil</i>	10	<i>Avoiding Moisture & Heat</i>	32
Using your Earlens Hearing Aid	11	<i>Warranty</i>	33
<i>Turning the Processor On/Off</i>	11	Troubleshooting.....	34
<i>Identifying Left or Right Device</i>	13	Warnings.....	36
<i>Putting on the Processor and Light Tip</i>	14	Precautions	38
<i>Removing the Processor and Light Tip</i>	16	Technical Information.....	42
<i>Changing Volume and Program</i>	17	Device Labeling Symbols	44
<i>Processor Alerts</i>	22		
<i>Telephone and Cellphone Use</i>	24		

Getting to Know Your Earlens Hearing Aid

The Earlens Hearing Aid uses a small Lens placed in your ear by a physician to activate your natural hearing system. The behind-the-ear Photon™2 Processor collects sound and transfers it to the Light Tip, which converts the sound signal to non-visible light. The Lens collects this light and gently activates your natural hearing system.

There are important components to your Earlens Hearing Aid that will be described in this section: the Lens, the Processor, the Light Tip, the Charger and mineral oil. The components that you will interact with include the Processor, Light Tip, Charger and mineral oil.

- 1 Sound enters the microphone on the Processor, which transforms the sound and sends the audio signal to the Light Tip.
- 2 The Light Tip converts the audio signal into light and then projects the light wave to the Lens, which makes direct contact with the eardrum.
- 3 When the Lens is activated by the light wave, it vibrates the eardrum gently at different frequencies—resulting in rich, natural sound.

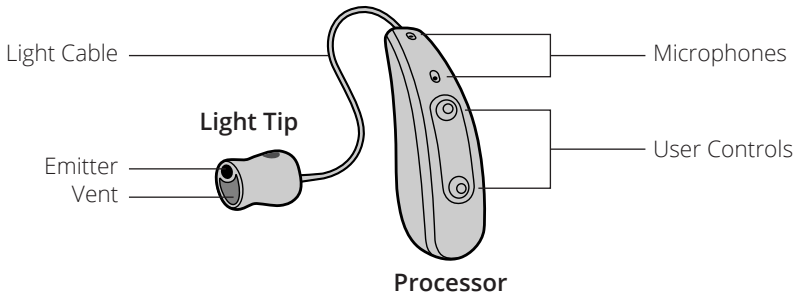


The Lens

The Lens is driven by light waves that contain sound information. When the Lens detects light waves, it gently activates your natural hearing system allowing you to hear sound. To keep your Lens functioning properly, you must apply Earlens mineral oil twice a week and avoid placing foreign objects in your ear (such as Q-tips, bobby pins, and your fingernails).

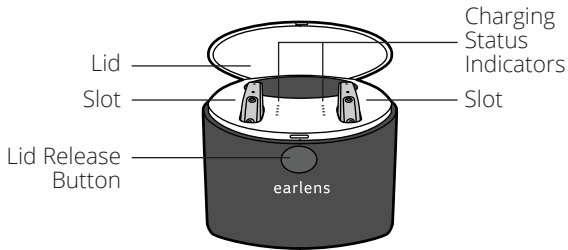
The Photon™ 2 Processor and Light Tip

The Processor sits comfortably behind your ear. It collects and sends sound signals to the Light Tip, which then converts the sound signals into non-visible light that is projected by the emitter. The light from the emitter is collected by the Lens.

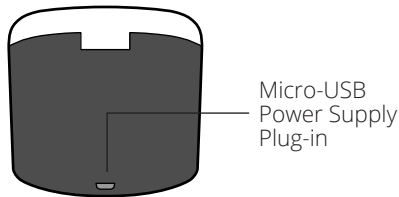


The Charger

The Charger can hold one or two devices. It features a USB-based AC wall power adaptor as its power source. The Charger includes an LED indicator display to let you know the charging status of your Processor(s).






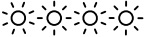


Front View of Charger



Back View of Charger

Charging Status Indicators

Charging Status Indicators		What It Means
	One flashing light	Charger connecting to Processor
	One solid light	Battery charging and below 33% charged
	Two solid lights	Battery charging and above 33% charged
	Three solid lights	Battery charging and 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

Mineral Oil

Mineral oil plays an important role in keeping the Lens in position and properly working. Apply two pumps of mineral oil to each ear twice a week, or follow the instructions of your physician if you are asked to use mineral oil more frequently. If you forget to apply the mineral oil to your ear as advised, your Lens may stop working or fall out. In the event that you forget to oil as scheduled, apply oil as soon as possible and then resume as advised.

Detailed mineral oil use instructions are available in the Care and Maintenance section of this manual.

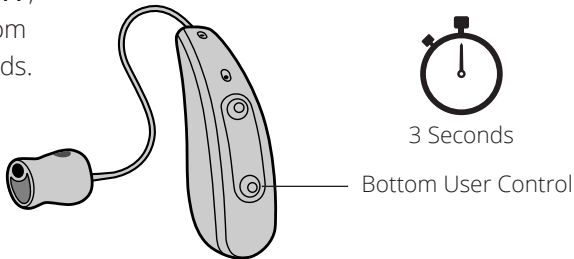


Using your Earlens Hearing Aid

Turning the Processor Off

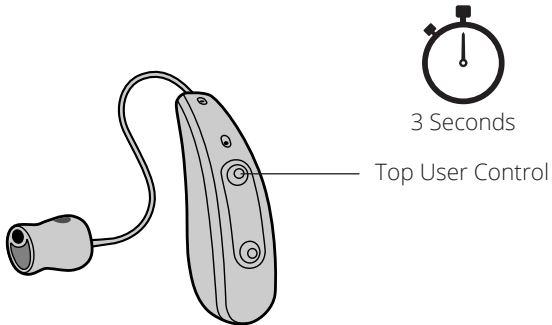
When you remove your Processor from a plugged-in Charger, it will be **ON**.

To turn the Processor **OFF**,
push and hold the bottom
user control for 3 seconds.



Turning the Processor On

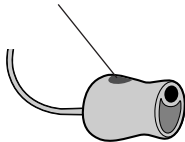
To turn the Processor **ON**, push and hold the top user control for 3 seconds.



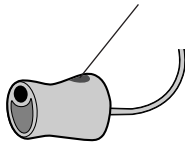
Identifying Left or Right Device

To identify a left or right device, look at the color of the indicator in the Light Tip.

Left
Blue indicates a
Left device

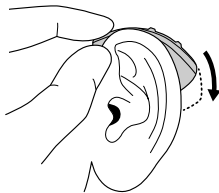


Right
Red indicates a
Right device



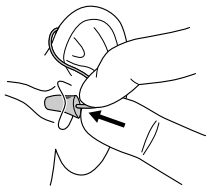
Putting on the Processor and Light Tip

It is important that the Light Tip is placed properly in your ear to optimally aim the light towards the Lens.



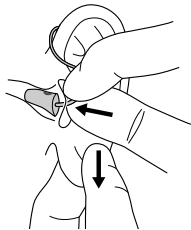
1

Place the Processor behind your ear, where it should rest comfortably.



2

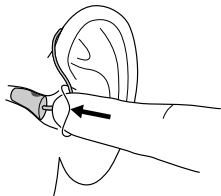
Hold the Light Tip between your thumb and index finger with the colored dot pointing up and the Positioning Lip pointing toward the back of the head.



3

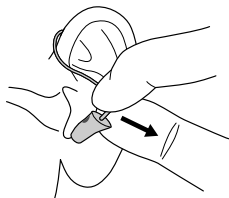
Slowly insert the Light Tip into your ear canal. Gently pulling your outer ear up and back may help with insertion.

Removing the Processor and Light Tip



4

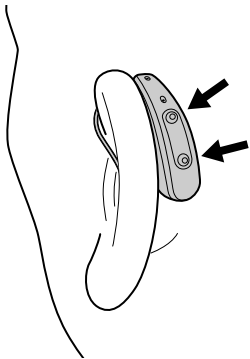
Gently push the Light Tip into your ear canal, pushing it as far as it will comfortably go, to ensure it is seated in the correct position.



1

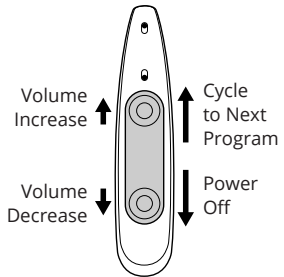
Grasp the Light Cable between your thumb and index finger near the Light Tip and gently pull it out of the ear canal.

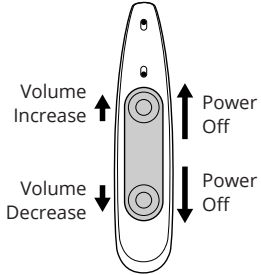
Changing Volume and Program



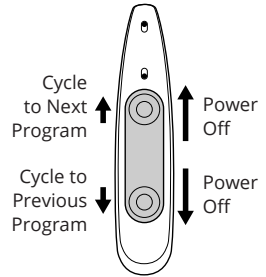
Your hearing professional can customize your user controls based on your preferences and needs. User controls can be set up to change volume, change programs or have multi-functionality to change both the volume and programs. Please discuss with your hearing professional how your user control settings have been customized and consult the tables on the next few pages for instructions.

User Control Options	Action/Press	
Volume & Program	Volume Increase = Short Press Up	↑
	Volume Decrease = Short Press Down	↓
	Cycle to Next Program = Long Press Up (3 seconds)	↑
	Power Off = Long Press Down (3 seconds)	↓

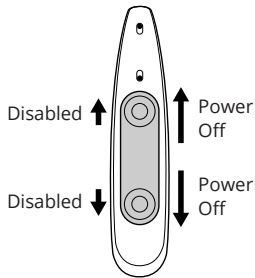


User Control Options	Action/Press	
Volume Only	Volume Increase = Short Press Up	
	Volume Decrease = Short Press Down	
	Power Off = Long Press Up (3 seconds)	
	Power Off = Long Press Down (3 seconds)	

User Control Options	Action/Press	
Program Only	Cycle to Next Program = Short Press Up	↑
	Cycle to Previous Program = Short Press Down	↓
	Power Off = Long Press Up (3 seconds)	↑
	Power Off = Long Press Down (3 seconds)	↓



User Control Options	Action/Press	
No Volume or Program Control Enabled	Disabled = Short Press Up	↑
	Disabled = Short Press Down	↓
	Power Off = Long Press Up (3 seconds)	↑
	Power Off = Long Press Down (3 seconds)	↓



Processor Alerts

Your hearing professional can program your Processor(s) to have a number of sound alerts that indicate a specific function. The following table provides a description of each alert.

Alert Type	Description of Alert	What it Means
Power On	3 tone melody	The Processor has powered on.
Power Off	4 descending tone melody	The Processor has powered off.
Battery	6 tone melody OR a voice alert that states "Battery"	The battery is low and the Processor will shut off in either 15 or 60 minutes.

Alert Type	Description of Alert	What it Means
Volume Change	1 quick beep	The volume has increased/decreased.
Default Volume Level	2 quick beeps	The volume is at the default programmed level.
Min/Max Volume	3 quick beeps	You are at the minimum or maximum limits of your volume control.
Program Change	P1 = 1 beep P2 = 2 beeps P3 = 3 beeps P4 = 4 beeps OR voice alerts that say the name of the program	The program has changed.

Telephone and Cellphone Use

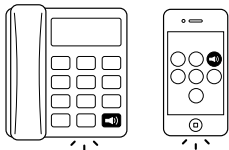
There are a few ways you can try to use your phone with your Earlens Hearing Aid.

1



Hold the upper portion of the phone over the microphones on your Processor, with the mouthpiece pointed towards your mouth.

2



If available, use the speaker phone feature on your phone.

3

The Earlens Hearing Aid features Made for iPhone compatibility. This feature allows you to take phone calls and stream media from your Apple device directly to your Processor(s). For the latest iOS and Apple device compatibility information, please go to www.earlens.com/connectivity.

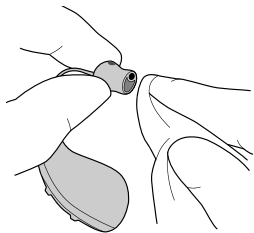
Charging and Battery Life

The Processor battery will last an average of 20 hours. It takes 4 hours in the Charger to completely recharge a fully depleted Processor battery. We highly recommend charging your Processor(s) in a dry and low-humidity location.

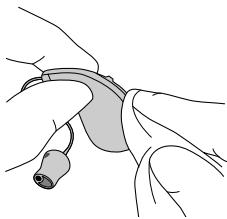
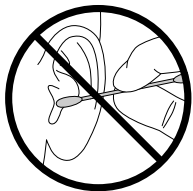
- 1 To charge, place the Processor and Light Tip into the Charger.
- 2 Wait until the indicator light turns solid to ensure the Processor is successfully charging.
- 3 If four indicator lights flash, the Processor is not charging. Remove the Processor from the Charger, replace back into the charging slot and immediately press of the top user control. If the indicator lights continue to flash, contact your hearing professional.

Cleaning and Maintenance

Daily Care



- 1 Check that there is no wax or debris on the Light Tip. If wax or debris is present, use a soft cloth, a baby wipe or other Isopropyl Alcohol (IPA) based wipes to remove.
- 2 If there is wax or debris in the Light Tip vent or covering the emitter, use a soft-bristle toothbrush, a pipe-cleaner or a hearing aid cleaning tool to gently clear the debris. Only perform cleaning when the device is off of the ear and **do not** use a sharp brush or tool when cleaning the Light Tip.



- 3** If you notice wax on the Light Tip, use a soft cloth to wipe the bowl of your ear. Never insert foreign objects into the ear, such as Q-tips, bobby pins or your fingernails. Insertion of foreign objects could result in pain, may damage your ear and may cause damage to the Lens.
- 4** Wipe the Processor with a soft cloth if you notice any moisture or debris.
- 5** Never use chemicals on the Processor or Light Tip.
- 6** Use a soft cloth to wipe the Charger when necessary.

Oiling Instructions (twice a week)

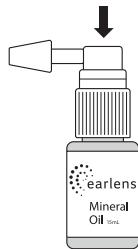
Oiling is required to keep the Lens in place and functioning properly. Apply two pumps of mineral oil to your ear canal at a minimum of twice a week.

Follow the instructions provided by your physician if he or she asks you to oil on a different schedule. If you have difficulty applying the mineral oil, consider having another person assist you.

Instructions for Oiling:

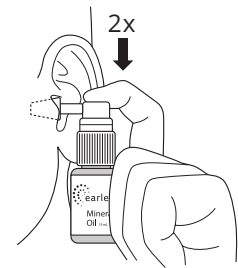
We recommend you oil your ears at bedtime, after you have removed your devices for the day. After you oil, you may notice a slight decrease in your hearing, which is temporary.

- After oiling, your ears may feel a little stuffy. This should subside on its own when the oil is absorbed.
- It is recommended that you reapply mineral oil after you go swimming, take a bath or enjoy any other activity that causes your ear canals to fill with water.
- Use only the mineral oil and container provided and/or recommended by your hearing provider or Earlens.



1

Before each use, prepare the mineral oil by depressing the pump until a constant stream is observed.



1-2 Minutes



- 2 With your head in an upright position, place the cone tip of the dispenser fully into the ear canal opening. Dispense **two pumps** of oil into the ear canal by depressing the pump twice.
- 3 Remove the dispenser from the ear and tilt your head to the side. Allow oil to run down to the eardrum by keeping your head tilted for **one to two minutes**. You may hear or feel the oil when it reaches the eardrum.
- 4 Repeat on the opposite ear.

Avoiding Moisture & Heat

Moisture and heat can damage your EarLens Hearing Aid. You can avoid this by taking these steps:

- Do not leave your devices in extreme heat.
- Do not wear your processor(s) in heavy rain, steam baths or showers.
- Do not dry your devices in a microwave or with any other heat source.
- Take off your processor(s) when applying hairspray, perfume, aftershave, insect repellent or any other harsh chemical as it can damage your device.
- If there is moisture on any component, wipe it off.

Warranty

Your Earlens Hearing Aid is covered by a warranty. Please talk to your hearing provider about the details of your warranty. You can register your Earlens Hearing Aid online at: www.earlens.com/register

Warranty Period

Start Date: _____

End Date: _____

Troubleshooting

Issue	Possible Causes	Possible Remedy
No sound	Battery is not charged.	Charge the Processor until at least 2 solid lights appear. If 2 or more solid lights appear, the battery is not the issue, contact your hearing professional.
Not loud enough	The Light Tip is covered with wax.	Wipe down with a soft cloth, baby wipe or other Isopropyl Alcohol based wipes to remove wax.
	The Light Tip is improperly inserted.	Remove and re-insert the Light Tip and check the position in a mirror if possible.
	Volume is set too low.	If your device features volume user control functionality, increase the volume. If you still require more volume, contact your hearing professional.

Issue	Possible Causes	Possible Remedy
Damage to Light Tip or Light Cable	Wear and tear.	Contact your hearing professional.
Sound distorted/ not clear	Battery is low.	Charge the Processor until at least 2 solid lights appear.
	Hearing aid is damaged.	Contact your hearing professional.
	Hearing aid setting is not optimal.	Contact your hearing professional.
Charger is flashing 4 lights	Something is wrong with the Charger or Processor.	Remove the Processor from the Charger, re-insert the device into the charging slot and immediately short press the top user control. Repeat removal and insertion up to 5 times. If the lights continue to flash, contact your hearing professional or call the EarLens Concierge at 1-844-730-5986.

Issue	Possible Causes	Possible Remedy
Whistling (feedback)	The Light Tip is not properly inserted.	Remove and re-insert the Light Tip and check the position in a mirror if possible. If the issue persists, contact your hearing professional.

Warnings



Before using the Earlens Hearing Aid, make sure you read and understand each of the following safety warnings:

- The Earlens Hearing Aid is considered MR 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.**

- You should not use therapeutic or medical diathermy using electromagnetic radiation (magnetic induction coils or microwave) from the shoulders up with Earlens Hearing Aid in place.
- The Processor and Light Tip unit contain a Class 1 laser product. It is safe to use under normal operating conditions. The Class 1 laser light is NOT visible. Do NOT look directly into the laser or aim directly into the eyes. Should any part of the Aid become damaged, discontinue use and contact your hearing professional.
- If you experience discomfort or pain in your ear, you should contact the ENT physician immediately. Only physicians trained in Ear, Nose & Throat procedures should place or remove the Lens.
- Do not insert foreign objects into your 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.
- Contact your hearing professional if you experience discharge from the ear or persistent discomfort or any other problems.

CLASS 1 LASER
PRODUCT

- Should the Processor become unusually warm or hot, promptly remove it, discontinue use and contact your hearing healthcare professional.
- Do not crush, short circuit, modify or disassemble any component of the Earlens Hearing Aid. Keep all components of the Earlens Hearing Aid out of the reach of children, pets and others, to avoid risk of swallowing.
- Do not incinerate any component of the Earlens Hearing Aid or use near an open flame. Handle waste from electronic equipment per local regulations.

Precautions



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

- If you have known nickel sensitivity/allergy, please be aware that the Lens component contains nickel that is coated with a parylene barrier. If you develop an allergic reaction, the Lens should be promptly removed.

- The Lens was 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 within the 1 year expected life.
- Only healthcare professionals trained in the fitting of hearing aids may fit the Processor and Light Tip.
- The EarLens Hearing Aid is custom designed and intended to be used only by a single patient.
- The Light Tip is designed to sit a set distance from the Lens. Sound output may deviate if the Light Tip is not inserted to the proper depth. If the sound output does deviate, you can reposition the Light 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.
- You may shower, bathe or swim with the Lens in place. Ear plugs may be used to prevent water from entering your 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 you have small or unusually shaped ear canals, you may be at greater risk for ear canal abrasions, either from the ear impression procedure or from Light Tip use.
- You should avoid getting the Processor wet, as it may damage the device. You must remove the Processor prior to showering, swimming, or bathing.
- You may experience a reduction in your 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 your ears, as this may cause the Lens to become dislodged or cause damage to the device.
- Failure to oil your ear canal twice a week may result in Lens displacement.
- Do not place any component of the Earlens Hearing Aid into a microwave, or near a significant source of static electricity.
- Use only the Earlens Charger and AC wall adaptor provided. Although other adaptors may look similar, they may cause damage to the Earlens Hearing Aid.

- Handle the components carefully and prevent hard knocks. Do not drop them as it may damage the Earlens Hearing Aid.
- If the Earlens Processor fails to operate or if it appears damaged, including the presence of battery leakage or swelling, promptly remove the Processor, discontinue use and contact your hearing 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 Hearing Aid. In the event that you perceive unexpected noise or interference in the presence of these devices, move away from the source to mitigate the potential interference. If you have further concerns you should remove the Processors and contact your hearing healthcare professional.

Technical Information

Earlens Hearing Aid FCC ID: 2AGDU-EL1.

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.

IMPORTANT! Changes or modifications not expressly approved by Earlens Corporation 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 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.

Device Labeling Symbols



Refer to
Instruction
Manual



Date of
Manufacture



MR Unsafe



Dispose
Electronic
Waste Properly



Product is a
Type BF Part



Keep Dry



Serial Number



Batch Code



Catalog Code



Ingress
Protection
Code



Class 1 Laser
Product

Rx Only

By Prescription
Only



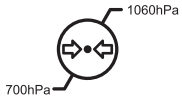
Humidity
Limitation



Equipment
Includes an
RF Transmitter



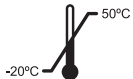
Caution



Atmospheric
Pressure
Limitation



FCC Approved
Equipment



Storage
Temperature
Limit

“Made for iPod,” “Made for iPhone,” and “Made for iPad” mean that an electronic accessory has been designed to connect specifically to iPod, iPhone, or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPod, iPhone, or iPad may affect wireless performance.

Apple, the logo, AirPlay, iPhone, iPad, iPod are trademarks of Apple Inc., registered in the U.S. and other countries.





Manufactured by:

Earlens Corporation, Inc.

4045A Campbell Ave.

Menlo Park, CA 94025 USA

+1 (844) 234-LENS

www.earlens.com



©2018 Earlens, Inc. All rights reserved. LBL00142vC February 2018
Patent Protected/Pending: www.earlens.com/patents