



Earlens Photon Hearing Aid User Manual



Earlens Photon Hearing Aid 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 Earlens Customer Service 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.

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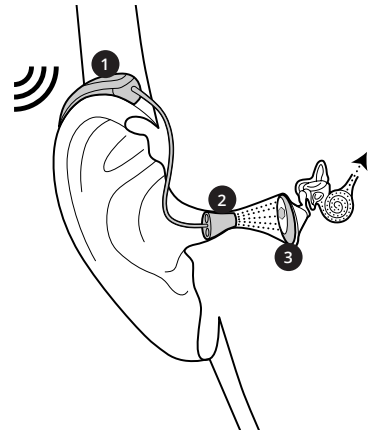
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Getting to Know Your Earlens Hearing Aid

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™ 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 Photon™ 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 Earlens Photon 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.

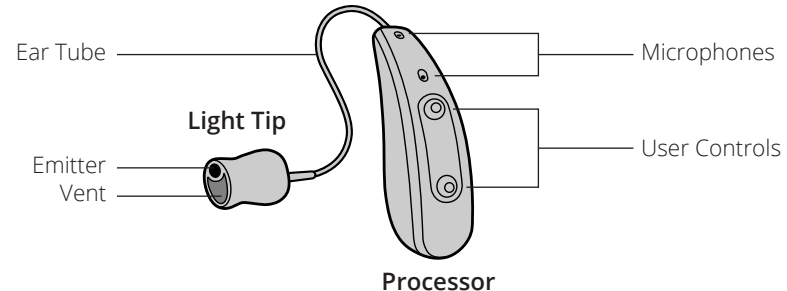


The Lens

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 mineral oil weekly and do not put foreign objects in your ear (such as Q-tips, bobby pins, and your fingernails).

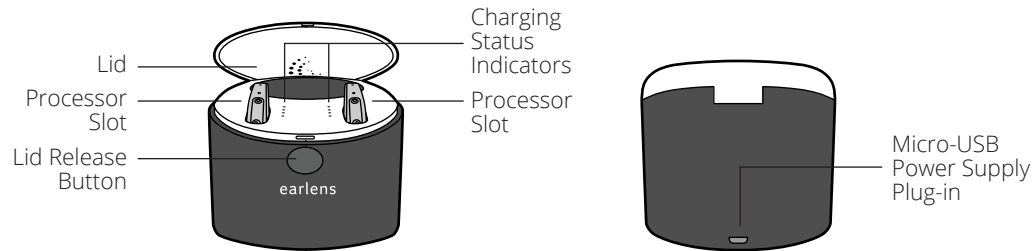
The Photon™ Processor and Light Tip

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 devices.



Front View of Charger

Back View of Charger

Charger Indicator Lights

Charger Indicator Lights		What It Means
	Single flashing blue light	Charger is attempting to connect with the Processor
	One solid blue light	Battery is charging and less than 33% charged
	Two solid blue lights	Battery is charging and is 33% charged
	Three solid blue lights	Battery is charging and is 66% charged
	Four solid blue lights	Battery is fully charged
	Four flashing blue lights	Charger is unable to connect with the Processor and is not charging

Mineral Oil

Mineral oil plays an important role in keeping the Lens in position and properly working. Apply two drops of mineral oil to each ear once 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.

Download the Earlens Control app to your Apple device to set an easy reminder for when to apply mineral oil.

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

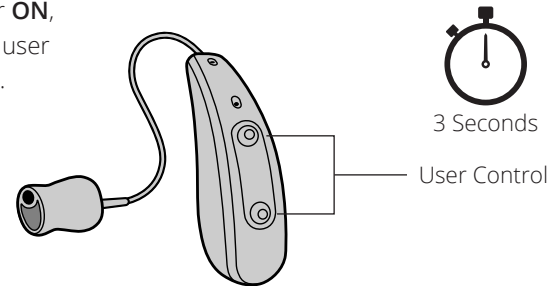


Using your Earlens Hearing Aid

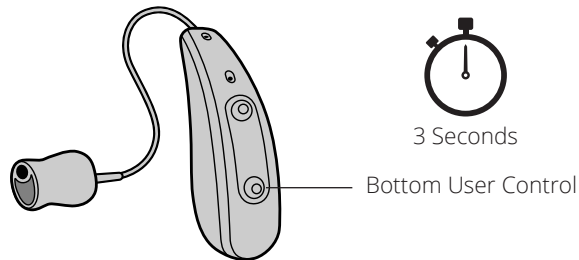
Turning the Processor On/Off

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

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



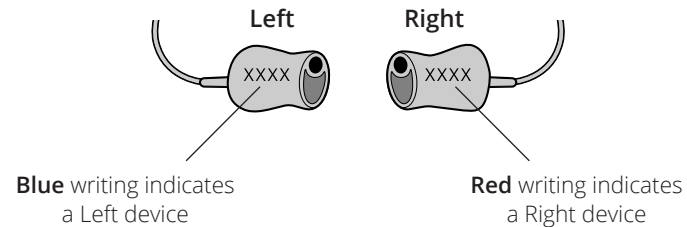
- 2 To turn the Processor **OFF**, push and hold the bottom user control for 3 seconds.



Identifying Left or Right Device

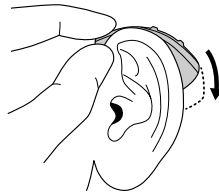
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To identify a left or right device, look at the color of the serial number printed on the Light Tip.



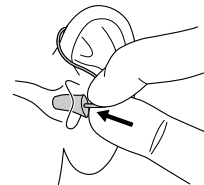
Putting on the Processor and Light Tip

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



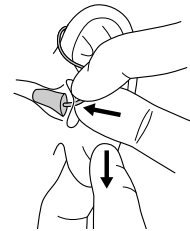
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Place the Processor behind your ear, where it should rest comfortably.



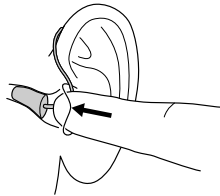
2

Hold the Light Tip between your thumb and index finger, with the serial number on the Light Tip oriented towards the back of your head.



3

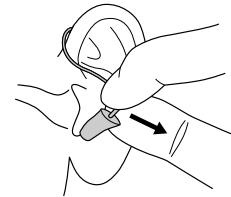
Slowly insert the Light Tip into your ear canal. You may need to move the outside of your earlobe up and down to help with insertion.



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.

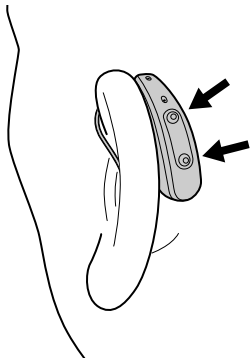
Removing the Processor and Light Tip



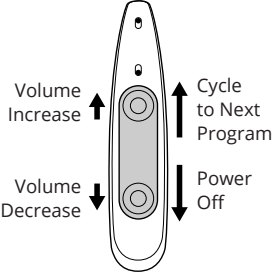
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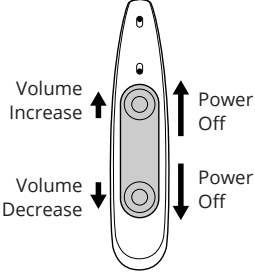
Grasp the Ear Tube between your thumb and index finger near the Light Tip and gently pull it out of the ear canal.

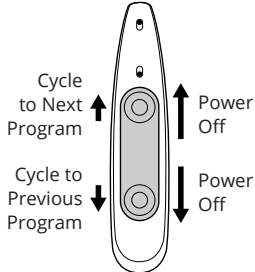
Changing Volume and Program

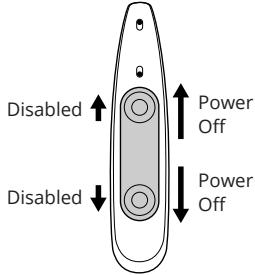


Your hearing professional can customize your user controls based on your preferences and needs. User controls can be set up to change volume, change programs or have multi-functionality to change both the volume and programs. Please discuss with your hearing professional how your user control settings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

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

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

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

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

Processor Alerts

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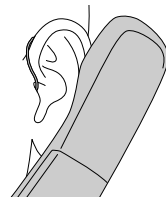
Your hearing professional can program your Processors to have a number of sound alerts that indicate a specific function. The following table provides a description of each alert.

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	You are at your home volume setting.
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.

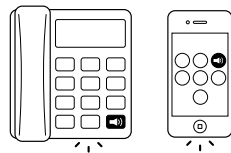
Telephone and Cellphone Use

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 If you have a mobile phone with Bluetooth technology, you may be able to directly stream your phone calls from your cell phone to your Earlens Hearing Aids. Please talk to your hearing professional or go to www.earlens.com for more information.

Charging and Battery Life

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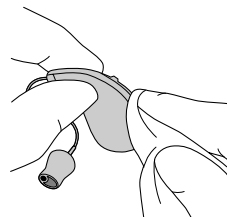
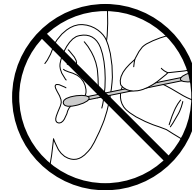
The Processor battery will last an average of 24 hours or more and a minimum of 16 hours on a full charge. It takes 4 hours in the Charger to completely recharge a fully depleted Processor battery.

- 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 the indicator lights flash, the Processor is not charging. Remove the Processor from the Charger, re-insert the device into the charging slot and immediately short press 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, 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.

Weekly Oiling

Oiling is required to keep the Lens in place and functioning properly. Apply 2 drops of mineral oil to your ear canal at a minimum of once per 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.

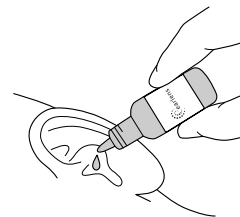
Instructions for Oiling:

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



1

Tilt your head to the side. Many users find that using a mirror or lying on their side is helpful when applying oil.

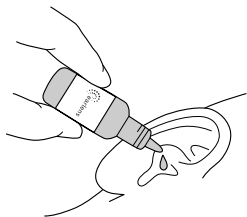


2

Apply the drops of mineral oil at the entrance of the ear canal. Allow the drops to run down to your eardrum by keeping your head tilted for one minute. You may hear or feel the oil when it reaches the eardrum.



1 Minute



3

Repeat for the opposite ear.

- 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.

Avoiding Moisture & Heat

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

- 1 Do not leave your device in extreme heat.
- 2 Do not wear your device in heavy rain, steam baths or showers.
- 3 Do not dry your device in a microwave or any other heat source.
- 4 Take off your device when applying hairspray, perfume, aftershave, insect repellent or any other harsh chemical as it can damage your device.
- 5 Wipe off your device if there is moisture on it.

Warranty

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Your hearing aid is covered by a warranty. Please talk to your hearing provider about the details of your warranty.

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.
	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.
Not loud enough	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 Ear Tube	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 lights flashing	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. If the indicator lights continue to flash, contact your hearing professional.

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 weekly 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



Catalog Code



Serial Number



Dispose Electronic
Waste Properly



Date of Manufacture



Caution



Keep Dry



Product is a Type BF Part



MR Unsafe

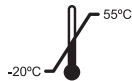
Rx Only

By Prescription Only



0459

CE Mark



Storage Temperature Limit



Class 1 Laser Product



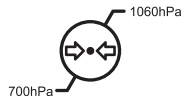
FCC Approved Equipment



Batch Code



Humidity Limitation



Atmospheric Pressure
Limitation



Equipment Includes an
RF Transmitter

“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.



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