

LINER  
OTC RIC Hearing Aids




Quick Start Guide

## Warranty

The warranty period for LINNER Mercury is one year from the date of purchase.

## Global customer service

If you encounter with any quality issue, please feel free to contact our support team, we are always glad to help.

 +1(888) 819-1558 ( 9am - 5pm Mon-Fri Pacific Time )

 support@linnerlife.com ( response within 24hours )

 www.linnerlife.com ( FAQ / instruction video )

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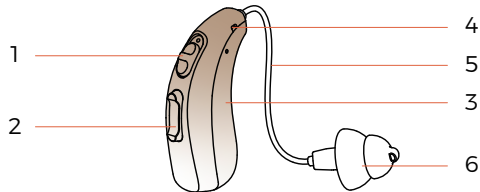
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# 01

## Know Your Hearing Aids

### Interfaces Accessory

#### Interfaces



#### Structure

1 Power ON/OFF

2 Volume Control/  
Program Switch

3 Shell

4 Microphone

5 Receiver

6 Ear Domes

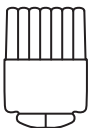
(The appearance shall be subject to the actual situation)

## Accessory

Cleaning tool



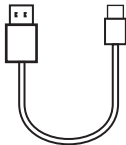
Replaceable tips



Extra domes



Type-C charging cable

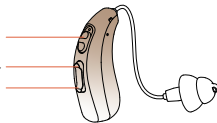


## Controls

Power Button

Volume+/Mode+

Volume-/Mode-



Item	Function	Operation
Power Control	Power on	Slide down power button
	Power off	Slide up power button
Volume Control	Left ear volume +	Click upper button for once
	Left ear volume -	Click bottom button for once
	Right ear volume +	Click upper button for once
	Right ear volume -	Click bottom button for once
Mode Switch	Left ear previous mode	Hold upper button for 2s
	Left ear next mode	Hold bottom button for 2s
	Right ear previous mode	Hold upper button for 2s
	Right ear next mode	Hold bottom button for 2s

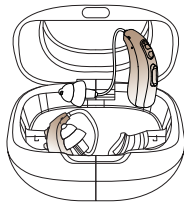
# 02

## Use Your Hearing Aids

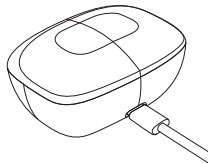
Charging  
Wearing  
Power on/off

### Charging

Put hearing aids into charging case, the charging case will charge hearing aids automatically.



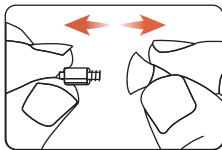
Connect charging case to any active charging port with included charging cable.



## Wearing

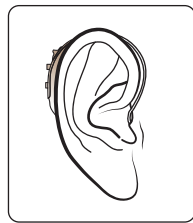
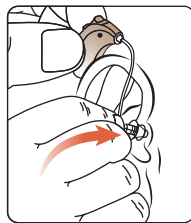
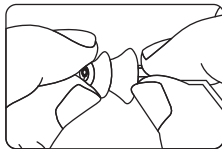
### 1) Fit Ear Domes

Remove earplugs: pinch the earplugs with your thumb, index finger and middle finger to separate the earplugs from the connector.



### 2) Fit Earplugs

Select appropriate earplugs according to the size of the ear canal, hold the earplugs and fit them into the connector of the hearing aid. They are required to be fitted in place.

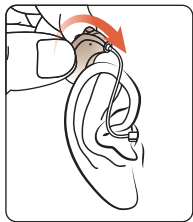


### 3) Wear hearing aids

Hold the bottom of the tube with your fingers and gently push the earplug into the ear canal.

### 4) Adjust hearing aids

Put the hearing aid behind the ear, and close to the head and comfortably over the pinna.



## 5) Remove hearing aids

Take off the hearing aids behind the ears.

Hold the bottom of the sound tube and pull it gently. After the earplug is loose, take it out and take it off together with the hearing aids.

## Power on/off

### Power on

Slide down power button, hearing aids will turn on, the hearing amplification will be enabled after 5 seconds.

### Power off

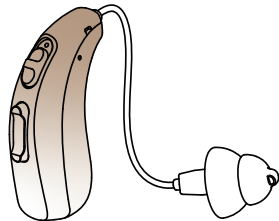
Slide up power button, the hearing aids will turn off.

### Battery life

The hearing aids can work for more than 20H when the battery is fully charged. The full charging boxes can charge hearing aids 3 times.

Model:FHE512,  
Input:DC5V $\approx$ 200mA,  
Output:DC4.2V $\approx$ 50mA,  
Battery:DC 3.7V 300mAh 1.1Wh

Power Adapter:  
Input:100-240V-50/60Hz, max 150mA,  
Output:DC5V $\approx$ 1A.



# 03

## Trouble Shooting

### Trouble Shooting

### Hearing Aid Maintenance and charging boxes

### Hearing Aid Maintenance

### Others

### Product Information

## Trouble Shooting

Problem	Cause	Solution
Whistling	Hearing aids is not worn correctly	Hearing aids is not worn correctly
	Too much earwax	Clean earwax or contact with an audiologist
Silent	Power off	Turn it on
	Low battery or no power	Charge the hearing aids
	Dirt blocks the earplug or tube	Clean the hearing aids
Small sound	Low volume	Turn up the volume
	Low battery	Charge the hearing aids
	Hearing aid is damped	Dehumidify it with a dry box
	Dirt blocks the earplug or tube	Clean the sound tube or the earplugs
High power Consumption	Hearing aid is still on when not in use	Please turn it off when hearing aid is not in use
	Hearing aid is damped	Dehumidify it with a dry box
Intermittent Sound	Dirt blocks the sound tube	Clean the sound tube
	Dirt blocks the earplugs	Clean the earplugs

If the above methods still cannot solve the problem, please contact the customer service center of our company directly.

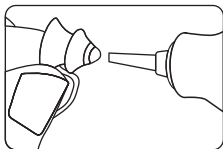


## Hearing Aid Maintenance and charging boxes

During the use of hearing aids, earwax (cerumen) produced by the ears will accumulate in the ear canal and the sound hole of the hearing aid. A large amount of accumulated earwax will affect the use effect of the hearing aid, so please clean your ear canal and maintain the hearing aid regularly.

### a) Clean Ear Domes

Remove the ear domes from the hearing aid, clean the earwax with a cleaning cloth or wash the ear domes with clean water, and wipe the ear domes dry. Please make sure there are no water droplets left. If there are tools like blowing balloons, you can use blowing balloons to dry the water droplets.



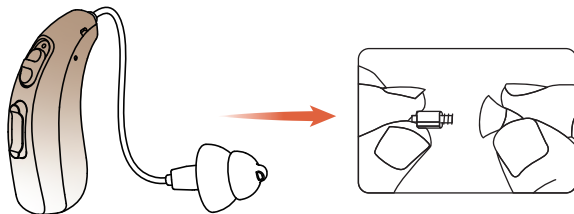
please clean and maintain the charging boxes regularly.



### b) Replace Ear Domes

#### 1. Remove Ear Domes

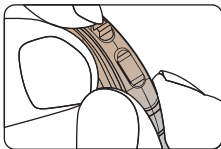
Hold the ear domes and sound tube connector with your left and right hands respectively to separate the ear dome and sound tube.



#### 2. Fit Ear Domes

### c) Clean Hearing Aid and charging box

- Please clean your hearing aid with a dry soft cloth.
- When wiping or cleaning the hearing aid, please do it on a soft desktop (for example, put a soft towel on the desktop) to avoid damage caused by accidental falling of the hearing aids and charging box.



**Remember:** do not use any liquid to clean the hearing aid and charging box.

### d) Dehumidification for Hearing Aids:

Please put the hearing aid in a special drying box to keep away from damaging moisture before sleeping every night for extending the life of the hearing aid.



**Remark:** Special drying box needs to be purchased separately.

### e) Anti-vibration:

If you don't use them when going out, please put the hearing aid in the shockproof box or shockproof bags.

## Hearing Aid Maintenance

### a) Dehumidification :

Any form of moisture is influential for hearing aid, dehumidification can extend the life of the hearing aid. Avoid using or storage in humid environment, and please dry the hearing aid on a regular basis.

### b) Water Prevention:

Avoid hearing aid contact with water. Remove the hearing aid when you are swimming, taking a shower, washing your hair, washing your face. If hearing aid accidentally falls into the water, do not use a dryer to dry it. You can dry it with a soft clean cotton cloth and put it in a ventilated environment. If a failure occurs, please contact with your local audiologist or contact with the staff from customer service center.

### c) High Temperature Prevention:

Never exposing hearing aids on extreme temperatures or prolonged exposure to sunlight.

### d) Falling Prevention:

Please do not drop your hearing aids or knock them against hard surfaces.

### e) Precautions for Electromagnetic Compatibility

- Classification by anti electric shock type: Internal power supply equipment.
- Classification according to the degree of protection against electric shock: Type B application part.
- Classification by operation mode: Continuous operation equipment.

### Notes: The Hearing Aid conforms to IEC60601-1-2 EMC and IEC 60118-13 requirements.

It is the responsibility of the user to ensure the electromagnetic compatibility environment of the instrument to function properly. User must install and operate the device based on the provided EMC information.

It is recommended to evaluate the electromagnetic environment before using the instrument to ensure that the surrounding environment will not cause strong electromagnetic interference to the instrument, otherwise it may interfere with the normal operation of the equipment.

Instructions for use: The ME EQUIPMENT or ME SYSTEM is suitable for healthcare environments and so on.

**Warning:** Only the power adapter and battery approved by manufacturer can be used. In order to avoid damage to the instrument, please do not change the charging parts.

Even if other devices meet the emission requirements of the corresponding national standards, the Hearing Aid may still be interfered by other devices.

**Warning:**In the home environment, this equipment may cause radio interference, so protective measures should be taken. It is forbidden to use the equipment near strong radiation source (such as unshielded RF source), otherwise it may interfere with the normal operation of the equipment.

**Warning:** Portable or mobile RF communication device might influence the performances of Hearing Aid, please avoid strong electromagnetic disturbance while using, such as close to the Hearing Aid, microwave oven, etc .

**Warning:** Use of this equipment adjacent to or stacked with other

**Warning:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Hearing Aid, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**Warning:**Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”

**Warning:**Do not approach active high-frequency surgical equipment and magnetic resonance imaging systems in radiofrequency shielded rooms, where the intensity of EMI disturbances is high.

**Warning:** Do not near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

**Warning:** Make sure that all electrical accessories connected to the Hearing Aid must comply with IEC 60601-1, if in doubt, consult the

technical service department or your local representative.

**Warning:** No unauthorized modification allowed of the ME EQUIPMENT.

According to the design purpose, the equipment complies with EMC regulations. Including the allowable electromagnetic interference level and necessary electromagnetic shielding performance of the electronic equipment specified by laws and regulations.

The complete elimination of electromagnetic interference is almost impossible unless all equipment that may produce high-frequency signals are excluded. Although some high-frequency equipment itself meets the requirements of EMC regulations, it is impossible to determine whether the radio signal generated by its high-frequency transmitter will affect the normal operation of the equipment when it works with considerable power near the equipment order to ensure the electromagnetic compatibility of the equipment, the equipment needs to be installed, debugged and used according to the attached documents. In case of such situation, please contact the personnel of the company for solution.

This equipment generates, uses, and can radiate RF 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:

- Operate in strict accordance with the instructions of the Hearing Aid instruction manual to ensure that the device is not subject to electromagnetic interference.
- Keep other devices away from this device to reduce the effects of electromagnetic interference.
- Reorient or relocate the receiving antenna. The effect of electromagnetic interference can be mitigated by adjusting the relative position/mounting angle between the device and other devices.
- Reduce electromagnetic interference by changing the wiring location of other device power/signal cables.
- Reduce electromagnetic interference by changing the power path of other devices.

**TABLE 1**

<b>Guidance and manufacturer's declaration-electromagnetic emission</b>		
The Hearing Aid is intended for use in the electromagnetic environment specified below. The customer or the user of the Hearing Aid should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Hearing Aid 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 equipment.
RF emissions CISPR 11	Class B	The Hearing Aid suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

**TABLE 2**

<b>Guidance and manufacturer's declaration-electromagnetic</b>			
The Hearing Aid is intended for use in the electromagnetic environment specified below. The customer or the user of the Hearing Aid should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material.
IEC61000-4-2	±2, 4, 8, 15 kV air	±2, 4, 8, 15 kV air	
Electrical fast transient/burst	± 2 kV for power supply lines	± 2 kV for power supply lines	N/A
IEC61000-4-4	± 1 kV for input/output lines		
Surge IEC 61000-4-5	± 1 kV differential mode	± 1 kV differential mode	N/A
	± 2 kV common mode		

Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	Dips: 0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270 and 315° 0% UT for 1 cycle at 0°	Dips: 0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270 and 315° 0% UT for 1 cycle at 0°	N/A
	70% UT for 25 cycles (50Hz), 30 cycles (60Hz) at 0°	70% UT for 25 cycles (50Hz), 30 cycles (60Hz) at 0°	
	Interruptions: 0% UT for 250 cycles (50Hz), 300 cycles (60Hz)	Interruptions: 0% UT for 250 cycles (50Hz), 300 cycles (60Hz)	
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<b>NOTE:</b> UT is the a.c. mains voltage prior to application of the test level.			

TABLE 3

Recommended separation distances between portable and mobile RF communication the equipment			
The Hearing Aid is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The Hearing Aid can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hearing Aid as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W(Watts)	Separation distance according to frequency of transmitter M (Meters)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	80MHz to 2.5GHz $d=2.3\sqrt{P}$
0,01	N/A	0.12	0.23
0,1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be determined 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.			
<b>NOTE 1 :</b> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
<b>NOTE 2 :</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

## Others

- The button should be used correctly and pressed gently as far as possible to avoid excessive force.
- The hearing aid professional for RECD measured to correct target of fitted OSPL90.
- Only to connect to equipment that conforms with international safety standards, if externally connected.
- This product will not restore normal hearing and will not prevent or improve hearing impairment resulting from organic conditions. This product is designed to help you make greater use of your remaining hearing. You should keep in mind that it can take time to become accustomed to hear new sounds.
- For best results, using the hearing aids as much as possible. In most of time, infrequent use of the hearing aids doesn't permit you to attain full benefit from them.
- The use of a hearing aid is only part of hearing rehabilitation and may need to be supplemented by auditory training and instruction in lipreading.

## Unpack and Check

- After unpacking, please check the actual category and quantity of accessories.
- Check the model marked on the manual is consistent with the model of hearing aid.






















### CAUTION

#### Contraindication

Patients with acute otitis external, tympanitis, chronic suppurative otitis media (in the period of purulent infection), acute suppurative otitis media and allergic to this material. Fitting hearing aid shall be undergone professional hearing test and fitting, and be used under the professional guidance of a doctor or a audiologist.



	Symbol for "User Guide must be read"		Symbol for "Consult instructions for use"
	Symbol for "MANUFACTURER"		Symbol for "Keep dry"
	Symbol for "Fragile, handle with care"		Symbol for "SERIAL NUMBER"
	Symbol for "Caution and warning"		Type B Applied Part
	Symbol for "Date of manufacture"		Symbol for "Note"
	Symbol for "Use-by date"		Indicates the device is a medical device
	Indicates a carrier that contains unique device identifier information		Indicates a medical device that needs protection from light sources
<b>IP22</b>	IP22: The first number 2: Protected against solid foreign objects of 12,5 mm $\phi$ and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15°		The harmful substances in the product meet the limited requirements.
	This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.		

	During transport or storage, the temperature should not exceed the limit values of -20° to 50° Celsius for a long period of time.
	The air pressure range between 86 and 106 KPa is appropriate.
	During transport or storage, the relative humidity should not exceed the limit values of 0% to 93% for a long period of time.

For each warning and safety sign, the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK.



**Manufacturer:** Austar Hearing Science & Technology (Xiamen) Co., Ltd.

**Address:** Building B8, Biomedical Industrial Park, No. 2064 Wengjiao West Road, Haicang District, Xiamen, China

**Preparation date:** 2023.06

## Product Information

### Main Application and Scope

Digital rechargeable RIC hearing aid is an assistive instrument which is used for compensation of the patient's hearing loss. It is applicable for the hearing loss with conductive, sensorineural and mixed-typed hearing loss caused by senility, tympanitis and disease etc.

### Product Model

FHE512

### Program Setting

Program	Features
P1	Normal Output
P2	Low Frequency Cut and High Frequency Cut
P3	High Frequency Cut

### Environment and Conditions Working environments:

Temperature: 0°C~+40°C, (32°F ~ 104°F), Humidity: 0%~80%RH, Voltage: DC 1.4V. Storage environments:

Temperature: -20°C~+50°C, (-4°F ~ 122°F), Humidity: 0%~93% Atmospheric pressure: 86KPa~106KPa.

Storage conditions: Room temperature, clean, dark, no corrosive gas and well ventilated room.

Transportation conditions: The packaged hearing aids can be transported by general cargo transportation method, and shall be protected from rain, exposure and collision during transportation.

## Impact on the Environment

Hearing aid is built in the rechargeable Lithium battery, please dispose of the afterused battery regarding of local regulations to protect the environment.

## Safety

Danger: To avoid being swallowed by children in accident, please keep the hearing aid away from children.

-Those who have undergone ear canal surgery are not recommended to buy this product directly. They should go to the hearing center to consult with an audiologist or a doctor before purchasing.

-A hearing aid should not be applied to both ears at the same time. Because the hearing loss of the right or left ear is different.

In case of battery leakage, please stop using the hearing aid and contact the customer service center.

-To avoid remove the hearing aid ear dome leaving it in the ear, wear and remove hearing aids gently.

-Hearing aid designed in a way that users cannot be unintentionally exposed to a SPL above the fitted OSPL90 in normal condition.

For hearing aids, the patient is also the operator.

## Technical Specification

Model	MAX OSPL90 (dB)	HFA OSPL90 (dB)	Peak Gain (dB)	HFA FOG (dB)	Latency (ms)	THD at		
						500Hz	800Hz	1600Hz
FHE512	<117	105	35	30	<6	≤5%	≤5%	≤5%

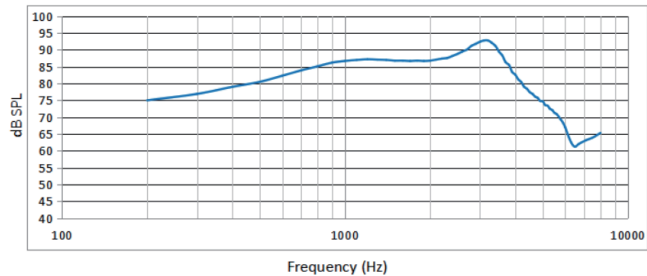
Model	Frequency Range (Hz)	Eq. Input Noise Level (dB)	Battery Current Drain(mA)	Attack Time (ms)	Release Time (ms)
FHE512	F1≤200; F2≥5000	<32	≤2	100	500

## Usage Period

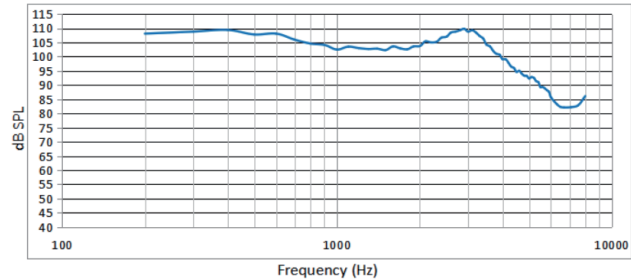
5 years

## Response Curve

### Reference Test Gain (60dB SPL)



### Maximum Output(OSPL90)



## Warnings

### **WARNING: If you are younger than 18, do not use this.**

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older. This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

### **WARNING: When to See a Doctor**

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.

- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable.
- Your ear feels painful or uncomfortable.
- You have a lot of ear wax, or you think something could be in your ear.
- You get really dizzy or have a feeling of spinning or swaying (called vertigo).
- Your hearing changed suddenly in the past 6 months.
- Your hearing changes: it gets worse then gets better again.
- You have worse hearing in one ear.
- You hear ringing or buzzing in only one ear.

### **WARNING: This hearing aid should not cause pain when inserting it.**

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

**These PRECAUTIONS point out situations which could cause minor or moderate injuries to the user or to the hearing aid.**

- You should familiarize yourself fully with the entire contents of this user manual before using the hearing aid to ensure personal safety and correct use. Contact the manufacturer for support if you experience unexpected operations or performance.
- Do not attempt to modify the shape of the hearing aid or slim tube yourself.

**These WARNINGS point out situations which could cause serious injuries to the user or to the hearing aid.**

- In some acoustic environments, over amplification can cause discomfort and damage to the patient's hearing.
- A hearing aid should only be used as directed by your physician or hearing healthcare provider.

- Do not use your hearing aid in explosive or oxygen-enriched areas. Allergic reactions to hearing aids are unlikely. However, if you experience itching, redness, soreness, inflammation, or a burning sensation in or around your ears, inform your hearing healthcare provider and contact your physician.
- You may notice accelerated accumulation of earwax when using your hearing aid. This is normal, but see your hearing healthcare provider if you continue to have difficulty.
- In the unlikely case that any parts remain in the ear canal after the removal of the hearing aid, contact a physician immediately. Report the event to your hearing healthcare provider as soon as possible.
- Remove your aids for CT and MRI scans or for other electromagnetic procedures.
- Never leave your hearing aids or batteries where small children and pets can reach them. If batteries are swallowed or inhaled, contact the local poison control center immediately.
- If you feel pain in or behind your ear, if it is inflamed, if skin irritation or accumulations of ear wax occur, please check with your hearing healthcare provider or physician.
- Your hearing aids have been adjusted for your hearing needs; please do not share your hearing device with other people.

## Caution and notices for users

**Caution: This is not hearing protection.**

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

**Caution: The sound output should not be uncomfortable or painful.**

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

**Caution: You might need medical help if a piece gets stuck in your ear.**

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

## Note: If you remain concerned, consult with a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

## Note: What you might expect when you start using a hearing aid.

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss. People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.

**Note: Tell FDA about injuries, malfunctions, or other adverse events.**

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088. You can also download a form to mail to FDA.