

User Manual

Rechargeable OTC Hearing Aids

FCC ID:2A445FAX916-B-L

FCC ID:2A445FAX916-B-R

FCC ID:2A445FAX916-B-C

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 Rechargeable OTC Hearing Aids 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 Rechargeable OTC Hearing Aids 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 Rechargeable OTC Hearing Aids 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 Rechargeable OTC Hearing Aids in explosive or oxygen-enriched areas. Allergic reactions to Rechargeable OTC 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 Rechargeable OTC Hearing Aids. 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 Rechargeable OTC Hearing Aids.

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.

Dear customer:

Thank you for choosing our Rechargeable OTC Hearing Aids!

The hearing aid is a very sophisticated electronic equipment which is used for hearing compensation for the one who has hearing impaired .

This manual will introduce you some basic use methods of hearing aid and the solutions of common problems to help you use hearing aid better. Please read it carefully and regard it as a user guide.

With any question, please be free to contact the customer service center.

1. Overview

This Rechargeable OTC Hearing Aids(Hearing Aid for below items) has been passed the strictly quality inspection to make sure the device in perfect performance.

a) Product Feature

The shape of the hearing aid conforms to the structure of the human ear canal and it is invisible and comfortable to wear. It is not only suitable for listening in quiet environments, but also for noisy environments.

b) Main Uses and Applicable Scope

The hearing aids are a pair of air conduction hearing aids intended for use by individuals 18 years and older with perceived mild to moderate hearing impairment.

c) Environment and condition

Working environments

Temperature: 0°C~+40°C (32°F ~ 104°F)

Humidity:0 % RH~80 % RH

Voltage:DC 3.7V.

Storage environments

Temperature:-20°C~+55°C (-4°F ~ 131°F)

Humidity: 0 % RH~93 % RH

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

d) Impact on the Environment

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

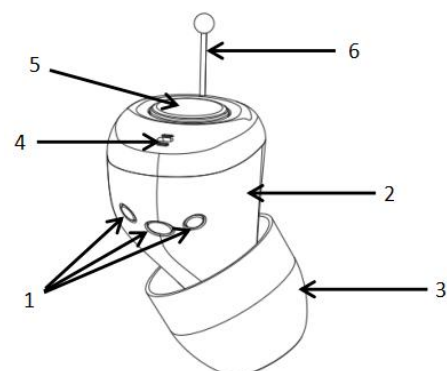
e) Safety

- 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.

2. Structural Characteristics and Operating Principle

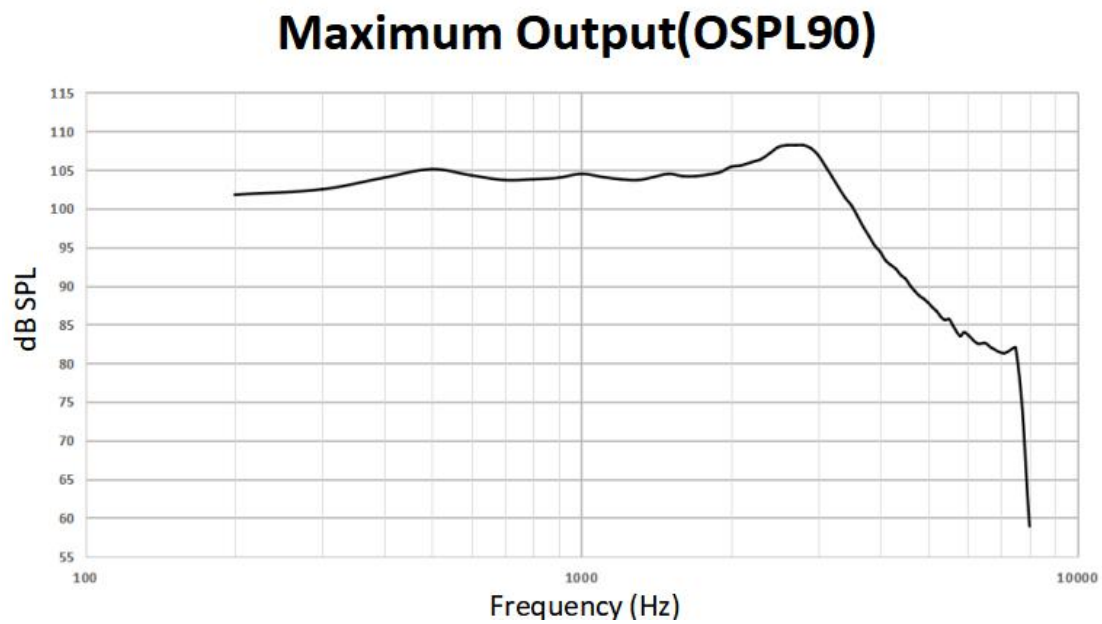
The product is mainly composed of microphone, signal amplification and processing circuit, receiver, volume control circuit, lithium battery, shell and embedded software.

1. Charging Port
2. Shell

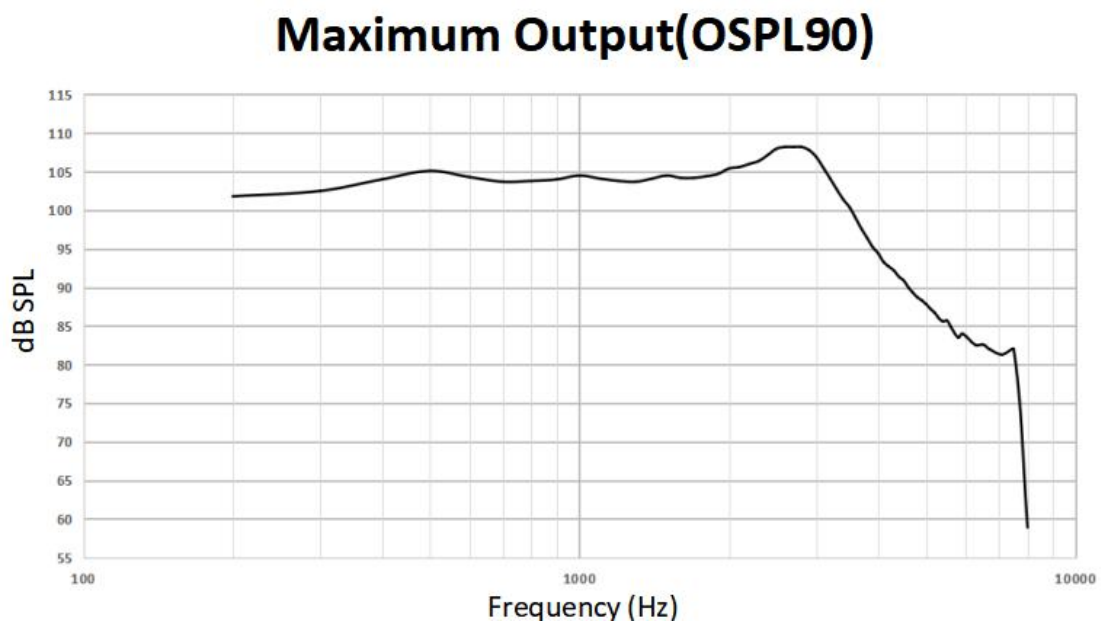


3. Ear Dome (The appearance shall be subject to the actual situation)
4. Microphone
5. Volume Control/Program Switch
6. Puller

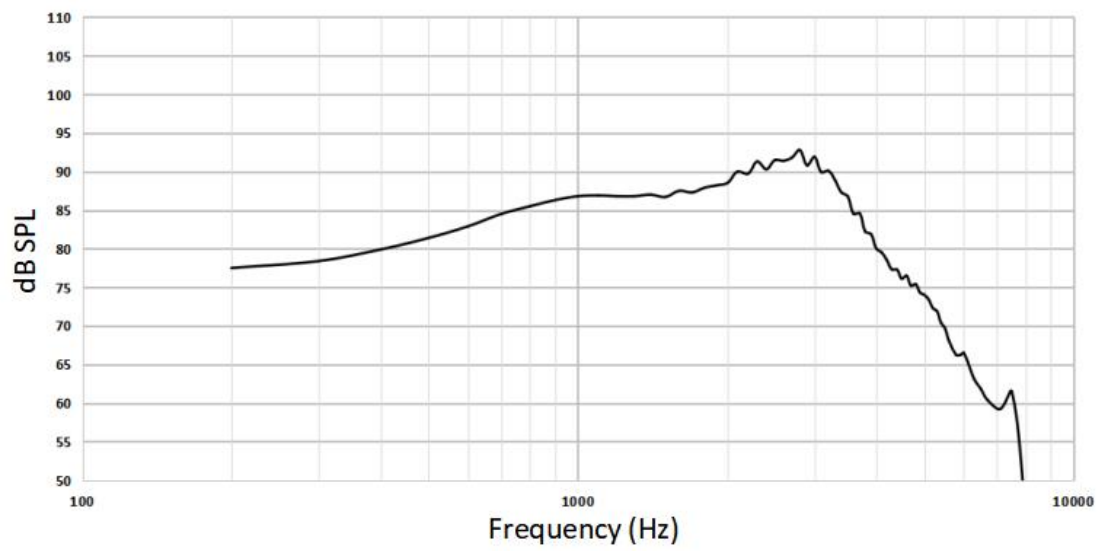
Response curve:



Response curve:



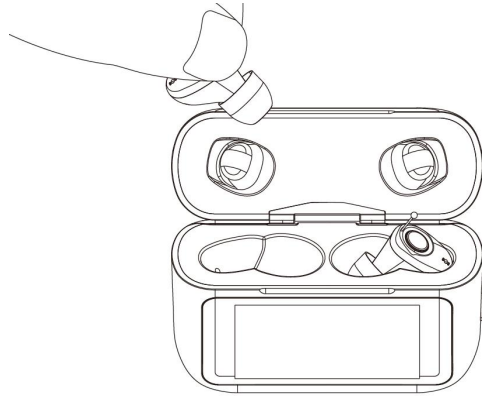
Reference Test Gain (60dB SPL)



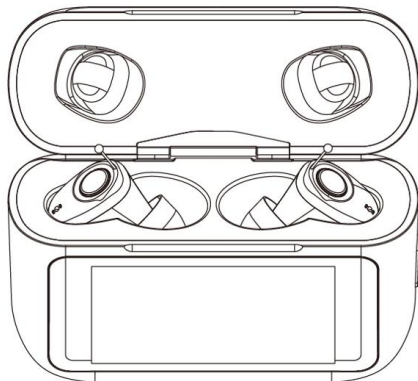
4. Steps for Wearing Rechargeable OTC Hearing Aids

a) Power ON/OFF

- **Power ON:** Take the hearing aid out of the charging box and it will turn on automatically.



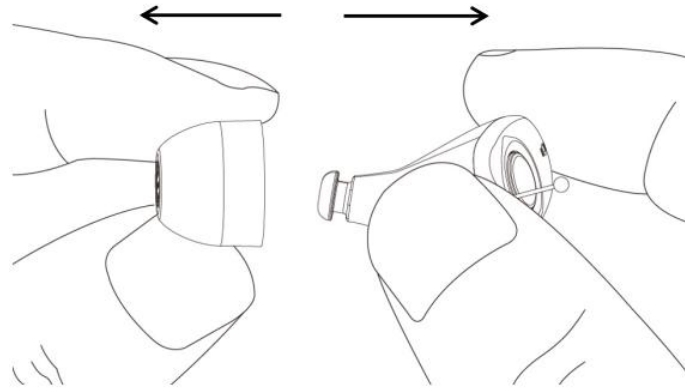
- **Power OFF:** The hearing aid will turn off automatically when it is put into the charging box.



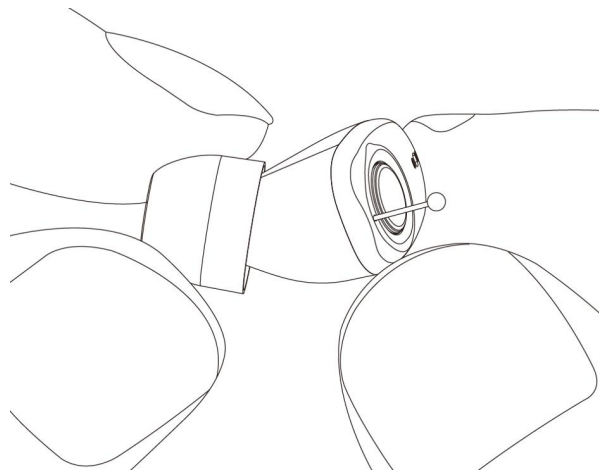
Note: Both ends of the charging line are connected with the power adapter and the charging box.

b) Fit Ear Dome

Remove Earplugs: Pinch the earplug with your thumb, index finger and middle finger to separate the earplug from the connector.

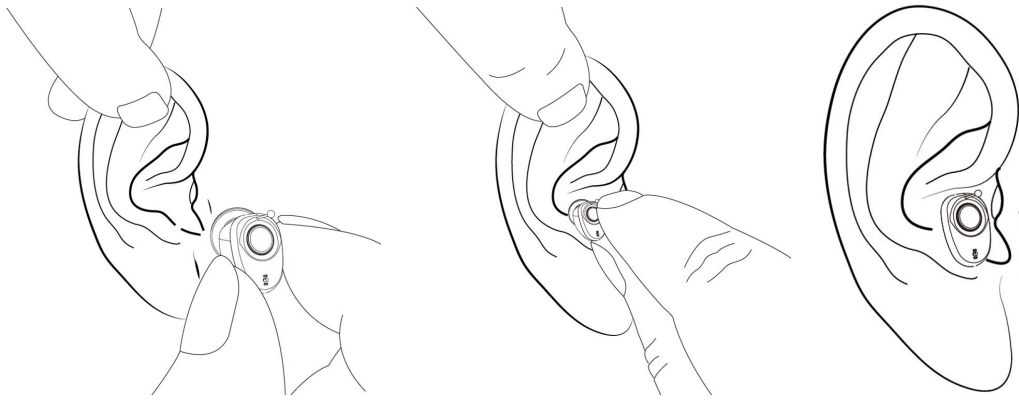


Fit Earplugs: Select appropriate earplug according to the size of the ear canal, hold the earplug and fit it into the connector of the hearing aid. It is required to be fitted in place.



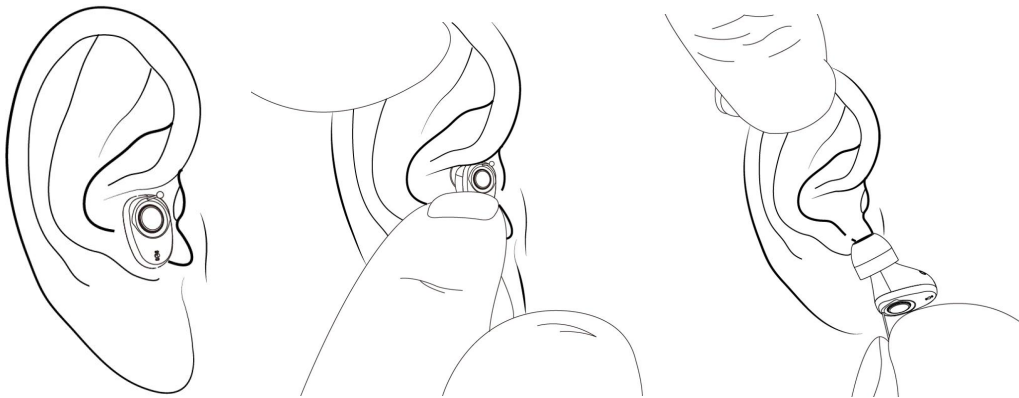
c) Wear Hearing Aid

Hold the hearing aid down with your thumb and forefinger and pull the cord behind it. Gently push the hearing aid into the ear with the tip of your index finger until it feels comfortable in the ear canal. Pull your outer ear back and up with your other hand to make it easier to wear your hearing aid. Gently move up and down with your index finger and open and close your mouth several times to check that the wearer is wearing it well.

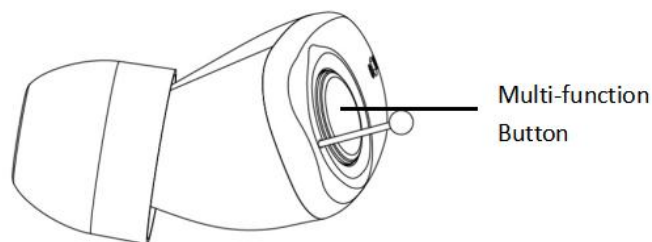


d) Remove Hearing Aid

Pinch the string between your thumb and forefinger and gently pull it out of your ear canal.



e) Volume Control/Program Switch



- Volume Control: short press the button to increase volume, quick double press the button to decrease volume.
- Program Switch: switch button 3 seconds long program cycle.
- Sleeping Mode or Power ON: Pressing the button for 8 seconds is a sleeping mode, and the hearing aid has no sound output. Press the button for 3 seconds again to wake up the hearing aid and restore normal operation.

5. Simple fault analysis and troubleshooting

Failure	Cause	Solution
Whistling	Hearing aid is not worn correctly	Wear it correctly again
	Too much earwax	Clean earwax
Silent	Power off	Turn it on
	Run low on battery/ Run out of battery	Charging the hearing aid
	Foreign matters block the hearing aid earplugs	Clean the earplugs
Small Sound	Low volume	Turn up the volume
	Low battery power	Charging the hearing aid
	Hearing aid is damped	Dehumidify it with a dry box
	Foreign matters block the hearing aid earplugs	Clean 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	The hearing aid sound hole is blocked by dirt	Clean the hearing aid
	Foreign matters block the hearing aid earplugs	Clean the earplugs

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

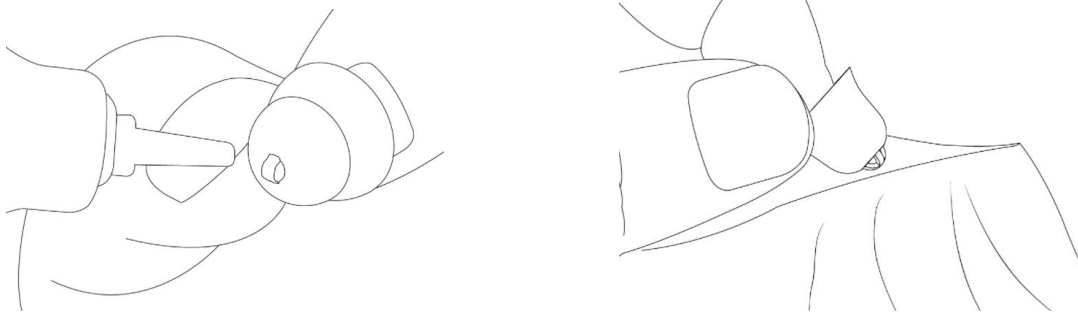
6. Maintenance of hearing aids and charging box

During the use of hearing aid, 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. please clean and maintain the charging box regularly.

a) Clean Ear Dome

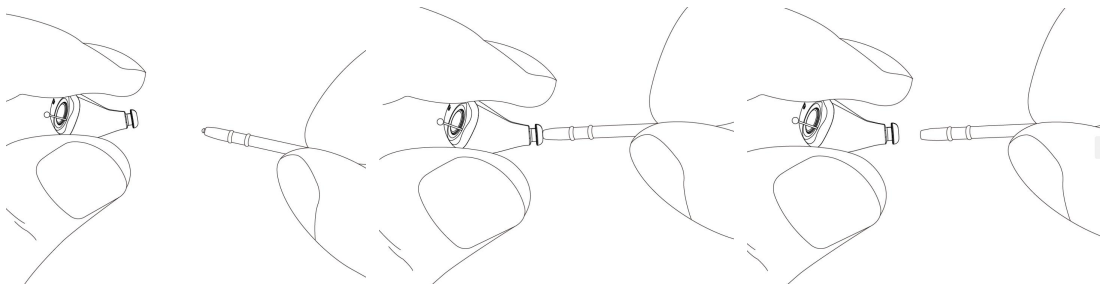
Remove the earplug from the hearing aid, clean the earwax with a cleaning cloth or rinse the

earplug with clean water, and dry the earplug, making sure no water droplets remain. If you use a balloon or similar tool, you can use a balloon to dry the water droplets.



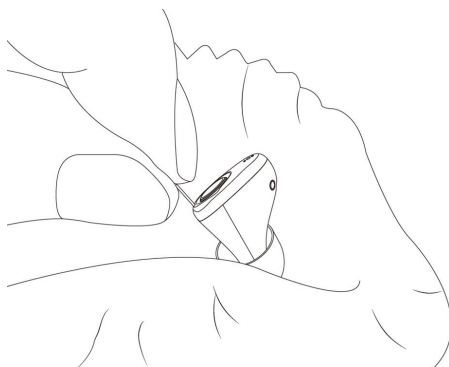
b) Replace wax filters

Wax filters comes in white as standard. Please replace wax filters according to the operating instructions on the package.



c) Clean the hearing aids and charging box

☆ Please clean your hearing aid with a dry soft cloth.



☆ Wipe or clean the hearing aid and charging box on a soft table (for example, place a soft towel on the table) to avoid damage when the hearing aid and charging box is accidentally dropped.

☆ Remember: Do not use any liquid to clean hearing aids and charging box.

d) Anti-Vibration

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

7. Precautions for Hearing Aid

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.

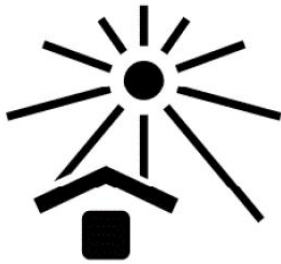
b) Water Prevention

Avoid hearing aid contact with water. Remove the hearing aid when you are swimming, taking a shower, washing your hair, and washing your face. If hearing aid accidentally falls into the water, do not use dryer to dry it. You can dry it with a soft, clean cotton cloth and put it in a ventilated environment. If there is any fault, please contact the fitting center where you purchased the hearing aid or directly contact the customer service center of our company.



c) High Temperature Prevention

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



d) Falling Prevention

Please do not drop your hearing aid 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 Rechargeable OTC Hearing Aids 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 Rechargeable OTC Hearing Aids 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 Rechargeable OTC Hearing Aids, please avoid strong electromagnetic disturbance while using, such as close to the Rechargeable OTC Hearing Aids, microwave oven, etc .

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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 Rechargeable OTC Hearing Aids, 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 Rechargeable OTC Hearing Aids 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.

FCC Statement:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

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.

Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer's declaration-electromagnetic emission		
The models is intended for use in the electromagnetic environment specified below. The customer or the user of the models should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The models use 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 models are suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Table 2: Guidance & Declaration - electromagnetic immunity

Guidance & Declaration — electromagnetic immunity			
The models are intended for use in the electromagnetic environment specified below. The customer or the user of the models should assure that they are 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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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 %.
Electrical transient/burst IEC 61000-4-4	fast ±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line	±0.5 kV, ±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models require continued operation during power mains interruptions, it is recommended that the models be powered from an uninterruptible power supply or a battery.
Power frequency (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.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3: Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

Guidance & Declaration - Electromagnetic immunity	
The models are intended for use in the electromagnetic environment specified below. The customer or the user of the models should assure that they are used in such an environment.	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands & amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands & amateur radio bands	
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014 +A1:20 20)	10V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014 +A1 :20 20)	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 , including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

f) 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.

8. 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.

9. Contraindication

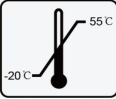
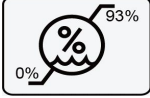
Patients with acute otitis external, tympanitis, chronic suppurative otitis media (in the period of purulent infection), acute suppurative otitis media and allergic to this material. Fitting hearing aid shall be undergone professional hearing test and fitting, and be used under the professional guidance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

10. Accessories list

Accessories List	Number	Unit
Ear domes	1	PC
User manual	1	PC
Adapter	1	PC
Type-C cable	1	PC
Brush	1	PC
Wax filter kit	1	PC

11.Symbol Information

	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”	IP22	IP22: The first number 2: Protected against solid foreign objects of 12,5 mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15°.
	Symbol for “Use-by date”		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		Symbol for “Note”

	resources.		
	During transport or storage, the temperature should not exceed the limit values of -20° to 55° Celsius for a long period of time.		During transport or storage, the relative humidity should not exceed the limit values of 0% to 93% for a long period of time.
	The air pressure range between 86 and 106 KPa is appropriate.		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



Manufacture: Austar Hearing Science and Technology(Xiamen) Co., Ltd.

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