

User Manual

Digital Rechargeable BTE Hearing Aids

FCC ID:2A445FAIP916-DW

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 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.

i 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.

i 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.

i 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 Digital Rechargeable BTE 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 Digital Rechargeable BTE 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

Digital Rechargeable BTE Hearing aid is equipped with digital intelligent function, multiple processing channels, intelligent adaptive noise reduction management system and efficient adaptive feedback suppression function etc.

This product is not only suitable for listening in a quiet environment but also suitable for a noisy environment. Product appearance design shows a new trend of the BTE hearing aid correspond with human body engineering principle, wearing comfortable and big power.

Software Description:

Embedded sound processing software based on low-power DSP.

b) Main Application and 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) Product Model

FAIP916-DW

d) Environment and Conditions

Working environments

Temperature: 0°C~+40°C (32°F ~ 104°F)

Humidity:0 % RH~80 % RH

Voltage: Hearing aid: DC 3.6V from battery or DC 5V from Charging case

Charging case: DC 5V from adapter or DC 3.7V from battery

Storage environments

Temperature:-20°C~+50°C (-4°F ~ 122°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.

e) 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.

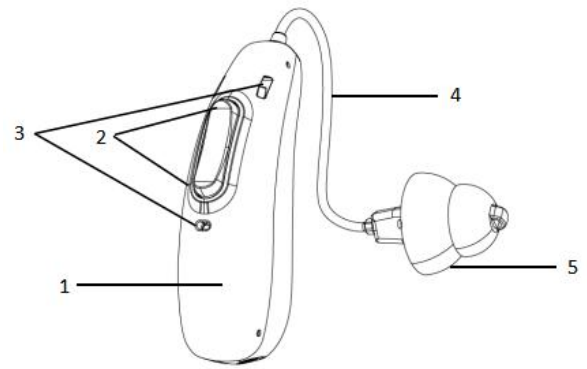
f) Safety

- 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

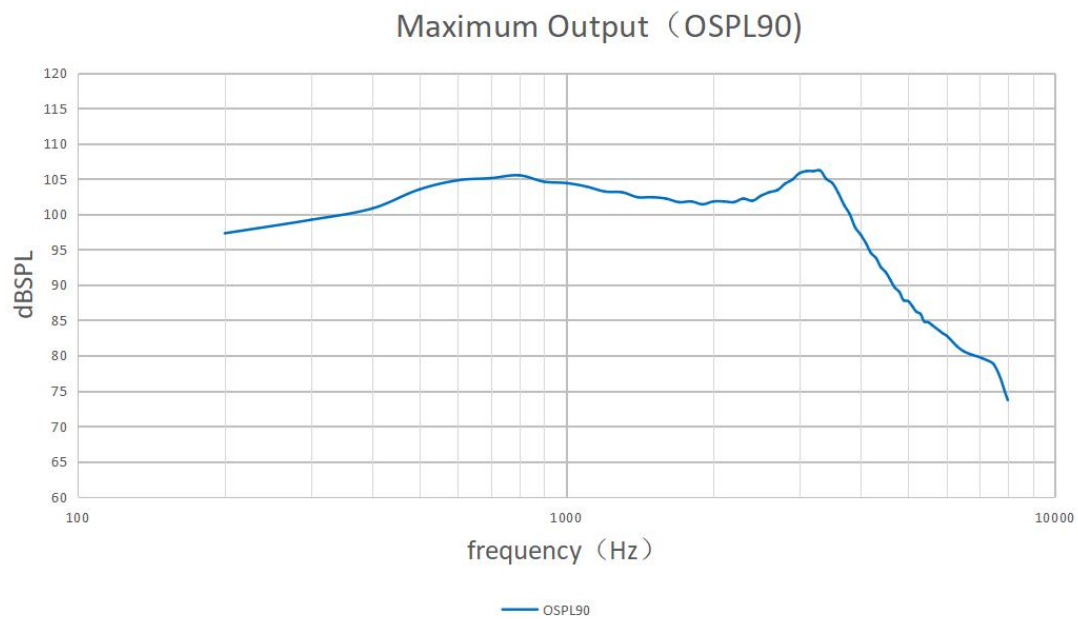
The product is mainly composed of microphone, signal amplification and processing circuit, receiver, volume control circuit, lithium battery, shell and embedded software.

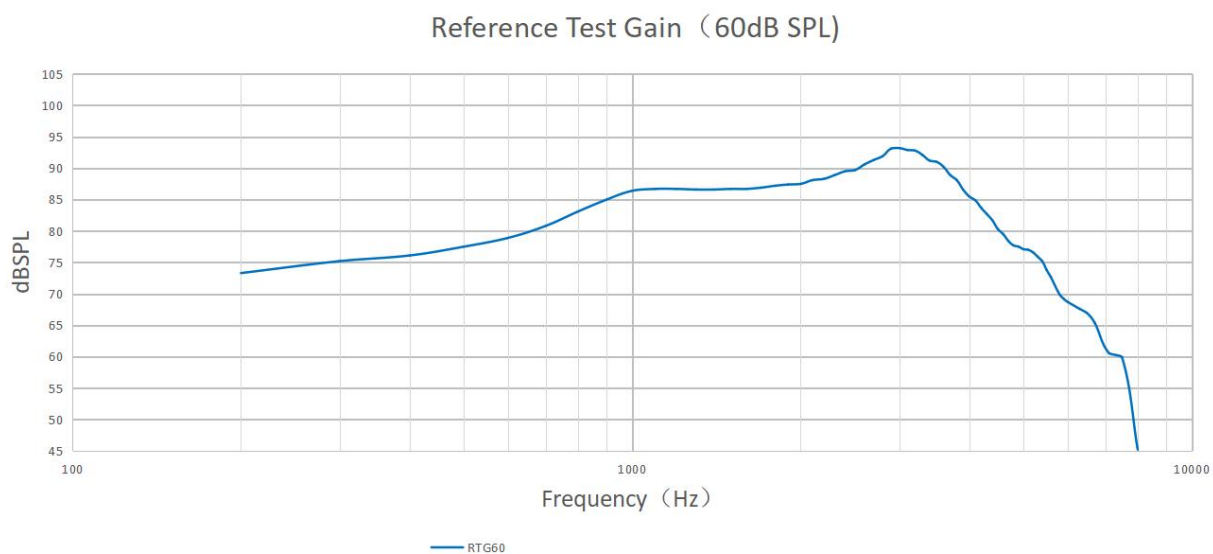
1. Shell
2. Volume Control/Program Switch
3. Microphone
4. Receiver
5. Ear Dome (The appearance shall be subject to the actual situation)



3. Technical Specification

Response curve

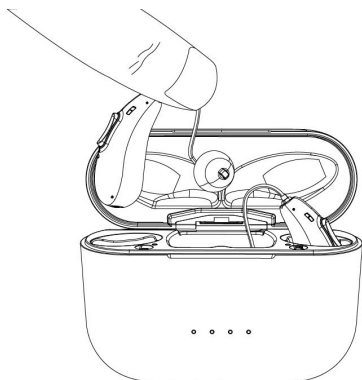




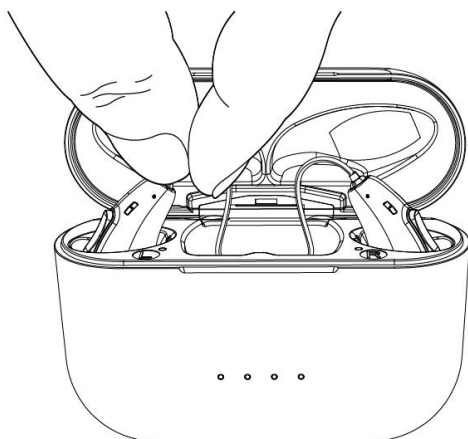
4.Steps for Wearing Hearing Aid and Use

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.

Battery life

The hearing aids can work for more than 16H when the battery is fully charged. The full charging boxes can charge hearing aids 3 times.

Hearing aids: battery:3.6V, 42mAh, 0.15Wh.

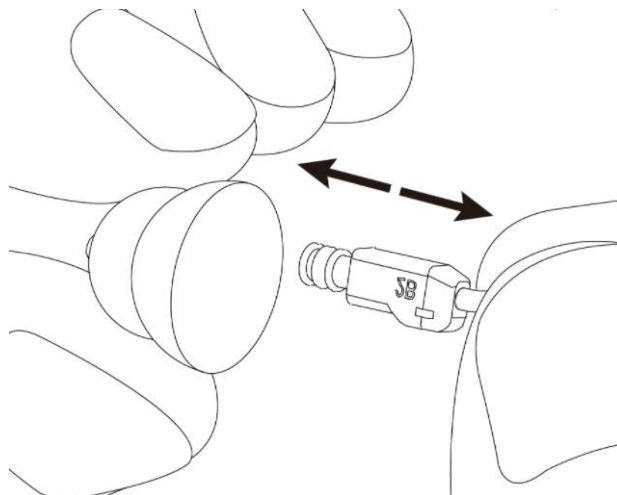
Charging box: FAC061, Input:DC5V== 1A, Output:DC5V== 30mA,

Battery:DC3.7V 500mAh 1.85Wh.

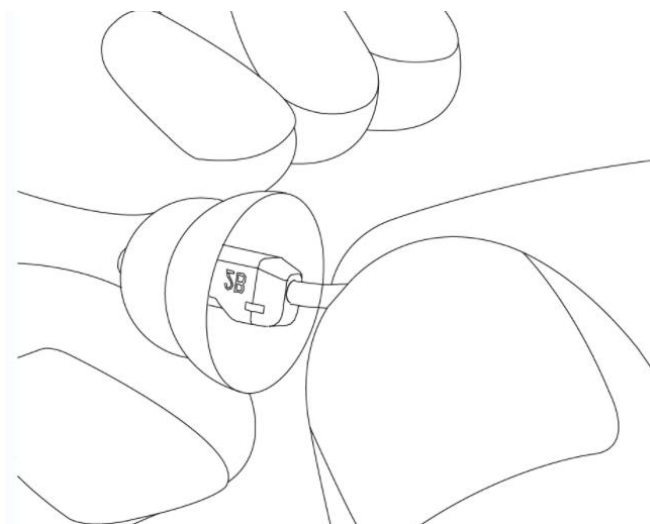
Power Adapter: Input:100-240V~50/60Hz, 0.35A, Output:DC5V== 1A.

b) Fit Ear Dome

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



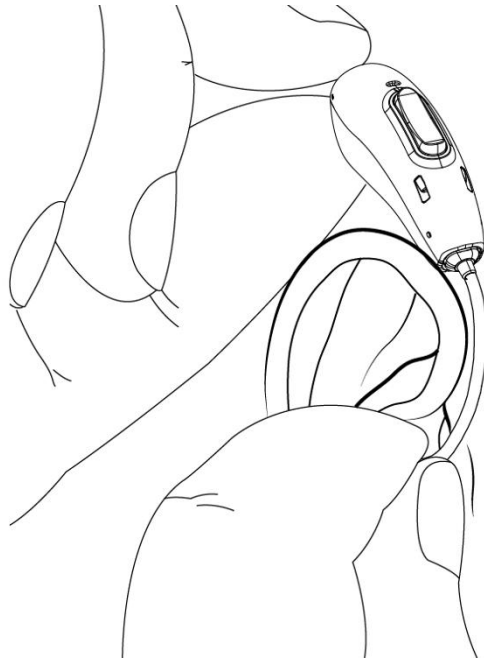
Fit Earplugs: Select appropriate earplug according to the size of the ear canal, hold the earplug and fit it into the connector of the hearing aid. It is required to be fitted in place.



c) Wear Hearing Aid

Steps:

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



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

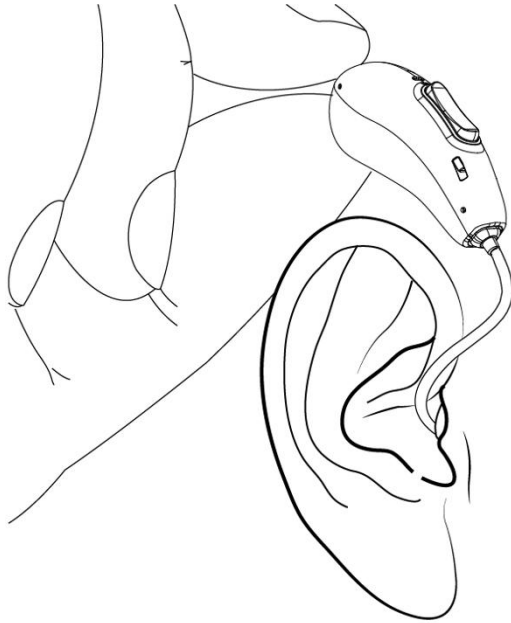
If it feels like the dome is falling out of your ear, it means that the dome is most likely too small for your ear. Try changing your dome to one that is a size larger.

If it feels like you have to squeeze or force the dome into your ear, it means that the dome is most likely too large for your ear. Try changing your dome to one that is a size smaller.

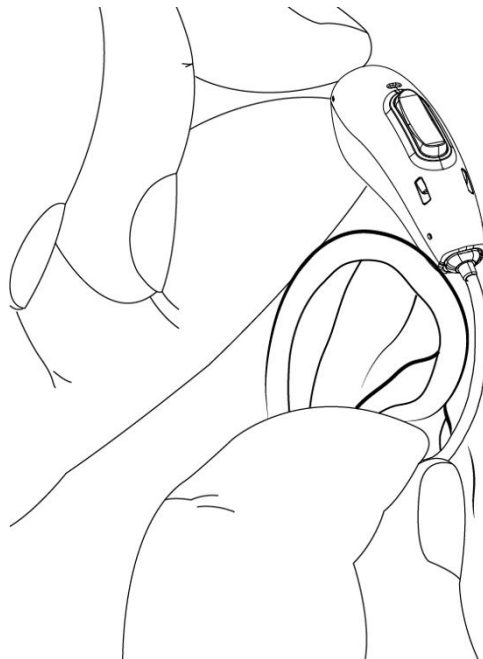


d) Remove Hearing Aid

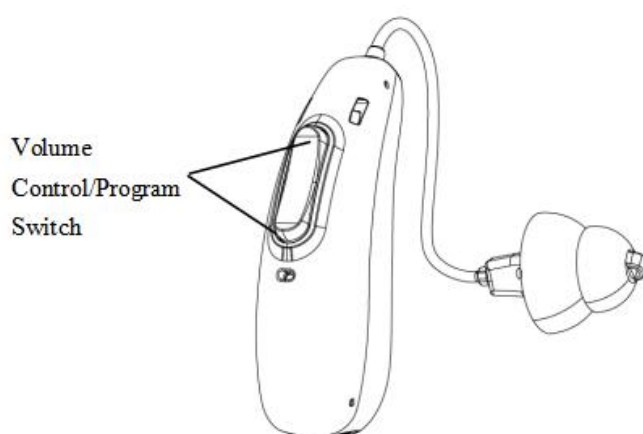
1. Take off the hearing aid behind the ear.



2. 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 aid.



e) Volume Control/Program Switch



Volume Control/Program Switch

- Volume Control: Push “+” to increase the volume and push “-” to reduce the volume.
- Program Switch: Push Volume Control “+” or “-” more than 2 seconds, program switching automatically. Kindly explain that user push “+” to make program switch in positive cycle and user push “-” to make program switch in reverse cycle.
- Sleeping Mode or Power ON : Pressing the button for 5 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. 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
	Low battery or no power	Charging the hearing aid
	Dirt blocks the earplug or the tube	Clean the earplug or the sound tube
Small Sound	Low volume	Turn up the volume
	Low battery power	Charge the hearing aid
	Hearing aid is damped	Dehumidify it with a dry box
	Dirt blocking the sound tube or the earplugs	Clean the sound tube or the earplug
High Power	Hearing aid is still on when not in use	Please turn it off when hearing aid is not in use

Consumption	Hearing aid is damped	Dehumidify it with a dry box
Intermittent	Dirt blocks the sound tube	Clean the sound tube
Sound	Dirt blocks the earplugs	Clean the earplugs

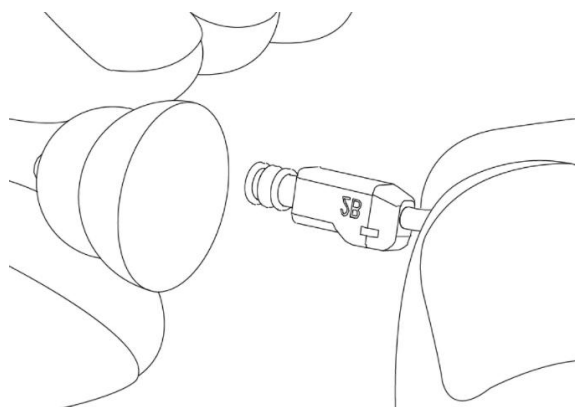
If the above methods still cannot solve the problem, please contact the customer service center of our company directly.

6.Maintenance of hearing aids and charging boxes

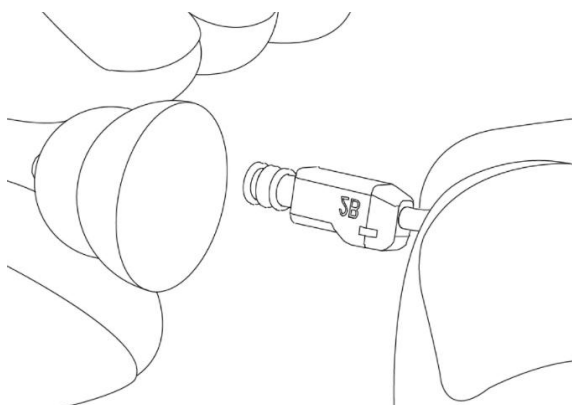
During the use of hearing aid, earwax (cerumen) produced by the ears will accumulate in the ear canal and the sound hole of the hearing aid. A large amount of accumulated earwax will affect the use effect of the hearing aid, so please clean your ear canal and maintain the hearing aid regularly. please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

a) Clean Ear Dome

- Remove the ear dome from the hearing aid.



- Clean the earwax with a cleaning cloth or wash the ear dome with clean water.
- Please wipe the ear dome dry and make sure there is no water droplets left. If there are tools like a blowing balloon, you can use a blowing balloon to dry the water droplets.



b) Clean Hearing Aid and charging box

- Use the small brush delivered in the packing box to clean the earwax at the sound outlet of the hearing aids.



- Please clean your hearing aid and charging box with a dry soft cloth.



Wipe or clean the hearing aids and charging box on a soft desktop (e.g. a soft towel can be padded 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 aids and charging box.

c) 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.

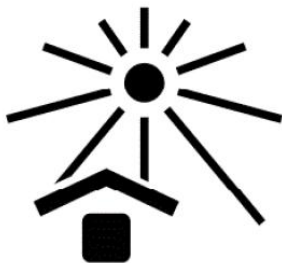
b) Water Prevention

Do not immerse the hearing aids in any liquid. Remove the hearing aids in advance and keep it properly when swimming, bathing, washing hair, washing face, etc Please wait until the ear canal is dry before wearing your hearing aids. after swimming and showering. In case the hearing aid falls into the water accidentally, do not dry it in the microwave oven or any dryer. You can dry it with soft and clean cotton cloth and dry it naturally 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.

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

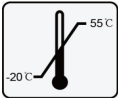
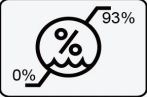
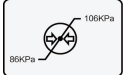
Patients with acute otitis external, tympanitis, chronic suppurative otitis media (in the period of purulent infection), acute suppurative otitis media and allergic to this material. Fitting hearing aid shall be undergone professional hearing test and fitting, and be used under the professional guidance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

10.Accessories list

Accessories List	Number	Unit
Ear domes	1	PC
User manual	1	PC
Charger boxes	1	PC
Type-C cable	1	PC
Cleaning tool	1	PC
Cerumen cap suit	1	PC
Adapter	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 resources.		Symbol for “Note”

	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



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Xiamen, Fujian, China

Post code: 361028

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Fax: +86-0592-5621123

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.