User Manual

Dear customer：

Thank you for choosing our Hearing Aid！

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 local hearing center or customer service center.

Content

1. Overview 3
a) Product Feature 3
b) Main Application and Scope 3
c) Product Model 3
d) Environment and Conditions 3
e) Impact on the Environment 4
f) Safety 4
2.Structural Characteristics and Operating Principle 4
3.Technical Specification 5
4.Steps for Wearing Hearing Aid and Use 7
a) Power ON/OFF 8
b) Fit Ear Dome 9
c) Wear Hearing Aid 10
d) Remove Hearing Aid 11
e) Volume Control/Program Switch 12
f) Usage of Application 13
5.Troubleshooting 17
6.Hearing Aid Maintenance 18
a) Clean Ear Dome 18
b) Clean Hearing Aid 19
c) Anti-Vibration: 20
7.Precautions for Hearing Aid 20
a) Dehumidification 20
b) Water Prevention 20
c) High Temperature Prevention 21
d) Falling Prevention 21
e) Precautions for Electromagnetic Compatibility 21
f) Others 27
8.Unpack and Check 27
9.Contraindication 27
10.Accessories list 27
11.Symbol Information 28

1. Overview

This device you choose is the new series hearing aid, rechargeable digital Hearing aid. All main components are from Europe and America with strict production control and accurate test ensuring the excellence quality of each hearing aid.

a) Product Feature

Digital rechargeable 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 hearing aid correspond with human body engineering principle, wearing comfortable and big power.

b) Main Application and Scope

The BTE 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

BTE hearing aid:FH312-B, FH311-B, FH310-B, FH309-B, FH308-B, FH307-B, FH306-B, FH305-B, FH304-B, FH303-B, FH212-B, FH211-B, FH210-B, FH209-B, FH208-B, FH207-B, FH206-B, FH205-B, FH204-B, FH203-B.
FH912-B, FH911-B, FH910-B, FH909-B, FH908-B, FH907B, FH906-B, FH905-B, FH904-B, FH903-B, FH812-B, FH811-B, FH810-B, FH809-B, FH808-B, FH807-B, FH806-B, FH805-B, FH804-B, FH803-B,FH712-B, FH711-B, FH710-B, FH709-B, FH708-B, FH707-B, FH706-B, FH705-B,FH704-B, FH703-B, FH612-B, FH611-B, FH610-B, FH609-B, FH608-B, FH607-B, FH606-B,FH605-B,FH604-B,FH603-B,FH512-B,FH511-B,FH510-B, FH509-B,FH508-B,FH507-B, FH506-B, FH505-B, FH504-B, FH503-B, FH412-B, FH411-B, FH410-B, FH409-B, FH408-B, FH407-B, FH406-B, FH405-B, FH404-B, FH403-B

BET-RIC:FHE512-B, FHE511-B, FHE510-B, FHE509-B, FHE508-B, FHE507-B, FHE506-B, FHE505-B, FHE504-B, FHE503-B, FHE412-B, FHE411-B, FHE410-B, FHE409-B, FHE408-B, FHE407-B, FHE406-B, FHE405-B, FHE404-B, FHE403-B.

d) Environment and Conditions

Working environments

Temperature: 0℃～+40℃

Humidity:0％RH～80％RH

Voltage: DC 3.5V

Storage environments

Temperature:-20℃～+50℃

Humidity: 0％RH～93％RH

Atmospheric pressure: 86KPa～106KPa.

e) Impact on the Environment

The BTE 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 explosion, please do not put the hearing aids and charging case into fire or microwave oven, and so on.
- Danger: To avoid being swallowed by children in accident, please keep the hearing aid and charging case away from children.
- This hearing aids and charging case can only be used by people with hearing loss, the rest cannot be used.
- 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.
- The patient is also the operator for the device.
- Only to connect to equipment that conforms with international safety standards, if externally connected.
- Software controlled fitted OSPL90 shall not exceed the selected value as a result of corrupt data transfer between programmer and Hearing aid.
- Special User:

（1）Children can’t wear the hearing aid without the guidance of adult.

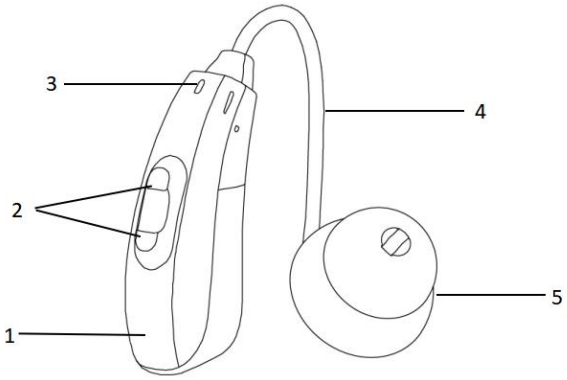
（2）Mental patients should consult a physician before wearing a hearing aid.

- Warning: Hearing aids are able to provide more than 132 dB SPL. The fitted OSPL90 does not increase if the control is disconnected or defective. It neet to the hearing aid professional for RECD measured to correct target of fitted OSPL90. The hearing aids should be fitted by the professional operator otherwise there may be a risk of impairing the remaining hearing of the patient; The hearing aid should be only used by the hearing impaired, not by any other.

2. Structural Characteristics and Operating Principle

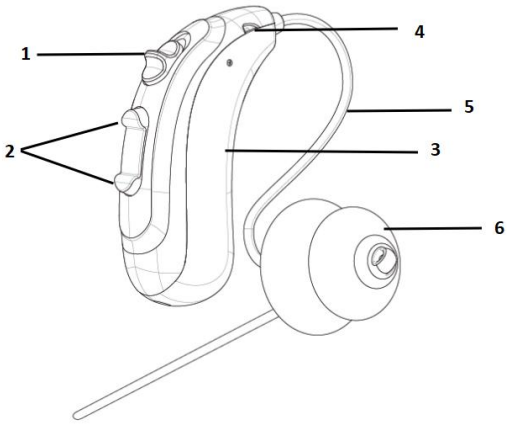
The product is mainly composed of microphone, signal amplification and processing circuit, receiver, volume control circuit, lithium battery, shell and embedded software.

BTE hearing aid (FCC ID: 2A445FH312-B)：



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

BTE-RIC:



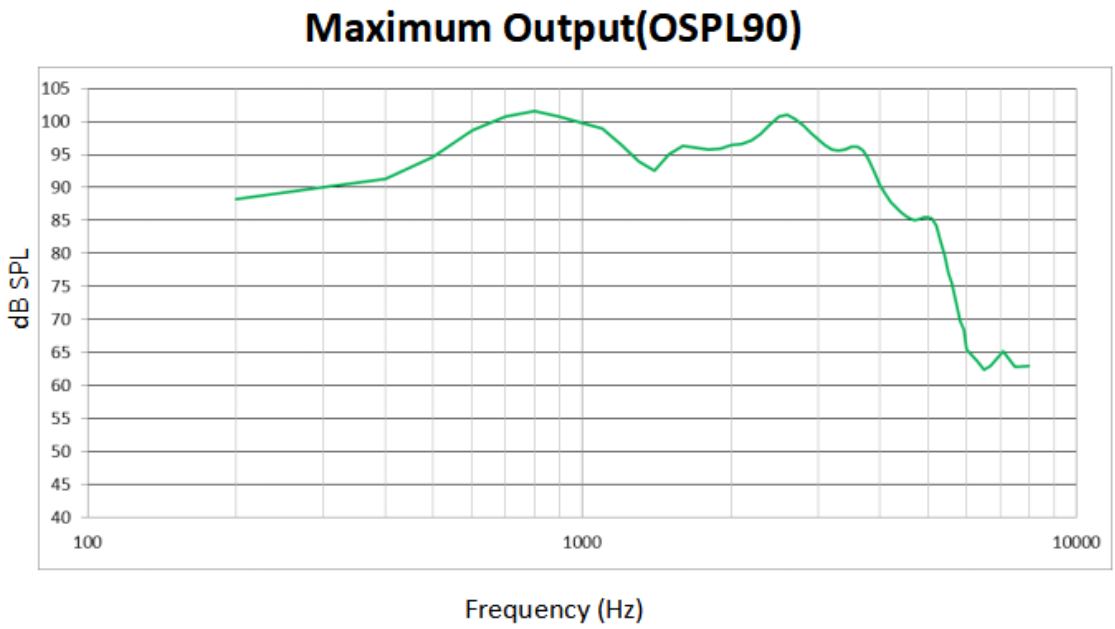
1. Power ON/OFF
2. Volume Control/Program Switch
3. Shell
4. Microphone
5. Receiver
6. Ear Domes(The appearance shall be subject to the actual situation)

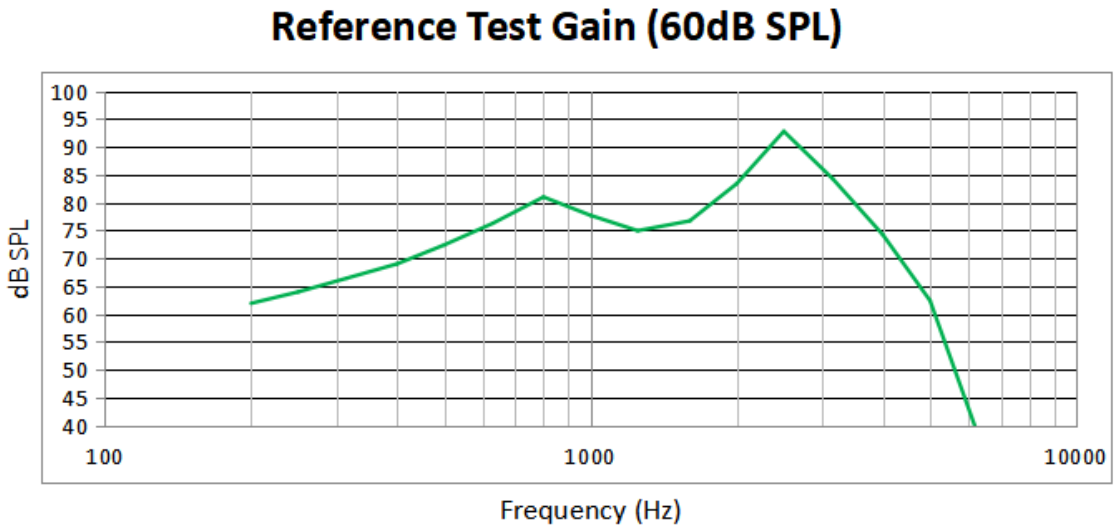
3. Technical Specification

Product Model	Max OSPL90 （+3dB）	HFA OSPL90 (±4dB)	Peak gain (+3dB)	HFA FOG (±5dB)	THD			Frequency Range(Hz)	Equivalent input noise(+3dB)	Battery Current Drain （mA）	Attack Time (±5mS)	Release time (±5m S)
					500Hz	800Hz	1600 Hz					
FH312-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH311-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH310-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH309-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH308-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH307-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH306-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH305-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH304-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH303-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH212-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH211-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH210-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH209-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH208-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH207-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH206-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH205-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH204-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FH203-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE512-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE511-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE510-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE509-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE508-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE507-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE506-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE505-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE504-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE503-B	117	105	35	30	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE412-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE411-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE410-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE409-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE408-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE407-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE406-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE405-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE404-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500
FHE403-B	117	103	33	28	≤5%	≤5%	≤5%	200--5000	<29	≤2	100	500

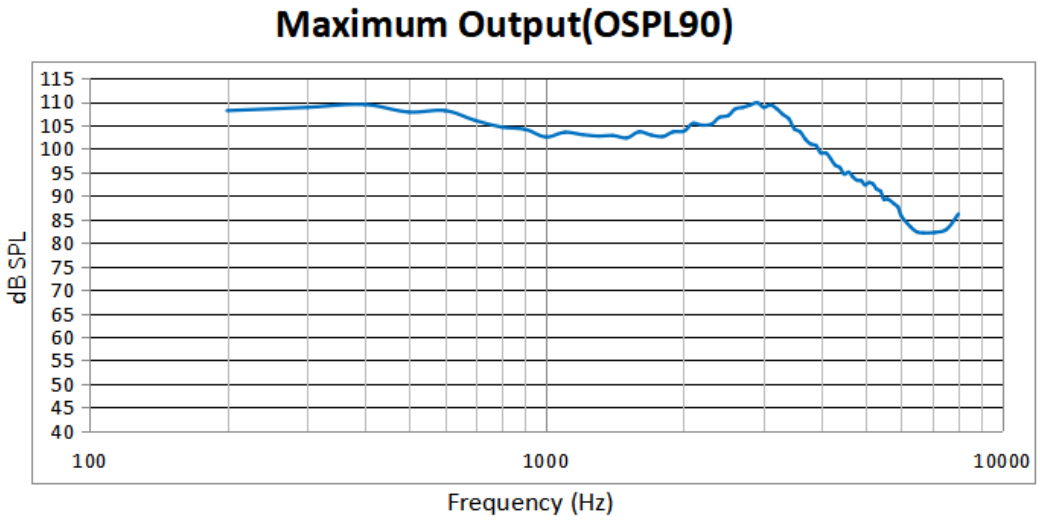
Response curve

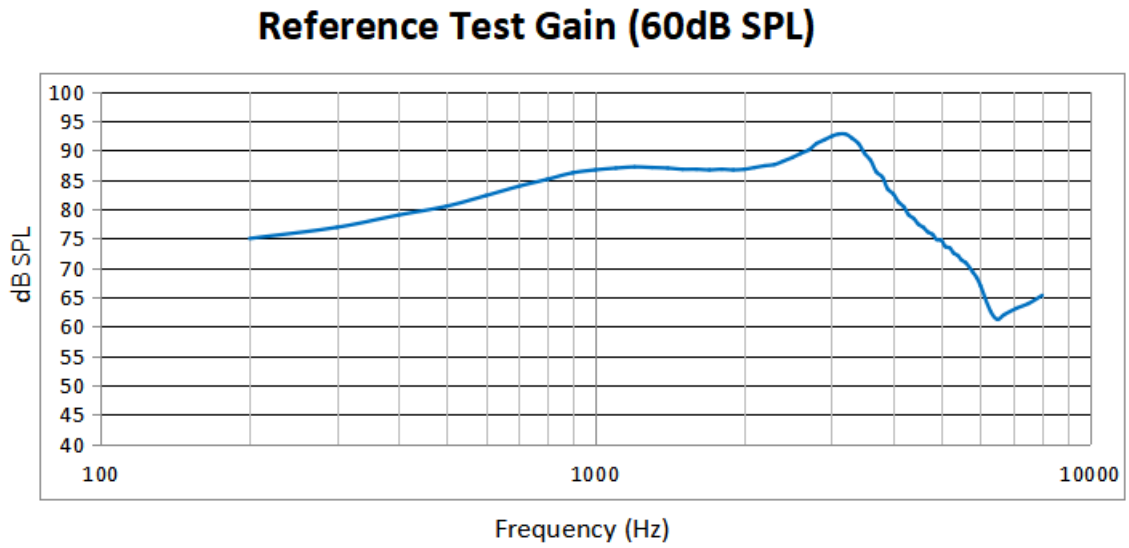
BTE hearing aid:





BTE-RIC:



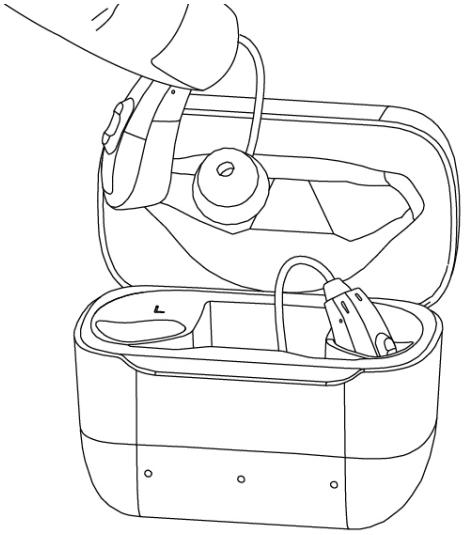


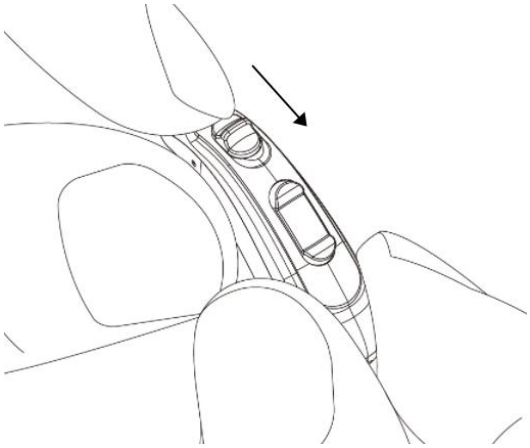
4. Steps for Wearing Hearing Aid and Use

a) Power ON/OFF

- Power ON: BTE hearing aid: Take the hearing aid out of the charging box and it will turn on automatically.
  BTE-RIC: Push button DOWN to start working.

BTE hearing aid: BTE-RIC:

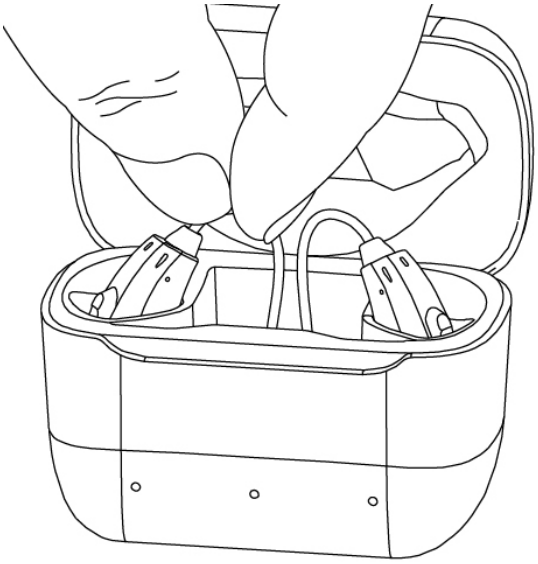


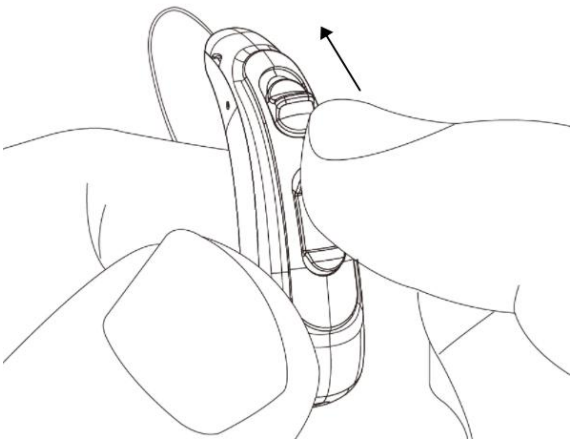


- Power OFF: BTE hearing aid: The hearing aid will turn off automatically when it is put into the charging box.

  BTE-RIC: Push button UP, power is off, hearing aid stop working.

BTE hearing aid: BTE-RIC:





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

Battery life

BTE hearing aid: The hearing aids can work for more than 20H when the battery is fully charged. The full charging case can charge hearing aids 4 times.

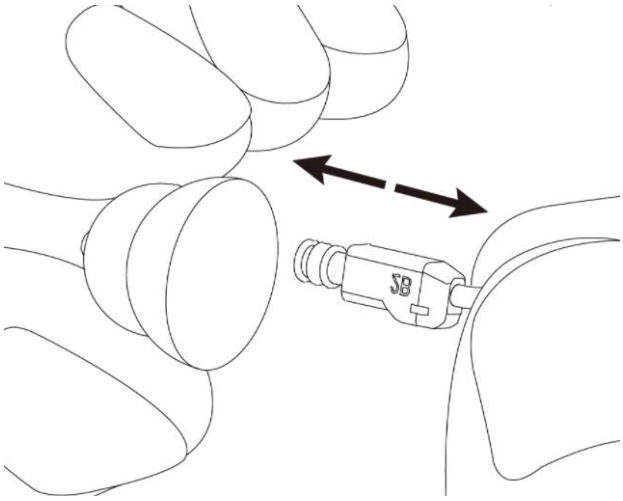
Model: FAC021, Input: DC5V 500mA, Output: DC4.2V 10mA, Battery: DC3.7V 400mAh 1.48Wh. Power Adapter: Input: 100-240V~50/60Hz, max 150mA, Output: DC5V 1A.

BTE-RIC: The hearing aids can work for more than 20H when the battery is fully charged. The full charging case can charge hearing aids 3 times.

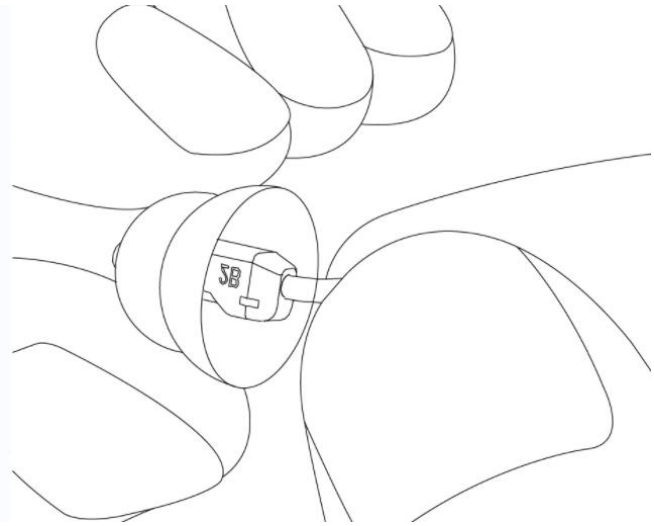
Model: FAC018, Input:DC5V 200mA, Output:DC4.2V 50mA, Battery:DC3.7V 300mAh 1.1Wh.
Power Adapter: Input: 100-240V~50/60Hz, max 150mA, Output:DC5V 1A.

b) Fit Ear Dome

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



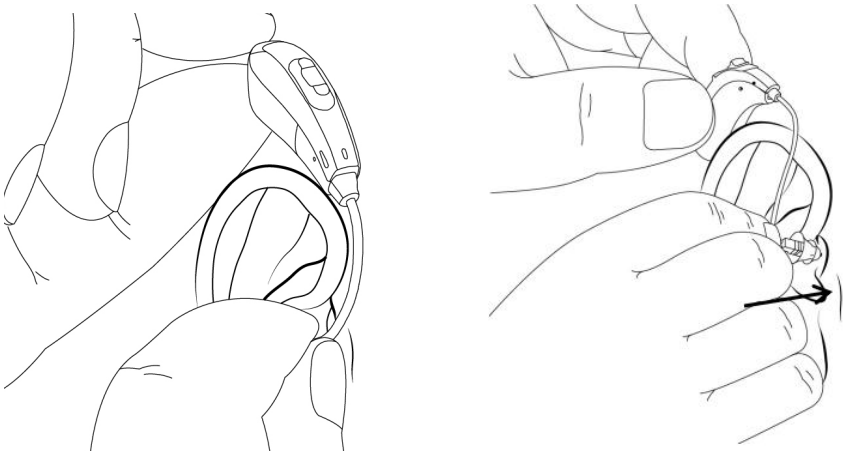
Fit Earplugs: Select appropriate earplug according to the size of the ear canal, hold the earplug and fit it into the connector of the hearing aid. It is required to be fitted in place.



c) Wear Hearing Aid

Steps:

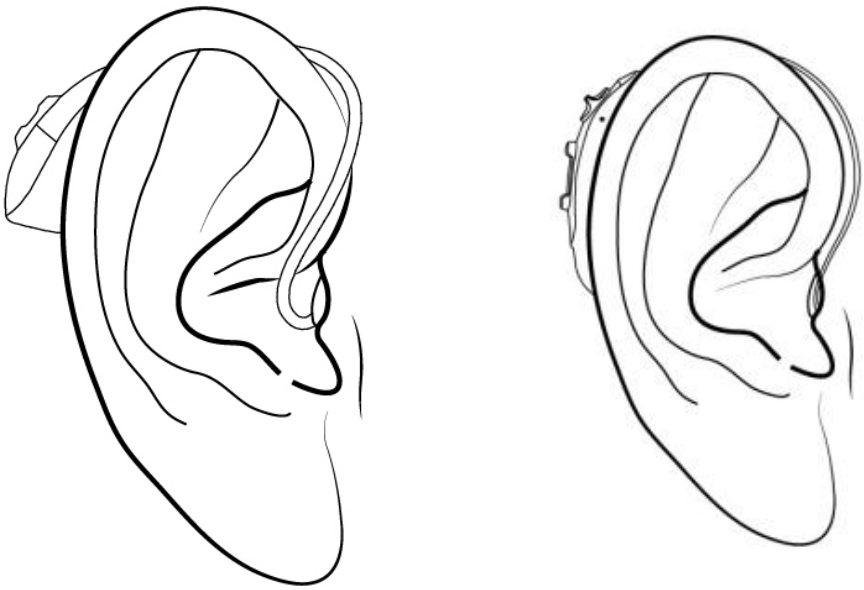
Hold the bottom of the tube with your fingers and gently push the earplug into the ear canal.



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

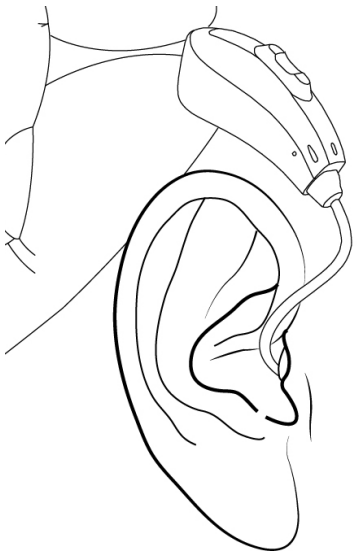
If it feels like the dome is falling out of your ear, it means that the dome is most likely too small for your ear. Try changing your dome to one that is a size larger.

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.

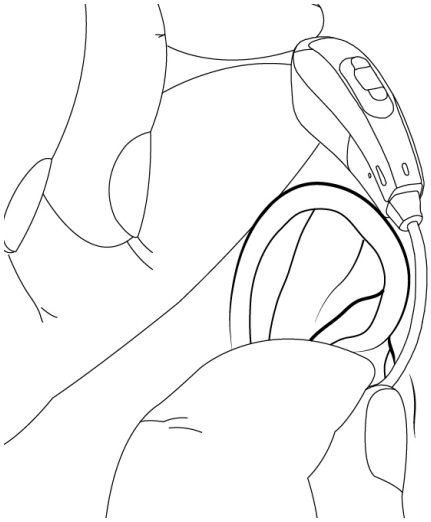


d) Remove Hearing Aid

1. Take off the hearing aid behind the ear.

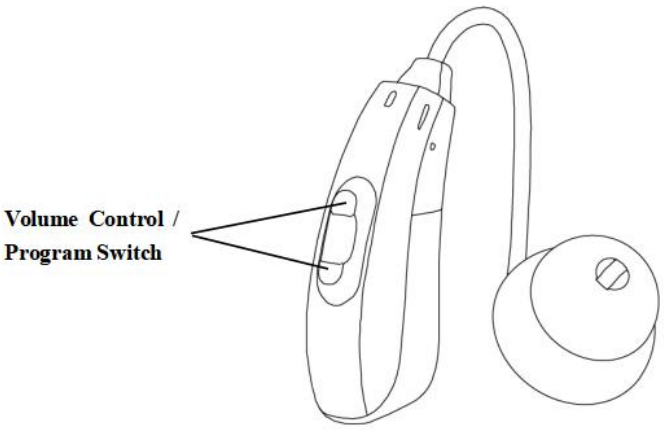


2. Hold the bottom of the sound tube and pull it gently. After the earplug is loose, take it out and take it off together with the hearing aid.

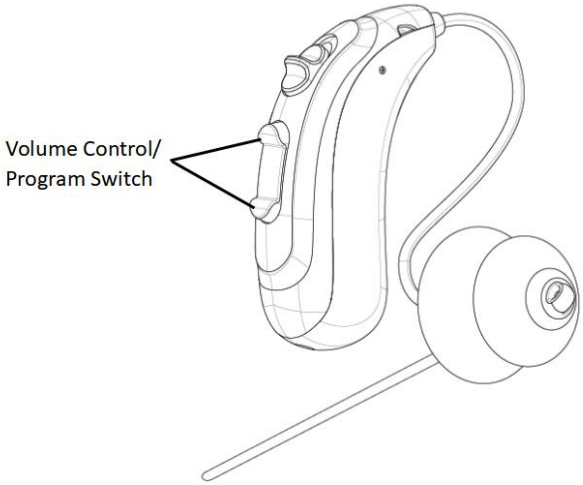


e) Volume Control/Program Switch

BTE hearing aid:



BTE-RIC:



Volume Control/Program Switch

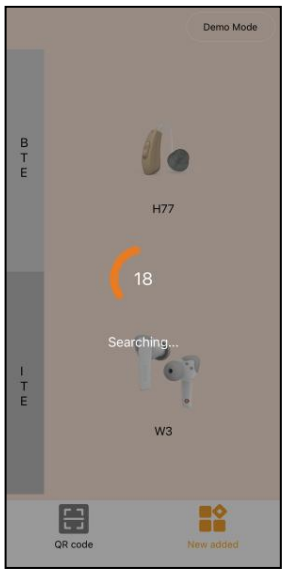
- Volume Control: Push“+” to increase the volume and push“-”to reduce the volume.
- Program Switch: Push Volume Control “+”or “-”more than 2 seconds, program switching automatically. Kindly explain that user push “+” to make program switch in positive cycle and user push “-” to make program switch in 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 5 seconds again to wake up the hearing aid and restore normal operation.

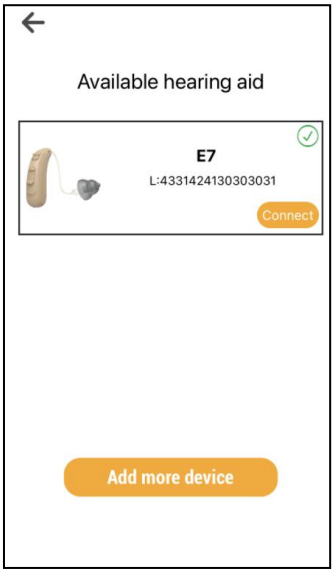
f) Usage of Application

You can use the mobile APP for volume control and program control, which will be more convenient for adjustment.

①Open the APP in the phone, search for hearing aids, and check available hearing aid

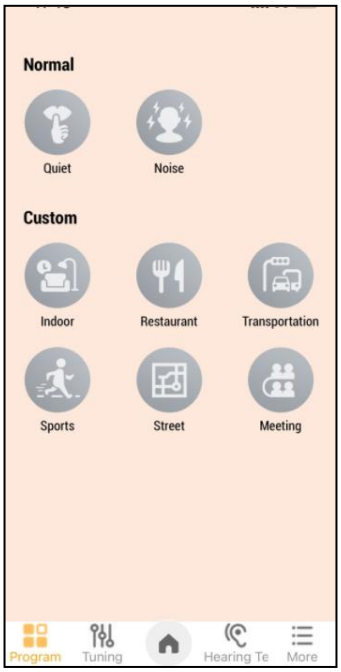
devices. User needs to click to confirm the connection.



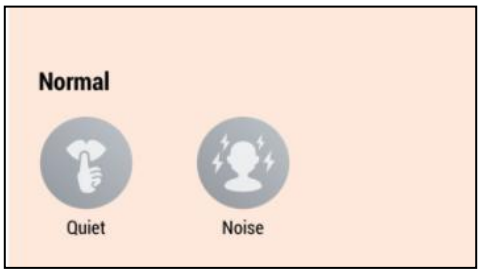


②Program switching: Different programs for different models of product.

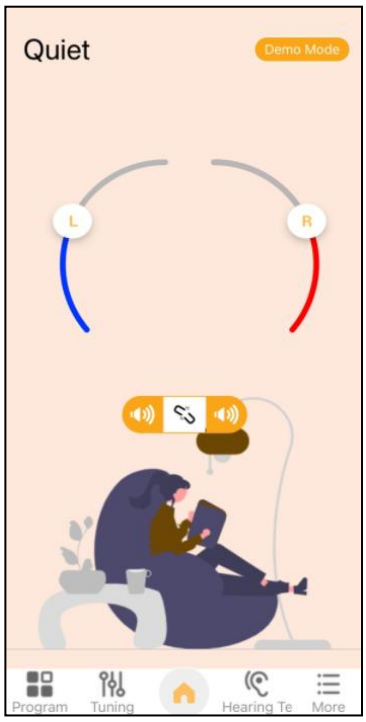
FH312-B, FH310-B, FH308-B, FH306-B, FH304-B, FH212-B, FH210-B, FH208-B, FH206-B, FH204-B, FHE512-B, FHE510-B, FHE508-B, FHE506-B, FHE504-B, FHE412-B, FHE410-B, FHE408-B, FHE406-B, FHE404-B: 3 models: Quiet, Noise, Custom.



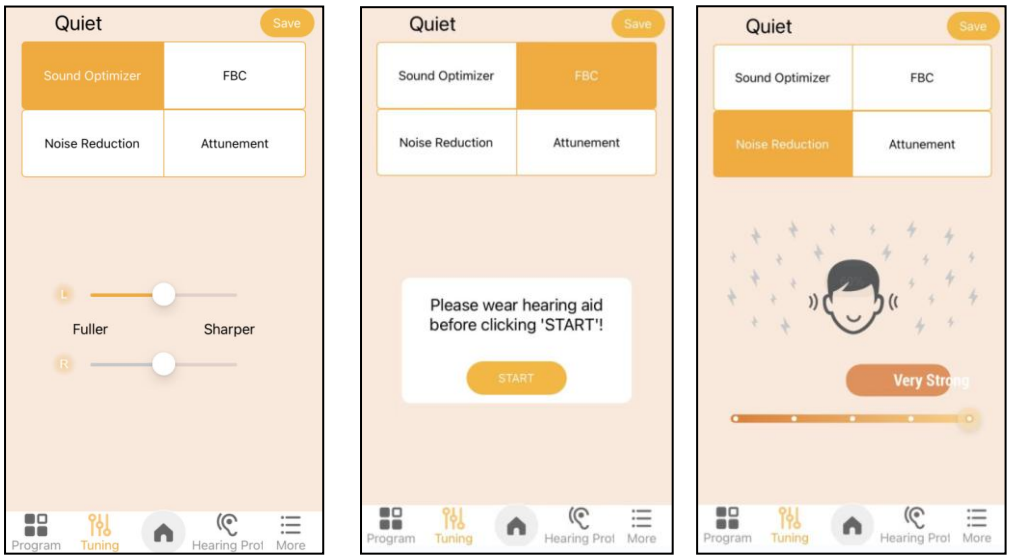
FH311-B, FH309-B, FH307-B, FH305-B, FH303-B, FH211-B, FH209-B, FH207-B, FH205-B, FH203-B, FHE511-B, FHE509-B, FHE507-B, FHE505-B, FHE503-B, FHE411-B, FHE409-B, FHE407-B, FHE405-B, FHE403-B: 2 models: Quiet and Noise.

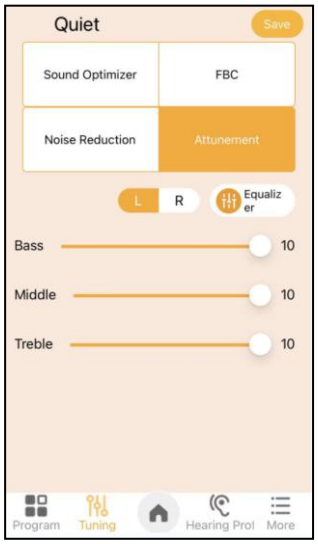


③Volume adjustment: Slide down to decrease the volume and up to increase the volume.

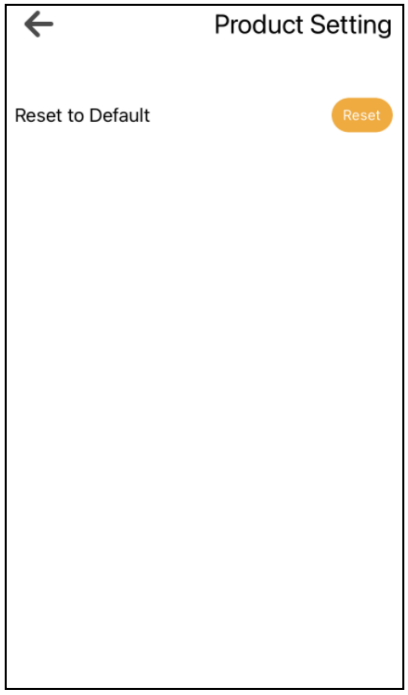


④Tuning: Click Tuning on the main interface to adjust sound optimizer, FBC, Noise reduction and Attunement.



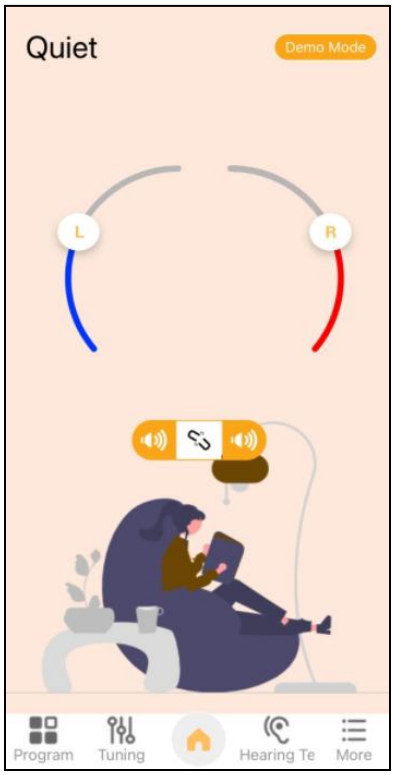


⑤Product setting: You can set reset to default in ear.



⑥Language setting: Set app language, including of Traditional Chinese, Simplified Chinese and English.

⑦Demonstration mode: Experience how to use the APP without connecting to the product.



5. Troubleshooting

Failure	Cause	Solution
Whistling	Hearing aid is not worn correctly Too much earwax	Wear it correctly again Clean earwax

Silent	Power off Low battery or no power Dirt blocks the earplug or the tube	Turn it on Charging the hearing aid Clean the earplug or the sound tube
Small Sound	Low volume Low battery power Hearing aid is damped Dirt blocking the sound tube or the earplugs	Turn up the volume Charge the hearing aid Dehumidify it with a dry box Clean the sound tube or the earplug
High Power Consumption	Hearing aid is still on when not in use Hearing aid is damped	Please turn it off when hearing aid is not in use Dehumidify it with a dry box
Intermittent Sound	Dirt blocks the sound tube Dirt blocks the earplugs	Clean the sound tube Clean the earplugs

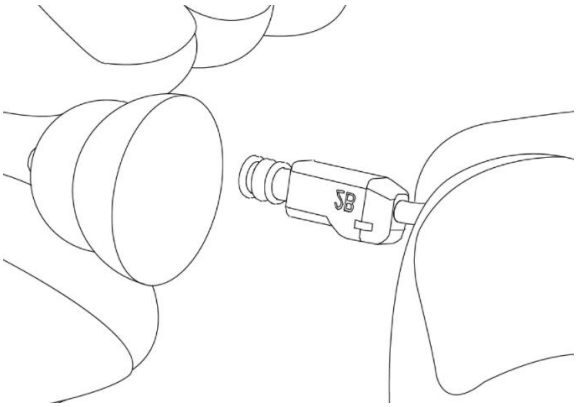
If the above methods still cannot solve the problem, please contact the fitting center where you purchased the hearing aid, or directly contact the customer service center of our company.

6. Hearing Aid Maintenance

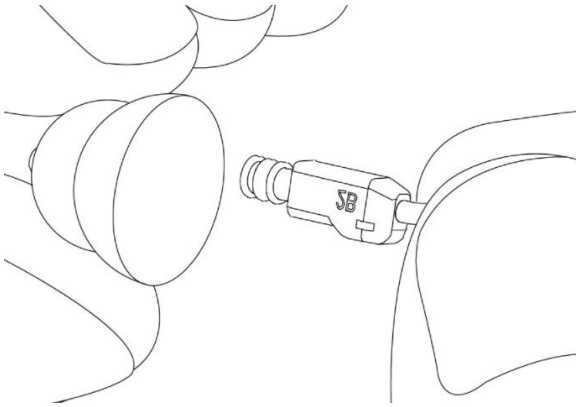
During the use of hearing aid, earwax (cerumen) produced by the ears will accumulate in the ear canal and the sound hole of the hearing aid. A large amount of accumulated earwax will affect the use effect of the hearing aid, so please clean your ear canal and maintain the hearing aid regularly.

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

- Please use the small brush to clean the earwax of the sound hole of the hearing aid.

- 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 aid.
☆ Remember: Do not use any liquid to clean the hearing aid.

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

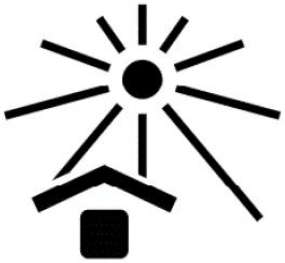
Any form of moisture is influential for hearing aid, dehumidification can extend the life of the hearing aid. Avoid using or storage in humid environment, and please dry the hearing aid on a regular basis.

b) Water Prevention

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 a failure occurs, please contact with the staff from customer service center.

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.
- For hearing aids that do not comply with requirements for explosive or oxygenenriched atmospheres: warning not to use the hearing aids in such areas.
- For hearing aids with wireless transmission: warning to check first before using the hearing aids system in areas where electronics or wireless devices are restricted.
- Classification by operation mode: Continuous operation equipment.

Notes: The In-The-Ear Hearing Aid conforms to IEC60601-1-2 EMC 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 In-The-Ear 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 In-The-Ear Hearing Aid, please avoid strong electromagnetic disturbance while using, such as close to the In-The-Ear Hearing Aid, 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 In-The-Ear 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 In-The-Ear 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 In-The-Ear 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

Guidance and manufacturer's declaration-electromagnetic emission		
The In-The-Ear Hearing Aid is intended for use in the electromagnetic environment specified below. The customer or the user of the In-The-Ear 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 In-The-Ear 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 In-The-Ear 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

Guidance and manufacturer's declaration-electromagnetic			
The In-The-Ear Hearing Aid is intended for use in the electromagnetic environment specified below. The customer or the user of the In-The-Ear 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 ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV	Floors should be wood, concrete or ceramic tile. if floors are

IEC61000-4-2		air	covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	N/A
Surge IEC 61000-4-5	± 1 kV differential mode ±2 kV common mode	± 1 kV differential mode	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	Dips: 0% U_T for 0.5 cycle at 0°, 45°,90°,135°,180°,225°,270 and 315°	Dips: 0% U_T for 0.5 cycle at 0°, 45°,90°,135°,180°,225°,270 and 315°	N/A
	0% U_T for 1 cycle at 0°	0% U_T for 1 cycle at 0°	
	70% U_T for 25 cycles（50Hz）, 30 cycles（60Hz）at 0°	70% U_T for 25 cycles（50Hz）, 30 cycles（60Hz）at 0°	
	Interruptions: 0% U_T for 250 cycles（50Hz）, 300 cycles（60Hz）	Interruptions: 0% U_T 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.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The In-The-Ear Hearing Aid is intended for use in the electromagnetic environment specified below. The customer or the user of The In-The-Ear Hearing Aid should assure that it is used in such an electromagnetic environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
			Portable and mobile RF communications equipment should

Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	0,15MHz–80MHz 3 V RMS outside the ISM band, [c] 6 V RMS in the ISM and amateur radio bands [d] 10V/m 80 MHz to 2.7 GHz	0,15MHz–80MHz 3 V RMS outside the ISM band, [c]6 V RMS in the ISM and amateur radio bands [d] 10V/m 80 MHz to 2.7 GHz	be used no closer to any part of The In-The-Ear Hearing Aid, including cables, in the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ,[a] should be less than the compliance level in each frequency range .[b] Interference may occur in the vicinity of equipment marked with the following symbol.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which The In-The-Ear Hearing Aid is used exceeds the applicable RF compliance level above, The In-The-Ear Hearing Aid should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating The In-The-Ear Hearing Aid. b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m. c:ISM bands between: 6.765MHz~6.795 MHz, 13.553 MHz~13.567 MHz, 26.957 MHz~27.283 MHz, 40.66 MHz~40.70 MHz d:ama-teur radio bands between: 1.8MHz~2.0MHz, 3.5MHz~4.0MHz, 5.3MHz~5.4MHz, 7MHz~7.3MHz, 10.1MHz~10.15MHz, 14MHz~14.2MHz, 18.07MHz~18.17MHz, 21.0MHz~21.4MHz, 24.89MHz~24.99MHz, 28.0MHz~29.7MHz, 50.0MHz~54.0MHz			

Table 4

Frequency Range and Level: RF wireless communication equipment			
Test Frequency (MHz)	Modulation	Minimum immunity Level (V/m)	immunity Level Applied (V/m)
385	18Hz PM 50%	27	27
450	1 kHz sine FM + 5 Hz deviation	28	28
710 745 780	217Hz PM 50%	9	9
810 870 930	18Hz PM 50%	28	28
1720 1845 1970	217Hz PM 50%	28	28
2450	217Hz PM 50%	28	28
5240 5500 5785	217Hz PM 50%	9	9
ATTENTION: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.			
a) For some services, only the uplink frequencies are included			

Table 5

Recommended separation distances between portable and mobile RF communication the equipment			
The In-The-Ear Hearing Aid is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The In-The-Ear Hearing Aid can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the In-The-Ear 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. NOTE 1 : At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			

NOTE 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

f) Others

- Keep the outer surface of the hearing aid clean, and often clean the earwax in the earplug.
- The Hearing aids should be sent to the fitting center for maintenance and inspection regularly to ensure that the hearing aids are in good condition.
- The touch button should be used correctly and pressed gently as far as possible to avoid excessive force.
- When the hearing aid is not used for a long time, the hearing aid should be put back into the charging box for shutdown.

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

BTE hearing aid:

Accessories List	Number	Unit
Ear domes	1	PC
☐ User manual	1	PC
Certification	1	PC
☐ Warranty card	1	PC
☐ Charger case	1	PC
☐ Type-C cable	1	PC
☐ Cleaning tool	1	PC
Cerumen cleaning strip	1	PC

BTE-RIC:

Accessories List	Number	Unit
Ear domes	1	PC
☐ User manual	1	PC
Certification	1	PC
☐ Warranty card	1	PC
☐ Charger case	1	PC
☐ Type-C cable	1	PC
☐ Cleaning tool	1	PC
☐ Cerumen cap suit	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 titled up to 15 º.
	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.		
	During transport or storage, the temperature should not exceed the limit values of -20 °to 50 ° 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.		

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.

Manufacturer: Austar Hearing Science and Technology (Xiamen) Co., Ltd.
Address: B8, Biomedical Industrial Park, NO.2064 Wengjiao West Road, Haicang Dist., Xiamen, Fujian, China
Postcode: 361028
Tel: +86-592-5900230
Fax: +86-592-5621123
Preparation date: 2022.11