

User Manual

Dear customer:

Thank you for choosing our Hearing Aid!

The hearing aid is 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.

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1. Overview

1.1 Product Name: BTE Hearing-aids (FCC ID: 2A445FHL9RLP-DW)

1.2 Product features

The BTE hearing-aid is a digital hearing aid, and has multiple signal processing channels, adaptive noise reduction management, adaptive feedback suppression and other functions. BTE hearing-aid is not only suitable for listening in quiet environment, but also suitable for noisy environment. The appearance design of the product conforms to the principle of ergonomics and is comfortable to wear.

1.3 Software version

Software name: Embedded sound processing software based on ultra-low power DSP

Version: V1.0

1.4 Data transfer protocol based on product embedded software Standard BLE communication protocol.

1.5 Model Number:

FHL9RMP-DW, FHL7RMP-DW, FHL5RMP-DW, FHL3RMP-DW,
FHL9RLP-DW, FHL7RLP-DW, FHL5RLP-DW, FHL3RLP-DW, FHL9RxS-DW,
FHL7RxS-DW, FHL5RxS-DW, FHL3RxS-DW

1.6 Program Setting

Program	Input setting/Function features
P1	
P2	
P3	
P4	
P5	
P6	

Above info will be filled by the audiologist according to the program file settings of the hearing aid.

1.7 Operation condition

Temperature: 0℃～+40℃

Relative Humidity: ≤80 %

Atmospheric pressure: 86KPa~106KPa

Voltage: DC 1.4V

1.8 Impact on environment

Please do not randomly abandon the battery after use. Please dispose of the used batteries according to local regulations.

1.9 Safety

- Danger: To avoid explosion, please do not put the hearing aids into fire or microwave oven, and so on.
- Danger: To avoid being swallowed by children in accident, please keep the hearing aid away from children.
- This hearing-aid 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 Users:
 - (1) Children need to wear hearing aids with the help of adults.
 - (2) Please consult your doctor before using hearing aids.

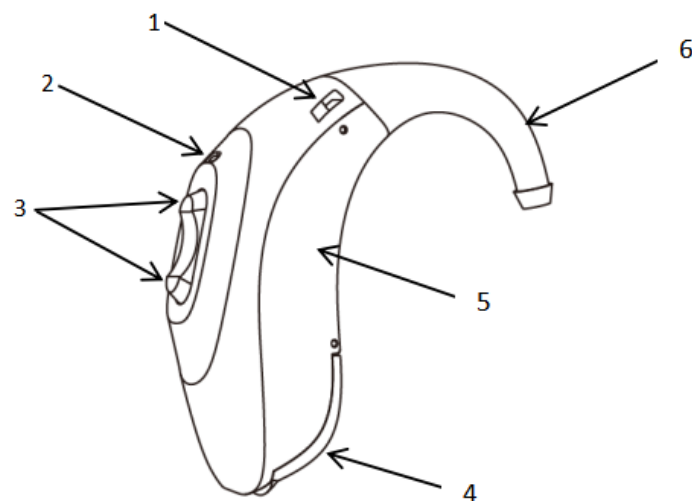
- Warning: Hearing aids are able to provide more than 132 dB SPL. The fitted OSPL90 does not increase if the control is disconnected or defective. It need to the hearing aid professional for RECD measured to correct target of fitted OSPL90. The hearing aids should be fitted by the professional operator 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. Technical Specification and Structural Characteristics

2.1 Structure characteristics

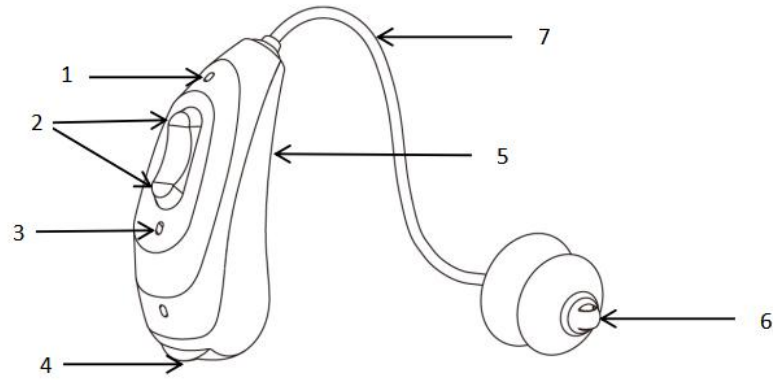
This hearing aid consists of microphone, signal magnify processing circuit, receiver, multi-functional button, zinc air battery, shell and embedded software(v1.0)

FHL Series:



- 1、 Front MIC 2、 Back MIC 3、 Multi-functional button 4、 Battery Door
5、 Shell 6、 Ear hook

FHL(X)R series:



- 1、Front MIC 2、Multi-functional Button 3、Rear MIC 4、Battery Door
5、Shell 6、Ear Domes 7、Horn module

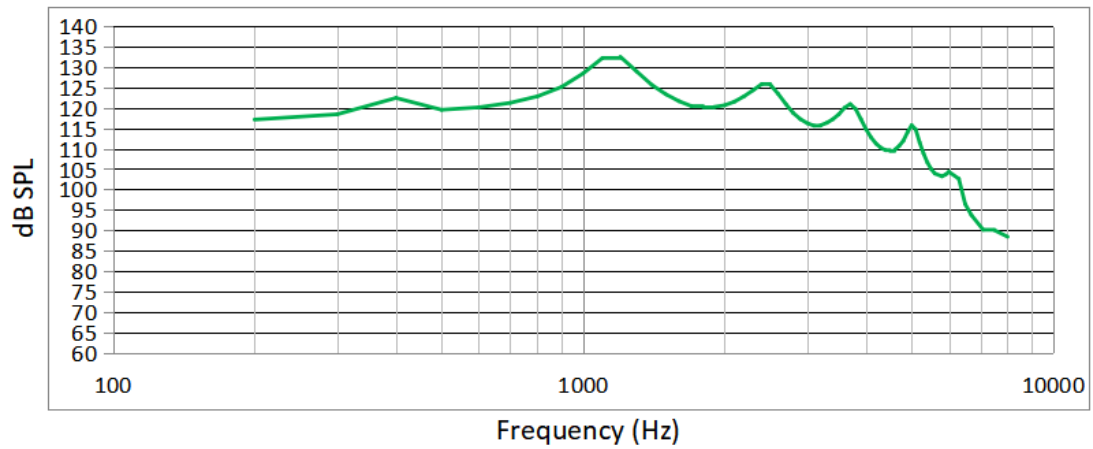
2.2 Technical Specification

Model	Max OSPL90 (+3dB)	HFA OSPL90 (± 4dB)	Peak gain (+3dB)	HFA FOG (± 5dB)	THD			Frequency Range (Hz)	Eq.Input Noise Level(dB)	Battery Current Drain(mA)	Attack Time (± 5mS))	Release time (±5mS)	High sensitivity of inductive pickup coil(dB)
					500Hz	800Hz	1600Hz						
FHL9SP-DW	132	126	67	63	5.0%	5.0%	5.0%	200-4500	25	5	6	200	75
FHL7SP-DW	132	126	67	63	5.0%	5.0%	5.0%	200-4500	25	5	6	200	75
FHL5SP-DW	132	126	67	63	5.0%	5.0%	5.0%	200-4500	25	5	6	200	75
FHL3SP-DW	132	126	67	63	5.0%	5.0%	5.0%	200-4500	25	5	6	200	75
FHL9MP-DW	126	119	57	53	5.0%	5.0%	5.0%	200-4500	25	5	6	200	70
FHL7MP-DW	126	119	57	53	5.0%	5.0%	5.0%	200-4500	25	5	6	200	70
FHL5MP-DW	126	119	57	53	5.0%	5.0%	5.0%	200-4500	25	5	6	200	70
FHL3MP-DW	126	119	57	53	5.0%	5.0%	5.0%	200-4500	25	5	6	200	70
FHL9RMP-DW	123	121	66	63	5.0%	5.0%	5.0%	200-4500	25	5	6	200	80
FHL7RMP-DW	123	121	66	63	5.0%	5.0%	5.0%	200-4500	25	5	6	200	80
FHL5RMP-DW	123	121	66	63	5.0%	5.0%	5.0%	200-4500	25	5	6	200	80
FHL3RMP-DW	123	121	66	63	5.0%	5.0%	5.0%	200-4500	25	5	6	200	80
FHL9RLP-DW	117	114	57	53	5.0%	5.0%	5.0%	200-4500	25	5	6	200	70
FHL7RLP-DW	117	114	57	53	5.0%	5.0%	5.0%	200-4500	25	5	6	200	70
FHL5RLP-DW	117	114	57	53	5.0%	5.0%	5.0%	200-4500	25	5	6	200	70
FHL3RLP-DW	117	114	57	53	5.0%	5.0%	5.0%	200-4500	25	5	6	200	70
FHL9RxS-DW	108	105	45	40	5.0%	5.0%	5.0%	200-4500	25	5	6	200	60
FHL7RxS-DW	108	105	45	40	5.0%	5.0%	5.0%	200-4500	25	5	6	200	60
FHL5RxS-DW	108	105	45	40	5.0%	5.0%	5.0%	200-4500	25	5	6	200	60
FHL3RxS-DW	108	105	45	40	5.0%	5.0%	5.0%	200-4500	25	5	6	200	60

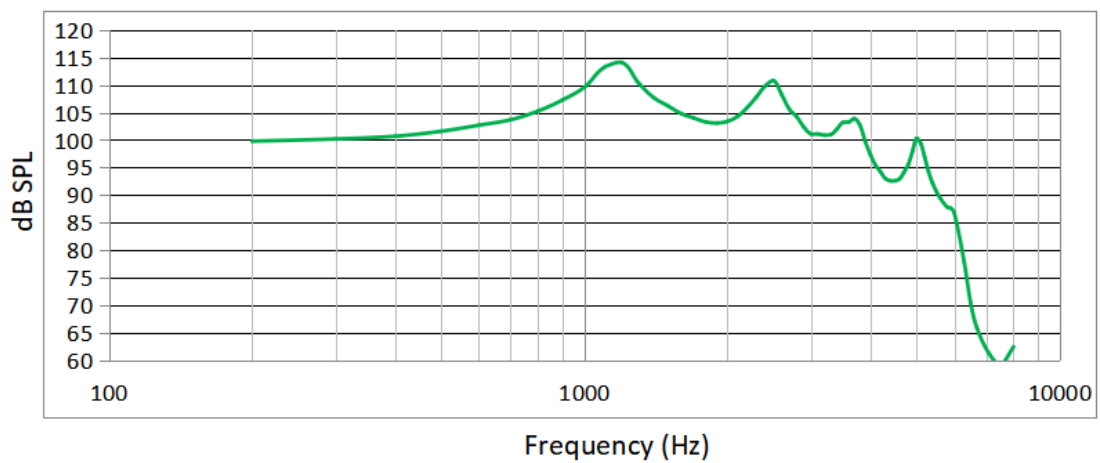
Response curve

FHL:

Maximum Output(OSPL90)

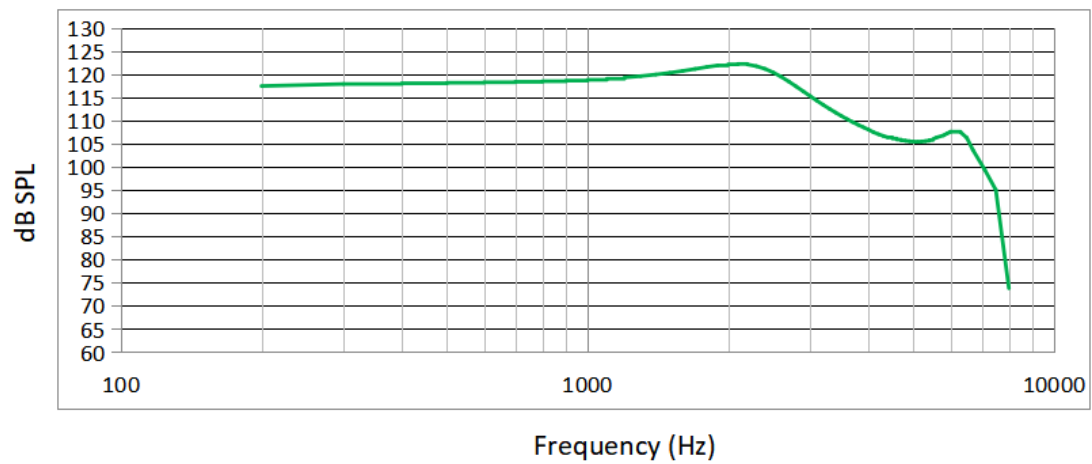


Reference Test Gain (60dB SPL)

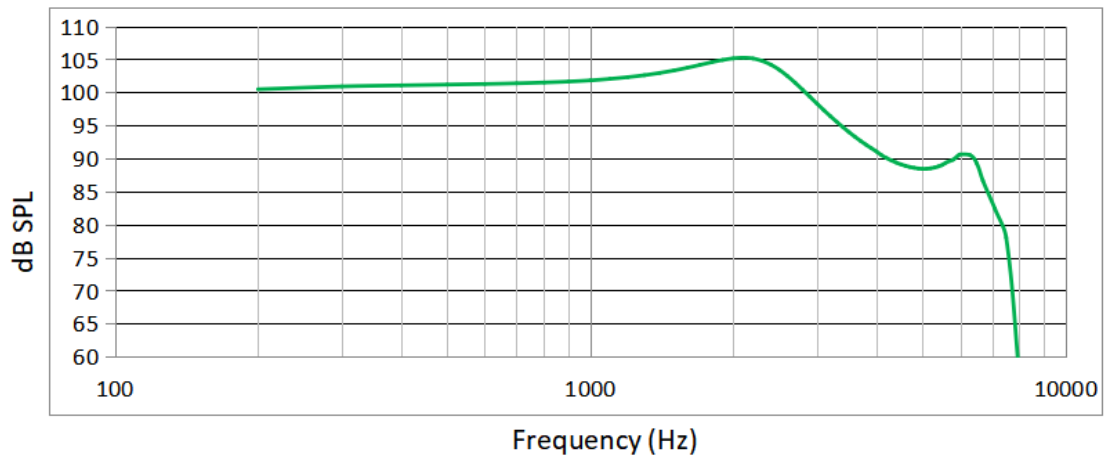


FHL(X)R:

Maximum Output(OSPL90)



Reference Test Gain (60dB SPL)



3. Indication and Target Users

3.1 Indication

Hearing compensation for air conductive hearing loss patients.

3.2 Target Users

Suitable for patients with air-conduct hearing loss, but children under 12 years of age need to be used under the supervision of an adult.

4. Contraindication

Acute otitis externa, tympanitis, chronic suppurative otitis media (in the period of purulent infection) and acute suppurative otitis media are not suitable for wearing hearing aids. Patients who are allergic to this material.

5. Precautions

- 5.1 The fitted hearing aids shall be undergo professional hearing test and fitting, and shall be used under the professional guidance of doctors or audiologists.

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 the best results, use 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.

It is good practice for a person with a hearing loss to have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear). Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists, or otorhinolaryngologists. The purpose of a medical evaluation assure that all medically treatable conditions that may affect hearing are identified and treated.

Children with hearing loss : In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation. Because hearing loss may cause problems in language, educational and social development of a child. An audiologist is qualified to assist the evaluation and rehabilitation of a child with hearing loss.

5.2 Dehumidification

Any form of moisture has an impact on the hearing aids. dehumidification can extend the life of the hearing aids. Avoid using or storage in humid environment, to dry the hearing aids on a regular basis.

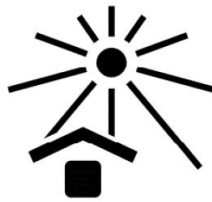
5.3 Water Prevention

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.



5.4 High Temperature Prevention

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



5.5 Falling Prevention

Hearing aids are precision electronic devices, which should avoid falling to the ground or violent vibration and attack.

5.6 Other precautions

- Do not wear hearing aids when receiving short wave hyperthermia, X-ray, MRI scan, CT scan or similar radiotherapy.
- Keep the surface of the hearing aids neat and clean the earwax in the earplugs frequently.
- The touch button should be used correctly and pressed gently as far as possible to avoid excessive force.
- Hearing aid shall be regularly sent to the fitting center for maintenance and inspection to ensure that the hearing aid is in good condition.
- Remove the hearing aid and make sure the earplugs don't stay in the ear.

You should see a hearing care professional if you:

- Visible congenital or traumatic deformity of the ear.
- History of ear infection or continuous drainage from the ear within the previous 90 days.
- Sudden unilateral or bilateral hearing loss onset within the previous 90 days.
- Have acute or chronic dizziness, poor dexterity, poor vision, or significant

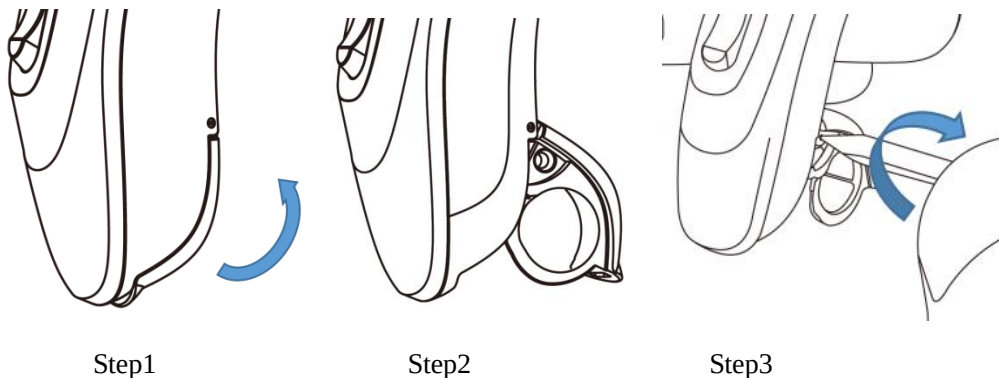
dementia.

- Suspect that you have significant ear wax accumulation or a foreign object in the ear canal. Symptoms of significant ear wax accumulation can may lead itching in your ear, a feeling of fullness in your ear, and/or reduced hearing.
- Experience pain or discomfort in the ear.
- Have a noticeable difference in hearing between ears.
- Have sudden onset or rapid worsening of tinnitus (ringing in the ear) in one or both ears within previous 90 days.

6. Steps for Wearing and Using Hearing Aid

6.1 Left and Right Ear Marking

FHL Series:



When the battery door is opened, grooves appear on the edge of the battery door; Insert the left (right) ear identification of the identification rod into the groove of the battery door, and rotate the identification rod. Red is the right ear, blue is the left ear.

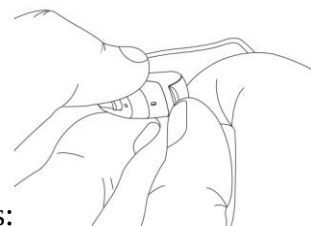
6.2 Insert the battery

- a) Check the battery model: Please use 13A battery.
- b) Open the battery door by gently picking the convex part of the battery door surface with your fingernail;

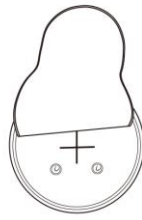
FHL Series:



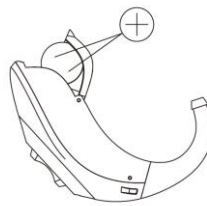
FHL(X)R Series:



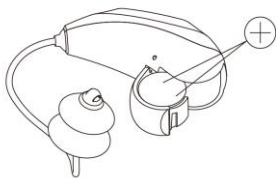
c) Remove the label on battery and expose it in the air for at least 1 minute;



d) Put the battery in and make sure the remark '+' of battery is in the same direction with the remark '+' of battery door;



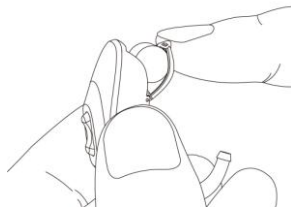
FHL Series :



FHL(X)R Series :

e) Close the battery door tenderly;

FHL Series:



FHL(X)R Series:

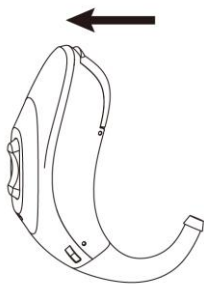


Low battery indicator: when the hearing aid is in low battery, you will hear indicator sounds(4 beeps, or other sound set up by dispensers) which the frequency is about 5 minutes/time. You are suggested to change the battery within 30 minutes.

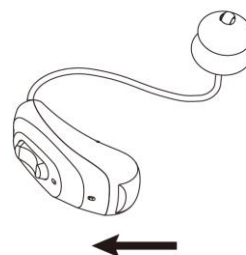
6.3 ON/ OFF

ON: hearing aid will turn on when close the battery door

FHL Series:

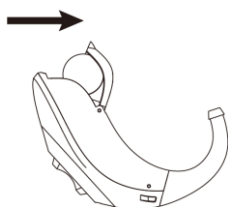


FHL(X)R Series:

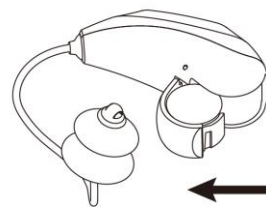


OFF: hearing aid will turn off when open the battery door

FHL Series:



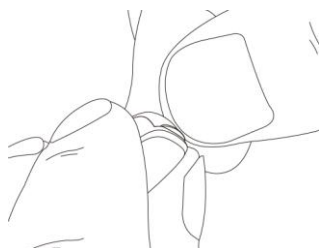
FHL(X)R Series:



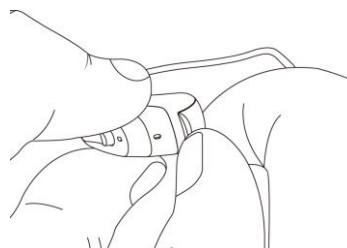
a) Remove the battery

Open the battery door by gently picking the convex part on the surface of the battery door with your fingernail. After the battery door is fully opened, take out the battery.

FHL Series:

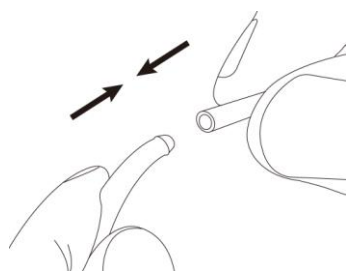


FHL(X)R Series:

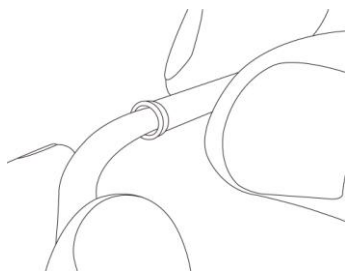


b) Wear hearing aid

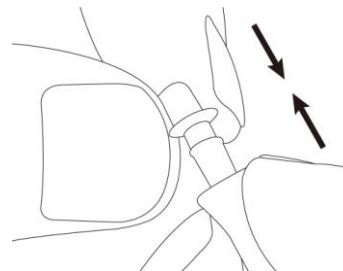
1. FHL Series hearing aid accessory assembly



Step1

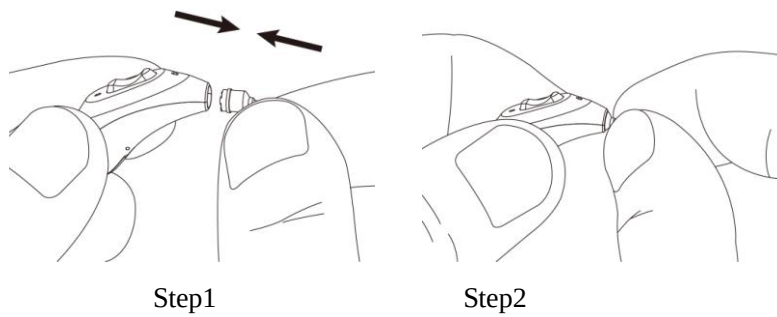


Step2



Step3

2. FHL(X)R Series hearing aid accessory assembly

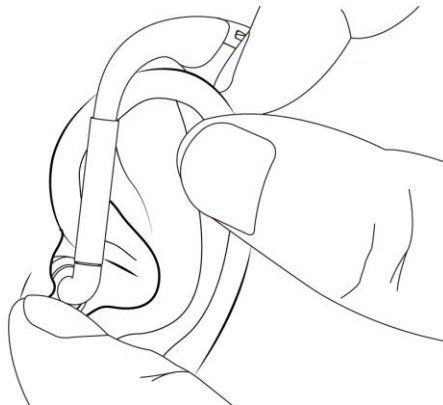


3. Steps for wearing hearing aids

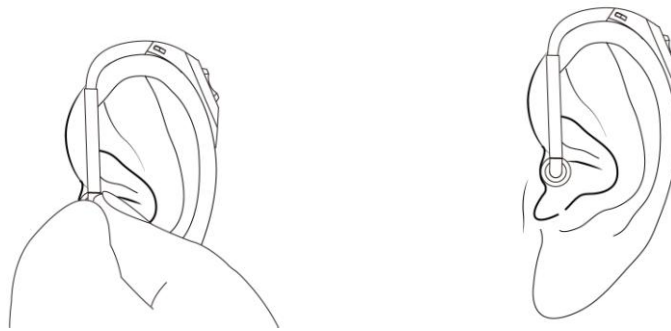
a) Hold the bottom of the acoustic tube with your fingers, and gently push the earplug into the ear canal;



b) Pull the ear back with the other hand, and rotate the earplug back and forth to adjust the earplug position until it is worn in place;



c) Place the hearing aid behind the ear and close to the head, with the ear hook hanging comfortably on the ear.

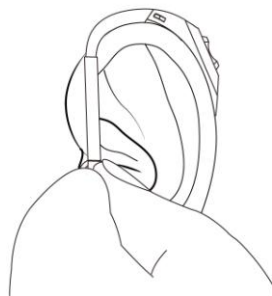


6.4 Remove the hearing aid

1. Remove the hearing aid from behind the ear;



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

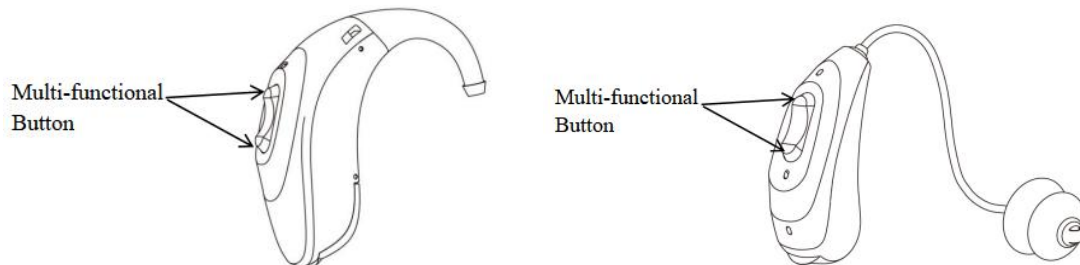


6.5 Program Switch

FHL and FHL(X)R Series:

Press and hold the Multi-functional button above to switch the program file from P1 → P2 → P3 → P4 → P5 → P6 → P1. Press and hold the Multi-functional button below to switch the program file from P1 → P6 → P5 → P4 → P3 → P2 → P1.

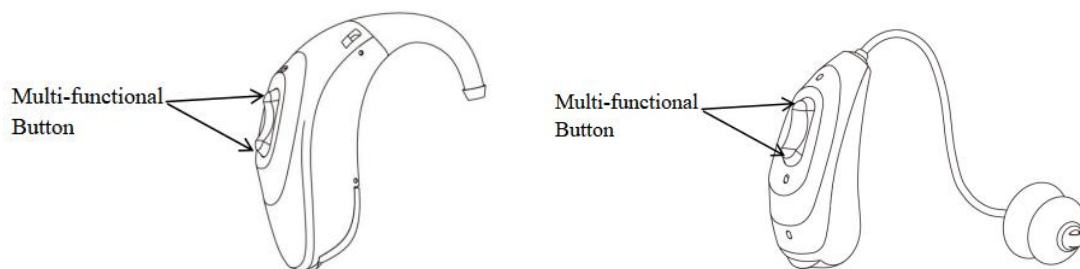
1. Press the Multi-functional button above (5s) for a long time to turn off Bluetooth, and the hearing aid will enter flight mode. When the hearing aid enters flight mode, it needs to be restarted to enable Bluetooth.



6.6 Volume Control

FHL and FHL(X)R Series:

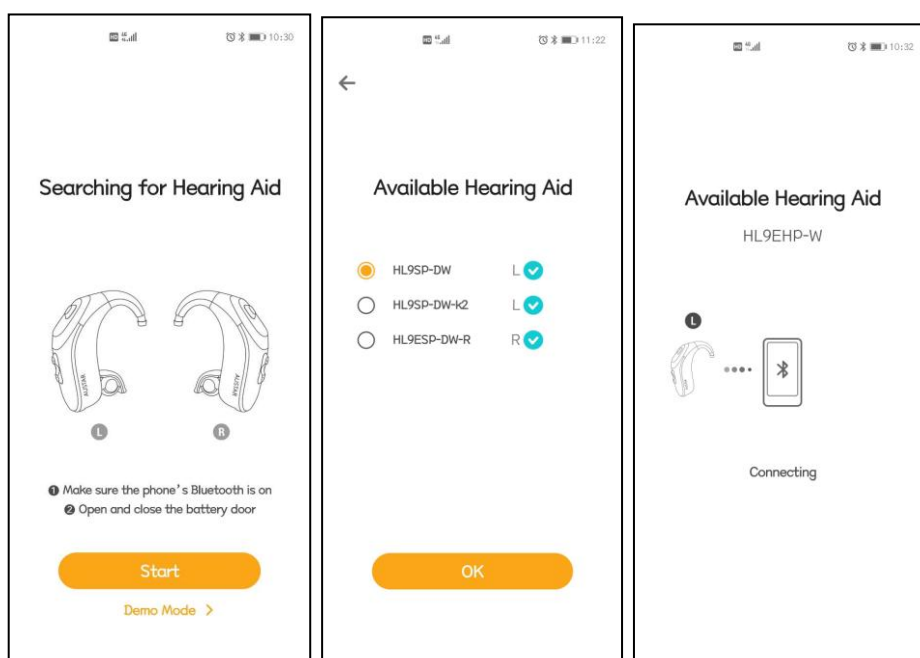
Shortly press the Multi-functional button above to gradually increase the volume, and press the Multi-functional button below to gradually decrease the volume.



6.7 APP Control

If the hearing aid model contains the character 'W', user can easily control the volume and program by mobile APP. Please contact the audiologist for download and use of the hearing aid.

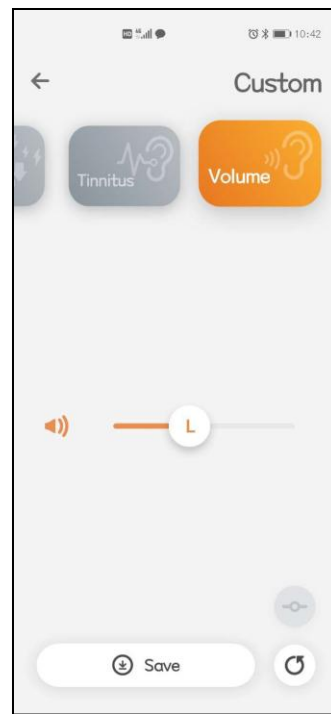
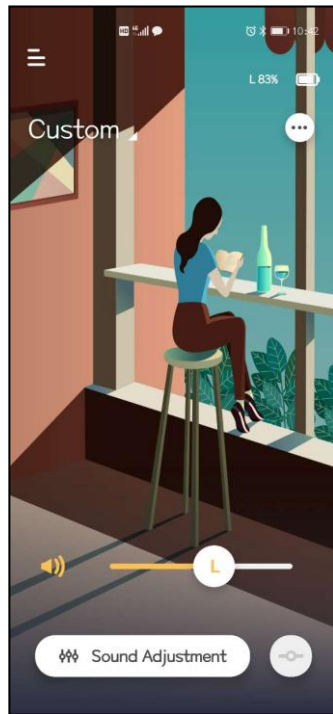
①Search for hearing aid: launch the mobile APP, search for the hearing aid, connect the device named.



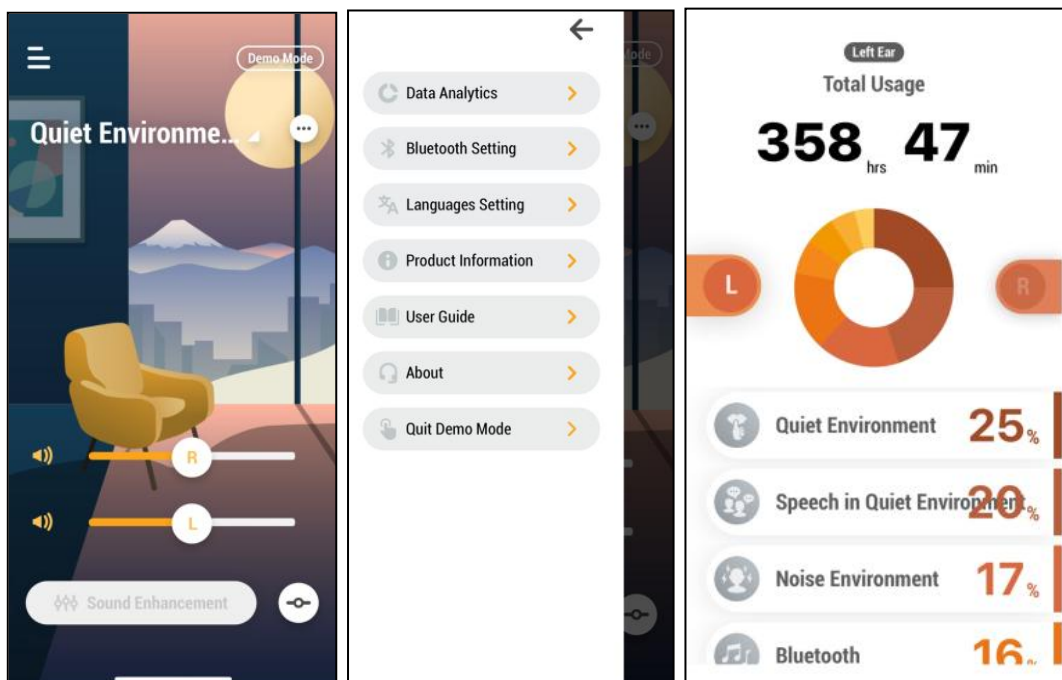
②Program switch: there are 7 programs in all to switch. Quiet environment, noise environment, chat in quiet environment, chat in noise environment, wireless blue tooth, wind noise and customized environment.



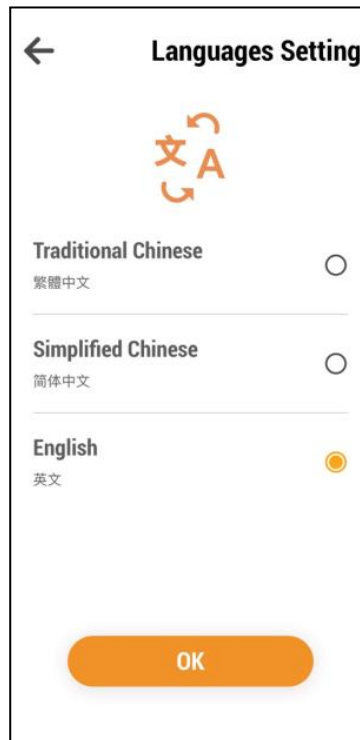
③Volume control: slide left to decrease the volume, and slide right to increase the volume.



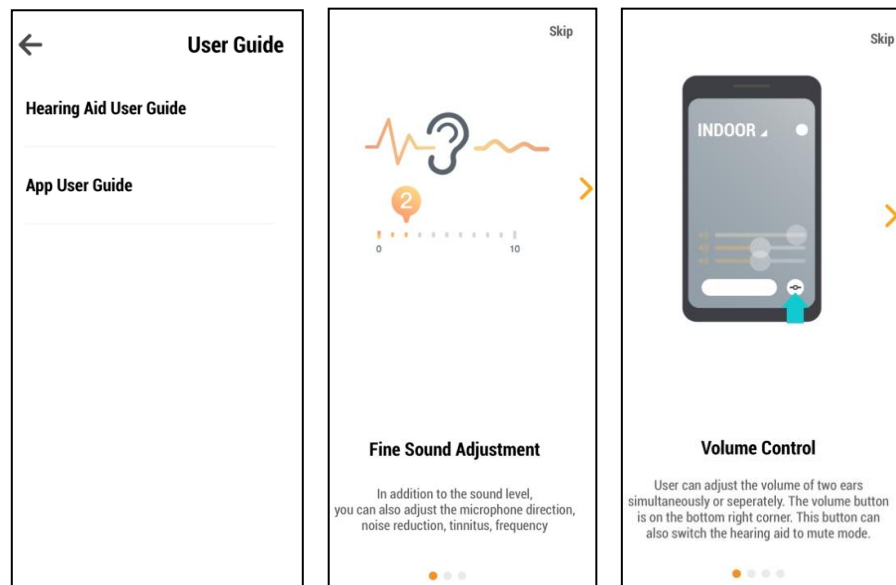
④Usage log: click the option in the upper left corner of the APP page, and multiple options will appear. Click the usage log to view the usage time of the hearing aid.



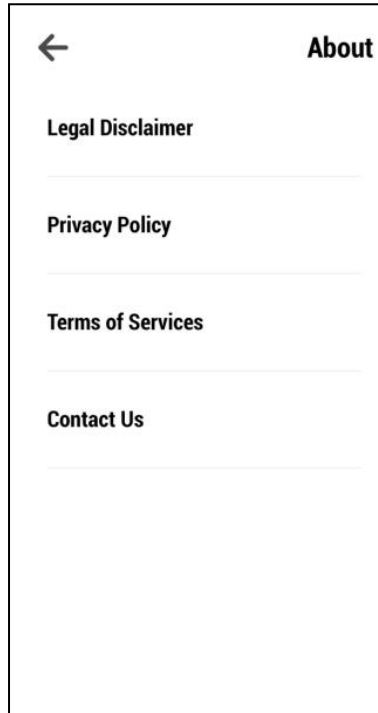
⑤Language setting: Set APP language, traditional Chinese, simplified Chinese and English.



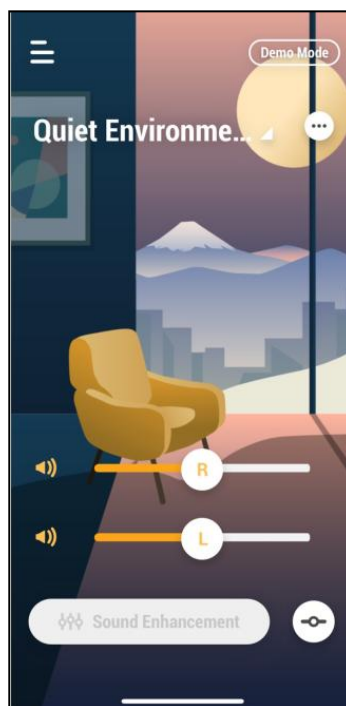
⑥User guide: hearing aid user guide and application user guide.



⑦About: Contact information and version involved.



⑧ Demo mode: experience how to use APP without connecting to the product.



7. Troubleshooting

Fault	Reason	Solution
Whistling	The earphone is not worn correctly Too much earwax in the ears	Wear correctly again Clean earwax

No sound	Powered OFF No battery in the hearing aid Low battery power or no power Sound hole is blocked by dirt Ear Dome is blocked by dirt	Power ON Install battery Change a new battery Clean hearing aid Clean ear dome
Small voice	Low volume Low battery Hearing aid gets wet Sound hole is blocked by dirt Ear Dome is blocked by dirt	Turn up the volume Change a new battery Dry the hearing aid Clean the hearing aid Clean ear dome
High power consumption	Hearing aid are not turned off when not using Hearing aid gets wet	Please turn off your hearing aid when not in use Dry the hearing aid
Intermittent voice	Battery failure Sound hole is blocked by dirt wax guard is blocked by dirt	Change a new battery Clean hearing aid Clean ear dome

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

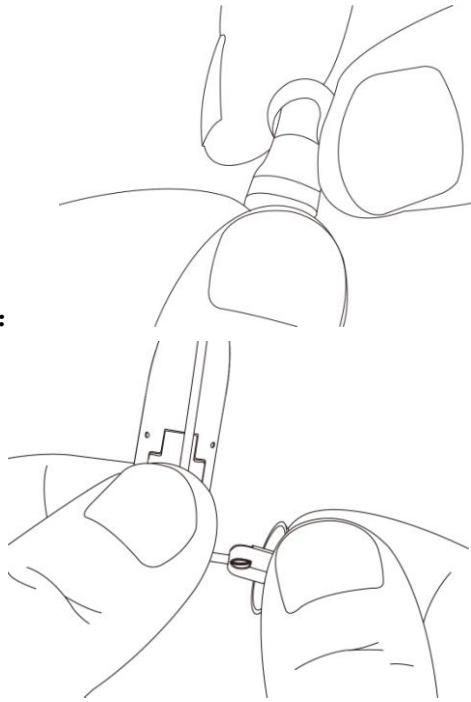
8. Maintenance of hearing aids

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

8.1 Clean ear dome

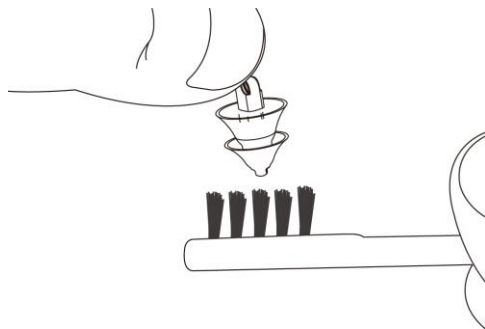
1. Remove the earplug from the sound tube;

FHL Series:



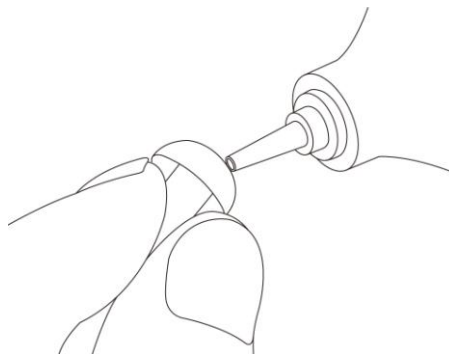
FHL(X)R:

2. Use the small brush (FHL (X) R series) and cleaning cloth distributed in the packaging box to clean earwax; Or rinse the earplugs with clean water.



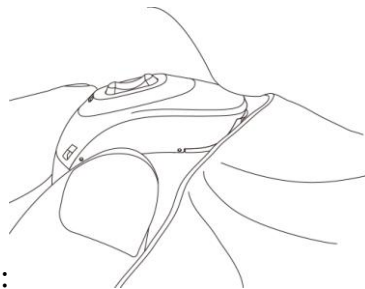
FHL(X)R:

3. Dry the earplugs and make sure there are no water drops left. If there are similar tools like blowing balloons, you can use blowing balloons to blow the water droplets dry.



8.2 Clean hearing aid

- Please clean the hearing aid in a soft and clean interface such as towel to avoid the damage of accidental drop.



FHL Series:



FHL(X) Series:

- Wipe or clean the hearing aid on a soft desktop (for example, a soft towel can be placed on the desktop) to avoid damage caused by accidental dropping of the hearing aid.
- Remember: Do not use any liquid to clean the hearing aid.

8.3 Dehumidification of hearing aids

Please put the hearing aid into a special drying box for drying before going to bed every night to prolong the service life of the hearing aid

Remarks: Special drying box shall be purchased separately.

8.4 Vibration prevention of hearing aids

When you do not need to use a hearing aid when going out, please put the hearing aid into a shock proof box or bag.

9. Electrical Safety Instructions

- 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) IEC61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 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 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	± 1 kV differential mode	N/A

	mode		
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: U_T 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
Conducted RF IEC61000-4-6	0,15MHz–80MHz 3 V RMS outside the ISM band, ^{c)} 6 V RMS in the ISM and amateur radio bands	0,15MHz–80MHz 3 V RMS outside the ISM band, ^{c)} 6 V RMS in the ISM and amateur radio bands	Portable and mobile RF communications equipment should be used no closer to any part of The In-The-Ear Hearing Aid, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

Radiated RF IEC61000-4-3	d)	d)	$d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.4 GHz 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.
	10V/m 80 MHz to 2.7 GHz	10V/m 80 MHz to 2.7 GHz	
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, an 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: amateur 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	80MHz to 800MHz	80MHz to 2,5GHz
	$d=1.2 \sqrt{P}$	$d=1.2 \sqrt{P}$	$d=2.3 \sqrt{P}$
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.			

10. Technical description

The supplier may provide circuit diagrams, component lists, drawing notes,

correction rules, or other data necessary for qualified technicians to help users repair the serviceable parts designated by the manufacturer.

11. Accessories List

FHL Series

Item	Qty	Unit
User Manual	1	PC
certificate	1	PC
Warranty Card	1	PC
Plastic Box	1	PC
Battery	1	PC
Ear Domes	1	SET
Left and right ear identification	1	SET

FHL(X)R Series:

Item	Qty	Unit
User Manual	1	PC
Certificate	1	PC
Warranty Card	1	PC
Plastic Box	1	PC
Battery	1	PC
Ear Domes	1	SET
Brush	1	PC

12. Unpacking and Check

- After unpacking, please check the accessories are consistent according to the list.
- Check the product model marked on the warranty card is consistent with that of the hearing aids.

13. Warranty of hearing aid

13.1 Free Warranty Coverage

All hearing aids produced by our company enjoy free warranty for faults caused by non-human factors from the date of purchase.

13.2 Warranty Period.

From the date of purchase, it should be non-human damage, free repairs are given within the warranty time, please check the warranty period on the warranty card.

13.3 Following situations are not covered by the free warranty.

- Damage caused by incorrect use or improper operation.
- Damage caused by self disassembly and assembly of the hearing aids.
- Damage caused by force majeure (flood, fire, earthquake, etc.).

14. Production date and Use period

It is the normal working time of the product. The product needs to be stored and used as required, and its expected function will be affected after the specified usage time (Such as failure to meet product performance indicators). Hearing aid products have a lifespan of 8 years. The date of manufacture is shown on the label.

15. Transport and storage restrictions

Temperature: $-20^{\circ}\text{C} \sim +50^{\circ}\text{C}$

Humidity: $0\% \text{ RH} \sim 93\% \text{ RH}$

Barometric pressure: $86\text{KPa} \sim 106\text{KPa}$

Storage conditions: normal temperature, clean, protected from light, non-corrosive gas and well-ventilated room.

Transportation conditions: The packaged hearing aid can be transported by general cargo transportation methods, and should be protected from rain, sun and collision during transportation.

16. Network Security

Data exchange: Bluetooth 5.0 BLE wireless connection.

Data encryption/data desensitization: Transmission of data is a test parameter required for the operation of the device and does not involve user information or clinical data.

Hardware and software environment: Hardware configuration: 8 core CPU processor;Running memory 4GB; The body stores 64GB.

Software operating environment: Above Android 8 and IOS 8.

Programmer	Manufacturer/Supplier
HiPro	Otometrics
Noahlink	HIMSA
Promira	TotalPhase Inc.
CAA	ON Semiconductor
DSP3	ON Semiconductor

In addition, the Bluetooth 5.0 BLE connection can only be used after the hearing aid is paired with the mobile APP.

17. Symbol Information

	Symbol for “User Guide must be read”		Symbol for “Consult instructions for use”
	Symbol for “Manufacturer”		Symbol for “Caution”
	Symbol for “Fragile, handle with care”		Symbol for “Keep dry”
	Symbol for “Date of manufacture”		Symbol for “Serial number”
	Symbol for “Use-by date”		Type B Applied Part
	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		The harmful substances in the product meet the limited requirements.

	promote the sustainable reuse of material resources.		
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Manufacture: Austar Hearing Science & Technology(Xiamen) Co., Ltd.

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

Post code: 361028

Tel: +86-0592-5900230

Fax: +86-0592-5621123

Preparation date: 2022.11

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.