

物料编号: 1.4.05.A61HT.001

工艺要求	惠州市锦好医疗科技股份有限公司包材文档		
材质：120G双胶纸 工艺：骑马钉 颜色：4色印刷 尺寸：90X90mm 总P数：52P（含封面封底） 正公差：1mm 负公差：0mm	文稿名称： JH-A61HT (医疗器械) OTC英文说明书		
	文件编号：JH-C-A61HT-20221027-01 版本号：V0		
	<input type="radio"/> 订单号： <input type="radio"/> 国标物料		
	制作：Victor	需求：Tibby	核准
	制作日期：2022年10月27日		

更改履历:

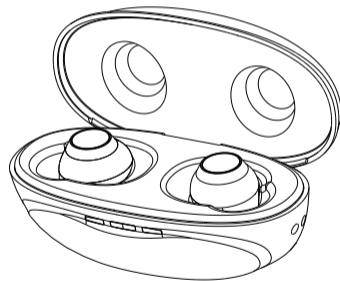


VER: A61HT-20221027-V0

OTC

HEARING AID 

Instruction Manual Model: JH-A61HT



Please read this user manual thoroughly and completely before using the product.

CONTENTS

I. Warnings	03
II. Cautious and Notices	09
III. HOW TO USE YOUR DEVICE	16
1. HOW TO APPLY EARTIPS	19
2. LEFT & RIGHT HEARING AID MARKINGS	20
3. WEAR/REMOVE HEARING AIDS	20
4. TURN ON/TURN OFF	22
5. VOLUME ADJUSTMENT	23
6. HEARING PROGRAMS CHANGE	24
7. HEARING AIDS CHARGING	25
8. HOW TO USE THE CHARGING CASE	26
9. BLUETOOTH FUNCTION	28
10. HOW TO USE THE APP	29

IV. MAINTENANCE AND CLEAN	34
V. HEARING AID AND CHARGING CASE CARE	36
VI. TROUBLESHOOTING GUIDE	37
VII. REGULATORY AND LEGAL INFORMATION	40
VIII. TECHNICAL SPECIFICATIONS	53
IX. ACCESSORIES	54
X. NORMALIZED SYMBOLS	55
XI. MAINTENANCE, STORAGE, AND DISPOSAL	56
XII. WARRANTY	57

I.WARNINGS

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

You should go to a doctor, preferably an ear-nose-throat doctor(an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

2.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
- 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

3.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.

4.WARNING:important safety instruction

The device should not be used in the following situations:

- Patients with chronic suppurative otitis media (CSOM),con

genital ear atresia, or any type of ear discharge

- Keep small parts (hearing instrument, eartips, battery or other detachable parts) that can be swallowed out of children's reach. Dropping, immersing in liquid, exposure to strong electromagnetic fields or excessive heat will damage the hearing aid. Remove devices prior to any type of X-ray, MRI, or CT scan. If parts become stuck in the ear canal, seek medical assistance—do not attempt to remove by yourself.
- Do not use at high volume for extended periods of time—ear injury can result.
- If you experience any pain or strong discomfort using the devices, remove and consult a doctor.
- Routine maintenance to keep the device clean is required. Ensure that eartips are free of debris and moisture at all times.
- Avoid shocks or dropping the product.
- Do not store or use the product in environments of high humidity or temperature (such as sauna room), to avoid damage.
- Batteries should be properly recycled and not disposed in the trash.
- Keep the devices away from children. Injury or damage

may result.

- Do not set volume levels too high. Listening with high-output devices for extended period of time at high volume levels can cause further hearing damage.
- Do not share your hearing aids with others. Using a hearing aid configured for someone else can result in hearing damage or injury.
- Monitor for any unusual skin reaction. If you notice any allergic reaction (itchiness, swelling, or rash), stop wearing the hearing aids and consult a medical specialist.
- Do not touch the hearing aids to any type of magnet or magnetized object. Your hearing aids are delicate electronic instruments and may be damaged by contact with strong magnetic fields.
- Do not attempt to open or repair the devices yourself. Damage can result and will void the warranty.
- Stay away from strong electromagnetic fields when using hearing aid to avoid unexpected damage.
- Do not store your devices in a hot/humid location. You should never leave your hearing aids near heating appliances or in direct sunlight.
- Do not leave your hearing aids in the car as inside temperatures can reach dangerous levels which could damage the

devices.

- If the Bluetooth function is available for your device, do NOT connect the hearing aid and headsets to the mobile phone via Bluetooth simultaneously - noise, distortion or any other unexpected problems may occur to your hearing aid.

- Please contact the MANUFACTURER:

For assistance, if needed, in setting up, using or maintaining your devices or to report any unexpected operation or events.

- Contact your hearing professional for assistance if needed.
- Do NOT fix your devices by yourself. Doing so will not only void the warranty but also cause further damage easily. -Check the “TROUBLESHOOTING GUIDE” first when failures occur to your devices.

Specific warnings / statements
Keep small parts away from children to avoid accidental ingestion
Do not use the devices in explosive or oxygen-enriched atmospheres, as doing so may damage the devices
Warning that it should only be used by intended person as using hearing aids designed for someone else may result in hearing damage

5.WARNING: do not use if any of the followings apply to you

- Congenital atresia of external ear or deformity of any part of the ear canal
- Deafness is unstable, and the degree of hearing loss often fluctuates
- Persistent headaches, dizziness, earaches, tinnitus or other symptoms that are not suitable for adaptation
- Sudden onset of hearing loss within the past 3 months; rapid progressive deafness; unilateral hearing loss or other acute ear disease
- Effusion (secretions/discharge) in the ear and/or frequent purulence (pus).
- Central deafness (central nervous system) or non-organic deafness.
- Patients with acute otitis externa and tympanitis.
- Patients with acute and chronic suppurative otitis media (in the period of purulent infection).
- Patients who are allergic to the materials of this product.

II.CAUTIONS AND NOTICES

1.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.

2.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.

3.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.

4.Note: If you remain concerned, consult 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.

5.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.

6.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.

7.Note:If you experience side effects, contact a hearing care professional.

Possible side effects from wearing the hearing aid may be:

- Dizziness
- Tinnitus
- Perceived worsening of hearing loss
- Nausea
- Headache
- Skin reaction
- Excessive ear wax accumulation

8.Note:Tips for better communication

It will take practice, time, and patience for your brain to adapt to the new sounds that your hearing aids provide. Hearing is only part of how we share thoughts, ideas and feelings.

Reading lips, facial expressions, and gestures can help the learning process and add to what amplification alone may miss.

(1) Please review the following simple communication tips for you:

- Move closer to and look at the speaker.
- Sit face-to-face in a quiet room if possible.
- Try out different locations to find the optimal places to listen
- Minimize distractions.
- Background noises may be frustrating at first; remember, you have not heard them for a while.
- Let others know what you need; keep in mind that people cannot “see” your hearing loss.
- Develop realistic expectations of what your hearing aids can and cannot do.
- Better hearing with hearing aids are a learned skill combin-

ing desire, practice, and patience.

(2) You will learn and adjust, it just takes a little time. Remember to be patient with yourself.

(3) For Your Family and Friends:

Your family and friends are also affected by your hearing loss.

Request that they:

- Get your full attention before beginning to speak.
- Look at you or sit face-to-face.
- Speak clearly and at a normal rate and level; shouting can actually make understanding more difficult.
- Rephrase rather than repeat the same words; different words may be easier to understand.
- Minimize distractions while speaking.

9.Caution

- The use of accessories and cables other than those specified by manufacturer, with the exception of cables sold by manufacturer as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- Do not use a mobile phone or other devices that emit

electro magnetic fields, near the unit. This may result in incorrect operation of the unit.

- Do not bring the device into any MRI, CT, diathermy, RFID and electromagnetic security systems such as metal detectors environment or near any of this equipment. Consult manufacturer if you have any questions.
- This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.

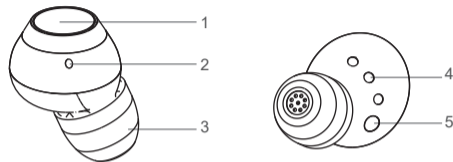
There is no guarantee that interference will not occur in a particular installation. Radiated or conducted electromagnetic signals can cause:

1)As to devices:

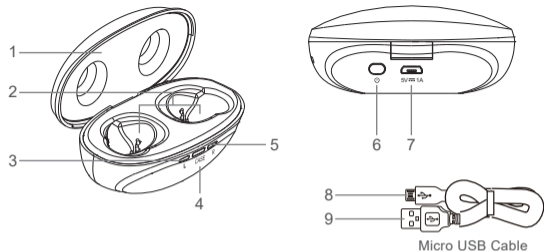
- Deviation of the values of pulse duration, amplitudes, and repetition frequencies, may impair the unit's essential performance. The device has passed EMC highest interference level test, and the parameters do not deviate the essential performance requirement.

- The device displays abnormally.
- 2) As to patients:
- The sensitivity of stimulation may be weaker or stronger, but it does not produce safety issues.
 - It cannot achieve expected effect.
- If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:
- If feeling too weak or too strong stimulation, adjust the strength level to an acceptable level.
 - If the device display is abnormal, power off and restart the device and check whether it shows properly.
 - Re-orient or re-locate the affected device.
 - Increase the separation between the unit and the affected device.
 - Power the equipment from a source other than that of the affected device.
 - Consult the service representative for further suggestions.

III.HOW TO USE YOUR DEVICE



- 1. Multi-function touch button** - switches between hearing programs and change the volume level
- 2. Microphone** - sound enters your hearing aids through the microphone
- 3. Eartip** - holds the hearing aids in place in your ear canal
- 4. Charging Contacts** - for hearing aids charging
- 5. In Ear Detection Sensor** - when the sensors detect blocked, the hearing aids will turn on



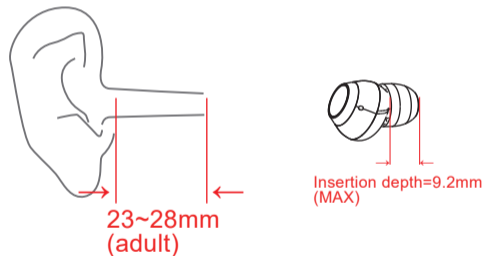
1. Upper Cover
2. Charging slots - charge and store the L/R hearing aid
3. Charging indicator light of hearing aid(L) - displays the charging status of the left hearing aid
4. Charging indicator light of charging case - displays the charging status of the charging case
5. Charging indicator light of hearing aid(R) - displays the charging status of the right hearing aid
6. Power switch - turns on/off the power supply of the charging case.
7. Charging port - connects the charging case to USB cable
8. Port B of USB cable
9. Port A of USB cable

Instruction for insertion depth

For adults, the average length of the ear canal has been estimated to be 23-28mm and the maximum insertion size of the hearing aid is 9.2mm.

So the distance from the eartip to the tympanic membrane after wearing the hearing aid is at least 13.8mm, which is greater than the lower limit of 10mm specified by OTC.

Therefore, the device is safe and complies with OTC regulations.



1. 【HOW TO APPLY EARTIPS】

Please follow the following steps to apply eartips. The eartips may remain in the ear canal with incorrect replacement when taking the hearing aids off the ear, which will cause hearing damage.

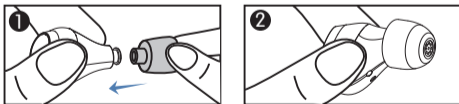
Step 1: Choose a suitable size of eartip.



Step 2: Push the eartip rim membrane outward.



Step 3: Hold on the end of the hearing aids and push firmly to ensure that the eartip is fastened securely.



Notes: Please pull the eartips gently to check if it is installed firmly and ensure the eartips won't fall off easily.

2. 【LEFT & RIGHT HEARING AID MARKINGS】

There is a L or R marking on the hearing aid. This will tell you that it is a left or a right hearing aid.



L marking is for left hearing aid.



R marking is for right hearing aid.

3 【WEAR/REMOVE HEARING AIDS】

Your hearing aids are equipped with in-ear detection sensor.

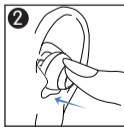
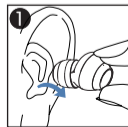
1) The hearing aids will enter the standby status automatically when removed from your ear.

2) The hearing aids will turn on automatically when placed back in your ear.

3.1 Wearing hearing aids

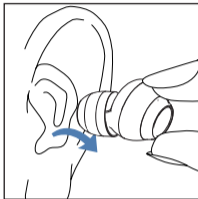
Step 1: Hold the hearing aids and place it in your right or left ear.

Step 2: Move the hearing aids slightly into auricle for holding.



3.2 Removing the hearing aids

Grasp the protruding hearing aids and remove it from your auricle gently.



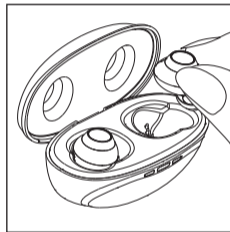
Notes:

1. The creak sound can be used as a reference to determine whether the hearing aids are secured.
2. If the hearing aids give out squeaking, please check if they are taken on correctly. If so, but the squeaking remains, please replace with the other size of eartip. When the hearing aids are not in use, please turn them off without delay.
3. When the hearing aids are not functioning properly, please check the "TROUBLESHOOTING GUIDE". If none of the solutions work, please contact our after-sales service team.

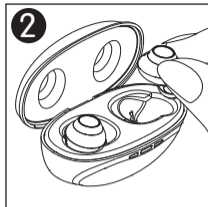
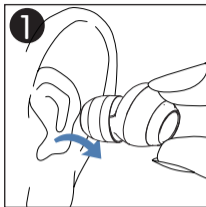
4. 【TURN ON/TURN OFF】

TURN ON: The hearing aids will turn on automatically in about 3 seconds when it is worn correctly .

You will hear prompt tone according to the hearing program(refer to "HEARING PROGRAM CHANGE")



Turn Off: The hearing aids will enter the standby status automatically when it is removed from your ear. When placed back into the correct slot of the charging case, they will turn off and start charging automatically.



5. 【VOLUME ADJUSTMENT】

- The hearing aids have six (6) volume levels.
- You could cycle the volume level from minimum to maximum by tapping the touching control area once. The hearing aids will give out the prompt tone “Beep”
- The hearing aids will give out the prompt tone “Beep-Beep-Beep” at maximum volume.



Touch Control area
one second

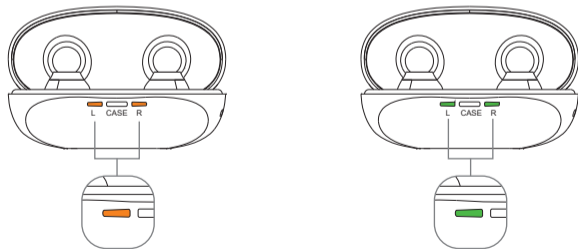
6. 【HEARING PROGRAMS CHANGE】

- There are four (4) preset programs in the hearing aids.
- You could change the hearing program by long-pressing the touching control area for about 3 seconds.
- The hearing aids are designed with the memory function: The hearing aids can record the previous hearing program automatically.
- The hearing aids will give out the beep tone to indicate which hearing program you are in.

Hearing program		Prompt tone
1	Standard	Beep
2	Restaurant	Beep Beep
3	Outdoor	Beep Beep Beep
4	Music	Beep Beep Beep Beep

7. 【HEARING AIDS CHARGING】

- The hearing aids will turn off and start charging automatically when placed back into the correct slot of the charging case.
 - The orange indicator light indicates that the hearing aids are charging and the green indicator light indicates that the hearing aids are fully charged.
 - The indicator lights of hearing aids will go out in about five minutes when the hearing aids are fully charged.
- *Note: Low battery warning: You will hear the notification sound when the remaining battery capacity is almost used out.



8. 【HOW TO USE THE CHARGING CASE】

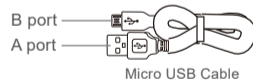
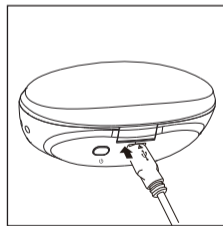
8.1 Charging case TURN ON/OFF

Press and hold the power switch of the charging case for about 5 seconds to turn off the charging case. You can turn the charging case back on or check the battery status by short press the power switch.

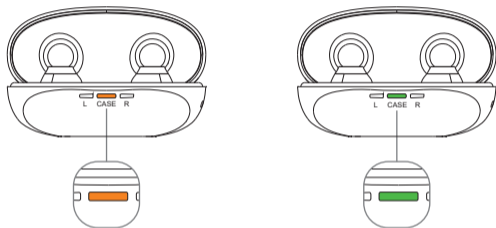
8.2 How to charge the charging case

Step 1: Connect the B port of the USB cable to the charging port of the charging case.

Step 2: Connect the A port of the USB cable to the power supply.



8.3 The orange indicator light indicates that the charging case is charging, and the green indicator light indicates that the charging case is fully charged.



8.4 The charging case will charge the hearing aids whatever the upper cover is open or closed. The charging process will stop automatically when the case and hearing aids are fully charged.

***Note:** Check the “TROUBLESHOOTING GUIDE” when failure occurs to your devices.

9. 【BLUETOOTH FUNCTION】

9.1 How to connect Bluetooth

- Be sure Bluetooth is available on your phone.

Step 1 : Remove your hearing aids from the charging case before connect Bluetooth.

Step 2 : Check the Bluetooth setting on your phone to "Pair New Device".

Step 3 : Select device name “OTC Clarity Units” to pair(connect) the Bluetooth of your phone.

Connection status	Prompt tone
Connect successfully	Connected
Disconnect	Disconnected

- Accept any prompts given by your phone regarding the Bluetooth connection.

Note: Once the first pairing is done, the hearing aids will reconnect to your phone automatically as long as Bluetooth of your phone is available.

Attention: Do NOT use the Bluetooth function of your hearing aids for any medical purposes.

9.2 Bluetooth function description

9.2.1 Listening to music

- Play or stop the music via the mobile phone or related device.
- Change the music volume via the mobile phone or related device.

9.2.2 Phone calls

- Answer the incoming call by short pressing the Multi-function button.
- Reject the incoming phone call by long pressing the Multi-function button for about 2 seconds.
- Hang up the phone by long pressing the Multi-function button for about 2 seconds.

10. 【HOW TO USE THE APP】

Read all the information in this instruction before using.
-Printed version of this instruction is available via customer support.

10.1 Download

*The "OTC Clarity" is compatible with iOS and Android. You could download it from the App Store or Google Play Store.
Requirement for running the app: iOS 14 or later; Android 5.0 or later.



*iPhone® is a trademark of Apple Inc., registered in the U.S. and other countries.

Android™ is a trademark of Google Inc.

IOS is a trademark of Cisco Inc.

- 10.1.1 Download the "OTC Clarity" for Apple devices

The "OTC Clarity" makes it easy to control and adjust your hearing aids with your compatible Apple device. Access app for iPhone, iPad and iPod touch-download on the App Store by following steps:

Step 1: Tap to start "App Store" on a compatible apple device.

Step 2: Search "OTC Clarity" on APP Store.

Step 3: Tap "GET" to download the "OTC Clarity" APP. Follow the system prompts to finish the installation.

Step 4: Tap to start the "OTC Clarity" APP.

- 10.1.2 Download the "OTC Clarity" for Android devices

The "OTC Clarity" makes it easy to control and adjust your hearing aids with your compatible Android device. Download the app by following steps:

Step 1: Tap to start "Google Play Store" on a compatible Android device.

Step 2: Search "OTC Clarity" on Google Play Store.

Step 3: Tap "GET" to download the "OTC Clarity" APP. Follow the system prompts to finish the installation.

Step 4: Tap to start the "OTC Clarity" APP.

10.2 Pairing with your hearing aids

Step 1. Turn on the hearing aids.

Step 2. Enable Bluetooth on the phone.

Step 3. Search the name "OTC Clarity Units" on the device.

Step 4. Tap to connect your hearing aids with your phone.

Step 5. Tap "OTC Clarity" to start. On the bottom of first screen, tap "connect aids"

*Search and connect the device name of "OTC Clarity Units-L" or "OTC Clarity Units-R".

Step 6. You are now ready to go.

10.3 Homepage

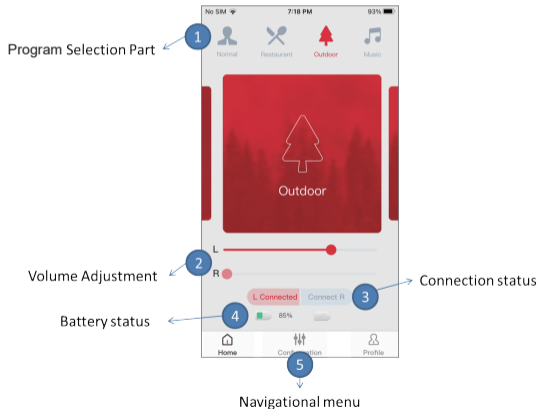
1. Program Selection Part

2. Volume Adjustment

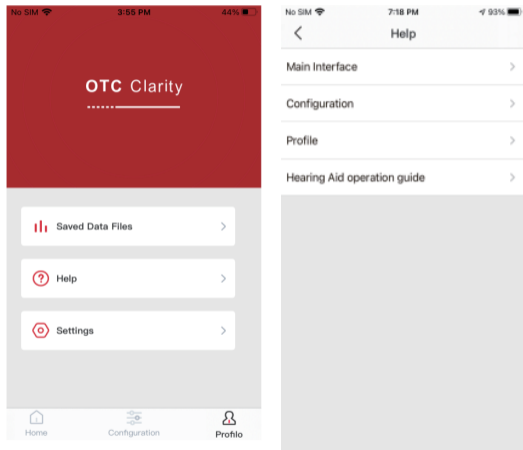
3. Connection status

4. Battery status

5. Navigational menu



*Note:Further instruction is available on “Profile” → “Help” .



IV. MAINTENANCE AND CLEAN

1. Daily maintenance

- Keep your devices clean and dry by using soft cloth or tissue, to avoid potential damage from humidity or perspiration.
- Do NOT use the electronic dryer to store the rechargeable hearing aid.

2. Care and maintenance

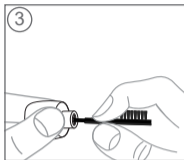
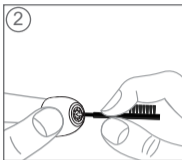
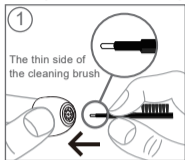
- Keep your devices away from children and pets.
- Keep your hearing aid away from high-temperature and/or high-humidity atmosphere.
- Do not poke the microphone with any sharp objects to avoid damage.
- Do not attempt to disassemble or repair your devices by yourself. Doing so will void your warranty.
- Clean the charging contacts of the rechargeable hearing aid with dry soft cloth irregularly to ensure the normal charging.

3. Cleaning

(1) Cleaning the eartips

- ① Clean up earwax adhered to the eartips by using the thin side of enclosed tool.

- Remove eartips from the hearing aid before cleaning, and push the eartips rim membrane outward



- ② Clean the eartips with alcohol and dry cloth and wait for the eartips to dry before attaching them to the hearing aid.



*Note:

- We recommend that changing the eartips every three months.
- If the eartips get stiff, brittle or discolored over time, please change them as soon as possible.

(2) Cleaning Tool

Using soft cloth or tissue to wipe any moisture or perspiration from the surface of the cleaning tool.

V. HEARING AID AND CHARGING CASE CARE

1. Hearing aid care

- Keep your hearing aid clean. Extreme temperature (heat or cold), moisture, and foreign substance can result in poor performance.
- Use the cleaning tool to clean debris adhered to the buttons, microphones, and charging contacts; inspect the receiver, eartips, and charging case regularly.
- Do NOT clean your hearing aid with water, solvent or oils.
- Charging contacts should always be kept clean and dry.
- Always store your hearing aid in the charging case when not in use.

2. Charging case care

- Keep your charger clean. Heat, moisture and foreign substance can result in poor performance.
- Use the enclosed cleaning brush to keep the charging ports clear of debris.
- Do not use water, solvents or cleaning fluids to clean the charging ports.
- Store your charger in a clean and dry location.

VI.TROUBLESHOOTING GUIDE

Issue	Possible Causes	Potential solution
Feedback or "whistling"	Are the hearing aids inserted correctly in your ears?	Reinsert the hearing aids in your ears.
	Is the volume very loud?	Reduce the volume.
	Are the eartips broken or clogged?	Replace the eartips
	Are you holding an object (e.g. a hat or a telephone mouthpiece) close to the hearing aids?	Move your hand away to create more space between the hearing aids and the object.
	Is your ear full of wax?	Visit your physician.

Issue	Possible Causes	Potential solution
No sound	Are the hearing aids turned on?	Turn the hearing aids on.
	Are the hearing aids charged?	Charge the hearing aids.
	Is the charging case charged?	Charge the charging case.
	Is your ear full of wax?	Visit your physician.
Hearing aids are not charging	Are the hearing aids sitting correctly in the charging case?	Reinsert the hearing aids in the charging case.
	Is the charging case charged or plugged into a power source?	Charge the charging case.

Hearing aids fault self-checking table

Issue	Possible Causes	Potential solution
Indicators light of hearing aids do not light up when hearing aids placed in charging case	Poor contact between hearing aids and charging case	Reinsert the hearing aids into the charging case
	Hearing aids are not inserted correctly into charging case	Insert hearing aids correctly into charging case
	Charging case is not connect to power supply	Connect charging case to external power supply
	Are the hearing aids charged?	Charge the hearing aids
	Dirty charging contacts	Clean the contact of the hearing aids and the charging case
Charging does not start	Hearing aids are not inserted correctly into charging case	Insert hearing aids correctly into charging case

Charging case fault self-checking table

VII.REGULATORY AND LEGAL INFORMATION

This part applies to the product with Bluetooth or APP function.

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 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.

Changes or modifications not expressly approved by manufacturer could void the user's authority to operate this 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.

This device complies with FCC radiation exposure limits set forth for general population. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Radio Technology: Bluetooth Low Energy (BLE) and proprietary technologies.

Radio Transceiver Frequency Range: 2.4 to 2.480 GHz

Radio Receiver Bandwidth: 2MHz.

Modulation Type: 1 Mb/s GFSK Peak Effective Isotropic

Radiated Power: 0 dBm.

This equipment has been tested and found to comply with the limits per CISPR 11 class B.

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC and mobile (cellular) telephones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, Medical devices in use may be susceptible to electromagnetic interference from other device. Electromagnetic interference may result in incorrect operation of the medical devices and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices.

This unit has been thoroughly tested and inspected to assure proper performance and operation! This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, the following tables recommend minimum separation distances between portable and mobile RF communications equipment and the RJADAT-1 unit.

1. Guidance and manufacture's declaration-electromagnetic emission-for all EQUIPMENT and SYSTEMS.

1	Guidance and manufacturer's declaration-electromagnetic emission		
2	Acupuncture treatment device is intended for use in the electromagnetic environment specified below. The customer of the user of Acupuncture treatment device should assure that it is used in such an environment.		
3	Emission test	Compliance	Electromagnetic environment-guidance
4	RF emissions CISPR 11	Class B Group 1	Acupuncture treatment device 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.

5	RF emissions CISPR 11	Class B Group 1	The hearing-aid treatment device is suitable for use in all establishments, other domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Class B	Class A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

2. Guidance and manufacture's declaration-electromagnetic immunity-for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity

Acupuncture treatment device is intended for use in the electromagnetic environment specified below. The customer or the user of Acupuncture treatment device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment–guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact discharge: ± 8 kV Air discharge: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Contact discharge: ± 8 kV Air discharge: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.



<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p><5% UT (>95% dip in UT) for 0.5 cycle</p> <p>40% UT (60% dip in UT) for 5 cycles</p> <p>70% UT (30% dip in UT) for 25 cycles</p> <p><5% UT (>95% dip in UT) for 5 sec</p>	<p>N/A</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of Acupuncture treatment device requires continued operation during power mains interruptions, it is recommended that Acupuncture treatment device be powered from an uninterruptible power supply or a battery.</p>
--	--	------------	---

3. Guidance and manufacture's declaration-electromagnetic immunity-for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration-electromagnetic immunity		
The acupuncture treatment device and acupuncture treatment device is intended for use in the electromagnetic environment specified below. The customer or the user of acupuncture treatment device should assure that it is used in such an environment.		
Immunity test	Conducted RF IEC 61000-4-6	Radiated RF IEC 61000-4-3
IEC 60601 test level	10 Vrms 150 kHz to 80 MHz	10V/m 80 MHz to 2.5 GHz
Compliance level	10 Vrms	10 V/m

Portable and mobile RF communications equipment should be used no closer to any part of The acupuncture treatment device and acupuncture treatment device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance


$$d = 1.2 \sqrt{P}$$

$$d = 1.2 \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$$

$$d = 2.3 \sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$$

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: 

NOTE1:

At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2:

These guidelines may not apply in all situations. Electro-magnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Fields strengths from fixed transmitters, such as basestations for radio (cellular/cordless) telephones and land mobile radios, a amateur radio, AM and FM radio broadcast and TV broadcast can not 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 Acupuncture treatment device is used exceeds the applicable RF compliance level above, Acupuncture treatment device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Acupuncture treatment device.

^b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

4. Recommended separation distances between portable and mobile RF communications equipment and the acupuncture treatment device

The acupuncture treatment device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The acupuncture treatment device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and acupuncture treatment device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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.

NOTE2:
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

VIII. TECHNICAL SPECIFICATIONS

Test Item	Program One	Program Two	Program Three	Program Four
Max. Output(OSPL90)	117dB(Max.)			
The full-on gain value (HFA FOG@50)	26dB±5dB	27dB±5dB	28dB±5dB	24dB±5dB
Frequency response bandwidth	F1<250Hz, F2>5000Hz			
The total harmonic distortion value	<5%			
The self-generated noise value	<32dB			
The Latency value	<15ms			
Frequency response smoothness	<12dB			

Test Standard: ANSI3.22-2014

Test Equipment: FONIX 8000

Test Coupler: HA-1

The standard ambient conditions shall be: Temperature: 23℃±5℃ (73°±9°F)

Relative humidity: 0% to 80%

Atmospheric pressure: 760(+37.5,-150)mm of Hg or 101.3(+5,-20)k-Pa

- The battery life of a hearing aid is up to 12 hours.
- The fully charged case offers 3 full charging cycles for a pair of hearing aids.
- The data is derived from the measured value of the product at the laboratory, not guaranteed values.












Status	Battery life
Bluetooth disconnected	About 20 hours
Bluetooth connected (without entertainment, phone call or using "OTC Clarity" APP)	About 10 hours
Bluetooth connected (with entertainment, phone call or using "OTC Clarity" APP)	About 3 hours

- The fully charged case offers about 3 full charging cycles for a pair of hearing aids.
- The data is derived from the measured value of the product at the laboratory, not guaranteed values.

IX. ACCESSORIES

Eartip ×6	holds the hearing aid in place in your ear canal
USB Cable ×1	used to charge the charging case
Cleaning Tool ×1	used to clean hearing aids and charging case
Manual ×1	used for users to read and understand how to use hearing aids and other objects

X.NORMALIZED SYMBOLS

	Follow operating instructions		
	B type applied part		
	Disposal in accordance with Directive 2002/96/EC (WEEE)		
	Date of manufacture		Manufacturer information
	Serial number		Five years
	Warning/ Danger: Improper use might cause serious injuries.		
	Medical Device		
Storage/Transport 	Permissible storage and transport temperature and humidity		
Operating 	Permissible operating temperature and humidity		

Notes: This hearing aid is produced under the strict quality system of Huizhou JINGHAO Medical Technology Co., Ltd.

● The device fulfills the provisions of the EC directive 93/42/EEC (Medical Device Directive) and the Harmonize Standard as IEC 60601-1, IEC60601-2-66, IEC60118-7, IEC 60118-13, EN ISO 10993-1/-5/-10 ENISO 14971, and FCC CFR47 Part 15. RED directive 2014/53/EU. (The RED information is applicable to our products with Bluetooth function) Subpart B, Class B.

XI.MAINTENANCE, STORAGE AND DISPOSAL

● Maintenance

- 1) We do not authorize any institution or individual to maintain and/or repair the product. If you suspect that the products may be in question, please contact us immediately.
- 2) The user must not attempt any repairs to the device or any of its accessories. Please contact us for any repair needs.
- 3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty. Warning : No modification of this equipment is permitted.

● Storage

- 1) Always store your rechargeable devices in the Charging Case when not in use.
- 2) Do not store or expose the devices and/or case to extreme hot/cold temperatures, moist/humid environments, or shock/vibration.
- 3) Keep the devices and case in following environmental ranges: -10°C~55°C, 10%-90%RH, 700-1060hPa
- 4) The hearing aids should be fully charged before used for the first time. The hearing aids should be charged at least every 6 months if they are not used for an extended period of time.

Disposal



Please dispose of the device in accordance with the directive 2002/96/EC - WEEE(Waste Electrical and Electronic Equipment). If you have any questions, please refer to your local authority responsible for waste disposal.


XII. WARRANTY

This limited warranty covers defects in material and workmanship for a period of one (1) year from the date of purchase, which includes the hearing devices, charger case, and cord within the warranty period.

Any damage caused by improper handling and care, exposure to elements or chemicals, or unauthorized service will not be covered by the warranty. All other damage claims excluded. A warranty claim must be submitted with the purchase receipt.

To return the item, you may also call: 0086-752-2299187 or write to hearingservice@hotmail.com or 23D floor, World Trade Center Building, No.1 Henan'an Road, Huicheng District, Huizhou, Guangdong Province, China Zip Code: 516007 to ensure that both your return and credit refund are processed accurately.

Huizhou Jinghao Medical Technology Co., Ltd.
Address: Floor 6, Huicheng Industry Building, No.9 Huifeng Dong'er Road, Zhongkai High-tech Zone, Huizhou City, Guangdong Province, China.
Tel: +86-752-2266961 Website: www.jinghao.cc
Email: emily@jhhearingaids.com

CERTIFICATE	
Product Name	Hearing Aid
Product Life	5 years
Model	JH-A61AT
Lot No.	Outside packaging
Inspector	
The product conforms to the national and industrial standards and has passed inspection.	

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.

Changes or modifications not expressly approved by manufacturer could void the user's authority to operate this 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.

This device complies with FCC radiation exposure limits set forth for general population. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC ID: 2A39M-JH22A61H

Radio Technology: Bluetooth Low Energy (BLE) and proprietary technologies.

Radio Transceiver Frequency Range: 2.4 to 2.480 GHz

Radio Receiver Bandwidth: 2MHz.

Modulation Type: 1 Mb/s GFSK Peak Effective Isotropic

Radiated Power: 0 dBm.

This equipment has been tested and found to comply with the limits per CISPR 11 class B.