

CERTIFICATE

Product Name	Hearing Aid
Product Life	5 years
Model	JH-D12
Lot No.	Outside packaging
Inspector	
The product conforms to the national and industrial standards and has passed inspection.	



VER: D12-20240603-V1

HEARING AID

Instruction Manual Model: JH-D12



Please read this user manual thoroughly and completely before using the product. This product should be used under the guidance of professionals.

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I.IMPORTANT SAFETY INSTRUCTIONS

Read all the information in this instruction manual and any other literature included in the box before using the device.

1. INTENDED USE

- The Hearing Aids are used for hearing compensation of patients with mild to moderate air conduction hearing loss.
- This hearing aids only be used for compensating the patients with hearing impairment, do not have hearing therapeutic value.
- Side effects
For the patients skin sensitive with silicon material, may be caused the ear canal pruritus. - First use may cause ear canal appear temporary maladjustment, such as slight pain.

2. WARNINGS

- 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 the devices in explosive or oxygen-enriched atmospheres, as doing so may damage the devices.

- The hearing aids should only be used by intended person as using hearing aids designed for someone else may result in hearing damage.

3. NOTICES

- 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.
- 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. You should never leave your hearing aids near heating appliances.
- 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 use the hearing aids adjacent to or stacked with other

equipment, it could result in improper operation. If such use is necessary, the hearing aids and the other equipment should be observed to verify that they are operating normally- volume.

- Please contact the MANUFACTURER:
 - For assistance, if needed, in setting up, using or maintaining your devices or to report any unexpected operation or events.
 - If any serious incident occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which you are established.

II. CONTRAINDICATION

The device should not be used in the following situations:

- Patients with chronic suppurative otitis media (CSOM), congenital ear atresia, or any type of ear discharge
- Anyone under 36 months old.
- Patients with chronic suppurative otitis media, congenital ear atresia to banned use.
- 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.

III. MATTERS NEEDING ATTENTION, WARNINGS AND TIPS

1. Do not immerse the hearing aid in any liquid. Remove the hearing aid before swimming or bathing. After swimming or bathing, wait for the ear canal to dry before wearing the hearing aid.
2. After removing the hearing aid at night, it should be placed in a base with a desiccant if possible, protected from high humidity environment.
3. The external surfaces of the hearing aid should be kept clean, and earwax in the eartips should be cleaned out daily.
4. Please choose the suitable product according to your hearing loss level(WHO standard on 2021).

Grade	Hearing threshold ⁺ in better hearing ear in decibels (dB)
Normal hearing	Less than 20 dB
Mild hearing loss	20 to < 35 dB
Moderate hearing loss	35 to < 50 dB
Moderately severe hearing loss	50 to < 65 dB
Severe hearing loss	65 to < 80 dB
Profound hearing loss	80 to < 95 dB
Complete or total hearing loss/deafness	95 dB or greater
Unilateral	< 20 dB in the better ear, 35 dB or greater in the worse ear

5. Please charge the devices regularly to avoid battery damage; The recommended charging interval of the devices is less than 28 days.

IV. TIPS FOR BETTER COMMUNICATION

It will take practice, time, and patience for your brain to adapt to the new sounds that your hearing aid 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 aid can and cannot do.

- Better hearing with hearing aid is a learned skill combining 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.

V. NORMALIZED SYMBOLS

	Follow operating instructions		
	B type applied part		
	Disposal in accordance with Directive 2012/19/EU (WEEE)		
	Complies with the Regulation (EU) 2017/745. Notified Body is SGS Belgium.		
	Date of manufacture		Manufacturer information
	Serial number		USE BY
	Warning/ Danger: Improper use might cause serious injuries.		
	Medical Device		
	Permissible storage and transport temperature and humidity		
	Permissible operating temperature and humidity		
	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany		
	Keep Dry		Comply with Directive 2011/65/EU
	Paper Packaging Recycling		

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 Regulation (EU) 2017/745 and the Harmonize Standard as IEC 60601-1, IEC60601-2-66, IEC60118-7, IEC 60118-13, EN ISO 10993-1/-5/-10 ENISO 14971.

VI. REGULATORY AND LEGAL INFORMATION

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 manufacturer's declaration-electromagnetic emission-for all EQUIPMENT and SYSTEMS.

Guidance and manufacturer's declaration-electromagnetic emission			
Hearing aids are intended for use in the electromagnetic environment specified below. The customer of the user of hearing aids should assure that it is used in such an environment.			
Emission test	Classified / Test Level	Compliance	Electromagnetic environment – guidance
Power line conducted emission test	CISPR 11, Class B, Group 1	N/A	Hearing aids use RF energy only for its internal - function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Radiated emission test	CISPR 11, Class B , Group 1	Pass	The hearing-aids are 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.
Harmonic current emission test	IEC 61000-3-2, Class A	N/A	
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 for all equipment and systems.

Hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of hearing aids should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	Contact discharge: ±2 kV, ±4 kV, ±6 kV, ± 8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact discharge: ±2 kV, ±4 kV, ±6 kV, ± 8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV

Radiated RF electromagnetic fields immunity test	10V/m,80MHz -2.7GHz 80% AM at 1KHz RF Band(IEC 60601-1-2:2014+ A1:2020 section 8.10 table 9)	10V/m,80MHz -2.7GHz 80% AM at 1KHz RF Band(IEC 60601-1-2:2014+ A1:2020 section 8.10 table 9)
Electrical fast transient and burst test IEC 61000-4-4	AC port:±2 kV Patient coupling port: ±1 kV 100kHz repetition frequency	N/A
Surge test IEC 61000-4-5	Line to line: ±500V, ±1kV Line to ground: ±500V,±1kV,±2 kV	N/A
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	30 A/m, 50Hz and 60Hz	30 A/m, 50Hz and 60Hz

Voltage dips, and interruption IEC 61000-4-11	0% UT; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	N/A
	0% UT; 1cycle and 70% UT; 25 cycles Single phase: at 0°	
	0% UT; 250 cycles	
Proximity magnetic fields immunity test	IEC 60601-1-2: 2014+A1:2020 section 8.11 table 11	IEC 60601-1-2: 2014+A1:2020 section 8.11 table 11
NOTE UT is the a.c. mains voltage prior to application of the test level.		

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

Guidance and manufacturer's declaration-electromagnetic immunity for equipment and system that are not life-supporting		
The hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of hearing aids 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 hearing aid 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. 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 hearing aids are used exceeds the applicable RF compliance level above, hearing aids should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating hearing aids.

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

4. Recommended separation distances between portable and mobile RF communications equipment and hearing aid

Hearing aids are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of hearing aids can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and hearing aids 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 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.

VII. MAINTENANCE AND DISPOSAL

Maintenance

Warning: No modification of this equipment is permitted.

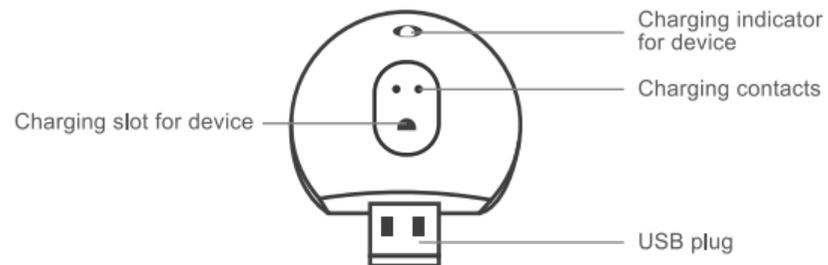
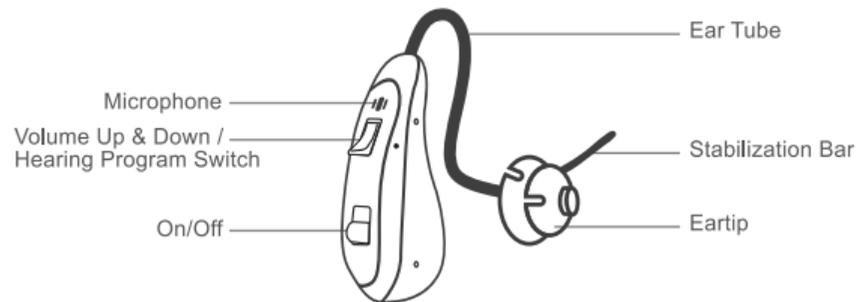
- 1) We do not authorize any institution or individual to maintain and/or repair the product. If you suspect that the products may be in question, please contact us immediately.
- 2) The user must not attempt any repairs to the device or any of its accessories. Please contact us for any repair needs.
- 3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

Disposal



Please dispose of the device in accordance with the directive 2012/19/EU - WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please refer to your local authority responsible for waste disposal.

VIII. HOW TO USE YOUR DEVICE



1. 【HOW TO APPLY EARTIP IT IS】

Please follow these steps to mount eartips, because Incorrect eartip replacement could result in the eartip being left in the ear when you remove the hearing aid.

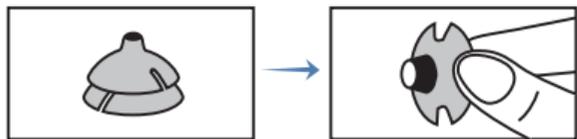
Step 1:

Choose a suitable size eartip.



Step 2:

Push the eartip rim membrane outward.



Step 3:

Hold on to the end of the ear tube and push firmly to ensure that the eartip is fastened securely.



Notes:

After the eartip is installed, pull the eartip gently to see if it is firmly installed and ensure the ear eartip does not fall off easily.

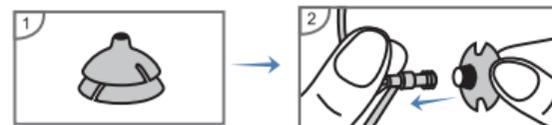
2. 【WEAR/REMOVE HEARING AID】

For comfort, turn off your hearing aid before you wear or remove them.

2.1 Wear hearing aid

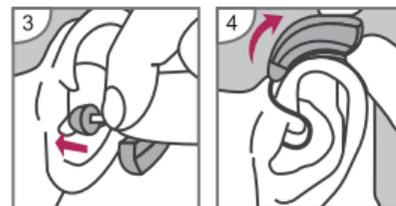
Step 1:

Choose a suitable size eartip and install in device.



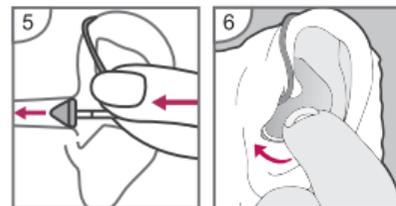
Step 2:

Gently wrap the hearing aid over your ear until it rests securely behind your ear.



Step 3:

Push the ear tube into ear canal until snug and comfort.



Step 4:

Place the Stabilization Bar in the pinna of your ear.

2.2 Remove the hearing aid

Step 1:

Turn the switch down to "OFF" and hearing aid turns off.



Step 2:

Remove the stabilization bar from the pinna of your ear. Using your thumb and index finger, gently pull the ear tubing loose from the ear.



Notes:

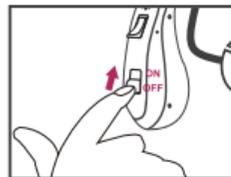
- It may be in a few circumstances that the eartip may still be attached to the auditory meatus after the hearing aid is taken out. In that case, please ask a professional doctor to take the eartip out.

- Before the hearing aid is appropriately secured, it may give out the creaking sound, which is a normal phenomenon. The creaking sound can be used as a reference to determine whether the hearing aid is secured. If the hearing aid gives out squeaking, please check if it is taken on correctly. If the squeaking remains, please replace it with the other eartips. When the hearing aid is not in use, please turn it off without delay.

3. 【TURN ON/TURN OFF】

Turn ON:

Turn the switch up to "ON" and hearing aid turns on.



Turn OFF:

Turn the switch down to "OFF" and hearing aid turns off.



4. 【VOLUME ADJUSTMENT】

The hearing aid has six(6) volume levels.

Push up the volume button to increase the volume. (Short push once).



Push down the volume button to decrease the volume. (Short push once).



When the volume is adjusted to highest or lowest level, it will give out the prompt tone of "Beep-Beep-Beep".

Note: The hearing aid can automatically record the previously tuned volume level.

5. 【HEARING PROGRAM SWITCH】

The hearing aid have four different hearing programs.

You can cycle through the four hearing programs by pushing up or down the “hearing program switch” button for three seconds. The hearing aid can automatically record the previously tuned hearing program.



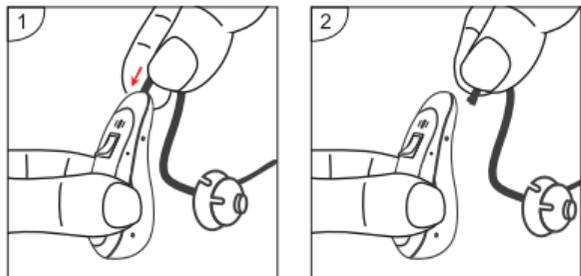
Hearing Program	Sound you will hear when activated
1	1 beep (“beep”)
2	2 beeps (“beep beep”)
3	3 beeps (“beep beep beep”)
4	4 beeps (“beep beep beep beep”)

Hearing Aid Key Patterns Switch-over Table

6. 【REPLACE EAR TUBE】

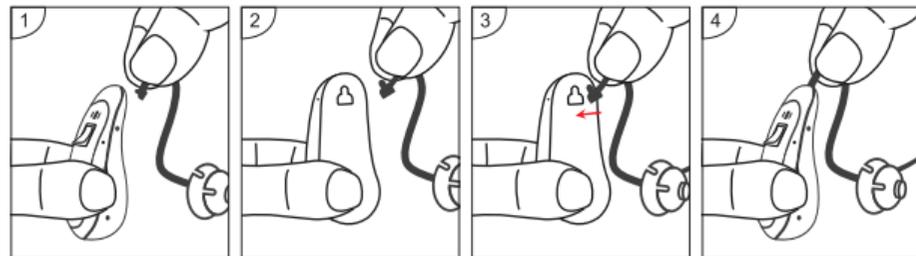
Step 1: Remove ear tube:

Grasp the base of the ear tube on the hearing aid with your index finger and thumb and pull it down until the tube is removed.



Step 2: Reconnect ear tube:

Grasp the root of the ear tube with your index finger and thumb and fit it into the recess of the hearing aid until the ear tube is fixed.



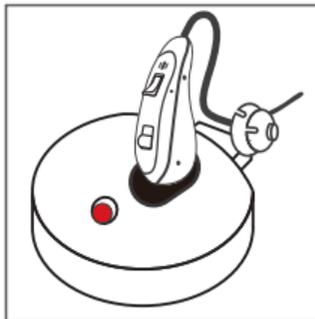
7. 【HEARING AID CHARGING】

First of all, turn off the hearing aid and then put it in the charging slot.

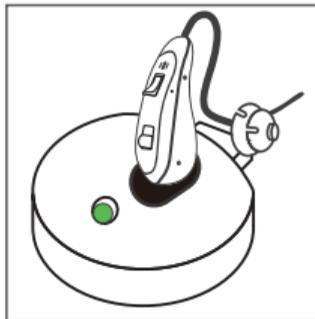
The indicator light of the charging base shows red indicating that the hearing aid is charging, and green indicating that the hearing aid is fully charged.

- When the hearing aid is not functioning properly, please check the “Troubleshooting Guide”.

If there is no solution, please contact our after-sales service team.



Red light: Device is charging



Green light: Device fully charged

IX. MAINTENANCE AND CLEAN

1. Daily maintenance

It is important to keep your device clean and dry. On a daily basis, wipe them clean using a soft cloth or tissue. To avoid potential damage from excess humidity or perspiration, the use of a drying kit is also recommended.

2. Care and maintenance

When not in use, store in a secure area away from small children and pets.

Do not place hearing aid or charging base near high-temperature areas such as stoves or direct sunlight.

Do not leave the device in a humid place for a long time, such as bathroom.

Take care not to poke the microphone holes with any sharp objects to avoid damage.
Do not disassemble or attempt any repairs by yourself. Doing so will void your warranty.

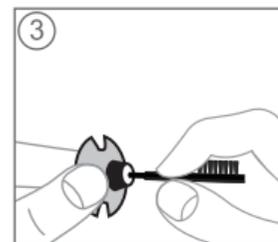
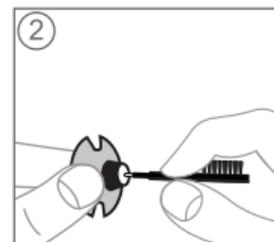
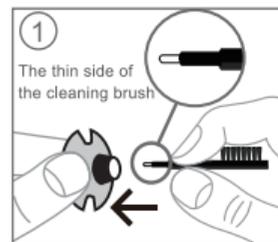
3. Cleaning

1) Cleaning the eartips

Remove any earwax buildup using the enclosed tool. Wipe clean with a tissue or soft cloth.

please use the thin side of the cleaning brush to clean the eartip of earwax and debris.

*Remove eartip from the hearing aid before cleaning, and push the eartip rim membrane outward.



③ Wipe the earwax with alcohol and a dry cloth. Wait for the eartips to dry before attaching them to the hearing aid.



*Note: We recommend that you change the eartip every three months. If the eartip get stiff , brittle or discolored over time, please change them sooner.

2) Cleaning Tool

Use a soft cloth or tissue to wipe any moisture, perspiration, or debris from the surface of the tool.

Note: Do not use alcohol or other cleaning solvents to clean the hook as this could damage the protective covering.

X. HEARING AID CARE

- Keep your hearing aid clean. Extreme temperatures (heat or cold), moisture, and foreign substances can result in poor performance.
- Use the cleaning brush tool or soft cloth to clean debris from around the buttons, microphones, and charging contacts; inspect the receiver, ear tips, and charging base regularly.
- Never use water, solvents, cleaning fluids or oils to clean your hearing aid.
- Charging contacts should always be kept clean and dry.
- Always store your hearing aid in the charging base when not in use or cleaning.

Charging Base Care

- Keep your charger clean. Heat, moisture and foreign materials can result in poor performance.
- Using the provided cleaning brush keep the charging ports clear of debris.
- Do not use water, solvents or cleaning fluids to clean the charging ports.
- Keep lid closed as much as possible to avoid dust and debris build up.
- Store your charger in a clean and dry location, i.e. a dresser or shelf rather than the bathroom or kitchen.
- To ensure the longest life of your rechargeable hearing aid batteries and the batteries in the charger:
- Fully charge hearing aid batteries every night.

Service and Repair

If, for any reason, your hearing aid and charger do not operate properly, do NOT attempt to fix it yourself. Besides possibly causing further damage, you are likely to violate any applicable warranties or insurance. Should your hearing aid and charger fail or perform poorly, check the Troubleshooting Guide section for possible solutions. If problems persist, contact us for assistance.

XI.TROUBLESHOOTING GUIDE

[Fault self-check] project	Possible Causes	Solution
No Sound	Volume too low	Increase volume if volume control available
	Device is not charged	Place charging the hearing aid until the indicator is lighted in green color
	Microphones are clogged	Clean out any debris from the mic holes
	Eartips or receiver tip are clogged	Clean out any debris from the eartips and receiver area with the cleaning brush
	Battery fully discharged	Connect the hearing aid to the charging base for charging
Voices are low, very weak, or unclear	Low battery	Charge the hearing aid
	Volume is set too low	Increase volume if volume control available
	Eartips are too loose	Tighten eartips
	Earwax in eartip	Clean the eartips with the cleaning tool or alcohol
	Hearing has changed	Contact your physician to report any sudden drop in hearing



Hearing aid plays notification sound	Indication for low battery	Charge hearing aid
Hearing aid is whistling in the charging base	Charger battery depleted	Ensure the USB cable is connected to the Charging Base plugged into power. The Base power status lights will shows a solid orange to indicate charging
	Incorrect orientation	Reposition your hearing aid in their slots, ensuring the contact points are touching the charge points in the base
After the hearing aid is connected, the device indicator is not lit	Poor contact between hearing aid and charging base	Reinsert the hearing aid into the charging base
	Hearing aid reverse	Check to see if the hearing aid is reversed and put the hearing aid in the right orientation

Hearing aid fault self-checking table

[Fault self-check] project	Possible Causes	Solution
Indicator light of hearing aid does not light up when hearing aid placed in charging inserts	Poor contact between hearing aid and charging base	Reinsert the hearing aid into the charging base
	Hearing aid reverse	Check to see if the hearing aid is reversed and put the hearing aid in the right orientation
	Hearing aid not inserted correctly into charger	Insert hearing aid correctly into charging base
	Charger not connected to power source	Connect charger to external power supply
Hearing aid indicator lights are dark or dim	Low battery	Connect USB cable to charge
	Charging contacts become dirty	Clean the contacts of the hearing aid and the charger
Charging does not start	Hearing aid not inserted correctly into charger	Insert hearing aid correctly into charger

Charging base fault self-checking table

XII. TECHNICAL SPECIFICATION

Model	JH-D12
Output. OSPL90 Max.	≤112dB+3dB
Max. full-on gain (FOG50)	≤42dB+3dB
EQ Input Noise	≤29dB+3dB
Frequency Range(Not narrower than)	250Hz~5000Hz
Total Harmonic Distortion	≤7%+3%
Battery current	≤10mA

XIII. Accessories List

Hearing Aid: 1
 Eartips: 3
 Cleaning Tool: 1 Manual: 1
 USB Cable: 1 Changing base: 1

* Optional accessories list:
 Adapter: 1

XIV. 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 aids, charger base 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.



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