USER MANUAL

Device name: Hearing aids

Model: JH-A40C

Please read the instructions carefully before operating the product.

Thank you very much for buying our hearing aids.
When you watch a film, or a play, have a meeting, or take classes, this product can help you to hear sounds clearly and loudly. While in a forest, if you want to hear very slight sounds, it will be a good choice.
Use of this product should under the guidance of healthcare professionals.
Please read the instructions carefully before operating the product.

I. INTRODUCE

1.1 What is hearing loss?
A speech frequency pure tone average (average of hearing thresholds at 0.5, 1, 2, and 4 kHz) of greater than 25 dB hearing level (HL) in both ears is defined as hearing loss per the World Health Organization criteria, and this is the level at which hearing loss begins to impair communication in daily life. (Extracted from the literature of: World Health Organization prevention of Blindness and deafness (PBD) program. Prevention of Deafness and Hearing Impaired Grades of Hearing Impairment).
1.2 What are hearing aids?
Jinghao hearing aids are air-conduction hearing aids to compensate of impaired hearing.
It is a body-worn device. The fundamental operating principle of hearing aids is to receive, amplify, and transfer sound to the ear drum of a hearing impaired person.

II. INTENDED USE

2.1 Intended purpose
For hearing compensation for patients with hearing loss.
2.2 Intended environment and patients
The hearing aids can be used in clinical and home environments.
Any patients if through the doctor diagnosed the hearing problems need use the hearing aids to compensation, including children, adult and elderly.
2.3 Side effects
- For patients with skin sensitivity to silicon material, it may cause ear canal pruritus.
- First use may cause the slight pain in the ear canal. This will be temporary.
2.4 Contraindication
The device is unsuitable and should not be used in the following situations:
- Patients with chronic suppurative otitis media, congenital ear atresia;
- The hearing aids are only to be used for compensating patients with hearing impairment. They cannot cure hearing impairment.

III. IMPORTANT SAFETY INSTRUCTIONS

3.1  Warnings

- Keep small parts (hearing instruments, eartips, battery and detachable parts) that can be swallowed out of children's reach.
- Do not use the devices in explosive or oxygen-enriched atmospheres.

- The hearing aids must only be used by a single intended person and not by others.
- Please check first before using the hearing aids in areas where electronics or wireless devices are restricted.
- Small children or mentally disabled persons should use hearing aids under the supervision of adults responsible for their safety.
- Dropping, immersing in liquid, strong electromagnetic fields or excessive heat will damage the hearing aids.
- If parts remain in the ear, please go to see a doctor as soon as possible, and do not take them out by yourself.
- Do not modify the hearing aids without authorization of the manufacturer.
- Do not set volume levels too high. Listening for extended periods at high volume levels can cause further hearing damage.
- If you feel uncomfortable while use these hearing aids, please stop using and seek for medical help.
- Infants under 36 months should not use this product.
- If you are scheduled for an MRI, please refrain from bringing your hearing aid into the fitting room. The magnetic field induced by the MRI may cause local heating of the device and lead to burns. Additionally, its magnetic property may cause it to adhere to the MRI equipment and potentially lead to malfunction.
- Do not exchange your hearing aids with others. Using the hearing aids configured for someone else may result in hearing damage or injury.
- Battery should be replaced by professional maintenance personnel. Replacing the battery by yourself will damage battery.
- Don not throw the scrapped battery as unsorted municipal waste, if possible, please recycle it. Do not throw it into fire!
- Do not dismantle and repair hearing aids by yourself.
- Do not use your hearing aids adjacent to or stacked with other devices, as this may result in improper operation. If necessary, hearing aids and other devices should be observed to verify their proper operation.
-- Do not disassemble or attempt any repairs by yourself. Unauthorized modification of ME equipment may result in danger。Doing so will void your warranty.
--Hearing AIDS are operated by patients themselves，Do not share your hearing aids with others. Using a hearing aid configured for someone else can result in hearing damage or injury.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result."

3.2 ⚠ Notice

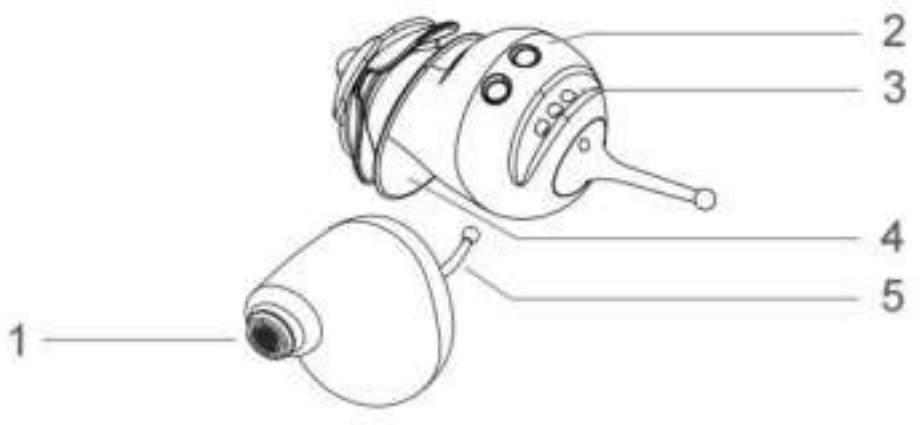
- Please periodically maintain and clean the products, avoid ear tips and microphone being blocked by ear wax and dust.
- Do not store or use hearing aids in high humidity, strong electromagnetic fields, or overheated environments.
- Observe for any unusual skin reactions. In some cases, wearing hearing aids may cause an allergic reaction, leading to itching or rash. If you notice any unusual skin conditions, please stop wearing the hearing aids and seek medical specialist promptly.
- Do not leave your hearing aids in a closed car in summer, as the temperature can rise to very high level which may damage the hearing aids.
-If there are any of the following situations, please contact the manufacturer

a) Need to provide assistance in setting up, using, or maintaining hearing aids;
b) Report unexpected operations or any adverse events.

Content

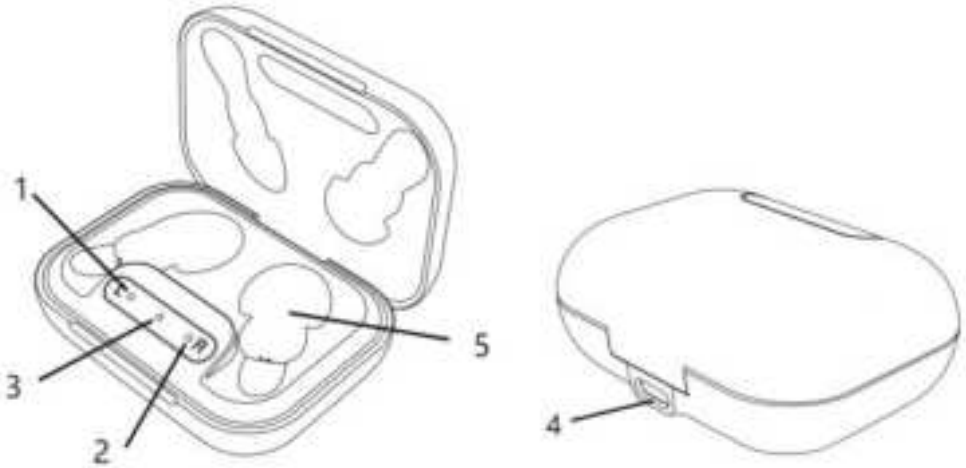
1. Get to know your device

1.1 Hearing aids



1.Sound Outlet - it sends amplified filtered and fine-tuned sound into your ear
2.Charging Contacts - necessary for hearing aids charging
3.Sound Inlet - it picks up sounds and sends them into hearing aids for digital signal processing
4.Eartip - eartips are soft silicon domes that ensure a comfortable and secure fit inside your ear
5.Thread - helps to insert and remove the hearing aids

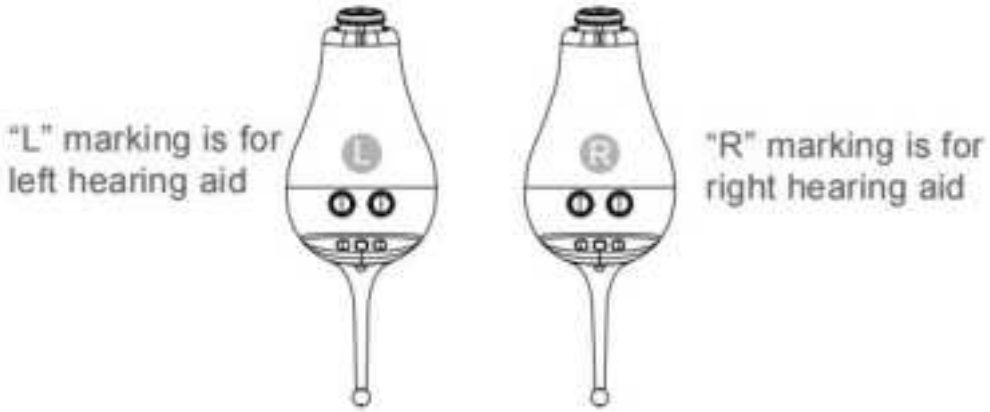
1.2 Charging case



1.Indicator light for left hearing aid - displays the charging status of hearing aid(L)
2.Indicator light for right hearing aid - displays the charging status of hearing aid(R)
3.Indicator light for charging case - displays the charging status of charging case
4.Charging port - connects the charging case to Type-C cable
5.Charging slots for hearing aids - charge and store the hearing aids

1.3 Left & Right hearing aid markings

There is a marking on the hearing aid, which helps to distinguish between left and right hearing aid.



2. Accessories

Items	Description
Eartip x 12	hold the hearing aid comfortably and securely in the ear canal
USB Cable x 1	used to charge the charging case
Cleaning Tool x 1	used to clean hearing aids and charging case
Manual x 1	used for users to read and understand how to use hearing aids and other objects.
Remote control x 1 (*Optional)	used to control the hearing aids(Volume, Program)

NOTE: Adapters must comply with IEC 60601-1or IEC 62368 standards
NOTE: Please use original accessories that supply by manufacturer. Using unqualified accessories may be reduced the safety and effectiveness of the device.

3. Activating and Using the hearing aid

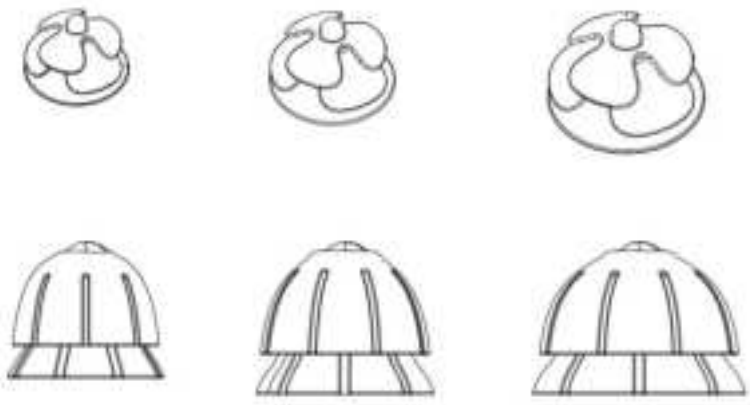
Please activate your hearing aids and its charging case before first use.
Plugging the charging case to the power source first, then placing the hearing aids inside the charging case.

3.1 Fitting eartips

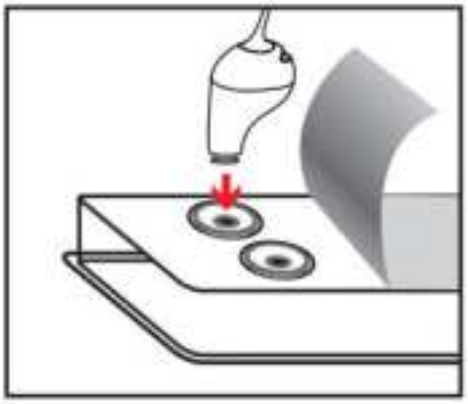
3.1.1 How to apply eartips

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

Step 1: Choose a suitable size of eartip.



Step 2: Press the hearing aid into a eartip until you feel a click.

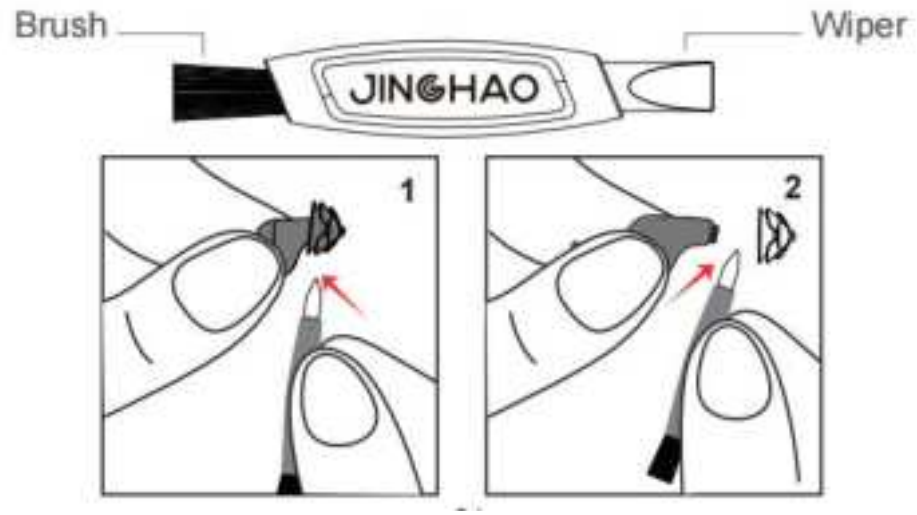


Notes: Please pull the eartips gently to check if it is installed firmly.

3.1.2 How to remove eartips

Step 1: Hold the hearing aid firmly.

Step 2: Use the wiper of cleaning tool to gently remove the eartips.



3.2 ON / OFF

3.2.1 Turn on

Your hearing aids will automatically turn on about 10 seconds after removal from the charging case.

You will hear “Power on” and Prompt tone according to the program when the hearing aids are turned on.

3.2.2 Turn off

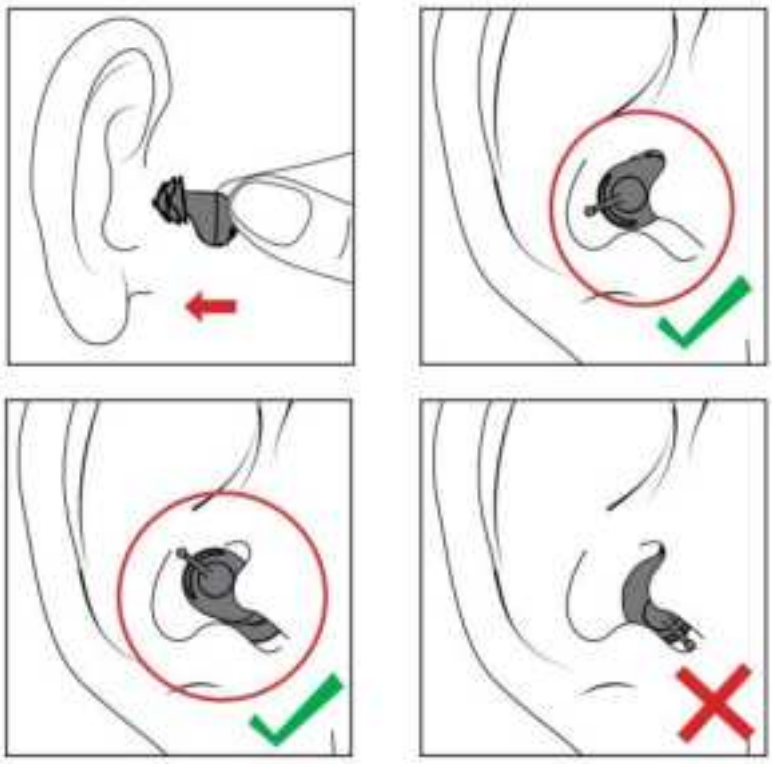
Your hearing aids will turn off and start charging automatically when placed back in the

charging case correctly.

3.3 Insert/Remove hearing aids

3.3.1 Inserting hearing aids

Step 1: Take out your hearing aids from charging case.
Step 2: Insert the hearing aids into your ear canal with the sound inlet facing outward. (Shown as picture)



Note:

- Hearing aids will whistle when inserted incorrectly. Reinserting them into your ear canal correctly. Do not block the sound inlet, Keep some space between the sound inlet and your ear.
- If whistling remains after reinsertion, replace the eartips with bigger size and try it again.
- If the hearing aids doesn’t work properly, please check the “Troubleshooting”. If none of the solutions work, contact our service team.

3.3.2 Removing hearing aids

Step 1: Grasp the thread and pull the hearing aids out from your ear gently.

Step 2: Place your hearing aids in the charging case.

3.4 Hearing control APP

The “Hearing control” APP makes it easy to control and adjust your hearing aids with your compatible iOS or Android devices.
Download on the App Store or Google Play Store by following steps:
Step 1: Tap to start “App Store” or “Google Play Store” on a compatible iOS or Android device.
Step 2: Search “Hearing control”.
Step 3: Tap “GET” to download the “Hearing control” APP. Follow the system prompts to finish the installation.
Step 4: Tap to start the “Hearing control” APP.
Step 5: Follow the novice guide to finish the setup.
Step 6: Start to personalize and fine-tune your hearing aid.

- Further instruction is available on Hearing control. (“More” → “Help”)
- Requirement for running the app: iOS 11 or later / Android 7.0 or later.

3.5 Volume control

- The hearing aids have six(6) volume levels.
- Adjust volume level via the "Hearing control" APP.

Action	**Prompt tone**
Volume up	Beep
Volume down	Beep
Volume Max.	Beep-Beep-Beep
Volume Min.	Beep-Beep-Beep

3.6 Programs switching

- There are four(4) preset programs in the hearing aids.
- You could switch the hearing programs via the "Hearing control" APP
- Different programs have different beeps as below.

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

● The hearing aids are designed with the memory function:The last setting can be remembered when the hearing aids turned off.

3.7 Bluetooth

Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc. and any use of such marks by JINGHAO is under license.

3.7.1 Bluetooth connection

● Be sure Bluetooth is available on your phone.
Step 1 : Turn on your hearing amplifiers before connecting Bluetooth.
Step 2 : Check the Bluetooth setting on your phone to "Pair New Device".
Step 3 : Select device name "HA Clarity" 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.
● Do NOT use the Bluetooth function of your hearing aids for any medical purposes.

3.7.2 Bluetooth function description

(i) Listening to music
● You could increase/decrease the music volume via your mobile phone
(ii) Phone calls
● You could answer/reject/hang up the phone call via your mobile phone

4. Using the charger

4.1 Charging the hearing aids

The hearing aids will start charging automatically when placed back into the correct slot of the charging case.

4.1.1 Hearing aid indicators

- The Blue indicator lights indicate that the hearing aids are charging.
- The white indicator lights indicate that the hearing aids are fully charged.
- You will hear “Please charge” when the hearing aids are almost run out of the battery.

4.2 Charging the charging case

- Plug the USB-C connector into the port on the charging case. Connect the other end to a power source.

4.2.1 Charger indicator

- Blue light indicates that your charging case is charging.
- White light indicates that your charging case is fully charged.
- Low battery warning: Indicator light will flashing blue when the charging case is almost run out of the battery.
- Check the “Troubleshooting” when failure occurs to your devices

⚠Warnings ： When the battery is low, please charge it in time

Note: Product interface only charging, no data transmission function

6. General information

6.1 Troubleshooting

6.1.1 Hearing aids fault self-checking table

Issue	Potential cause	Potential solution
Feedback or “whistling	Are the hearing aids worn correctly in your ears?	Reinsert the hearing aids in your ears.
	Is the volume very loud?	Reduce the volume.
	Improper size of eartips.	Replace the eartips for bigger size and try again.
	Are the eartips broken or clogged?	Replace the eartips
	Are you holding an object close to the hearing aids?	Move your hand away to create more space between the hearing aids and the objects.
	Is your ear full of wax?	Visit your physician.
No sound, Voice is weak or fuzzy	Low battery	Charge the hearing aids.
	Volume is too low.	Increase the volume level.
	Microphone is clogged.	Clean debris or earwax from microphone.
	Is your ear full of wax?	Visit your physician.
Hearing aids can not connect with the Hearing control APP.	Are the hearing aids turned on?	Turn the hearing aids on.
	Bluetooth function of your mobile device is OFF.	Turn on the Bluetooth function of your mobile device.
	Hearing aids are occupied by other mobile device.	Disconnect from other mobile device and try to connect again.

Hearing aids can not connect with the mobile phone Bluetooth.	Misrecognize the Bluetooth broadcast name.	Bluetooth broadcast name: HA Clarity.
	Bluetooth function of your mobile device is OFF.	Turn on the Bluetooth function of your mobile device.
	Hearing aids are occupied by other mobile device.	Disconnect from other mobile device and try to connect again.
Music or phone call function is not working after connecting successfully.	Hearing aids do not get the permission of your mobile phone about media or phone.	Set permission to your hearing aids.
	Do-not-disturb mode of your mobile phone is ON.	Turn off the do-not disturb mode of your mobile phone.

6.1.2 Charging case fault self-checking table

Issue	Potential cause	Potential solution
Indicator light of charging case is not light up or flashing.	Adapter is not powered	Power the adapter or replug to the power supply
	Charging case is connect to the USB cable incorrectly.	Check and connect charging case to USB cable correctly.
	Battery over-discharging.	Charge the charging case for a period of time.
Charging case can not charge the hearing aids.	Are the hearing aids sitting correctly in the charging case?	Reinsert the earbuds in the charging case.
	Charging contacts are dirty	Clean the charging contacts of hearing aids and charging case.

6.1.3 Remote control unit faults self-checking table

Issue	Potential cause	Potential solution
Fail to connect with hearing aids.	Are the remote control unit turned on?	Turn on the remote control unit.
	No power.	Charge the remote control unit.
	Hearing aids are occupied by Hearing control APP.	Disconnect your hearing aids from Hearing control APP and try to connect again.

6.2 Technical specifications

Test Standard：IEC 60118-7:2005
Test Equipment：FONIX 8000
Test Coupler：HA-1
The standard test 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) kPa

1) Hearing aids technical specifications	
Test Items	
Max.Output(OSPL90)	≤117dB+3dB
The full-on gain value(HFA FOG@50)	22dB±5dB
The total harmonic distortion value (THD)	＜5
Equivalent input noise level (EIN)	＜32dB
The Latency value	14ms
Frequency response	f1＜250Hz, f2＞5000Hz
Hearing aid Battery life (Hearing aid function Single full charge service time)	⩾15h
2). Battery life & Discharge time of the charging case	
Test Items	
A pair of hearing aids charging times with fully charging case(Single full charge service time)	2 times

Item	Operation environment	Storage & transportation environment
Temperature	-10℃~40℃	-10℃~+55℃
Relative humidity	30%RH-75%RH	10%RH-90%RH
Atmospheric pressure	86kPa~106kPa	70kPa-106kPa

● The data are derived from the measured value of the product at the laboratory, not guaranteed values.

Time to warm from minimum storage temperature before use:
1 hour (ambient temperature 68°F or 20°C)
Time to cool from maximum storage temperature before use:
1 hour (ambient temperature 68°F or 20°C)

7. How to take care for your device

Please follow the advice below for the best user experience and to prolong your devices' lifetime.

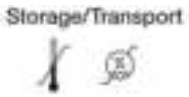
- Do not drop your hearing aids or knock them against hard surfaces.
- Do not use sharp tools to dislodge ear wax. Sticking household items into your devices can seriously damage them.
- Keep your devices away from high-temperature and/or high-humidity atmosphere.
- Keep your devices clean and dry by using cleaning cloth to avoid potential damage from humidity or sweat.
- Do not swim, shower or sauna while wearing the hearing aids.
- You devices should never be rinsed or submerged in water as water drops may block

sound or damage the electrical components of the hearing aids.

- Do not attempt to dry the hearing aids or charging case in an oven, microwave or other heating equipment. This will cause them to melt and may cause burns to your skin.
- Do not clean your devices with water,solvent or cleaning fluids.
- Always remove your hearing aids when using hair care products. The hearing aids can become clogged and cease to function properly.
- Store your devices in a clean and dry location
- Do not use the electronic dryer to store the rechargeable hearing aids.
- Inspect the hearing aids, eartips, and charging case regularly. Remove earwax and debris from your devices by using enclosed cleaning tools.
- Charging contacts should always be kept clean and dry.
- Do not disassemble or attempt any repairs by yourself. Doing so will void your warranty.

8. Normalized symbols

	Follow operating instructions
	B type applied part
	Disposal in accordance with Directive 2012/19/EU (WEEE)
CE 1639	Complies with the European Medical Device Regulation 2017/745. Notified Body is SGS.
	Medical Device
	Manufacturer information
	Authorized representative in the European Community.
	Date of manufacture
	Serial number
	Warning/ Danger: Improper use might cause serious injuries.
	Keep Dry
	Unique device identifier
IP54	IP code of the device: this device's grade of against ingress of solid foreign objects-It can prevent the entry of solid objects larger than 12.5

	mm; the grade of waterproof is Protected inclined stream
	MR Unsafe. Do not use the device under Magnetic Resonance (MR) environment
	Permissible storage and transport temperature and humidity
	Permissible operating temperature and humidity

9. Storage and disposal

9.1 Storage

1) If you don't use it, turn off the hearing aids, and then put it into the charging box.
2) Don't put the device under the sunshine, high temperature and moist environment or someplace which maybe get in touch with fire.
3) Keep the device storage in following environmental ranges:
-10~55℃, 10%~90%RH, 700-1060hPa

9.2 Disposal

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

10. Guarantee

This limited warranty covers defects in material and workman-ship for a period of one (1) year from the date of purchase, which includes the hearing devices, charger case within the warranty period. Any damage caused by improper handling and care, exposure to chemicals, or unauthorized modification will not be covered by the warranty. All other damage claims excluded. A warranty claim must be submitted with the purchase receipt.
If you want to maintenance hearing aids, please contact the manufacturer or after-sales service center.

11. Report adverse events

If you think you are undergo adverse event that has a causal relationship with the hearing aids , you shall report to the manufacturer and the competent authority of the Member State in which you stay.

12. Electromagnetic compatibility

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 communica-tions equipment and the RJADAT-1 unit.

Electromagnetic emission

Guidance and manufacturer´s declaration – electromagnetic emission		
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.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	Hearing aids 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	Hearing aids are 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 IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Electromagnetic immunity

Guidance and manufacturer´s declaration – electromagnetic immunity			
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**	**Electromagnetic environment -guidance**
Electrostatic discharge IEC 61000-4-2	±2 kV, ±4 kV, ±6 kV, ± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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 %.
Electrostatic transient/ burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 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	± 0.5 kV, ± 1 kV differential mode line-line	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % U_T (100 % dip in U_T) for 1 cycle at 0° 70 % U_T (30 % dip in U_T) for 25/30 cycles at 0° 0 % U_T (100 % dip in U_T) for 250/300 cycle at 0°	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Hearing aids requires continued operation during power mains interruptions, it is recommended that Hearing aids be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

IEC 61000-4-8			
IMMUNITY to proximity magnetic fields	65A/m, Modulation: Pulse modulation, 2.1KHz Test frequency:134.2K Hz; 7.5A/m, Modulation: Pulse modulation, 50KHz Test frequency:13.56 MHz;	65A/m, Modulation: Pulse modulation, 2.1KHz Test frequency:134.2K Hz; 7.5A/m, Modulation: Pulse modulation, 50KHz Test frequency:13.56 MHz;	/
NOTE: U_T is the a. c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bands and amateur radio bands[a]	N/A	Portable and mobile RF communications equipment should be used no closer to any part of Hearing aids , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz

Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 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).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range [d] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

a /The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b /The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c/ 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 / is used exceeds the applicable RF compliance level above, the / should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the /.

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

Recommended separation distances between

Recommended separation distances between portable and mobile RF communications equipment and Hearing aids

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 of transmitter /W	Separation distance according to frequency of transmitter /m		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
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.

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

Recommended separation distances between RF wireless communications equipment

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

Frequency /MHz	Maximum Power /W	Distance /m	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including
450	2	0.3	28	28	

710	0.2	0.3	9	9	cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E = \frac{6}{d}\sqrt{P}$ 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 transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- The device fulfills the provisions of the Harmonize Standard of IEC 60601-1,IEC 60601-2-66,IEC 60118-7,IEC 60118-13. ISO 10993-1/-5/-10,ISO14971.

Warning

Pay attention to electromagnetic environment because product may be subject to electromagnetic field. Keep away from products or facility with strong magnetic waves emission in installation and use, e.g. radio signal tower, high frequency electro tome, NMR device, etc.

The device may produce electromagnetic field interference to other electrical equipment, but it complies with requirement of electromagnetic compatibility standard. Portable and mobile RF communication device may have an impact on it.

Do not use this device with other devices around or stacked. If must, observe if it functions well on that condition.

Using accessories and cables apart from therapy cables, diagnostic test cables and power line sold as accessories of components may result in the increase of equipment or system emission or decline of noise immunity

FCC regulatory conformance:

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.

(2) This device must accept any interference received, including interference that may cause undesired operation.

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

NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user’s authority to operate the equipment.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

FCC ID:2A39N-ZHJHHA

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IC regulatory conformance
This device complies with CAN ICES-003 (B)/NMB-003(B).
This device complies with Industry Canada licence-exempt RSS standard(s). 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.
Cet appareil est conforme à la norme CAN ICES-003 (B)/NMB-003 (B).
Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :
(1) l'appareil ne doit pas produire de brouillage, et
(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

RF Exposure
This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment.
Cet équipement est conforme aux limites d'exposition aux radiations de la IC définies pour un environnement non contrôlé.