

Z1359 英文说明书

材质: 80g双胶纸

成品尺寸: 103 x 104mm

总页数: 64p

颜色: 4c

工艺: 胶装

公差: +0.5mm; -0.5mm

CERTIFICATE	
Product Name	OTC Intelligent Hearing Aids
Product Life	5 years
Model	Nano
Lot No.	Outside packaging
Inspector	
The product conforms to national and industry standards and has passed inspection.	

UNICE Intelligent Medicine Shenzhen Ltd.

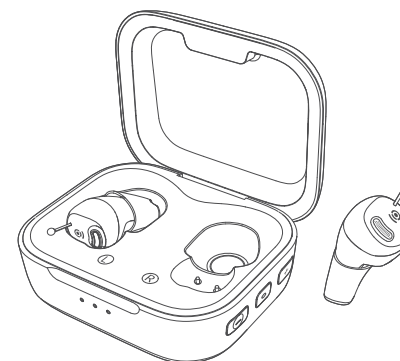
☎ 1(959)-206-0088

✉ support@cearvol.com JP: CSJP@cearvol.com

📍 14/F, Tower B, Building 7, Baoneng Science and Technology Park, Qingxiang Road #1,
Longhua New District, Shenzhen, China, 518129

🌐 www.cearvol.com

CEARVOL



Instruction Manual

OTC Hearing aids

Nano

 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 18 or older.
- This Over–the–counter (OTC) hearing aid is for users who are 18 or 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.

 WARNING

When to see a doctor.

- 01) 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.
- 02) Your ear was injured or deformed, such as in an accident.
- 03) You have seen blood, pus, or fluid coming out of your ear in the past 6 months.
- 04) Your ear feels painful or uncomfortable.

- 05) You have a lot of ear wax, or you think something could be in your ear.
06) You get really dizzy or have a feeling of spinning or swaying (called vertigo).
07) Your hearing has changed suddenly in the past 6 months.
08) Your hearing changes: it gets worse, then better again.
09) You have worse hearing in one ear.
10) You hear ringing or buzzing in only one ear.

 WARNING

This hearing aid should not cause pain when inserting it.

- Remove the 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 does not go away, contact your hearing healthcare professional.

 WARNING

Risk of injury!

- Always wear the hearing aid with a sleeve.
Make sure that the sleeve is completely attached.
Ensure that only a single sleeve is attached to each hearing aid.
In the very rare case that the sleeve gets stuck in the ear canal and you

cannot remove it yourself, please contact a physician.
Do not insert the sleeves in your ears without the hearing aid attached.

 WARNING

- In case you have any doubt whether this device is appropriate for you, consult a licensed physician before using this device.
- This hearing aid is intended for you only and should not be worn by others.

 Notice

- This hearing aid is intended for you only and should not be worn by others.

 WARNING

Choking hazard!

- Your hearing aids contain small parts which can be swallowed.
01) Keep hearing aids, batteries and accessories out of reach of children and pets.
02) If parts have been swallowed, consult a physician or hospital immediately.

 CAUTION

This is not hearing protection.

- You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you are 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.

 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.

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.

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.

 CAUTION

- Read this user guide thoroughly and completely to avoid damage and injury.

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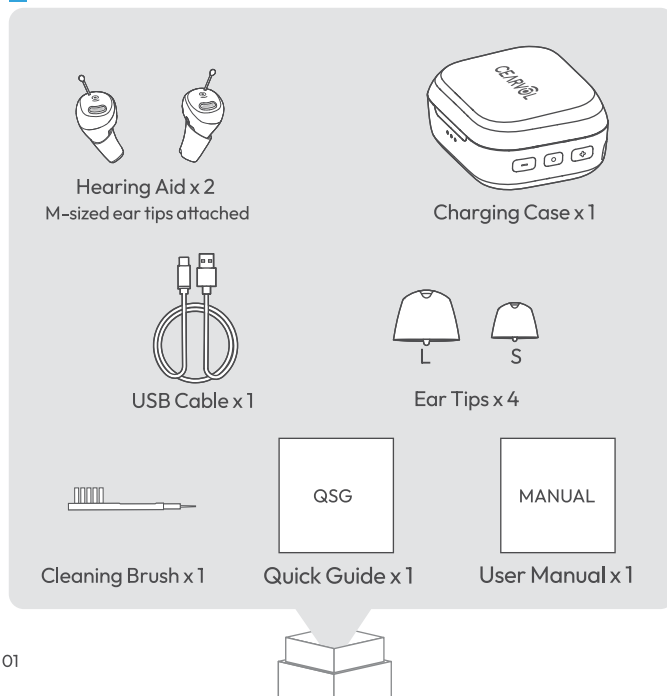
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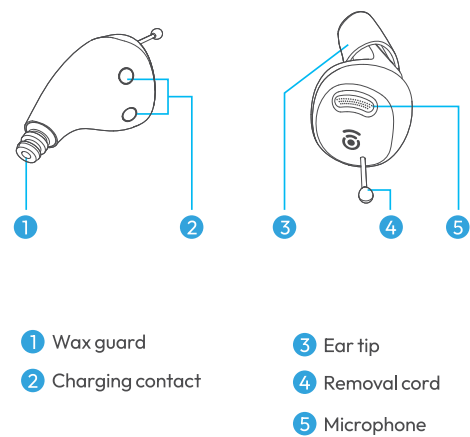
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What You'll Find In The Box



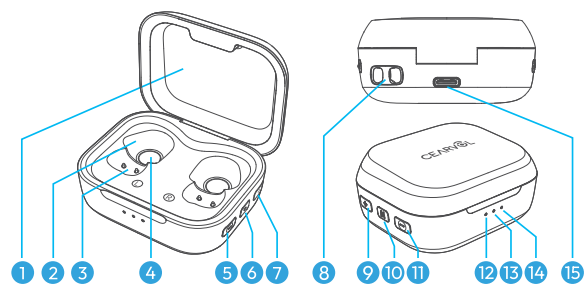
01

Get To Know Your Hearing Aids



02

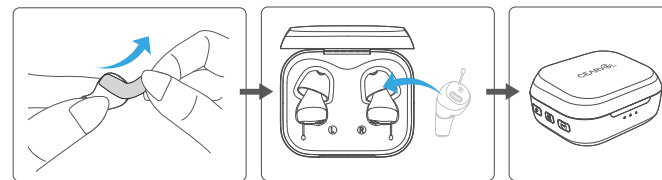
■ Get To Know Your Charging Case



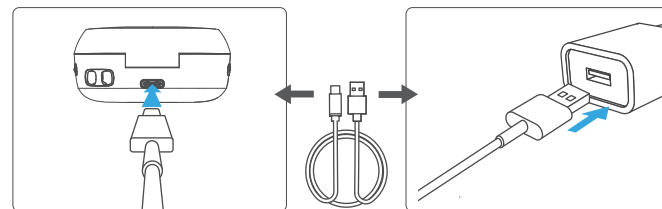
- | | |
|---------------------------------------|---|
| 1 Lid | 8 Lanyard hole |
| 2 Hearing aid charging slots | 9 Left hearing aid volume “+” button |
| 3 Charging contacts | 10 Hearing mode switch button |
| 4 UV sterilization light | 11 Left hearing aid volume “-” button |
| 5 Right hearing aid volume “-” button | 12 Left hearing aid charging indicator |
| 6 Preset program switch button | 13 Charging case charging indicator |
| 7 Right hearing aid volume “+” button | 14 Right hearing aid charging indicator |
| | 15 Type-C charging port |

■ Charge Your Device

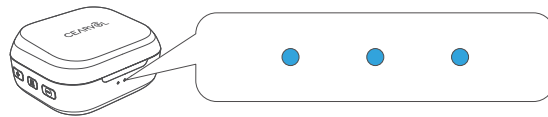
Remove the hearing aids from the charging case, peel off the insulation film, then place them back into the charging slots and close the lid.



Connect the charging case to a suitable power adapter (not included) using the provided USB cable.



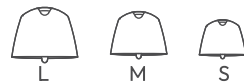
While charging, the three lights on the front of the charging case blue light pulses. When fully charged, the blue light changes to a steady glow.



■ How To Install Ear Tips

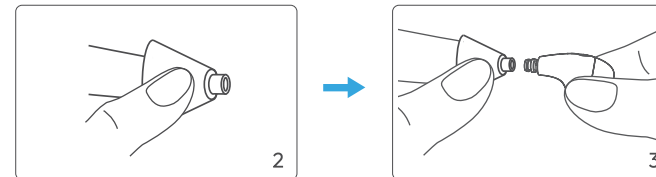
Please follow the steps below to install the ear tips, as incorrect ear tip replacement may cause the ear tip to accidentally remain in your ear when removing the hearing aid.

01) Choose an ear tip size that fits you from the provided options.



02) Hold the ear tip by its edge with both hands, flip it outward, then pinch the edge with your index finger and thumb (as shown in the illustration).

03) Hold the hearing aid with one hand and the ear tip with the other, then firmly attach the ear tip to the hearing aid (as shown in the illustration).

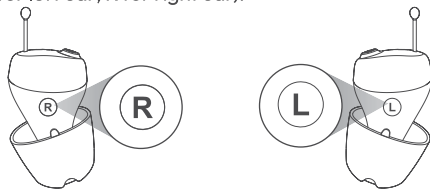


! Notice

- After installation, gently tug on the ear tip to ensure it is securely attached and not easily detachable.

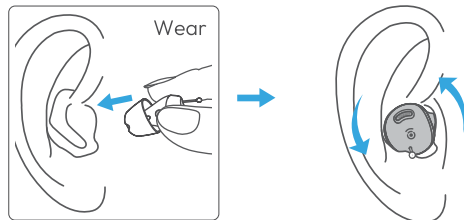
How to Wear and Remove the Hearing Aids

Correctly identify the left and right hearing aids to wear them on the appropriate ears. The “L” and “R” marks on the hearing aids indicate left and right (L for left ear; R for right ear).



01 Wearing

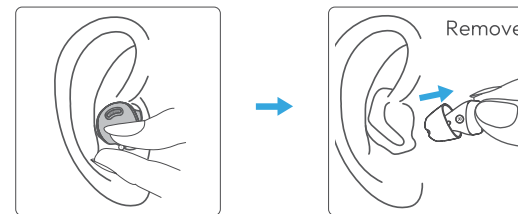
- Pinch the body of the hearing aid with your index finger and thumb; gently insert it into your ear canal and twist it until it feels comfortable.



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02 Removing

- Gently pinch the edge of the hearing aid's removal cord to take it out of the ear canal.



! Notice

- 01) If the hearing aid whistles, check if the ear tip is properly inserted. If it still whistles after confirming correct wearing, try a different size ear tip. If it persists, reduce the volume to a comfortable level. Turn off the hearing aid when not in use to avoid battery drain.
- 02) If the hearing aid malfunctions, refer to the troubleshooting table. If issues persist, contact customer service.

Safety Risk:

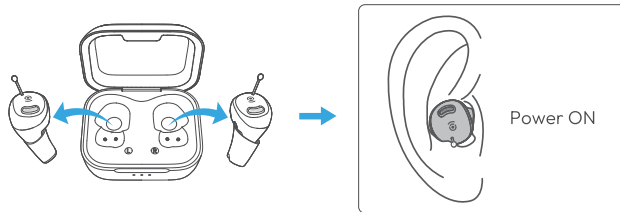
- In rare cases, when removing the hearing aid, the ear tip may accidentally remain in the ear canal. Seek medical assistance immediately; do not attempt to remove it yourself or with non-professionals to avoid ear damage.

08

Power ON/OFF

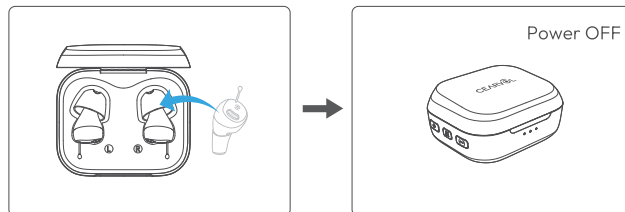
Power ON:

- After properly wearing the hearing aid, it will automatically turn on within 10 seconds, accompanied by a startup tone.



Power OFF:

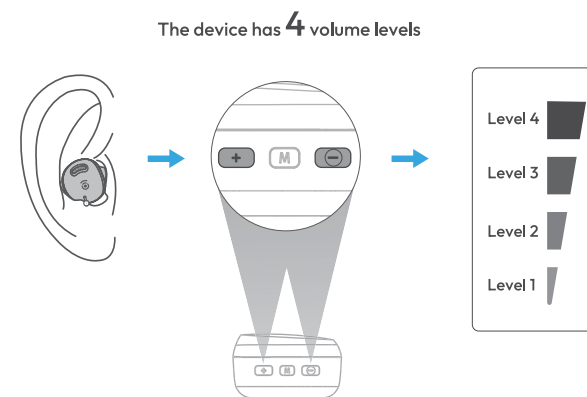
- Place the hearing aids back into the charging case and close the lid to turn them off automatically.



Volume Adjustment

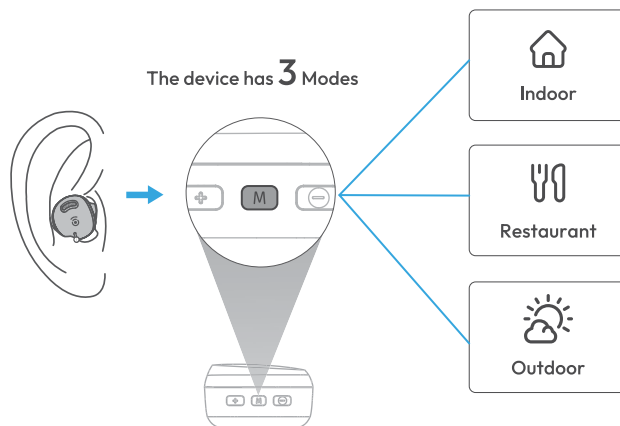
01) The hearing aid has 4 volume levels.

02) When the hearing aid is on, press the "+" or "-" buttons on the charging case to adjust the volume for the left or right hearing aid.



Mode Switching

- 01) The hearing aid has 3 modes.
- 02) Switching modes: When the hearing aid is on, press the "M" button on the left side of the charging case to cycle through the modes. Each mode change is accompanied by an audible indicator (see Table 1).



Notice

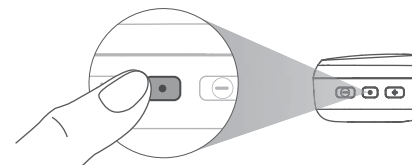
- The hearing aid has a memory function and will automatically recall the last-used volume and mode settings when turned back on.

Mode	Prompt sound
Indoor	Indoor mode
Restaurant	Restaurant mode
Outdoor	Outdoor mode

Table 1: Hearing aid mode prompt sound

Preset Program Switching

- The hearing aid has 3 preset programs.
- Switching preset programs: When the hearing aid is on, press the " " button on the right side of the charging case to cycle through the hearing compensation programs. Each change is accompanied by an audible indicator (Table 2).



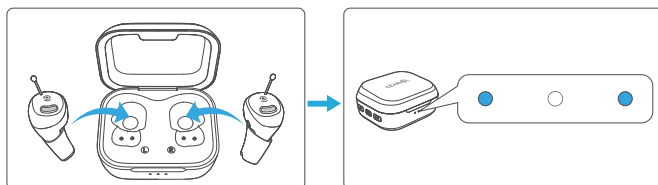
Program	Audible Indicator
Mild	 "Program 1"
Mild-to-Moderate	 "Program 2"
Moderate-to-Severe	 "Program 3"

Table 2

3. The hearing aid has a memory function and will recall the last-used volume and mode settings.

How To Charge Your Hearing Aids

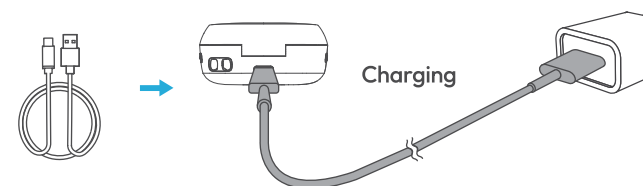
- Place the hearing aids into the designated left and right slots in the charging case. The hearing aids will automatically attach magnetically to the charging contacts. The charging indicator light states are shown in Table 3.



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How To Charge The Charging Case

- 01) Insert the USB Type-C charging cable into the charging port of the case.
- 02) Plug the other end of the cable into a power adapter .
- 03) The charging status indicator lights are shown in Table 3.



! Notice

- 01) When not in use for a long time, charge the hearing aids and charging case regularly, recommended to fully charge every 1-3 months.
- 02) If charging issues occur within the warranty period, refer to the "Charging Troubleshooting Table" in this manual. If unresolved, contact customer service.

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Hearing Aid		
● Blue ○ OFF		
Working Conditions	Power Level	Indicator Light Status
Hearing aid in the charging case (charging case not connected to power)	1-30%	Blue light flashes quickly and continuously
	31-95%	Blue light breathes and flashes continuously
	96-100%	Blue light stays on for 5 minutes, then turns off
Hearing aid in the charging case (charging case connected to power)	1-30%	Blue light flashes quickly and continuously
	31-95%	Blue light breathes and flashes continuously
	100%	Blue light stays on, turns off immediately when the charging case is disconnected from power Charging Case

Table 3-1

Charging Case		
● Blue ○ OFF		
Working Conditions	Power Level	Indicator Light Status
Charging case not connected to power	< 30%	Blue light flashes quickly and continuously
	> 30%	Blue light turns off
Charging case connected to power	1-30%	Blue light flashes quickly and continuously
	31-95%	Blue light breathes and flashes continuously
	96-100%	Blue light stays on
	100%	Blue light stays on, turns off immediately when the charging case is disconnected from power

Table 3-2

■ UV Sterilization

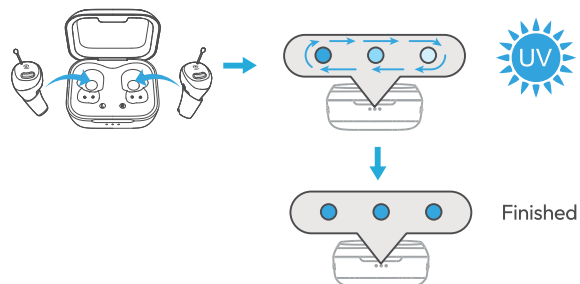
! Notice

The UV sterilization function will be activated only when the charging case is connected to power and the lid is closed.

Do not open the charging case lid while the UV sterilization light is working, to avoid UV light leakage, which could harm the human body.

When the UV sterilization light is working, the indicator lights will show the following status:

The three indicator lights on the charging case will light up sequentially from left to right, repeating in a cycle, until the UV sterilization process is complete. Once the sterilization is finished, the indicator lights will return to showing the charging status of the hearing aids.



■ Technical Information

Test item	2cc coupler
Output	
OSPL 90 (Peak)	<117dB SPL
Full-on gain (Peak)	30±5dB

Frequency range and noise	
Frequency range	250–5500 Hz
Equivalent input noise	≤32 dBA
Total harmonic distortion 500 Hz, 70 dB SPL	10%
Latency	10ms

Battery	
Battery runtime	Up to 54 hours
Battery capacity in the charger	180 mAh (666mWh)

All measurements performed according to ANSI 3.22-2014

Operating conditions

Temperature Range: 32°F – 104°F (0°C – 40°C)

Humidity Range: 0 – 95% RH

Pressure Range: 70 – 110 kPa

Storage/transport conditions

Temperature Range: -13°F – 158°F (-25°C – 70°C)

Recommended temperature range for best bat

Performance: -4°F – 113°F (-20°C – 45°C)

Humidity Range: 0 – 90% RH

Pressure Range: 70 – 110 kPa

Product FAQ**Hearing aid troubleshooting checklist**

Question	Possible reasons	Suggested solutions
Hearing aid has no sound	Battery is dead.	Place the hearing aids into the charging case to charge.
	Sound outlet or microphone inlet is blocked.	Clean the sound outlet or microphone inlet.
	Not worn correctly, infrared light not sensed.	Remove the hearing aid, reinsert it, adjust the angle, and clean the filter of the light-sensing part until sound is produced.
	Ear cap/cerumen cap is blocked.	Clean the ear cap/cerumen cap.

Hearing aid troubleshooting checklist		
Question	Possible reasons	Suggested solutions
Sound is weak and unclear	Battery power is insufficient.	Place the hearing aids into the charging case to charge.
	Volume is too low.	Increase the volume.
	Ear tips is loose.	Adjust the ear tip and then rewear the hearing aid tightly.
	Sound outlet or microphone inlet is blocked.	Clean the sound outlet or microphone inlet.

Charger troubleshooting checklist		
Question	Possible reasons	Suggested solutions
Charging case does not light up	Adapter is not powered.	Check if the adapter is plugged in properly, check if the 110/220V AC socket has power, and if there is any poor contact.
	USB cable is not plugged in properly.	Check if both ends of the USB cable are loose, replug and ensure they are fully inserted.
Can't charge the hearing aid	Hearing aid is not placed into the charging slot according to the left and right ear positions.	Follow the charging instructions to place the hearing aid back into the charging case's charging slot.
	Charging case battery is depleted.	Connect the USB cable to charge the charging case.
	Charging contact points are dirty.	Use a clean, dry cloth to clean the charging contact points.

Charger troubleshooting checklist		
Question	Possible reasons	Suggested solutions
Charging case charging indicator light does not turn on or flashes	After the charging case indicates low battery, it was not charged in time.	Avoid continuing to use the charging case after the low battery warning; charge it promptly. If the indicator light does not turn on or flashes, insert the USB cable and charge continuously for more than 2 hours to restore it to normal charging state. If it still cannot be restored, please contact after-sales service.
After inserting the hearing aid into the charging case correctly, It does not automatically turn off	Charging case battery is depleted.	Charge the charging case promptly to restore its battery to a working state.

Charger troubleshooting checklist		
Question	Possible reasons	Suggested solutions
After charging, the hearing aid does not turn on, and when placed back into the charging case correctly, the charging Indicator light does not turn on	Charging case battery is depleted.	Charge the charging case promptly to restore its battery to a working state.

Safety instruction and warranty card

1 Introduce

- 1.1 What's is hearing loss?

A speech frequency puretone average (average of hearing thresholds at 0.5, 1, 2, and 4 kHz) of greater than 25 dB hearing level (HL) in both ears was defined as hearing loss per 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's the hearing aids?

OTC Intelligent Hearing Aids are used the air-conduction type to compensate of impaired hearing. It is a wearable sound,amplifying device. The fundamental operating principle of hearing aids is to receive, amplify, and transfer sound to the ear drum of a hearing impaired person.

2 Intended use

- 2.1 Medical purpose

The patient is an intended operator OTC Intelligent Hearing Aids Buds is an air-conduction hearing aid, and it is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

- 2.2 Intended patients and environment

The hearing aids are expected to be used in both indoor and outdoor environments. It is intended to amplify sound for individuals aged 18 or older with perceived mild to moderate hearing impairment, The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

- 2.3 Side effects

- 01) Users who are sensitive to silicone materials may experience itching in the ear canal.
- 02) Initial use may cause temporary discomfort or slight pain in the ear canal as the user adjusts to the device.

3 Important safety instructions

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

- **3.1 Contraindication**

The device is unsuitable and should not be used in the following situations:

- 01) Users with chronic suppurative otitis media, congenital ear atresia are prohibited from use;
- 02) OTC intelligent hearing aids are intended only to compensate for hearing loss and do not provide any therapeutic treatment.
- 03) Medical hearing aid buds must not be used by individuals under 18 years of age.

- **3.2 Warnings**

- 01) Keep small parts (such as the hearing instrument and detachable components) out of reach of children, as they may be swallowed. Dropping, immersing in liquid, strong electromagnetic fields or excessive heat will damage the hearing aids. If any part remains in the ear (such as the ear tip), consult a doctor immediately. Do not attempt to remove it yourself.

- 02) Dispose of used hearing aids and battery cases according to local battery recycling regulations. Do not throw them into fire. Do not disassemble the hearing aids yourself. If the devices need repair or adjusted, please contact the manufacturer and send them back. Device may be damaged if serviced by an unauthorized person.

- **3.3 Notice**

- 01) Do not use the product in potentially explosive or hazardous environments.
- 02) Do not use the device at high volume for extended periods, as it may damage your hearing.
- 03) Accessory equipment connected to the charging case must be certified according to the respective IEC 60601/62368 standards. Set the volume to the minimum when not wearing.
- 04) Regularly clean and maintain the device. Avoid blocking the earplugs or sound inlet with foreign objects, as this can affect sound amplification performance.
- 05) Avoid shocks or dropping the device. Do not store or use it in high humidity or high-temperature environments, such as saunas.
- 06) Don't use the product in potential explosive or dangerous environment.

- 07) Keep the device out of children's reach. It may cause injury or damage the device.
- 08) Do not use the device in oxygen-rich environments. Avoid using the hearing aids for excessively long periods without breaks.
- 09) Do not set volume levels too high. Listening for extended periods at high volume levels can cause further hearing damage. Special care must be taken because these hearing aids are high-output devices.
- 10) If the noise is too loud, stop using and contact the distributor.
- 11) This device is intended for individual use. Do not share your hearing aids with others, as doing so may cause hearing damage.
- 12) Monitor any unusual skin reaction. In some instances, wearing a hearing aids can cause an allergic reaction leading to itchiness or rashes. If you notice any unusual skin condition, stop wearing the hearing aids and see a medical specialist.
- 13) Keep the hearing aids away from magnetic objects. hearing aids may be damaged if exposed to magnetic objects.
- 14) Always inform your doctor that you are wearing a hearing aid when diagnosing or treating a disease; remove hearing aids if necessary. (If you undergo treatment while wearing the hearing aids, they may be damaged.)
- 15) Do not touch the inside. The inside of the hearing aids contains many delicate parts that are precision adjusted. Never pry the inside of the

- hearing aids with a needle or similar object.
- 16) Use the power adapter and USB cable specified in the instructions. If you are unsure, contact your distributor.
- 17) When the LEDs indicate that the charging case is fully charged, unplug it as soon as possible to avoid overcharging.
- 18) Do not place the hearing aids in hot or humid environments. Avoid leaving them near heat sources, in direct sunlight, or in bathrooms and near humidifiers.
- 19) In a closed car in summer, the temperature can rise to very high levels. Do not leave your hearing aids in a car.
- 20) Store and use the device in an appropriate environment to avoid device damage. Detailed environmental requirements can be found on page 26: transport and storage.
- 21) Radio wave emissions from mobile phones may cause noise in the hearing aids or result in reduced volume.
- 22) Check and replace the ear tips regularly. If you run out of replacements, contact your distributor. Do not attempt to repair the hearing aids while they are in use. Remove them before performing any maintenance.
- 23) If you need help with setup, use, or maintenance of the hearing instrument, or to report any abnormal operation or incidents, please contact the manufacturer.

4 Maintenance and clean

● 4.1 Daily maintenance

- 01) It is important to keep your hearing aids clean and dry. On a daily basis, clean the hearing aids using a soft cloth or tissue.
- 02) In order to avoid damage due to humidity or excessive perspiration, the use of a drying kit is recommended.

● 4.2 Care and maintenance

- 01) Store the device in a dry place out of reach of children and away from direct sunlight.
- 02) Do not expose the hearing aids to heat from stoves, etc. Also, avoid leaving it in places with high humidity.
- 03) Operate the controls with care. Do not press hard.
- 04) If the hearing aid falls into water, wipe it with a dry cloth and have it inspected by the manufacturer or distributor.
- 05) Do not poke or touch the microphone with your fingernail, a pin, or other sharp objects, as this may damage it.
- 06) Do not disassemble or attempt to repair the device yourself. Contact the manufacturer or distributor for assistance.
- 07) Use a cleaning stick and brush to remove any earwax buildup in the earpiece.

- 08) Normally, the user can adjust the hearing aids with the gain adjustment button. We strongly recommend that you return the device to the manufacturer annually for adjustment and calibration for better use of your hearing aids.

● 4.3 Clean

Keep your hearing aids clean. Heat, moisture and foreign substances can result in poor performance.

- 01) Use a cleaning brush or soft cloth to clean debris from around the user control, microphone and battery compartment; inspect the receiver, earbud or eartip and wax guard regularly. Clean and disinfect earbuds shells and ear tips with 75% alcohol twice a week. Avoid allowing alcohol to enter the hearing aids.
- 02) Never use water, solvents, cleaning fluids or oil to clean your hearing aids.
- 03) Charging contacts should always be kept clean and dry.

Federal Communication Commission interference Statement

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, users are encouraged to try to correct the interference by one or more of the following measures:

- 01) Reorient or relocate the receiving antenna.
 - 02) Increase the separation between the equipment and receiver.
 - 03) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - 04) Consult the dealer or an experienced radio/TV technician for help.
- Caution: Changes or modifications not expressly approved by Cannice could void the user's authority to operate the equipment.

FCC Warning

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.

Any Changes or modifications not expressly approved by the party

responsible for compliance could void the user's authority to operate the equipment.

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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

MIC: 220-JP9818 (Charging case)

MIC: 220-JP9819 (Earbuds)

FCCID: 2ADTV-NANO



This product is RoHS compliant.

This product is in compliance with Directive 2011/65/EU and UK The Restriction of the use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012, and its amendments, on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

- **Electromagnetic Compatibility and Risk Warning**

Through the electromagnetic compatibility test, Medical Hearing-Aid Buds comply with the following standards:

IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral Standard: Electromagnetic disturbances– Requirements and tests EC 60601-2-66:2019: Medical electrical equipment– Part 2-66: Particular requirements for the basic safety and essential performance of

hearing aids and hearing aid systems.

Please strictly follow the guidelines below. Failure to do so may result in electromagnetic interference with other devices, reduced electromagnetic immunity, or loss of essential device functions. Portable and mobile RF communications equipment may affect the normal operation of this medical device. Please maintain a safe distance between the communication equipment and this device. Specific distance requirements are provided in the table.

The length of USB cable should not be longer than 1.8 meters. If the cable is damaged, please contact our company for repair or replacement, otherwise may cause excessive electromagnetic interference. If there is damage, please contact our company in time. Don't repair or replace any components without permission, otherwise it may cause excessive amounts of electromagnetic interference.

Using accessories or cables that are not approved for this device or system may increase emissions or reduce immunity. Please use only the accessories and cables specified by Cannice.

This equipment should not be used in close proximity to or stacked with other devices. If such use is unavoidable, ensure that the device can operate properly in that configuration.

Electromagnetic compatibility statements can be found in Tables 4 to 4-3.

**Medical Hearing-Aid Buds
Electromagnetic Statement Table 4**

Guide and Cannice's Statement – Electromagnetic Emission		
Medical Hearing-Aid Buds intend to be used in the following electromagnetic environment.		
Launch Experiment	Compliance	Electromagnetic Environment – Guide
Radio Frequency Emission CISPR 11	Group 1	Medical Hearing-Aid Buds use RF energy only for its internal function. So its RF emission is very low, and the possibility of interference with electronic devices is very small
Radio Frequency Emission CISPR 11	Class B	Medical Hearing-Aid Buds are suitable for use in all non – domestic and not directly connected to all facilities of the residential public low-voltage power supply network
Harmonic Current Emission IEC 61000-3-2	Not applicable	
Voltage Fluctuations & Flicker IEC 61000-3-3	Compliance	

Table 4-1

Guide and Cannice's Statement – Electromagnetic Immunity			
Medical Hearing-Aid Buds intend to be used in the following electromagnetic environment and the purchaser or user shall ensure that it is used in the electromagnetic environment.			
Immunity Test	IEC Test Level Guide	Coincidence Level	Electromagnetic Environment – Guide
Electrostatic Discharge IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±2kV, ±4kV, ±6kV, ±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	The ground shall be wood, concrete or ceramic tile. If the ground is covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient and Burst IEC 61000-4-4	±2kV 100kHz repetition frequency	Not applicable	Not applicable

Table 4-2

Surges IEC 61000- 4-5	Line to line: ±0.5kV, ±1kV Line to ground: ±0.5kV, ±1kV, ±2kV	Not applicable	Not applicable
Voltage Dips and Interruption IEC 61000- 4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Not applicable	Not applicable
	0% UT; 1 cycle and 70% UT; 25 cycles Single phase: at 0°		
	0% UT; 250 cycle		

Table 4-3

Power frequency magnetic field immunity IEC 61000- 4-8	30A/m 50Hz or 60Hz	30A/m, 50Hz and 60Hz	In the event of malfunction, it may be necessary to keep Medical Hearing-Aid Buds away from the power frequency magnetic field or install a magnetic shield in the field. And the power frequency magnetic field in the expected installation site shall be measured to meet the requirements below the Coincidence level.
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Table 4-4

Proximity magnetic fields immunity IEC 61000-4-39	30kHz, CW, 8A/m	30kHz, CW, 8A/m	While communication might not be possible when the device that includes radio equipment is tested in its passband, the device shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.
	1342kHz, Pulse modulation 2.1kHz, 65A/m	1342kHz, Pulse modulation 2.1kHz, 65A/m	
	1356MHz, Pulse modulation 50kHz, 7.5A/m	1356MHz, Pulse modulation 50kHz, 7.5A/m	
Note: UT refers to the DC grid voltage before the voltage is applied			

Table 5-1

Guide and Cannice's Statement - Electromagnetic Immunity
The Medical Hearing-Aid Buds intend to be used in the following electromagnetic environment and the purchaser or user shall ensure that it is used in the electromagnetic environment.

Table 5-2

Immunity Test	IEC 60601 Test Level Guide	Coincidence level
Conducted disturbances, induced by RF fields IEC 61000-4-6	3V, 0.15MHz ~ 80MHz 6V, in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	Not applicable
Radiated RF Electromagnetic fields immunity IEC 61000-4-3	10V/m 80MHz ~ 2.7GHz 80% AM at 1kHz	10V/m, 80MHz ~ 2.7GHz 80% AM at 1kHz RF Band 10V/m, 0.65-0.96GHz and 1.4-2.7GHz

Table 5-3

Electromagnetic Environment - Guide

Portable and mobile radio communication equipment should not be closer to any part of Medical Hearing-Aid Buds including cable than the recommended isolation distance. The distance should be calculated using the formula corresponding to the transmitter frequency.

Recommended isolation distance

$$d=1.2 \sqrt{P} \quad 150\text{kHz} \sim 80\text{MHz}$$

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

$$d=2.3 \sqrt{P} \quad 800\text{MHz} \sim 2.7\text{GHz}$$

In the formula:

P--Maximum output rated power of transmitter supplied by transmitter Cannice, in watts (W) as the unit;

d--Recommended isolation distance in Meter (m) as the unit.

The field strength of a fixed RF transmitter is determined by the investigation of the electromagnetic field^a and each frequency^b range should be lower than the Coincidence level.

Interference may occur near the device marking the following symbol. 

Table 5-4

Note1: In the MHz and MHz frequency, the higher frequency band should be used.

Note2: These guides may not be appropriate for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and the human body.

^a Fixed transmitter field strength in theory cannot be accurately predicted, Such as: wireless (cellular phone / cordless) and ground mobile radio base station, amateur radio, FM radio and television broadcasting etc. In order to assess the electromagnetic environment of fixed RF transmitters, electromagnetic site survey should be taken into account. If the measured field strength of the Medical Hearing-Aid Buds is higher than the RF compliance level, the Medical Hearing-Aid Buds should be observed to verify its normal operation. If observed performance is abnormal, supplemental measures may be necessary, such as reorienting the direction or location of the Medical Hearing-Aid Buds.

^b The field strength should be less than V / m over the whole frequency range of KHz to MHz.

Table 6-1

Recommended separation distance between portable and mobile radio-frequency communication equipment and Medical Hearing-Aid Buds.

Medical Hearing-Aid Buds intend to be used in a controlled electro-magnetic environment for RF radiation disturbance. Based on the maximum output power of the communication device, the purchasers or users of Medical Hearing-Aid Buds can maintain the minimum distance between the portable and mobile RF communication devices (transmitters) and Medical Hearing-Aid Buds to prevent electromagnetic interference.

Table 6-2

Transmitter maximum rated output power	Isolation distance corresponding to different frequency of transmitter /m		
	150 KHz ~ 80 MHz $d=1.2\sqrt{P}$	80 MHz ~ 800 MHz $d=1.2\sqrt{P}$	800 MHz ~ 2.7 GHz $d=2.3\sqrt{P}$
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

Table 6-3

For transmitters maximum ratings not listed above, the recommended separation distance in meters (m) as a unit, can be determined by the corresponding transmitter frequency bar formula, where P is the maximum rated output power of the transmitter provided by the transmitter Cannice, in Watt (W) as a unit.

Note1: In the MHz and MHz frequency, the higher frequency band should be used.

Note2: These guides may not be appropriate for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and the human body.

● For Products That Include Batteries

Instructions for Users on Removal, Recycling and Disposal of Used Batteries Do not attempt to disassemble the product's battery on your own. We strongly recommend that you leave such tasks to qualified professionals to ensure safety and compliance with warranty terms. For products with a built-in battery that lasts for the lifetime of the product, removal may not be possible for the user. In such cases, authorized recovery centers should handle the dismantling of the product and the removal of the battery.

If, for any reason, it becomes necessary to replace such a battery, the procedure should be performed by authorized service centers. In the European Union and other regions, it is prohibited to dispose of any

battery with household trash. All batteries must be disposed of in environmentally sound manner. Contact your local waste-management officials for information environmentally sound collection, recycling and disposal of used batteries.

● **Warning:**

Danger of explosion if battery is incorrectly replaced. To reduce risk of fire explosion or leakage of flammable liquid/gas, don't disassemble, crush, puncture, short external contacts, expose to temperature above 60°C(140° F), sunshine or smoke, expose to extremely low air pressure or dispose of in fire or water. Replace only with specified batteries. The symbol indicating 'separate collection' for all batteries accumulators shall be the crossed-out wheeled bin shown below:



● **WARNING-For Products Contain Coin/Button Cell Batteries**

DO NOT INGEST BATTERY. CHEMICAL BURN HAZARD. This product contains a coin/button cell battery. If the coin/button cell battery is swallowed, it can cause severe internal burns in just 2 hours and can lead to death. Keep new and used batteries away from children. If the battery compartment does not close securely, stop using the product and keep it away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.

● **Normalized symbols**

	Follow operating instructions		
	B type applied part		
	Disposal in accordance with Directive 2012/19/EU (WEEE)		
	Date of manufacture		Manufacturer information
	Serial number		Medical device
	Warning/ Danger: Improper use might cause serious injuries.		
	Indicates the manufacturer's batch code so that the batch or lot can be identified		
	Permissible storage and transport temperature and humidity		
	Permissible operating temperature and humidity		
	Keep Dry		Comply with Directive 2011/65/EU
	Paper Packaging Recycling		
IPX5	IP code of the device: this device's grade of against ingress of solid foreign objects –Not dust proof; the grade of waterproof is splash proof type, liquid from any direction into the shell without harm.		

● **Manufacturer**



ShenZhen Cannice Technology Co.,Ltd.

Address: 20/F, Tower A, Building 7, Baoneng Science and Technology Park, Qingxiang Road #1, Longhua New District, Shenzhen, China, 518129

Tel: +86-755-61880577

Website: <http://www.cannice.hk>

● **Producer**

Guangxi Cannice Precision Technology Co.,Ltd.

Block C, South of Longtuan West Road Zhongshan Town, Zhongshan County HezhouGuangxi 542600 China

● **Important Safety Instructions For All Products:**

- 01) Read these instructions.
- 02) Keep these instructions.
- 03) Heed all warnings.
- 04) Follow all instructions.
- 05) Clean only with a dry cloth.
- 06) Do NOT wear the hearing aids while charging.

- 07) Do not install this apparatus near any heat sources such as radiators, heat registers, stoves or other apparatus (including amplifiers) that produce heat.
- 08) Protect the power cord from being walked on or pinched, particularly at plugs, convenience receptacles and the point where they exit from the apparatus.
- 09) Use only attachments/accessories specified by the manufacturer.
- 10) Do not use your device outdoors during a thunderstorm. Doing so may result in electric shock or device malfunction.
- 11) Refer all servicing to qualified service personnel. Servicing is required when the apparatus has been damaged in any way, such as when the power-supply cord or plug is damaged, liquid has been spilled or objects have fallen into the apparatus, or the apparatus has been exposed to rain or moisture, does not operate normally or has been dropped.
- 12) Do not expose this apparatus to dripping or splashing, and ensure that no objects filled with liquids, such as vases, are placed on the apparatus.
- 13) The mains plug of the power-supply cord shall remain readily operable.

14) This apparatus is intended to be used only with the power supply and/or charging cable provided by the manufacturer. The following instructions may not apply to waterproof devices. Refer to your device user manual or quick start guide for more waterproof instruction if any.

-Do not use this apparatus near water.

-Do not expose this apparatus to dripping or splashing, and ensure that no objects filled with liquids, such as vases, are placed on the apparatus.

● **Warning:**

to reduce the risk of fire or electric shock, do not expose this apparatus to rain or moisture.

Caution

Risk of electric shock. do not open.



This symbol on the product means there is uninsulated, dangerous voltage within the product enclosure that may present a risk of electrical shock.



This symbol on the product means there are important operating and maintenance instructions in this guide

■ Support

● Support

Have questions? We're here to help. If your Cearvol devices experience any issues, please consult the Solutions Guide on the previous pages. We are also standing by and ready to help you. Simply give us a call at **1(959)-206-0088** to speak with our friendly Professional Support team. You can also access our Troubleshooting Hearing Helper from the Cearvol app or by visiting **www.cearvol.com**

● Warranty Policy

We are committed to ensuring your satisfaction with your Cearvol devices. If you are not satisfied with your purchase, you may return the product within 30 days of receipt. Our devices come with a 3-year warranty period. For assistance or any inquiries, please contact our customer service team at **1(959)-206-0088**. We are here to help.

■ Contact Us

● Well, that's it!

You've made it to the end. Bravo! Now, get out there and start hearing life to the fullest.

 **1(959)-206-0088**

MON-FRI 9AM-6PM PST

 **www.cearvol.com**



 **Email: support@cearvol.com**