

JIUYEE FREE

Smart Bluetooth Hearing Aid (ITE)

JIUYEE

JIUYEE • HEARING AID



Manual

Smart Bluetooth Hearing Aid (ITE)

Please read this user guide carefully before using your hearing aids and keep it properly for future reference.

Conventions used in this manual

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

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

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

Warning: when to see a doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

Your ear has a birth defect or an unusual shape Your ear was injured or deformed in an accident.

You saw blood pus or fluid coming out of your ear in the past 6 months.

Your ear feels painful or uncomfortable.

You have a lot of ear wax, or you think something could be in your ear.

You get really dizzy or have a feeling of spinning or swaying (called vertigo)
Your hearing changed suddenly in the past 6 months.

Your hearing changes: it gets worse then gets better again.

You have worse hearing in one ear.

You hear ringing or buzzing in only one ear.

Warning: this hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

Caution: this is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead

of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

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.

Caution: you might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the ear tip, 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:if you remain concerned, consult a professional

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

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.

Note: tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem, FDA calls them "adverse events," and they might include: skin irritation in

your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc. Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088 . You can also download a form to mail to FDA.

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Models

This manual is for FREE M1 hearing aid products.

Intended use

The Smart Bluetooth Hearing Aid (ITE) are a pair of user-fitted wireless air conduction hearing aids intended for use by individuals 18 years and older with perceived mild to moderate hearing impairment.

Indications for use

The hearing aid 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.

Contraindications

The hearing aids do not apply to patients who:

Suffer from acute otitis externa, myringitis, chronic suppurative otitis media (insuppurative

infection stage), or acute suppurative otitis media.

Are allergic to the materials of the hearing aids.

⚠ Precautions

- (1) Do not place the hearing aids in the humid and high temperature environments and avoid shock, light, and collision.
- (2) Do not place the hearing aids near objects with strong magnetism, otherwise it will affect the sensitivity of the hearing aids.
- (3) Do not immerse the hearing aids in any liquid. Remove the hearing aids before swimming and showering and wear them after your auditory meatus is dry.
- (4) Regularly clean the ear wax in the ear tips to keep the hearing aids surface clean and dry.
- (5) Properly use the function and gain control switches Turn on/off them gently to avoid excessive force.
- (6) If you feel uncomfortable during use, please choose larger double-layer ear tips while ensuring comfort, or contact customer service (customer service email: service@jiuyee.com)
· Instructions for safe use and maintenance of the rechargeable battery: Use the original charging

accessories and charging cable with the same technical specifications as the product. Use an appropriate USB cable to charge the product (output:5VDC).

- The hearing aids are not equipped with medical device adapters. Please configure an adapter that meets medical device standards. The rechargeable battery should not be overcharged or over discharged because this may affect its capacity and service life.
- If you do not use the rechargeable battery for a long time, replace it. Store it after it is fully charged. We recommend that you charge the battery at least once a month. This helps extend the battery service life.
- Hearing aids cannot be used during charging.

General warning

To ensure your personal safety and proper use of the hearing aids, you should be fully aware of the following general warnings. If you encounter accidental operations or serious exceptions during your use of the hearing aids, consult your hearing aid fitting expert. (service@jiuyee.com) Please note that the hearing aids are only intended to assist hearing and cannot help you restore normal auditory perception, nor do they prevent or improve hearing impairment due to organic diseases. The use of hearing aids may require speech training and instruction by lipreading. Please note

that if you do not wear the hearing aids on a regular basis, you may fail to fully benefit from them. Therefore we recommend that you wear the hearing aids for a long time and maintain good wearing habits to maximize the benefits.

- We recommend that you use the hearing aids as per the user guide or the guidance of customer service, as improper use may result in sudden or permanent hearing impairment.
- Do not allow others to wear your hearing aids, as each person has a specific hearing condition, and improper use may result in permanent hearing impairment.
- Swallowing the hearing aids and their components can cause injury. Keep the hearing aids and their components out of reach of children or others who may be injured.

Patients with active implants should be aware of the following conditions:

- The hearing aids have been fully tested and characterized for ensuring human health pursuant to international standards for human exposure (Specific Absorption Rate, SAR), induced electromagnetic power, and safe voltage level for human body.
- Exposure values detected on the hearing aids are well below the internationally recognized SAR. The induced electromagnetic power and voltage of human body are in line with relevant human health standards and within the safety limits specified in standards for ensuring coexistence with active medical implants such as pacemakers and cardiac defibrillators.

- If you have an active brain implant, consult the manufacturer of your implant device for specific interference risks.
- Patients with cochlear implants should be aware of the following conditions: If you use a cochlear implant (CI) in one ear and a hearing aid in the other, be sure to always keep the CI at least 1 cm away from the hearing aid. The magnetic fields formed by the CI sound processor, coils, and magnets may permanently damage the speaker in the hearing aid. Therefore, do not place the two devices too close to each other when removing them (e.g. for cleaning). Do not put them in the same package.
- Remove the hearing aids before X-ray, CT, MR, and PET scans, electrotherapy or surgery, as they may be damaged when exposed to strong electromagnetic fields.
- Do not expose the hearing aids to extreme heat, such as in a hot vehicle exposed to the sun.
- Do not dry the hearing aids in a microwave or other ovens.
- Chemicals in cosmetics, hairspray, perfume, suntan lotion, and insect repellents will cause damage to the hearing aids. Before you use them, be sure to remove the hearing aids and dry the hearing aids before the next use.
- Special care should be exercised in selecting, installing, and using hearing aids with a maximum sound pressure level that exceeds 132 dB SPL (2 cc coupler), as these hearing aids may impair your remaining auditory sense.

- The hearing aids and ear tips may accelerate accumulation of ear wax. In rare cases, other non-allergic substances used in the hearing aids may cause skin irritation or other side effects.
- If the aforementioned conditions occur, consult the physician.
- We have performed a thorough interference test on the hearing aids in compliance with the most stringent international standards. However, the hearing aids may still be subject to interference from other devices such as mobile phones CB series and store alarm systems, and other devices. In such cases, keep the hearing aids further away from the interfering device.

Principles

The input transducer converts the input acoustic energy into electrical energy and transmits it to the signal processing unit. Then, the signal processing unit performs A/D conversion to the input signal.

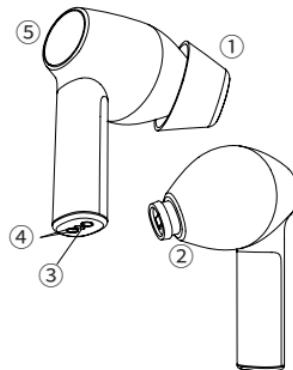
The digital signal processor processes and amplifies the signal, and then the signal is transmitted to the output transducer after D/A conversion. Finally, the output transducer transmits the sound into the auditory meatus through air conduction.

Structure and composition

The product consists of a main device and accessories. The device is constituted by parts such as microphone, signal processor, battery, outer shell and voice receiver. Accessories include ear tips, charging case and charging cable.

Hearing aid overview

- ① **Ear tips:** put the receiver firmly in the ear canal.
- ② **Receiver:** Output sound
- ③ **Microphone:** collect sound
- ④ **Pogo pin :** charge
- ⑤ **Touch:** accept or reject an incoming call.



The ear tips of the voice receiver can choose one of the following types according to the severity of your hearing loss.



1. Conical ear tips

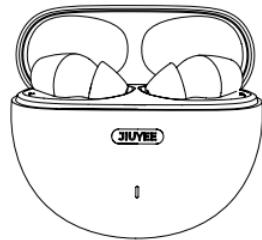


2. Round ear tips



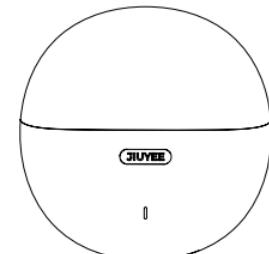
3. Double layers ear tips

Open the charging case and take out the hearing aids, then the hearing aids will be turned on right after they are taken out.



Turn on

Put both hearing aids in the charging case and close it, then the hearing aid will be turned off.



Turn off

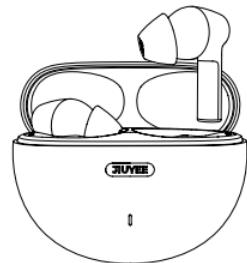
Activation of the hearing aids

Step 1: Open the charging case and take out one hearing aid.

Step 2: Remove the protective film from the hearing aid.

Step 3: Put the hearing aid back in the charging case and close it.

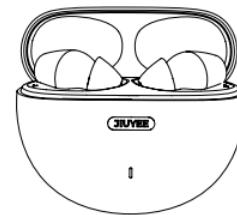
(The same steps need to be followed for another one)



Step 1



Step 2



Step 2

Plug in the USB cable and charge for at least 5 minutes (The charging case light is on) The activation is completed.



Step 5: Wear the hearing aids correctly, and the hearing aids will be automatically turned on after 5 seconds.

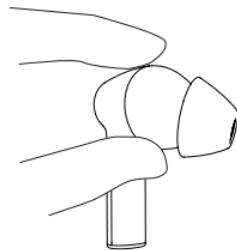


⚠ Function experience

In order to get the best experience please follow the “Download JIUYEE app ” “Step For Android system ”or “For iOS system”and “Fine tuning” to fine tuning your device.

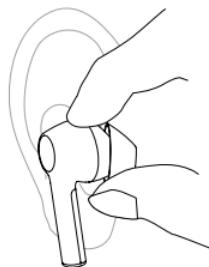
Hearing aids wearing instructions (right ear R for example)

1. Pick up the hearing aid host part with your right hand.



2. Wear the hearing aid

Push the hearing aid into the right ear canal and rotate slightly to adjust until you feel comfortable. (not stuffy, not painful, not loose). Make sure that the hearing aid is firmly embedded even if you nod your head up and down or shake your head from side to side.

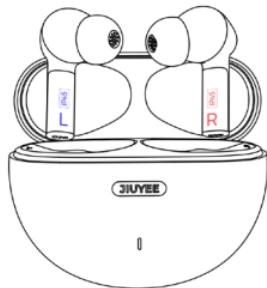


Wearing the hearing aids correctly can help you prevent squeaking and drop, effectively which is usually caused by an incorrect way of wearing.

Try and choose the ear tips

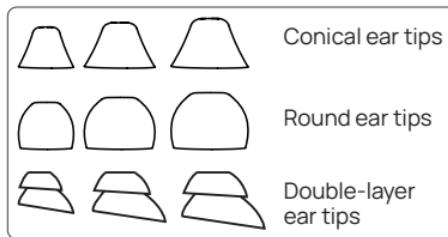
Step 1:

Identify left and right before wearing (left: L blue Right: R red)



Step 2:

Try on the hearing aids with original ear tips. If uncomfortable, remove the tips and select a pair of suitable ones.



Make sure you have tried all types of ear tips and choose the one that suits you best.

Warning: If the ear tips are not suitable to your ear canal, it will cause discomfort and squeaking when using.

Download the JIUYEE app

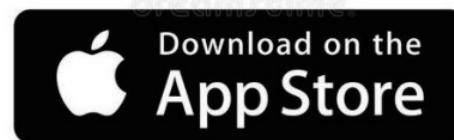
⚠️Notice: The JIUYEE app is developed to provide you with the best hearing experience.

Please be sure to download the app before use through one of the following ways :

1. Download the app by scanning the following QR code.
2. Search “JIUYEE” in the “Google Play” for an Android system and download it.
3. Search “JIUYEE” in the “APP store” for an iOS system and download it.

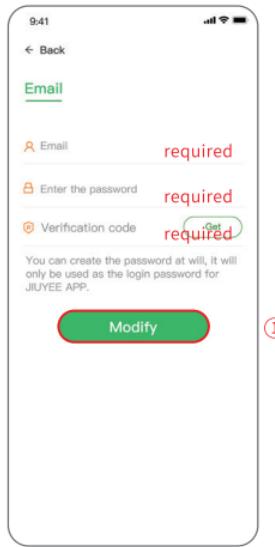


JIUYEE QR Code

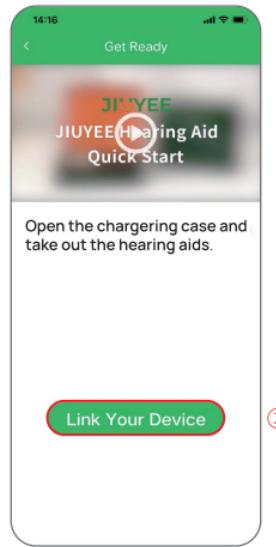


Connect hearing aids to the JIUYEE app

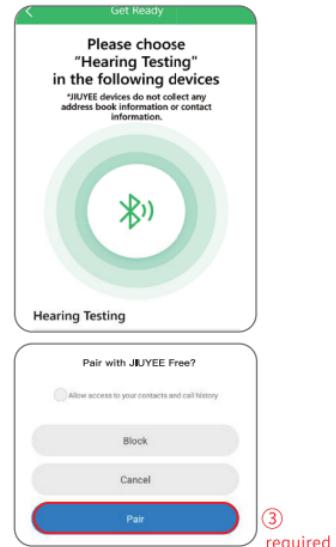
For Android system (① ~ ③)



①



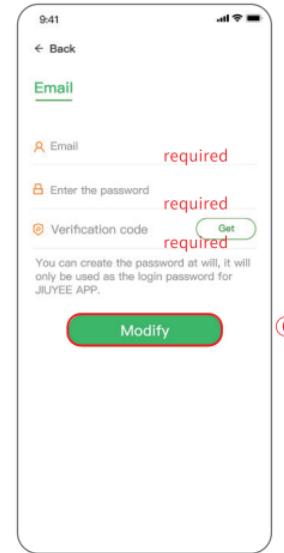
②



③

required

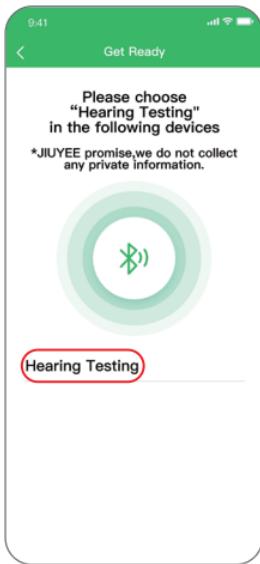
For iOS system (① ~ ⑧)



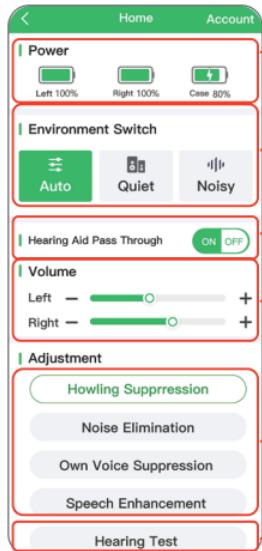
APP Home page



- ① Refer to "Fine tuning"
- ② Personal hearing testing report
- ③ E-mail



Fine tuning

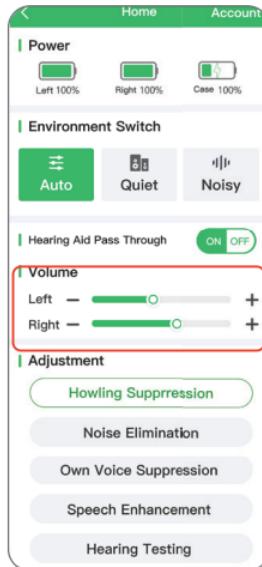


- ① Battery levels.
- ② Environment modes.
You can keep hearing aid mode sync with bluetooth mode when switch the button to "ON"
- ③ The only device volume adjustment needs to be implemented .
- ④ Fine tuning of hearing aids parameters.
You are recommended to test your hearing level before using the hearing aids.
- ⑤
- ⑥

Device volume adjustment

After the hearing aids are worn correctly and turned on, audio gain adjustment is enabled in the hearing aid mode.

The hearing aids need to be connected to the JIUYEE app to adjust device volume within the fine tuning page.



Answer or hang up the phone

When you hear the phone ring through your hearing aid, press the touch area to answer it. When you're on a call through the hearing aid, press the touch area to hang up.



Use the hearing aids

In order to make the hearing aid more adaptable to you, please conduct one-month wearing practice.



Week1

You are recommended to wear the hearing aids for 1 to 2 hours every day in a quiet environment. For example, you can talk with your families, do some housework or read books at home.



Week2

You are recommended to wear the hearing aids for 3 to 4 hours every day in a quiet environment. For example, you can talk with friends and relatives in communities or parks.



Week3

You are recommended to wear the hearing aids for 5 to 6 hours every day in a slightly noisy environment. For example, you can talk with strangers and families in restaurants or supermarkets.



Week4

After practicing the hearing aids in the above scenarios, you can wear them all day and use them for study, communication, entertainment and other daily activities.

Explanation of hearing aids howling

JIUYEE hearing aids are designed with a new anti-Feedback system that can effectively prevent howling in most scenarios. However, the howling may still occur in some special circumstances. If a howling sound occurs, please troubleshoot as per the following suggestions.

1. The ear tips or earwax guard is occluded with earwax .

Remove the ear tip and clean off the earwax guard, or replace the guard with a new one .

2. The ear tip is loose.

Gently push the ear tip into your canal so that the ear tip can fit the canal tightly.

3. The ear tip is poorly fit and not soundproof.

Try to choose a pair of double-layer ear tips while ensuring that they fit well in your ears.

4. Occasional howling sound

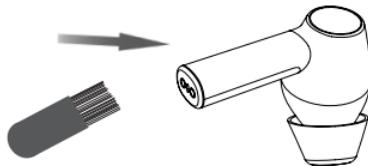
Enable the "Howling Suppression" function in the app and change the settings.

Hearing aid cleaning and maintenance

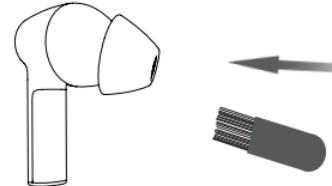
When cleaning the hearing aids, place them on a soft surface to avoid damage caused by dropping.

Device cleaning and disinfection:

1. Use a dry, soft cloth or cotton swab to clean the hearing aids. It is recommended to clean the ear canal and the hearing aids at least once a week; do not use hydro-alcoholic or cleaning solutions for they could damage electronic circuits.
2. Clean the microphone port. Use a clean brush to carefully remove dirt from the opening. Do not press the brush into the opening.



Clean the microphone



Clean the hearing aid receiver port

Ear tips cleaning and maintenance

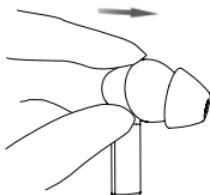
Remove ear tips, rinse with water and dry them out; or use 70%~80% (body ratio) medicinal alcohol for disinfection, and dry them out. If the ear tips are covered with cerumen, you need to clean your ears or replace the ear tips.

⚠ Note: Do not use detergents, industrial alcohol or gasoline to wash, and do not let liquid flow into the product when cleaning and disinfecting it.

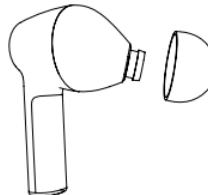
Replace ear tips

Replace ear tips by following the steps below.

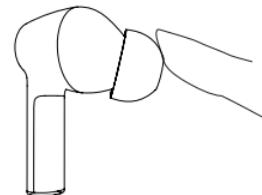
Step 1: Hold one end of the receiver and pull out the ear cap.



Step 2: Insert the connector in the middle of the ear cap to secure the connection.



Step 3: Push hard to ensure the ear cap is secured.



Hearing aid (BT model features)

1. Call mode

You can use it to answer the phone by pressing your finger on the touch area for 0.5 seconds. Likewise, press on the touch area for 0.5 seconds to hang up a call.

2. Music mode

The volume can be adjusted on the phone.

Anti-loss function

If the hearing aids fall off your ears and are not put back into the charging case, they will sound an alarm within 20 minutes and this alarm lasts for 2 minutes. Then the subsequent alarms will be triggered once every 2 minutes.

Clean and disinfect the hearing device

After a certain period of use, the hearing device automatically reminds the user with a voice notification to replace the ear tips and remove ear wax. When you clean the hearing aids, place them on a soft surface to prevent them from being damaged by accidental falling.

Troubleshooting

When something goes wrong during your use of the hearing aids, please refer to the solutions in the table below to deal with it.

Items	Possible reasons	Solutions
No sound	Blocked ear tips	Clean or replace earwax guard
	The LED light is not on when the charging case is opened	Charge
	Low battery	Charge
Small sound	Low volume	Turn up the volume
	Blocked earwax guard	Clean earwax guard
	Dead hearing aid battery	Put the hearing aids back in the charging case to charge them
	Loose ear tips	Tighten the ear tips
Failure to connect to Bluetooth	The previous Bluetooth pairing record is not deleted	Press and hold the case button for 10 seconds for pairing
Hearing aid squeaking	Too much earwax in the ear canal	Clean the ear canal and seek medical attention if necessary
	The hearing aids do not fit well	Please wear the hearing aids properly
	Aging of hearing aids and other reasons	Replace the hearing aids

After-sales service and warranty

Return policy:

1. Returns and exchanges: No returns and exchanges are allowed after unpacking.2. Warranty period: 1 year valid from the date of purchase.3. Warranty: In case of repair/replacement due to non-product quality or performance failures, all expenses (freight included) shall be borne by the user. HUNAN JIUYEE Medical Technology Co, Ltd. provides after-sales service to your hearing aids, and you can consult customer service for detailed service policies. (www.jiuyee.com or service@jiuyee.com) You can consult a customer service representative about using and troubleshooting your hearing aids. Then the representative will guide or assist you to resolve the issue immediately.

Environmental protection

The Hearing aids are electronic components which should be discarded in accordance with national, regional, and local regulations

Transport and storage conditions

(1) Ambient condition requirements for proper operation:

- Ambient temperature: 0°C to 40°C ;

- Relative humidity: 10%-90%;

- Atmospheric pressure: 86 kPa-106 kPa

(2) Store the hearing aids in a room with no corrosive gas and good ventilation and the following environmental requirements should be met:

- Ambient temperature: -10°C to 40°C ;

- Relative humidity: 10%-90% .

- Atmospheric pressure: 86 kPa-106 kPa.

(3) Handle with care to avoid collision or strong impact.

Technical description

Electrical classification:

Electric shock type classification: internal power supply

Degree of protection against liquid entry: IPX5

Electric shock degree classification: Type B

Protection against liquid entry: Type BF application part

The device is not AP or APG

Device operation mode: continuous operation

Software version: V1.0

Technical parameters

Model	Max. OSPL ₉₀	HFA OSPL 90	Full-on acoustic gain (HFA)	Delay value
FREE M1	≤110dB+3dB	105dB±4dB	30dB±5dB	< 5ms

Equivalent input noise level	Total harmonic distortion	Frequency response range (≥)	Rated supply current consumption	Mode
≤ 28dB	≤ 3%+3%	200Hz~5000Hz	3mA	BLE

Regulatory and legal information.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The hearing aid is intended for use in the electromagnetic environment specified below. The user of the hearing aid should assure that it is used in such an environment.			
Emissions Test			
RF emissions CISPR 11	Group 1	Group 1	The hearing aid uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Class B	The hearing aid is 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.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The hearing aid is intended for use in the electromagnetic environment specified below. The user of the hearing aid should assure that it is used in such an environment..

Immunity Test	IEC60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air
Radiated RF EM Fields IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Immunity Test	IEC60601 Test Level	Compliance Level

Proximity fields from RF wireless communications equipment IEC 61000-4-3	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz
	9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz	9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz
	27 V/m; 385 MHz; Pulse modulation 18 Hz	27 V/m; 385 MHz; Pulse modulation 18 Hz
	28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine	28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine
	28 V/m; 810, 870, 930 MHz ;Pulse modulation 18 Hz	28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz
	28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz	28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz

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.

RF Exposure

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

FCCID:2BFK3-FREEM1

Interpretation of graphics, symbols, and abbreviations used in medical device label.

	General warning sign		Manufacturer
	Type BF applied part		Upward
	Production batch number		Keep dry
	Use-by date: Indicates the date after which the medical device is not to be used		Keep away from sunlight
	Fragile! Handle with care!		Number of stacking layers

	Separate disposal symbol for waste electrical and electronic devices (comply with local laws and regulations)		Radio Frequency (RF) transmitter Your hearing aid contains an RF transmitt
SN	Indicates the serial number so that a specific medical device can be identified		Humidity limitation
	Temperature limit		Atmospheric pressure limitation

Package list

Description	Quantity	Description	Quantity
Hearing aid	1 (left and right)	Ear tips	18
Charging case	1	Charging cable	1
Cleaning brush	1	Manual	1
Certificate	1	Quick start	1

Registrant / Manufacturer / After-sales service unit: Hunan JIUYEE Medical Technology Co, Ltd.

Official website: www.jiuyee.com

Address of manufacturer: 2nd Floor, Building 5, North Area of Comprehensive Bonded Area, First Ring South Road, High-tech Zone, Hengyang, Hunan, China.

Service life: 3 years

Production date: Refer to the qualified label in the package

Date of preparation of the instructions: 2023.8.24

You may write to [service@jiuyee.com] to request a paper copy of this information and other labeling.