

OTC In-the-Ear Hearing Aid

A-68

User Manual

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1. Mandatory Safety Warnings

 **WARNING:** Do not use if you are younger than 18. See a physician, preferably an ear, nose, and throat (ENT) specialist, because your condition may require specialized care. Over-the-counter (OTC) hearing aids are only for users age 18 and older.

 **WARNING:** When to see a doctor immediately. See a doctor right away if you have:

- Visible ear deformity or injury
- Ear discharge in the past 90 days
- Sudden or fluctuating hearing loss
- Persistent dizziness (vertigo)
- Single-sided hearing loss
- Excessive impacted earwax inside ear canal
- Foreign object or impact injury in ear

 **WARNING:** This hearing aid should not cause pain. Remove the device if it causes pain or discomfort during insertion or wear. If pain persists, stop use and contact the manufacturer or a hearing healthcare professional.

 **WARNING:** PROLONGED EXPOSURE TO HIGH VOLUME MAY CAUSE PERMANENT HEARING LOSS. Use the lowest comfortable volume.

 **WARNING:** Choking hazard. Small parts may be swallowed. Keep away from children under 3 years.

 **WARNING:** THIS DEVICE IS NOT FOR SEVERE OR PROFOUND HEARING LOSS.

 **WARNING:** NOT FOR SINGLE-SIDED DEAFNESS.

 **WARNING:** DO NOT MIX WITH NON-OTC HEARING AIDS.

 **WARNING:** If you have questions about your hearing aid or experience persistent discomfort, consult a hearing healthcare professional.

NOTE: Allow 1–4 weeks for adaptation. Full adaptation may take 1–3 months. This device does not restore normal hearing and will not cure or prevent hearing loss.

Report Adverse Events: Contact FDA MedWatch at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

NOTE: This device may occasionally be affected by strong nearby electromagnetic fields. If this occurs, move away from the source.

Ear Canal Safety Reminder: Use included ear tips to keep a 10 mm minimum gap between the sound outlet and eardrum; direct contact may cause permanent hearing damage.

2. Intended Use

- ① This over-the-counter (OTC) in-the-ear (ITE) hearing aid is intended for adults (18 years and older) with mild to moderate permanent hearing loss. It is a self-fitting, self-operating device designed to amplify sound for better communication in daily environments. It is not intended for severe or profound hearing loss, single-sided deafness, or use by children.
- ② This device is intended only for mild to moderate permanent hearing loss. You may be a candidate if you:
 - Have trouble hearing speech in noisy places
 - Struggle to follow conversations in groups
 - Have difficulty hearing on the phone
 - Feel tired when listening
 - Need higher TV/radio volume than others

3. Product Specifications

Parameter	Specification
Type	OTC ITE Hearing Aid
Model	A-68
Max OSPL ₉₀	≤ 113 dB SPL
HFA OSPL ₉₀	110dB
FullOn Gain	48dB
Frequency Response	220 Hz – 6500 Hz
Total Harmonic Distortion	≤5%
Equivalent Input Noise	≤29 dB
Latency	≤10 ms
Dimensions(mm)	31.4×13.5×17.9
Weight(g)	5.3
Continuous Amplification Runtime	8 hours

Parameter	Specification
Bluetooth Version	5.3
Protocol	A2DP, AVRCP, HFP, HSP
Range	Up to 10 meters

4. Manufacturer Information

- **Manufacturer:** SHENZHEN SHENRUI MEDICAL CO., LTD
- **Address:** Floor 4, Building C, Fuyongli Xinhua Funing High-Tech Industrial Park, Fuyong Street, Baoan District, Shenzhen 518103, CHINA
- **Tel:** +86 755 2357 6042
- **Country of Origin:** Made in China
- **UDI Note:** UDI code printed inside charging case; full data available via FDA GUDID database
- **FCC ID:**

5. What's in the Box

NO	Item	Qty
1	Hearing Aids	2 (Left and Right)
2	Charging Case	1
3	USB Type-C Charging Cable	1

6. Environmental Conditions

Condition Type	Parameters
Normal Operating Conditions	Ambient temperature: 10° C to 40° C Relative humidity: ≤ 80% Atmospheric pressure: 80 kPa to 106 kPa
Transport and Storage Conditions	Ambient temperature: 0° C to 38° C Relative humidity: ≤ 80% Note: Protect packaged devices from direct sunlight, rain, snow, and mechanical impact.

7. Getting Started

7.1. Power On / Off

Action	How To	Indicator
Power On	1) Remove from charging case (automatic). 2) Or, press & hold button for 5	Blue light (1 sec) + Startup tone.

	seconds.	
Power Off	1) Place into charging case (automatic) 2) Or, press & hold button for 5 seconds.	White light (1 sec) + Shutdown tone.

7.2. Charging Your Hearing Aids and Case

7.2.1. Charge the Hearing Aids

- 1) Open the cover of the charging case, put the earphones into the corresponding left and right charging slots, close the lid, and the charging case will automatically charge the earphones;
- 2) It takes about 1 hour to fully charge the earphones and about 2 hours to fully charge the charging case.

Headphone status	LED status	Headphone power
The warehouse is charging	Blue light breathing indicates that at least one host is charging	Battery<100%
full	The blue light goes out after both units are fully charged	Battery =100%
Not charged	extinguished	--
Bluetooth pairing	Blue and white lights flash alternately	--

- Regularly clean and wipe the charging contacts of the earbuds and charging case.

7.2.2. Charge the Charging Case

- 1) Insert one end of the small head of the data cable into the charging port on the charging case, and the other end into the adapter;
- 2) Connect the adapter to the power supply; The white light of the charging box is flashing, indicating that the charging case is charging; When the white light goes out, it means that the charging is complete;
- 3) A fully charged charging case can provide about 3~4 charges for both earphones.

Charging case status	Charging case LED status	Charging case power
Charging	White light breathing	The charging box is charged at <100%
full	The white light went out	Charging case battery =100%
Not charged	extinguished	--

- Use the power adapter (DC5V/1A) and charging cable (1A)。

7.3. Instructions for safe use and maintenance of batteries

- Battery model specifications: rechargeable lithium battery; DC voltage: 3.7V; Battery cycle life ≥ 300 charge/discharge cycles under normal usage.

7.3.1. Battery usage instructions

- ▶ If using a rechargeable battery, please fully charge it before the first use;
- ▶ If the hearing aid is not used for a long time, its battery will be seriously insufficient due to self-discharge;
- ▶ When the volume of the hearing aid becomes low during use (cannot play a hearing aid role), the power should be turned off immediately and charged in time;
- ▶ It is important to turn off and charge your hearing aids when not in use (this will better protect your hearing aid battery). Otherwise, it will cause the battery to be over-discharged;
- ▶ The harm of over-discharging the battery will reduce the battery capacity and affect the service life of the battery to varying degrees.
- ▶ When charging with AC power, the power supply should be unplugged in time when charging is over.

7.4. Bluetooth Pairing(non-medical use, no hearing aid function)

- 1) When you open the charging case for the first time (the earphones have not been paired with any device), the earphones will automatically trigger the Bluetooth pairing mode, if the earphones have been paired with the device and the device is not nearby, you need to wait 30 seconds for the earphones to automatically enter the Bluetooth pairing mode.
- 2) Open the Bluetooth search device on your mobile phone.
- 3) Select "A-68" to pair. Bluetooth pairing successful. The headphones will play a "Boom" tone.

FCC RF Compliance Notice

1. 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.

2. 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:
 - (1) Reorient or relocate the receiving antenna.
 - (2) Increase the separation between the equipment and receiver.
 - (3) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - (4) Consult the dealer or an experienced radio/TV technician for help.
3. 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.

 **Caution:** Any changes or modifications not expressly approved by the manufacturer could void the user's authority to operate this equipment under FCC rules.

To comply with FCC RF exposure limits, avoid prolonged close contact between the hearing aid and your head during audio streaming. Disable all Bluetooth wireless functions before boarding aircraft.

FCC Radiation Exposure Statement

The device has been evaluated to meet general RF exposure requirement.

The device can be used in portable exposure condition without restriction.

7.5. Hearing Aid Mode

Volume adjustment in hearing aid mode: Press the button briefly each time to increase the volume by one level, and press again at maximum volume to enter the minimum level.

7.6. Music mode (Bluetooth connection status)

Pause/start music: Double-tap.

7.7. Phone mode (non-medical use, no hearing aids)

- 1) In the case of Bluetooth pairing, when a call comes in, click the button to answer the call, and press and hold for 1 second to reject the call;
- 2) During a call, press and hold for 1 second to hang up the call.

7.8. Wake up Siri (non-medical use, no hearing aid function)

Short press the headphones for 1 second to activate the iPhone assistant/Siri.

7.9. Factory reset

The host is in the charging case, press and hold the charging box button for 8 seconds to restore the settings to the host, and establish a TWS connection with the left and right ears, and the blue light flashes 5 times.

7.10. Wearing instructions

- 1) The earphones have left and right L/R recognition;
- 2) Use your index finger and thumb to push the receiver into the ear canal, cover the microphone outside the ear, adjust the headset and microphone to the optimal position, and wear it is completed

8. Maintenance

- 1) Regular cleaning of hearing aids can protect the health of hearing aids and users.
- 2) Regularly clean the case with a sponge soaked in detergent to prevent clogging the microphone port.
- 3) At night, it should be placed in a box with desiccant and dried overnight.
- 4) Clean the sound outlet regularly to prevent earwax buildup. Use a soft, dry cloth if needed.
- 5) If you need more cleaning and maintenance guidance, please contact customer support.
- 6) Regularly inspect your hearing aids for any damage. If service is needed, contact customer support.
- 7) Product disinfection method: use 70%-80% (volume ratio) ethanol solution to wipe the surface of the object 2 times for 3 minutes.

9. Troubleshooting and maintenance

When your device encounters problems in use, please refer to the methods in the table below for simple treatment:

Symptom	Root Cause	Corrective Action
Howling	Incorrect wearing position	Re-seat the hearing aid properly.
No sound output	1) Device is off 2) Battery depleted 3) Volume too low	1) Power on the device 2) Fully charge the device 3) Increase the volume
Low volume output	1) Low battery 2) Volume set too low 3) Earwax obstruction at the sound outlet	1) Fully charge the device 2) Increase the volume 3) Clean earwax from the sound outlet

Symptom	Root Cause	Corrective Action
Charging case indicator does not illuminate	No power to the adapter/charger	1) Verify the adapter is properly connected 2) Confirm the power outlet is live and there is no loose connection
Charging indicator does not activate when earbuds are inserted / No charging	1) Improper placement / poor contact 2) Contaminated charging contacts	1) Remove and reinsert earbuds correctly after the indicator turns off 2) Inspect and replace the charging cable if defective 3) Clean charging contacts with a clean, dry cloth

10. APP DOWNLOAD INSTRUCTIONS

The hearing aid is fully functional without the app. The app is an optional tool for additional personalization and fine-tuning. Scan the QR code to download the app.

Scan the QR code to download the app.

iOS Version

Android Version

Google Version

Search for the app: Viva Hear



iOS Version



Android Version



Google Version