

Beyond User Manual foreign edition 061224 SA1

| ELEHEAR Beyond Hearing Aids | | | | |
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Contents

Contents. 3

PREAMBLE.. 3

INSTRUCTIONS FOR USE.. 4

I. Accessory List 5

II. Product Structure. 5

III. Operation Guide. 6

IV. Maintenance and Cleaning. 11

V. Troubleshooting Guide. 11

VI. General Warnings. 11

VII. Technical Specifications. 14

VIII. Explanation of Graphical Symbols Used in Medical Device Labeling. 15

IX. FCC Requirement 15

X. Cybersecurity. 16

XI. Product Warranty. 16

PREAMBLE

Thank you for choosing ELEHEAR Beyond Hearing Aids to enhance your hearing experience and improve your quality of life.

These hearing aids are individually fitted and fine-tuned to meet your specific hearing needs; therefore, they are not suitable for use by others.

To ensure optimal performance, please read this user manual carefully before using your hearing aids. It is essential to operate the devices according to the instructions provided. Improper handling may result in damage.

Should you have any questions regarding the use or maintenance of your hearing aids, please do not hesitate to contact your hearing care professional.

INSTRUCTIONS FOR USE

Principles of Hearing Aids

ELEHEAR Beyond Hearing Aids utilize a microphone to capture environmental sounds, which are then converted into electrical signals. These signals are transmitted to a digital chip within the hearing aid, where they undergo advanced processing, including filtering and amplification. The result is a clear and amplified electrical representation of the external sound. This processed signal is then delivered to the receiver (speaker) located in the earpiece, where it is converted back into acoustic sound waves. These sound waves travel through the middle ear to the inner ear, where they are detected by the auditory nerve and transmitted to the brain for sound perception.

Hearing Aids Structural Components

The primary components of hearing aids include the main unit (Housing the microphone and battery), receiver, ear caps, and charging case.

Hearing Aids Scope of Application

Empirical fitting, for hearing compensation in patients with air-conducted hearing loss.

CONTRAINDICATIONS

Individuals with acute external otitis, tympanitis, acute suppurative otitis media, chronic suppurative otitis media (in the stage of purulent infection), and those allergic to the materials of this product are not suitable for wearing.

PRECAUTIONS

1. Hearing aids should be professionally examined and audiotically tested before use, and should be used under the guidance of a doctor or a professional dispenser of hearing aids.
2. Pay attention to the moisture-proof, shock-proof, high-temperature-proof, light-proof, and drop-proof features of the products.
3. Never immerse your hearing aid in any liquid. Remove your hearing aid before swimming and washing your hair and showering; wait for the ear canal to dry after swimming or showering before putting on your hearing aid.
4. Avoid proximity to strong magnetic objects, as this may affect the sensitivity of the hearing aid.
5. If you feel uncomfortable during the use of the ear, please try to choose the appropriate ear cap replacement under the premise of comfort, or consult after-sales service.
6. Hearing aid surfaces should be kept clean and earwax should be removed from ear caps or other acoustic devices frequently.
7. You should correctly use the program and the volume switch to control the program, try to open and close it gently, and avoid excessive force.
8. Please use the special accessories provided by our company or authorized dealers, the use of other accessories may affect the safety and effectiveness of the product.

Feedback (Acoustic Feedback)

New hearing aid users often experience an effect known as acoustic feedback, commonly referred to as "whistling." This occurs when amplified sound leaks out of the ear canal and is picked up by the hearing aid's microphone, creating a feedback loop. It is more likely to occur at higher volume settings.

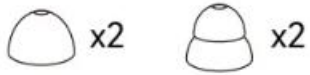
Common causes of acoustic feedback include:

- Excessive earwax buildup in the ear canal
- Improper hearing aid fit or placement
- Deterioration of hearing aid components over time
- Incorrect ear tip size or style
- Obstruction or compression of the hearing aid microphone port

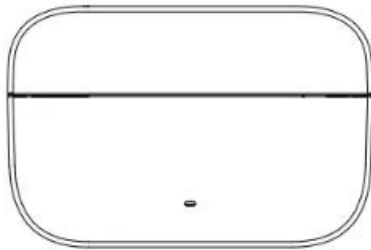
I. Accessory List



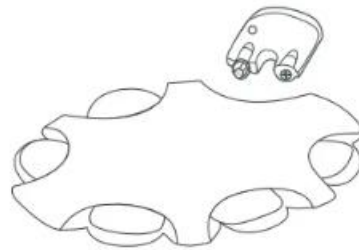
Hearing aid x2



Ear caps(S / M / L) x2
.....

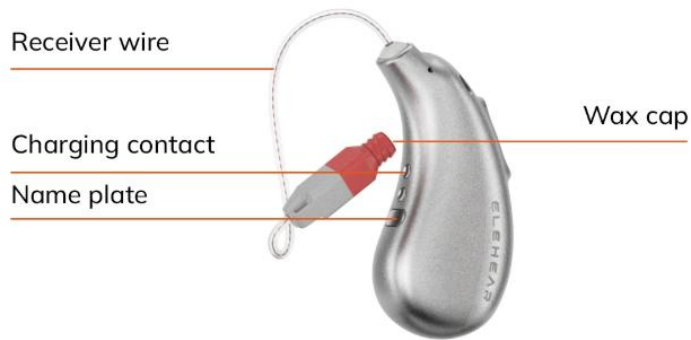


Charging case x1



Wax cap tool x1

II. Product Structure



III. Operation Guide

3.1 Charging Prior to First Use:

It is recommended to fully charge both the charging case and hearing aids for 2.5 hours before initial use.

3.2 Download the ELEHEAR APP.

The APP enables you to set up and personalize your hearing aid according to your hearing preferences and manage its settings. Ensure that you download the app before using the product.

Please start the operation according to the following steps:

- (1) Open the web browser on your phone and go to: <https://elehear.com/pages/app-page> to download the app. You can also use the QR code below.
- (2) Connect your hearing aid to your cell phone.
- (3) Follow the instructions in the app to complete the setup of your hearing aid.

3.3 BLUETOOTH STREAMING

The ELEHEAR Beyond has Bluetooth® to connect with devices like Apple iOS or Android phones. When connected to a phone, it can play music and answer calls hands-free.

(1) On your phone:

- Turn on Bluetooth.

· Search for devices.

(2) Take out the hearing aid from the case, and it will start pairing with Bluetooth, making a "Pairing" sound.

(3) When connected, you'll hear "Connected," and your phone will show "ELEHEAR Beyond Connected."

The Bluetooth connection is ready, so you can now use the hearing aids for calls, music, and more.

Answer Calls

While on a call, use the volume up or down button to adjust the call volume. Play Music

Press the volume up or down button to adjust music volume.

Note: · Connect the hearing aids to the phone within 30 minutes after taking them out. After this time, the ELEHEAR Alpha Pro Bluetooth won't be detectable. If this occurs, return them to the charging case and then take them out to reconnect. · Before boarding a flight, ensure to deactivate the Bluetooth function unless you receive authorization from the flight crew. · The ELEHEAR Alpha Pro is compatible with versions prior to Bluetooth 5.3.

3.4 WEARING

(1) Differentiate between the left and right hearing aids. The left ear device features a blue receiver, while the right ear device is equipped with a red receiver.

(2) Position the hearing aid on the corresponding ear. The hearing aid body should rest near the upper part of your ear. The curved segment of the receiver wire should encircle the front of your ear.

(3) Completely insert the ear cap into your ear canal.

(4) Refine the position of the receiver wire to ensure a comfortable fit.

Note:

Initially, the ear caps might feel unusual or cause slight itchiness in your ear canal. If discomfort arises, replace the ear caps in other sizes which fits your ear better.

The structure of the ear canal varies from person to person, and selecting an inappropriate ear cap size may result in difficulty removing the ear caps. If you have any concerns regarding the selection of the ear cap size, please contact us or consult a doctor for assistance.

3.5 Powering On/Off

Power On: The hearing aids will power on automatically when removed from the charging case. Alternatively, when powered off, press and hold the volume up button

for 3 seconds.

Power Off: Place the hearing aids into the charging case and close the lid securely. The hearing aids will power off automatically. To power off manually, press and hold the volume up button for 5 seconds.

3.6 Volume Adjustment

Short press the Volume Up button to raise the volume, short press once to raise the volume by one notch (seven notches in total), every time you raise the volume by one notch, the hearing aid will emit a "ding" sound, and when it reaches the highest volume, you will hear a "dingding" sound.

Short press the volume down button to turn down the volume, short press once to turn down the volume by one step (a total of seven steps), every time you turn down the volume by one step, the hearing aid will emit a "ding" sound, and when it reaches the lowest volume, you will hear a "dingding" sound.

3.7 Restoring factory settings

To restore your hearing aid to factory settings, press and hold the reset button on the charging case for 7 seconds, at which time the white light will flash on and off after 5 seconds.

3.8 Charging

3.8.1 Charging the hearing aid Place the hearing aid in the charging case and make sure the lid is tightly closed; the hearing aid will charge automatically. It takes 1.5 hours to fully charge the hearing aid. In the default setting (hearing aid mode), the battery life is up to 18 hours.

3.8.2 Charging the charging box Connect the charging box to the mains for full charging. This procedure can take up to 2.5 hours to fully charge the charging box of the hearing aid cartridge.

3.8.3 Charging status

Hearing aid battery level indicator

| Indicator Status | Battery Level |
|---|--------------------------------------|
| 1/2/3 lights blinking | Battery level \geq 1% and $<$ 33% |
| 1 light always on, 2/3 lights blinking | Battery level \geq 33% and $<$ 66% |
| 1/2 lights always on, 3 lights blinking | Battery level \geq 66% and $<$ 90% |
| 1/2/3 lights always on | Battery level \geq 90% |

Charging Case Indicator Light (Non-charging Status)

| Indicator Status | Battery Level |
|--|-------------------------------|
| 1 light blinking, and off after 5 seconds | Battery level < 10% |
| 1 light always on, and off after 10 seconds | Battery level ≥ 10% and < 33% |
| 1/2 lights always on, and off after 10 seconds | Battery level ≥ 33% and < 66% |
| 1/2/3 lights always on, and off after 10 seconds | Battery level ≥ 66% |

Charging Case Indicator Light (Charging Status)

| Indicator Status | Battery Level |
|----------------------------------|-------------------------------|
| 1/2/3 lights blinking | Battery level < 10% |
| | Battery level ≥ 10% and < 33% |
| 1 light always on, 2/3 blinking | Battery level ≥ 33% and < 66% |
| 1/2 lights always on, 3 blinking | Battery level ≥ 66% and < 97% |
| 1/2/3 lights always on | Battery level ≥ 97% |

The charging case can recharge the hearing aid up to 4 times.

Note: Use the specified power adapter (DC 5V/1A) and power cord (3A). When charging in a safe environment, make sure the device system meets the requirements of the GB9706.1-2020 standard.

3.9 Replacement of ear caps

3.10 Measure your receiver wire size

Step 1:

Ask a friend or family member to help (recommended).

They can make things easier by checking that the receiver wire sizing tool is on your ear correctly and taking a photo for you.

Note:

If nobody's around to help, you can use a mirror to check the receiver wire sizing tool and use your phone camera to take a photo.

Step 2:

Locate the receiver wire sizing tool provided in the box. You'll use it to measure which receiver wire size you need for each ear.

Step 3:

Compare the red and blue sides of the tool. Use the red side to measure your right ear and the blue side to measure your left ear.

Step 4:

Place the tool on your right ear. It should hook around the front of your ear and lie flat against the side of your head. Make sure that the dotted line near the top of the tool is level and aligned with the top of your ear.

Step 5:

Ask a friend or family member to take a photo of your ear. Make sure that you can see your ear canal in the photo.

Note:

If you're taking the photo yourself, rest your elbow on a surface and hold your phone facing you. Position yourself so that you can see your face in your phone's front-facing camera display. Then, turn your head and take a photo of your ear.

Step 6:

Look at the photo and see which colored band aligns with the top of your ear canal. The number in the band is the receiver wire size you need.

Step 7:

Repeat steps 4 – 6 for your left ear.

Note:

You may need a different receiver wire size for each ear.

Step 8:

Compare your measurements for each ear.

- **If you need size 2:** Size 2 receiver wires come attached to the hearing aids, so you already have the

correct size for that ear.

• **If you need size 1 or 3:** Order a replacement receiver wire through the Contact Center.

Call (888) 669-1099

IV. Maintenance and Cleaning

Daily Cleaning:

Wipe the surface of the hearing aids with a clean, dry, lint-free cloth or the provided cleaning brush. Never use cleaning solutions, solvents, or abrasive cleaners on the hearing aids.

Weekly Cleaning:

Use a soft, slightly damp cloth or a specialized hearing aid cleaning wipe to clean the surfaces of the hearing aids and receivers.

Monthly Maintenance:

Inspect the ear tips for the presence of earwax. Clean or replace the ear tips as needed. Use only a soft, damp cloth to clean the ear tips. Do not use water or cleaning solutions.

Check the wax guards for blockage. Replace the wax guards according to the instructions provided to maintain optimal sound quality.

V. Troubleshooting Guide

| Issue | Reason | Solution |
|----------------|---|--|
| Howling | Loose ear caps | Take off the ear caps and put them back on |
| | The ear caps are not the right size | Replace ear caps with appropriate size |
| | Excessive earwax | Clean ears |
| | Hearing aid volume is too loud | Turn down the volume or consult an audiologist |
| | Receiver wire cracked or damaged | Consult an audiologist |
| | When the hearing aid is placed in the charging compartment, the charging contacts are not in good contact | Cleaning the charging contacts of the hearing aids and charging case |
| | The charging case is out of power | Charge the charging case |
| Silent | Power off | Power on |
| | No battery or low battery | Timely charging |
| | The sound outlet of the receiver is blocked | Cleaning the Receiver Sound Outlet |

| Issue | Reason | Solution |
|-------------------------------|--|---|
| Low Volume | Volume set too low | Volume adjustment |
| | Battery is low | Charge or replace the battery in time |
| | Ear caps are too loose | Replace ear caps |
| | Clogged ear caps | Cleaning ear caps |
| | Excessive earwax | Clean the ear canal or seek medical support |
| | Changes in hearing loss | Consult an audiologist |
| The Indicator Light Is Not On | Hearing aids are not placed correctly | Reposition so that the charging contacts make full contact |
| | The charging case is out of battery | Charge the charging case |
| Bluetooth Connection Failure | Phone bluetooth turning off | Turn on the bluetooth |
| | Previous Bluetooth pairing records not cleared | Long-pressing the button on the charging case for 7s and reconnect the device |

VI. General Warnings

To ensure your safety and the proper use of your ELEHEAR Beyond hearing aids, please carefully review the following warnings:

Hearing aids do not restore normal hearing. They are designed to amplify sound and improve hearing ability in individuals with hearing loss. Hearing aids cannot reverse or prevent hearing loss caused by underlying medical conditions.

Hearing aids are part of a comprehensive hearing healthcare plan. Optimal benefit may require additional interventions such as auditory training and speechreading therapy. Consistent and regular use of hearing aids is essential for maximizing their effectiveness.

Consult your hearing care professional in case of adverse events. If you experience any unexpected issues, discomfort, or potentially serious incidents related to the use of your hearing aids, discontinue use and contact your hearing care professional immediately. They can provide guidance, address concerns, and report the event to the manufacturer and/or relevant authorities if necessary.

Use of Hearing Aids

- Professional fitting and adjustment are essential. ELEHEAR Beyond hearing aids should only be used under the guidance and supervision of a qualified hearing care professional. Improper fitting or use can lead to further hearing damage.

- Do not share hearing aids. Hearing aids are individually programmed and fitted to each user's unique hearing needs. Sharing hearing aids can result in improper amplification levels and potential harm to another person's hearing.

Choking and Ingestion Hazard

- Keep hearing aids and their components out of reach of children and individuals who may be at risk of swallowing small objects.
- If a hearing aid or any of its parts are swallowed, seek immediate medical attention.

Explosion Hazard

- ELEHEAR Alpha Pro hearing aids are safe for use in normal environments. However, they have not been tested or certified for use in potentially explosive atmospheres. Do not use hearing aids in environments with explosion hazards, such as mines, areas with high concentrations of oxygen, or locations where flammable anesthetics are handled.

Malfunction Risk

- Be aware that hearing aids can malfunction unexpectedly. If you rely on your hearing for safety-critical tasks, such as driving, be mindful that your hearing aids could stop functioning. This could be due to various factors, including battery depletion, moisture in the sound tube, or earwax blockage.

Environmental Awareness

- Avoid operating your hearing aids in situations that require your full attention, as this may divert your focus from potential hazards. Adhere to all local traffic laws and regulations regarding the use of electronic devices while driving. Active Implantable Devices.

Active Implantable Devices

- ELEHEAR Alpha Pro hearing aids have undergone rigorous testing and meet international standards for human exposure to electromagnetic emissions, including Specific Absorption Rate (SAR), induced electromagnetic power, and voltage.
- The levels of these emissions are well below the internationally recognized safety limits for human health and are safe for use in proximity to active medical implants, such as pacemakers and defibrillators.
- If you have an active implant, particularly a brain implant, consult with your implant manufacturer regarding potential risks of electromagnetic interference.
- Maintain a safe distance (at least 30 cm) between multi-functional tool pen containing magnets (e.g., pens with magnets) and your implanted device. Avoid carrying such objects in a breast pocket.
- Always follow the recommendations and guidelines provided by the manufacturer of your implantable cardiac device, including pacemakers and defibrillators, regarding the use of magnets.

Cochlear Implants

- If you wear a cochlear implant (CI) in one ear and an ELEHEAR Beyond hearing aid in the other, maintain a minimum distance of 1 centimeter between the two devices at all times. The magnetic fields generated by the CI components, including the sound processor, coil, and magnet, can permanently damage the speaker in the hearing aid. Avoid placing the devices in close proximity, especially when removing or cleaning them. Do not store the CI and hearing aid together in the same container.

If the Ear cap Remains in the Ear Canal

- In rare cases, the ear cap may remain in the ear canal when the receiver is removed. To avoid pushing the ear cap against the eardrum, do not attempt to reinsert the sound outlet tube into the ear canal. If this occurs, consult an audiologist for further guidance.

X-rays, CT, MR, PET Scans, Electrotherapy, and Surgery

- Because hearing aids can be damaged by exposure to strong electromagnetic fields, remove your hearing aids before undergoing X-rays, CT, MR, PET scans, electrotherapy, surgery, or entering other environments with strong electromagnetic fields.

High Temperatures and Chemicals

- Hearing aids should never be exposed to extreme heat, such as in a vehicle exposed to direct sunlight.
- Do not dry hearing aids in a microwave or other ovens.
- Chemicals in cosmetics, hairspray, perfumes, lotions, sunscreens, and insect repellents can damage hearing aids. Always remove your hearing aids before using such products and allow them to dry thoroughly before use.

Connecting External Devices

- When using an auxiliary input cable and/or connecting directly to an external device, the safety of the hearing aid is determined by the external signal source. When connecting to an external device plugged into a wall socket, it is important that the device complies with the safety standards of GB 9706.1.

High Power Devices

- Special care should be taken when selecting, fitting, and using hearing aids with a maximum sound pressure capability of more than 132 dB SPL (2CC coupling cavity), as there may be a risk of damage to the hearing aid user's residual hearing.

Possible Adverse Reactions

- Hearing aids and ear caps may lead to the accelerated accumulation of cerumen.
- In rare cases, other non-allergenic substances used in hearing aids may cause skin irritation or other side effects. If this occurs, consult your doctor.

Use in Airplanes

- Your hearing aid contains Bluetooth functionality. When on an airplane, you must activate flight mode or turn off your hearing aids unless the flight crew permits you.

Use of Third-Party Accessories

Only use accessories, transducers, or cables supplied by the manufacturer. Non-original accessories may reduce the electromagnetic compatibility (EMC) of the device.

No Modification of Hearing Aids

- Changes or adjustments not expressly approved by the manufacturer will void the equipment warranty.

Interference

- Hearing aids have been thoroughly tested for interference in accordance with the most stringent international standards. However, hearing aids may be interfered with by other devices (e.g., some cell phones, civil band systems, store alarm systems, and other devices). If this happens, increase the distance between the hearing aid and the interfering device.

Environmental Protection

Please do not discard end-of-life batteries, the device, or accessories at will. Disposal of waste and residue should be in accordance with corresponding national laws and regulations.

VII. Technical Specifications

| Max OSPL90 (dB) | High-Frequency Avg. OSPL90 (dB) | Full-on Gain High-Frequency Avg. (dB) | Equivalent Input Noise Level (dB) | Total Harmonic Distortion (%) | Frequency Response Range (Hz) | Current Consumption (mA) | Color |
|-----------------|---------------------------------|---------------------------------------|-----------------------------------|-------------------------------|-------------------------------|--------------------------|--------|
| 114+3 | 108+/-4 | 35+/-5 | 29+3 | 2+3 | 250Hz ~ 7000Hz | 12 | Silver |

Technical Description

Electrical Safety Classification: Internally powered equipment

Protection Against Electric Shock: Type B applied part

Mode of Operation: Continuous operation

Externally Connected Devices: Any external equipment connected to these hearing aids and powered from the mains supply must comply with GB 9706.1-2020 or equivalent safety standards.

Bluetooth Version: 5.3

Software Version: V1.0

Operating and Storage Conditions

1. Normal Operating Conditions:

- a. Ambient Temperature: 0°C to 40°C (32°F to 104°F)
- b. Relative Humidity: ≤ 80%, non-condensing
- c. Atmospheric Pressure: 86 kPa to 106 kPa
- d. Operating Voltage: 3.85V, with a relative error of +5%, -10%

2. Storage Conditions: Products should be stored in a well-ventilated area free from corrosive gases and materials. The environment should meet the following conditions:

- a. Storage Temperature: -10°C to 40°C (14°F to 104°F)
- b. Relative Humidity: ≤ 80%, non-condensing
- c. Atmospheric Pressure: 86 kPa to 106 kPa










3. Handle with care, avoid impacts

4. Time to warm from minimum storage temperature before use: 1 hour

Time to cool from maximum storage temperature before use: 1 hour

VIII. Explanation of Graphical Symbols Used in Medical Device Labeling

MEDICAL DEVICE IMAGES

| | |
|---|--|
|  | Points out a situation that could lead to serious, moderate, or minor injuries. |
|  | According to IEC 60601-1, the applied parts of this device are classified as type B. |
|  | Do not dispose of the device with general domestic waste. Read more in section 'Disposal information'. |
|  | Easily breakable. |
|  | Upwards. |
|  | Keep the device dry. |
|  | Avoid exposure to sunlight. |
|  | Follow instructions for use. |
|  | Medical device. |

IX. FCC Requirement

FCC ID: 2BF4W-RIC03

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

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.

RF warning for Portable device:

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

X. Cybersecurity

Operating Environment: Digital Signal Processor (DSP) chip;

Software Environment: Real-Time Operating System (RTOS);

Security Software: Not applicable;

Security Software Updates: Not applicable;

Data and Device Interface: Commands for adjusting hearing aid parameters are

transmitted via Bluetooth protocol. Data is stored in binary format;

User Access Control Mechanism:

User Authentication: The hearing aids can be discovered and paired with devices using Bluetooth.

User Permissions: Data exchange is limited to paired and connected devices.

XI. Product Warranty

Warranty Coverage: All Receiver-in-canal hearing aids by the company have 12-month free warranty for non-human failure from purchase date. Exclusions: Damage from incorrect/improper use. Damage from self-disassembly or part assembly. Damage from force majeure (flood, fire, earthquake, etc.). Note: Please refer to www.elehear.com for the latest user manual.