



Alpha ^{OTC}

User Manual

WELCOME

We value your selection of the ELEHEAR Alpha hearing aids to enrich your daily experiences and improve your quality of life.

Please note that these hearing aids are custom-tailored and optimized for an individual's unique hearing profile. As a result, they may not be suitable for others. Prior to utilizing your hearing aids, we strongly recommend thoroughly reviewing this user manual. This will ensure that you can derive the utmost benefit from your hearing aids. It is crucial to adhere to the instructions provided in this manual during operation to prevent any potential damage to the hearing aid due to improper use.

For any inquiries regarding the operation and maintenance of your hearing aids, we encourage you to reach out to your audiologist or hearing specialist.

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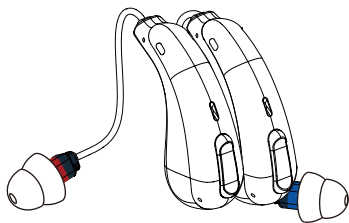
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INTENDED USE

The ELEHEAR Alpha hearing aids are designed to be utilized by individuals aged 18 and above who experience mild to moderate hearing impairment.

WHAT'S IN THE BOX



Hearing aid x2



x2



x2



x2



x2

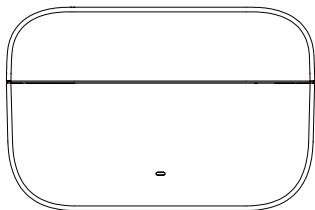


x2

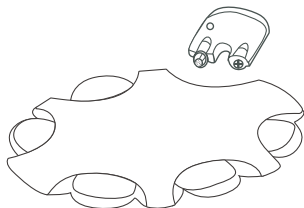


x2

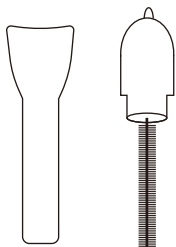
Ear caps (S / M / L) x2



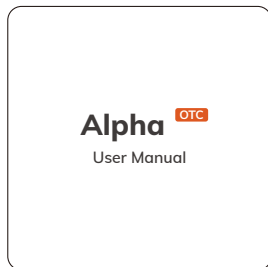
Charging case x1



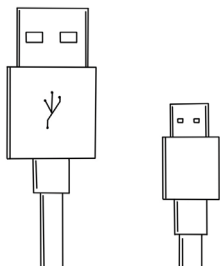
Wax cap tool x1



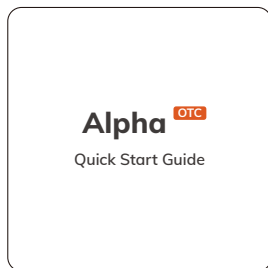
Multi-function tool pen x1



User manual x1



USB Type-C to USB-A cable x1



Quick Start Guide x1

PRODUCT OVERVIEW

3.1 ELEHEAR Alpha (FRONT)



3.2 ELEHEAR Alpha (BACK)



3.3 CHARGING CASE



Hearing aid
charging indicator

Charging case
charging indicator

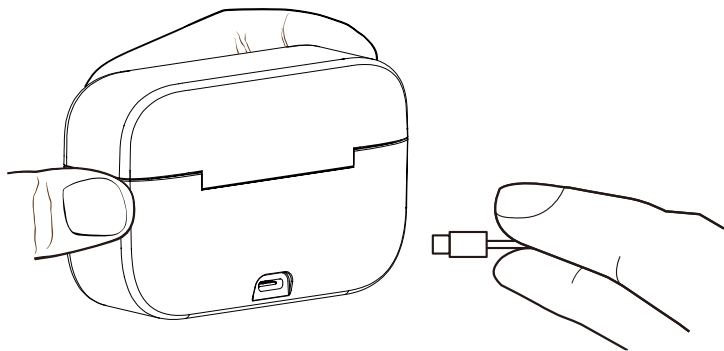
Reset button

Charging port



OPERATION GUIDE

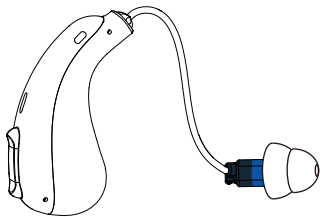
4.1 CHARGING BEFORE USE



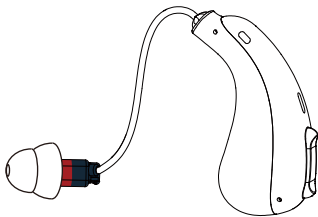
We recommend fully charging both the hearing aids and the charging case for a duration of 2.5 hours prior to usage.
(Refer to page 21 for charging instructions.)

4.2 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.

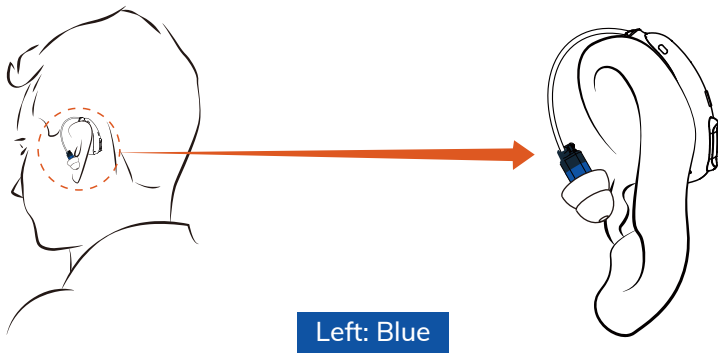


Left: Blue

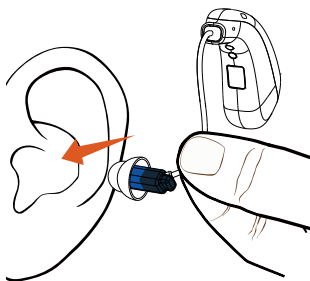


Right: Red

(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.

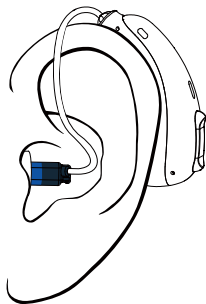


(3) Completely insert the ear cap into your ear canal.



Left: Blue

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

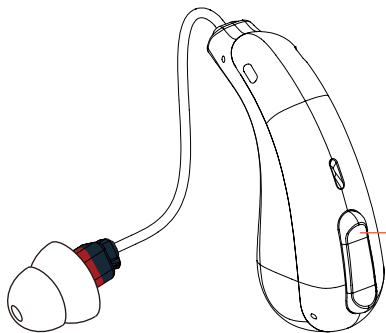


Left: Blue

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.

4.3 ON/OFF



Press the volume
up button for 3s

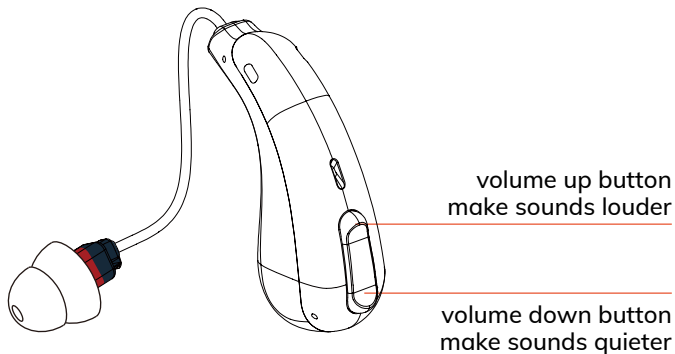
Power On:

Open the charging case, and the hearing aids will turn on when taken out. Or, press and hold the volume up button for 3 seconds.

Power Off:

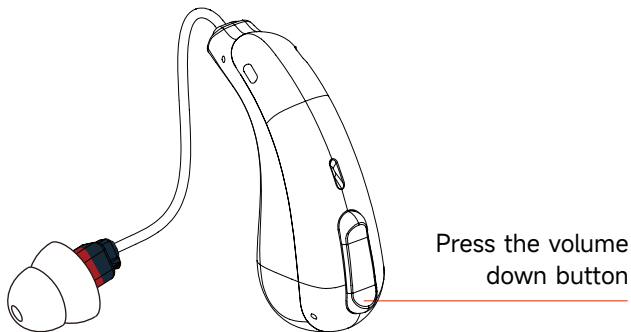
To turn off the hearing aids, put them in the charging case and close the lid. They will be powered off automatically. Or, press and hold the volume up button for 5 seconds to shut them down.

4.4 ADJUSTING VOLUME



The volume buttons are situated on the rear of each hearing aid. You can effortlessly adjust the volume to increase or decrease the sound level. When the volume reaches its highest or lowest point, you will hear a 'dingding' sound.

4.5 SWITCHING MODES

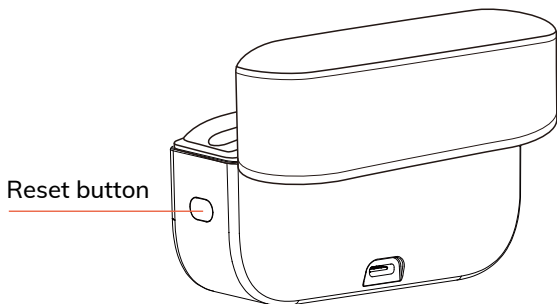


Press the volume
down button

To change modes, press and hold the volume down button for 3 seconds. You'll hear a beep when switching to new mode.

Mode	General Mode (Default)	Restaurant Mode	Outdoor Mode	TV Mode
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4.6 RESTORING TO FACTORY SETTINGS

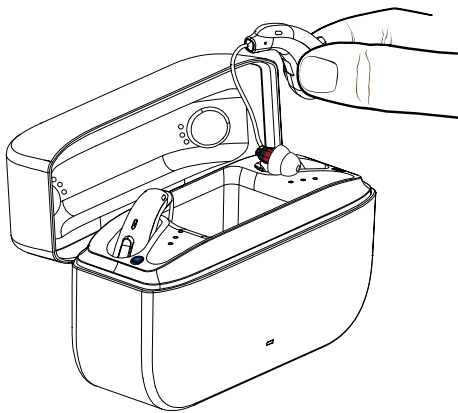


To restore the ELEHEAR Alpha to factory settings, follow these steps:

1. Ensure that the hearing aids are powered on when restoring them to factory settings.
2. Open the lid of the charging case.
3. Press and hold the reset button on the charging case for 7 seconds.
4. The white light will flash and then turn off after 5 seconds.

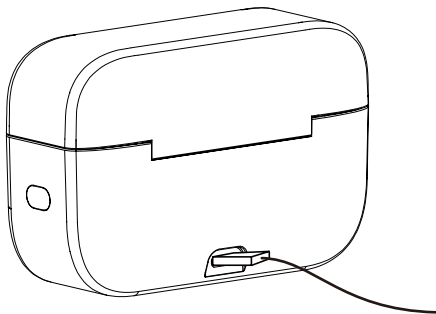
4.7 CHARGING

4.7.1 CHARGING THE HEARING AIDS






Insert the hearing aids into the charging case and securely close the lid. This will initiate automatic charging of the hearing aids. A complete charging cycle for the hearing aids requires 1.5 hours. Under default settings, the battery lasts for up to 20 hours.




4.7.2 CHARGING THE CHARGING CASE





To achieve a complete charge, connect the charging case to a power source. This process requires a maximum of 2.5 hours to charge both the hearing aids and the charging case.

4.7.3 CHARGING STATUS

Hearing Aids Power Indicator	LED Status	Power
	1 light is always on, and then turns off after 10s	$1\% \leq \text{power} < 33\%$
	2 lights are always on, and then turn off after 10s	$33\% \leq \text{power} < 66\%$
	3 lights are always on, and then turn off after 10s	Power $\geq 66\%$

Charging Case Power Indicator (not charging)	LED Status	Power
	Orange light pulsing, and then turns off after 5s	power $< 10\%$
	Orange light is always on, and then turns off after 10s	$10\% \leq \text{power} < 20\%$
	Green light is always on, and then turns off after 10s	Power $\geq 20\%$

Charging Case Charging Indicator (charging)	LED Status	Power
	Green light pulsing	1 % ≤ power ≤ 97%
	Green light is always on	Power > 97%

The charging case is capable of providing power for an additional 7 charges to the hearing aids.

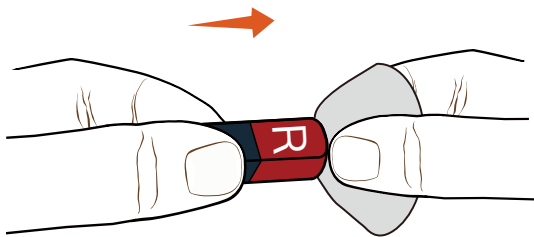
Note: Use the specified power adapter (DC 5V/1A) and charging cable (3A). When charging in a safe environment, ensure that the ME system meets the requirements of the IEC60601-1 ME equipment and systems standard.

MAINTENANCE AND CLEANING

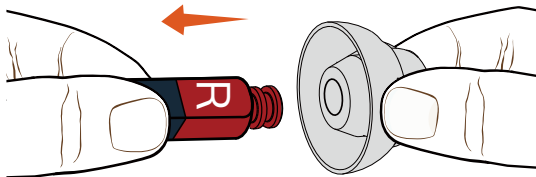
5.1 REPLACING EAR CAPS

To ensure the best sound, wear hearing aids properly with the right-sized ear cap. Try different sizes if it feels uncomfortable or the sound is not clear.

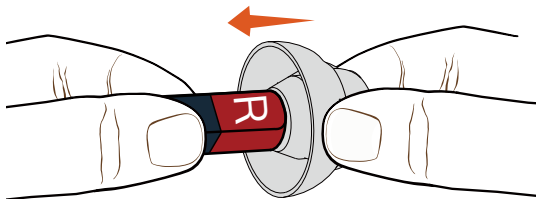
Follow these steps:



(1) Hold one end of the receiver and gently remove the ear cap.

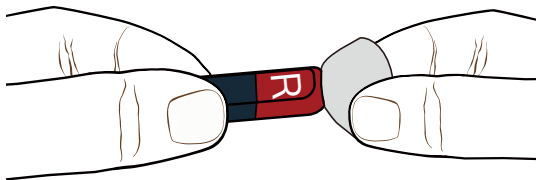


(2) Take a new ear cap and place the receiver at the center of it.

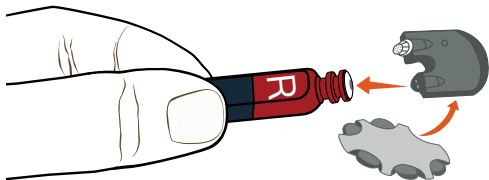


(3) Slide the ear cap onto the receiver outlet. The receiver and ear cap should fit snugly together.

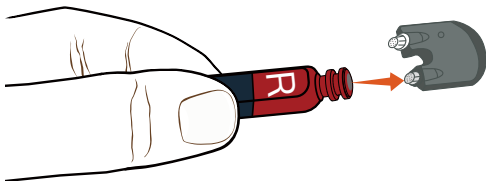
5.2 REPLACING WAX CAP



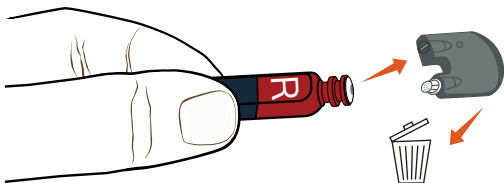
(1) Take off the ear cap from the receiver.



(2) The wax cap tool has two ends: one for removing the old wax cap and the other for putting on the new one.

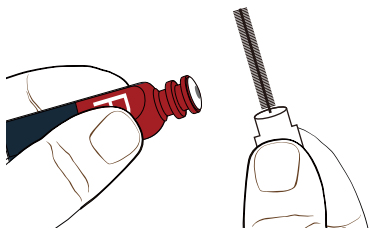


(3) Insert the empty end into the old wax cap on the hearing aid, take out and dispose of the old wax cap.

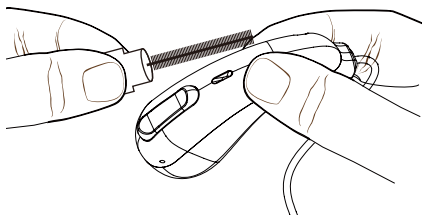


(4) Use the other end with the new wax cap and put the white part into the receiver's end. Press it firmly, remove the tool, and dispose of it.

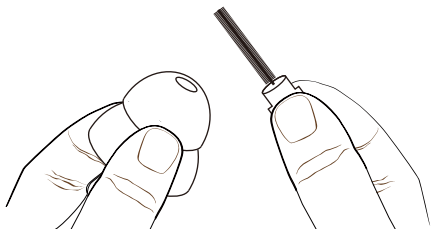
5.3 CLEANING



(1) Maintaining the hearing aid's cleanliness and dryness is crucial. Be cautious to prevent water and liquids from entering the hearing aid during daily use.



(2) Clean the hearing aid's surface daily by wiping it with a dry cloth or paper towel. Use the provided cleaning brush to gently clean the receiver wire and microphone.



(3) Over time, earwax might accumulate on the ear cap. Use a cleaning brush to remove it or gently wipe it with a damp, soft cloth. Do not directly wash it with water or liquid detergent.

TROUBLESHOOTING GUIDE

Issue	Reason
Howling	Loose ear caps
	The ear caps are not the right size
	Excessive earwax
	Hearing aid volume is too loud
	Receiver wire cracked or damaged
	When the hearing aid is placed in the charging compartment, the charging contacts are not in good contact
	The charging case is out of power
Silent	Power off
	No battery or low battery
	The sound outlet of the receiver is blocked

Solution

Take off the ear caps and put them back on

Replace ear caps with appropriate size

Clean ears

Turn down the volume or consult an audiologist

Consult an audiologist

Cleaning the charging contacts of
the hearing aids and charging case

Charge the charging case

Power on

Timely charging

Cleaning the Receiver Sound Outlet

Issue	Reason
Low Volume	Volume set too low
	Battery is low
	Ear caps are too loose
	Clogged ear caps
	Excessive earwax
	Changes in hearing loss
The Indicator Light Is Not On	Hearing aids are not placed correctly
	The charging case is out of battery

Solution

Volume adjustment

Charge or replace the battery in time

Replace ear caps

Cleaning ear caps

Clean the ear canal or seek medical support

Consult an audiologist

Reposition so that the charging contacts make full contact

Charge the charging case

TECHNICAL PARAM

Parameter Name	Alpha Hearing Aid Values
Max-OSPL90	$\leq 112\text{dB} + 3\text{dB}$
HFA-OSPL90	$106 \pm 4\text{dB}$
HFA-FOG50	$32 \pm 5\text{dB}$
Frequency Range	$300\text{Hz} \leq F \leq 6000\text{Hz}$
THD	$500/800/1600\text{Hz} \leq 2\%+3\%$
EQ Input Noise	The actual measured value should be $< 32\text{dB}+3\text{dB}$
Battery Current	2.8mA

The technical characteristics according to IEC 60118-0.

Maximum Output(OSPL90)

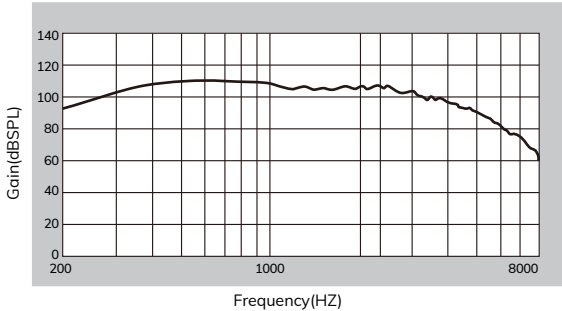


Figure 1: Nominal OSPL90 curve as measured in a 2 cc coupler.

Full-On Gain(FOG50)

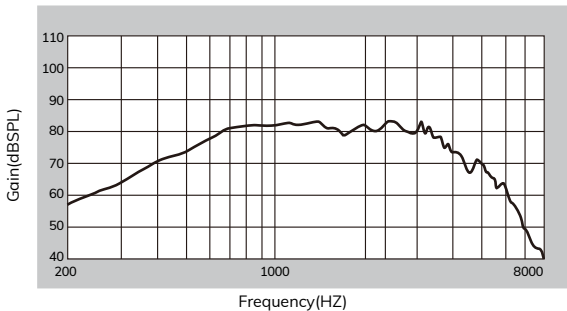


Figure 2: Nominal frequency response curve as measured in a 2 cc coupler.

TECHNICAL INFORMATION

Electrical Safety Classification:

Protection against electric shock: Internal power supply

Applied parts: Type B

Mode of operation: Continuous operation

External Connection Device:

If an external device connected to this product uses mains power, it must adhere to IEC60601-1 or equivalent safety standards.

Software Version: V1.0.0

IMPORTANT INFORMATION

PRODUCT APPLICABLE ENVIRONMENT

(1) Hearing aids work best in:

Temperature: 5°C to 40°C

Humidity: $\leq 80\%$

Pressure: 86 kPa to 106 kPa

(2) For transport or storage:

Transport: 5°C to 45°C

Storage: -20°C to 45°C

Humidity: $\leq 80\%$

Pressure: 86 kPa to 106 kPa

(3) Handle with care, avoid impacts.

(4) Allow 15 minutes to warm up from minimum storage temp or cool down from maximum storage temp before use.

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.

WEARING GUIDELINES

WEARING GUIDELINES

1. This product is not suitable for individuals with the following conditions:

(1) Absolute Contraindications:

- Loss of auditory nerve
- Sudden or rapidly progressing hearing loss
- Recent sudden tinnitus or tinnitus in one ear
- Unexplained deafness in one ear or noticeable uneven deafness
- Pain in either ear

(2) Relative Contraindications:

- Poor general health
- Uncontrollable emotional state
- Congenital ear canal atresia or external ear deformity
- Excessive foreign objects in the ear canal
- Unstable fluctuating hearing loss
- Persistent symptoms like headache, dizziness, earache, tinnitus, or discomfort
- Recent acute ear issues such as sudden deafness, rapid progressive deafness, or acute ear diseases in the last 3 months
- Middle ear fluid with recurrent pus discharge
- Non-organic central deafness
- Acute external ear infection, middle ear infection, or chronic suppurative otitis media (during the purulent infection stage).

OTHERS:

1. Unauthorized repairs can harm equipment and repair personnel. Do not replace parts yourself. If issues arise, send it to the manufacturer for repair.
2. Use only authorized accessories to avoid damaging the unit or risking harm.
3. Unattended parts during patient use are meant for the operator.
4. Keep the device away from kids and pets to prevent them from choking on small parts.
5. The ear cap uses silicone gel; parts touching the skin are ABS and PC materials. Watch for possible allergies.
6. Due to its small size, keep the hearing aid away from kids/pets to prevent damage.
7. Confirm use of the HEARING AID SYSTEM in electronics-restricted areas.
8. If you have otitis media, ear canal inflammation, or exposed middle ear cavities, avoid using aids with earplugs or wax protection.
9. Cotton, dust, bright light, and high temps can affect performance. Avoid such conditions.

10. Don't wear hearing aids during X-rays, scans, or surgery due to electromagnetic fields. Loud sounds over 132dB could harm hearing. Take off aids when near strong fields or loud noise.
11. Avoid extreme heat like leaving aids in a hot car.
12. Don't use aids in high oxygen/pressure places; risk of fire/explosion.
13. If you have implants like pacemakers:
 - (a) Keep wireless aids 15 cm from implants. If issues, turn off wireless and consult implant maker.
 - (b) Keep magnets 15 cm from implants.

DISPOSAL

1. Do not discard devices or accessories that have reached their shelf life or usage period. These should be recycled by the manufacturer.
2. Dispose of packaging materials following local rules and regulations to prevent negative ecological impact.

IMPORTANT FCC COMPLIANCE INFORMATION

Modifications not approved by the responsible party may void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Its operation must adhere to two conditions:

- (1) The device must not cause harmful interference.
- (2) The device must accept all received interference, including that which might lead to undesired operation.

Note: This equipment is tested and meets the standards for a Class B digital device under FCC Rules. It's designed to minimize interference in homes. However, improper installation or use might lead to radio interference. While efforts are made to prevent it, some interference might still occur in specific setups.

Interference Solutions:

If this equipment disrupts radio or TV reception (determined by turning it off and on), try these steps:

1. Adjust the receiving antenna's position.
2. Increase space between equipment and receiver.
3. Plug the equipment into a different circuit than the receiver.
4. Seek assistance from a dealer or radio/TV technician.

Transmitter Guidelines:

1. Do not place this transmitter near another antenna or transmitter.
2. The device complies with RF exposure requirements and can be used in portable conditions without limitations.

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.).