

ITE(In-The-Ear) Hearing Aid (TC1600-11J)

Product Operating Manual

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Catalog

I. Product Brief Introduction	2
II. Operating Instructions	3
III. Instructions for use	5
IV. Maintenance	5
V. Environmental Conditions	6
VI. Contraindications	7
VII. Matters Needing Attention and Contents of Other Warnings and Tips	7
VIII. Production Date, Service Life or Expiration Date	9
IX. Interpretation of Graphics, Symbols and Abbreviations Used in Labels of the Medical Device	10
X. Declaration of Conformity	10
XI. Description of Electrical Safety	11
XII. After-sales Service	15
XIII. Preparation/Revision Date of this Operating Manual:	16

I. Product Brief Introduction

Product Name: ITE(In-The-Ear) Hearing Aid

Scope of application: Through fitting, it can be used by patients with air-conduction hearing loss to compensate their hearing.

Structural composition: It consists of a microphone, a signal processing and amplifying circuit, a receiver, a battery, a shell and a charging base.

Working principle:

- (1) The hearing aid is an amplifier, the microphone converts the induced sound into an electrical signal, the digital signal processing amplifier circuit converts the electrical signal to A/D, uses the digital signal processor for a series of processing, amplification, and finally outputs the amplified sound through the headset, so that the hearing loss can effectively use its residual hearing in a certain way.
- (2) Hopping Channel Type:GFSK(1Mbps)(79 channel); $\pi/4$ -DQPSK (2Mbps)(79 channel);8-DPSK (3Mbps) (79 channel)
- (3) Antenna Gain:1.8dBi

1. Performance parameters

Product performance:

Model specification	Output sound pressure value		Full-range sound gain		Frequency response range (not narrower than) (HZ)
	Maximum OSPL ₉₀ (dB)	High frequency average OSPL ₉₀ (dB)	Maximum value	High frequency average (dB)	
TC1600-11J	113	110	48	40	280~6900

Bluetooth parameters:

Bluetooth version	V5.3
Bluetooth protocol	A2DP1.3 AVRCP1.6 HFP1.7
Transmission distance	\geq 10m

Battery charging and discharging parameters:

Continuous working time after full charge	4 hours under telephone mode 5 hours under music mode 6 hours under Hearing aid mode
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Charging time	1.5 hours by earphone charging 5 hours by charging box charging
Battery capacity of single earphone/charging box	35mAh/420mAh

⚠ The specification parameters are laboratory test data.

2. Schematic diagram of the product



⚠ Please tear off the insulating sticker before use.

II. Operating Instructions

1. Product ON&OFF

Long press the headset button for 3 seconds to manually turn on, and the white light will be on for 1 second; Press and hold for 6 seconds to turn off the headset manually and turn on the green light for 1 second.

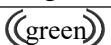
2. Wear instructions

1. Choose a suitable earphone membrane head to put over the earphone sound outlet;
2. Hold the earphone with index finger and thumb, and push the earphone membrane head side into the ear canal;
3. Gently pull down the earlobe, and use your index finger to push the earphone to the best position, thus completing the wearing.

3. Charging instructions

(1) Charging the hearing aid

1. Open the charging box cover and put the earphones into the corresponding left and right charging slots;
2. The charging indicator is steady green, indicating that the headset is charging. If the green light is off, and the white light is off after 60 seconds, it indicates that the headset is charged.
3. It takes about 1.5 hours for the earphone to be fully charged.

Status	Legend	Earphone indicator
In charging	 (green)	The green light is on.
Full charging	 (White)	The green is off, and the white is off after 60 seconds

⚠ Regularly clean and wipe the charging contacts of earphones and charging box; When the earphone is low in battery, you will hear the prompt sound of "low battery" when wearing it, and it can be used for at least half an hour. At this time, it can be used for 2 hours after charging for 15 minutes.

(2) Charging the charging box

1. Insert the small end of the data cable into the charging interface on the charging box, and the other end into the adapter;
2. Connect the adapter to the power supply; The white indicator of the charging box blinks, indicating that the charging box is charging; When the charging white indicator is steady on, it indicates that the charging is complete.
3. A fully charged charging box can provide about 3 times of charging for two earphones.

Status	Legend	Charging box indicator lights
In charging	 (White)	White light flashing
Full charging	 (White)	White light on

(3) Instructions on the safe use and maintenance of the battery

Battery model specification: rechargeable lithium battery; DC voltage: 3.7V; Battery cycle life ≥ 300 times.

Instructions for battery use:

- If you use rechargeable batteries, please fully charge them before using them for the first time;

- ▶ When 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 smaller during use (when it can't help hearing), the power supply should be turned off immediately and it should be charged in time;
- ▶ It is very important to turn off the power and charge the hearing aid when it is not in use (this will better protect the hearing aid battery)! Otherwise, the battery will be over-discharged;
- ▶ The harm of battery over-discharge will reduce the battery capacity and affect the service life of the battery to varying degrees;
- ▶ When charging with AC power supply, unplug the power supply in time if the charging is finished. If necessary, you can ask your fitter for help.

III. Instructions for use

1. Bluetooth pairing (non-medical use, no hearing aid function)

- 1.1 Take the earphones out of the charging box and wear them.
- 1.2 Turn on the mobile phone Bluetooth to search the device
- 1.3 Select “TC1600-11J ”for pairing.

2. Phone mode (non-medical use, no hearing aid)

In the case of Bluetooth pairing, when a call comes in, click the button to answer the call; Hold down for 3 seconds to reject the call;
During a call, press the key to end the call.

3. Volume adjustment

When the aid is turned on, click the button to add or subtract the aid volume in a loop.
Please adjust the multimedia volume through the relevant APP of the mobile phone.

IV. Maintenance

1. Product maintenance methods:

- (1) Cleaning the hearing aid regularly can protect the health of hearing aid and user.
- (2) Regularly clean the shell with a sponge soaked with detergent to prevent the microphone mouth from being blocked.
- (3) In the evening, it should be put in a box with dry agent and dried all night.
- (4) Repeated use of earplugs should be cleaned regularly with a small brush to prevent blockage by cerumen.
- (5) If you need more cleaning and maintenance instructions, please consult the fitter.

(6) The hearing aid should be regularly sent to the fitting center for maintenance and inspection to ensure that it is in good condition.

(7) Product disinfection method: Wipe the surface of the object twice with 70%-80% (volume ratio) ethanol solution for 3min.

(8) Please use the device according to the instructions, and only maintain the surface of the hearing aid during the use of the patient.

2. Troubleshooting and maintenance

When your equipment has problems in use, please refer to the methods in the following table for simple treatment:

Fault phenomenon	Possible reasons	Processing method
Screech	1. Too much cerumen in the ear canal 2. The position of the earphone membrane head is not correct. 3. The volume is too high	1. Clean the ear canal 2. Take it out and put it on again 3. Turn down the volume
No sound	1. The battery is low 2. The sound hole is blocked 3. Touch switch failure 4. Battery failure	1. Charge it. 2. Clean the sound hole 3. Send it for repair 4. Send it for repair
Noise	1. The battery is low 2. Battery failure	1. Charge it. 2. Send it for repair

If these methods still can't eliminate the fault, please ask the fitter for help. If you need maintenance, please contact the hearing aid fitting center or directly contact the original factory customer service.

V. Environmental Conditions

1. Normal working conditions

Ambient temperature: 10°C-40°C Relative humidity: ≤80%

Atmospheric pressure: 86Kpa - 106Kpa

2. Environmental conditions for transportation and storage with packaging and transportation and storage between two uses

Transportation: The packaged hearing aids can be transported by general cargo transportation, but it should be protected from direct exposure, rain, snow or mechanical collision. The transportation environmental conditions shall be: The temperature is 0-38°C, the relative humidity is not more than

80%, Atmospheric pressure: 86Kpa - 106Kpa, and the atmospheric pressure is 86Kpa-106Kpa.

Storage: For long time storage, the hearing aids should be stored in a warehouse with ambient temperature of 0-38°C, relative humidity of no more than 80%, atmospheric pressure of 86Kpa-106Kpa, with good ventilation conditions and without corrosive odor affecting the performance of hearing aid.

Instructions: Under the environmental condition of 20°C, the time from the lowest storage temperature of 0°C after use or the highest storage temperature of 38°C after use to the time when the product is ready to use the hearing aid function is less than 10 seconds.

VI. Contraindications

Patients with acute otitis externa, myringitis, chronic suppurative otitis media (in the period of purulent infection) and acute suppurative otitis media, and who are allergic to the material of this product are not suitable to wear air conduction hearing aids.

VII. Matters Needing Attention and Contents of Other Warnings and Tips

1. The product is used by people with hearing loss. Before fitting the hearing aid, the patient should undergo professional examination and hearing test and it can only be used under the guidance of a doctor or a professional hearing aid fitter.
2. Moisture-proof, shock-proof and high temperature-proof.
3. Do not immerse the hearing aid in any liquid, and remove the hearing aid before swimming, washing your hair or taking a bath; After swimming or bathing, wait for the ear canal to dry before wearing it.
4. After removing the hearing aid, put it in the charging box to avoid losing or bumping.
5. The surface of the hearing aid should be kept clean, the earwax at the sound outlet of the hearing aid should be cleaned regularly, and the earphone membrane head should be cleaned and disinfected regularly to avoid the infection and inflammation of the external auditory canal caused by wearing it for a long time. Please stop using it immediately and consult a doctor if you have symptoms such as redness and swelling in contact with the skin.
6. The function and volume control switch should be used correctly, and the switch should be turned on and off lightly as far as possible to avoid excessive and big force.
7. The hearing aid should be regularly sent to the fitting center for maintenance and inspection to ensure that it is in good condition.
8. If you don't use this product for a long time, please turn it off after fully charging and put it in a cool and dry place.

9. Please use the charging cable included with the device to charge. When using a power adapter to charge, use an adapter that meets IEC 60601-1 or other appropriate safety standards or a power adapter certified by CCC. When using the charging cable, care should be taken to avoid the possibility of accidentally causing strangulation or causing people to fall.

10. Do not remove the hearing aid by yourself. Unauthorized modification of the device may cause damage to the device, such as battery short circuit fire.

11. The following unsafe practices should be avoided:

—— Use earphone membrane other than those specified in the manual.

12. Leakage from the battery will damage the hearing aid.

a) Please turn off the hearing aid when not in use to save power.

b) If the hearing aid is not used for a long time, and the battery is completely exhausted for a long time, it may not be activated.

13. High temperature, high humidity, strong magnetic field ($>0.1\text{T}$), X-ray and mechanical pressure may damage the hearing aid.

a) Do not place the hearing aid in an environment with high temperature, high humidity and high vibration.

b) Do not place it in direct sunlight.

c) Do not use it when taking a bath, washing your face, shaving or making up.

d) Do not use it in places with short wave, strong magnetic field, high frequency field or X-ray.

e) Do not put it in the microwave oven.

f) Do not let the it immerse in any liquid, and remove it before swimming and washing your hair and bathing;

g) After swimming or washing, don't put on it until the ear canal is dry.

h) After it is removed at night, it should be placed in a box with dry agent, protected from light, high temperature and humidity, and protected from falling and collision.

14. Please don't use the hearing aid in an environment with explosion hazard.

15. The device and its accessories may contain some small parts. Please keep the device and its accessories out of children's reach. Please ensure that children use hearing aids under proper supervision to avoid swallowing accidents. In the event of a children swallow accident, please seek medical attention immediately.

16. Please place the charging data cable out of the reach of children to avoid strangulation accidents of children.

17. Patients with acute otitis externa, myringitis, chronic suppurative otitis media (in the period of purulent infection), acute suppurative otitis media, and those who are allergic to the material of this product should not wear this hearing aid.

18. A few users who wear hearing aids for the first time complain that they will have ear blocked feeling and the speak voice of themselves is too loud. Generally, they will gradually adapt within three months.

19. The patient (i.e. the operator) should avoid placing the plug in a difficult place to operate.

20. The earphone sound part of the hearing aid shell and ear cap are the application part of the product.
21. When the device performance changes, pay attention to check the device usage.
22. Prohibit children and pets from touching hearing AIDS to prevent hearing AIDS from being damaged.
23. Portable and mobile RF communication devices may affect the performance of hearing AIDS, and avoid strong electromagnetic interference when used, such as near signal towers, mobile phones, microwave ovens, etc.
24. It is recommended that operators meet 8 years of education level.
25. It is recommended that the operator choose the appropriate environment when using the hearing aid, such as the home environment and public places, but be careful to avoid places with high electromagnetic intensity.
26. Warning: Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ITE Hearing Aid .including cables specified by the manufacturer.
27. Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

28. FCC Requirement

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.

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.

VIII. Production Date, Service Life or Expiration Date

The production date of the hearing aid is shown on the label, and the service life is 3 years.

IX. Interpretation of Graphics, Symbols and Abbreviations Used in Labels of the Medical Device

	Keep dry and afraid of rain		Temperature limit
	Follow the operating instructions		Universal warning symbol
	Type BF application part		Non ionizing radiation
L	Left earphone logo	R	Right earphone logo
IP22	Level of preventing particles and water from entering the product		Products should not be put into the trash can after being discarded, and should be recycled professionally.

X. Declaration of Conformity

	Harmful substance					
Name of parts	Plumbum (Pb)	Hydrargyrum (Hg)	Cadmium (Cd)	Chromium VI (Cr ⁶⁺)	Polybrominated biphenyl (PBB)	Polybrominated diphenyl ether (PBDE)
Circuit board (including LCD)	0	0	0	0	0	0
Battery	0	0	0	0	0	0
Shell	0	0	0	0	0	0
Installation material	0	0	0	0	0	0

The table is compiled according to SJ/T 11364.

O: It means that the content of the harmful substance in all homogeneous materials of the part is below the limit requirements specified in GB/T 26572.

X: It means that the content of the harmful substance in at least one homogeneous material of the component exceeds the limit requirements specified in GB/T 26572.

Remarks: The label marked on this product (as shown on the right diagram) meets the requirements of China < SJ/T 11364 >, and indicates the environmental protection service period, which refers to the normal use condition.



The "harmful substances" shown in this table will not cause any harm to human body and environment under normal use of the product.

The "harmful substances" and their existing components displayed in this table provide consumers and recycling practitioners with information on the existence of related substances, which is helpful for proper disposal of products when they are discarded.

Prompt explanation of *Regulations on WEEE(Waste Electrical and Electronic Equipment) Recycling*

Our company advocates environmental protection and low-carbon consumption experience. It is suggested that users who own our products should abide by the relevant laws and regulations on the WEEE recycling when they no longer need this product, and hand it over to local manufacturers with nationally recognized recycling qualifications for recycling, so as to reduce the waste of resources and protect the natural environment of the earth.

XI. Description of Electrical Safety

1. Category of hearing aid

Device power supply voltage: Internal power supply d.c.3.7V

The device does not belong to AP type or APG type

Device protection type: BE type

Device operation mode: Continuous operation

Earphone waterproof level: IP22

2. Electromagnetic compatibility of hearing aids

High-power equipment will have electromagnetic interference to hearing aids, such as pacemakers.

Please consult a doctor when using similar equipment. The electromagnetic compatibility of hearing aids conforms to IEC 60118-13 Electroacoustic Hearing Aids Part 13: Electromagnetic compatibility (EMC),

The field strength of RF (radio frequency) test signal when the hearing aid meets the immunity of IEC 60118-13	
	Proximity compatibility When it is in the following strong field, $IRIL \leq 55dB$, and the field strength is expressed in V/m

Frequency range GHz	0.08~0.8	0.8~0.96	0.96~1.4	1.4~2.0	2.0~3.0	0.08~0.8
Microphone mode	/	3	/	2	/	/



Notes:

- ITE hearing aids meet the requirements of IEC 60601-1-2 and EN60601-1-2 standard for electromagnetic compatibility.
- Users should install and use according to the electromagnetic compatibility information provided by the accompanying documents.
- Portable and mobile RF communication devices may affect the performance of ITE hearing aids, so avoid strong electromagnetic interference when using them, such as being close to mobile phones and microwave ovens;
- The guidelines and manufacturer's statement are detailed in the annex.



Warnings:

- ITE hearing aids should not be used close to or stacked with other devices. If they must be used close to or stacked, they should be observed and verified to operate normally in the configuration they are used.

Guidelines and Manufacturer's Statement-Electromagnetic Emission		
The ITE hearing aids is expected to be used in the following electromagnetic environment, and the buyer or user of it should ensure that it is used in this electromagnetic environment:		
Emission Test	Conformity	Electromagnetic Environment-Guidelines
CISPR 11 RF Emission	Group 1	ITE hearing aids use radio frequency energy only for their internal functions. Therefore, its radio frequency emission is very low, and the possibility of interference to nearby electronic equipment is very small.
CISPR 11 RF Emission	Class B	
IEC 61000-3-2 Harmonic emission	Not applicable	ITE hearing aids are suitable for use at home and in all facilities directly connected to the public low-voltage power supply network of residential houses for home use.
IEC 61000-3-3 Voltage fluctuation/flicker emission	Not applicable	

Guidelines and Manufacturer's Statement-Electromagnetic Immunity			
<p>The ITE hearing aids is expected to be used in the following electromagnetic environment, and the buyer or user of it should ensure that it is used in this electromagnetic environment:</p>			
Immunity test	IEC60601 test level	Conforming level	Electromagnetic Environment-Guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The floor should be made of wood, concrete or tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%.
EFT/B (Electrical Fast Transient/Burst) IEC 61000-4-4	±2kV for power supply cord ±1kV for input/output line	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV differential mode voltage ±2 kV common mode voltage	Not applicable	Not applicable
Voltage sag, short-term interruption and voltage change on power input line IEC 61000-4-11	<5 % U_T , lasting for 0.5 weeks (On $U_{T,sag}$ of >95%) 40 % U_T , lasting for 5 weeks (On $U_{T,sag}$ of 60%) 70 % U_T , lasting for 25 weeks (On $U_{T,sag}$ of 30%) <5 % U_T , lasting for 5s (On $U_{T,sag}$ of >95%)	Not applicable	Not applicable
Power frequency magnetic field (50/60Hz) IEC 61000-4-8	3A/m	3A/m	The power frequency magnetic field should have the horizontal characteristics of power frequency magnetic field in typical places in typical commercial or hospital environments.
<p>Note: U_T refers to the AC network voltage before the test voltage is applied.</p>			

Guidelines and Manufacturer's Statement-Electromagnetic Immunity			
<p>The ITE hearing aid is expected to be used in the following electromagnetic environment, and the buyer or user of it should ensure that it is used in this electromagnetic environment:</p>			
Immunity test	IEC60601 test level	Conforming level	Electromagnetic Environment-Guidelines
RF conduction IEC TR 61000-3-4	3 Vrms 150 kHz to 80 MHz	/	<p>Portable and mobile RF communication devices should not be used closer to any part of the ITE hearing aid than the recommended isolation distance, including cables. The distance should be calculated by the formula corresponding to the transmitter frequency.</p> <p>Recommended Isolation Distance</p> $d = 1.2\sqrt{P}$
RF radiation IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where, P is the maximum rated output power of the transmitter provided by the transmitter manufacturer in watts (W), and d is the recommended isolation distance in meters (m).^b</p> <p>The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field ^a, and it should be lower than the conforming level in each frequency range ^b.</p> <p>Interference may occur near the equipment marked with the following symbols.</p> 
<p>Note 1: At the frequencies of 80MHz and 800MHz, the formula of higher frequency band is adopted.</p> <p>Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.</p>			
<p>a The fixed transmitter field strength, such as base stations of wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts, and television broadcasts, cannot be accurately predicted theoretically. In order to evaluate the electromagnetic environment of fixed RF transmitter, the investigation of electromagnetic field should be considered. If the measured field strength of the ITE hearing aid is higher than the RF conforming level of the above application, the ITE hearing aid should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorienting or repositioning the ITE hearing aid.</p> <p>b In the whole frequency range from 150 KHz to 80 MHz, the field strength should be lower than 3 V/m.</p>			

Recommended isolation distance between portable and mobile RF communication equipment and ITE hearing aid			
Rated maximum output power of transmitter/W	Isolation distance corresponding to different frequencies of transmitter /m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

For the transmitter's rated maximum output power not listed in the above table, the recommended isolation distance d , in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the transmitter's rated maximum output power provided by the transmitter manufacturer, in watts (W).

Note 1: At the frequencies of 80 MHz and 800 MHz, the formula of higher frequency range is adopted.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

3. Description of key components

The manufacturer promises to provide technical data such as circuit diagram and component list to the testing technicians under the condition of meeting relevant conditions. Key components of hearing aid include: Microphone, receiver, movement.

XII. After-sales Service

Dear users, thank you for choosing this hearing aid product. Products purchased through formal channels shall enjoy the three-guarantee service stipulated by the state according to law.

When your equipment breaks down, please refer to the method described in the "Simple Fault

Checklist" in this manual for handling. Please call our after-sales hotline at 0755-83302640 if you encounter any problems in use.

National Unified Service Hotline: 0755-83302640

Guarantee Card			
Product Model		User's Name	
Serial No.		User Contact Tel	
Dealer Name			
Dealer Tel			
Date of Sale			
Dealer Address			

Guarantee Reminder

1. This three-guarantee voucher is only applicable to the three-guarantee service of the host and accessories.
2. Please take good care of this three-guarantee voucher, and please show this voucher and related invoices when enjoying the three-guarantee service.
3. Man-made damage belongs to non-warranty scope.
4. Any product failure caused by the user upgrading the unofficial upgrade package belongs to non-warranty scope.
5. The normal wear and tear of the product in use or the damage caused by physical pressure, electromagnetic interference or other irresistible factors belong to non-warranty scope.
6. Those that have exceeded the three-guarantee period belong to non-warranty scope.
7. Do not disassemble the hearing aid by yourself. If the parts are damaged due to disassembly by yourself, it will not be included in the warranty scope.
8. The hearing aid is not resistant to corrosive liquids such as seawater, acid-base solvents and chemical reagents. Any damage or defect caused by misuse or improper use will not be covered by the warranty.

XIII. Preparation/Revision Date of this Operating Manual: July 17, 2024

Version: A/0