United Imaging Microelectronics 联影微电子

Business Unit	**HA BU**
Project Name	**Sogne BTE**
Product Name	**BTE hearing aids**
FCC ID	**2BV7W-SHW-13**

9010100314-EUD-BTE-01
Instructions for Use
BTE hearing aids

Valid from: December 20, 2025

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Author	Checked by	Approved by
Signature: Date:	Signature: Date:	Signature: Date:

History

Version	Author	CR No.	Change Contents
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Preface

Thank you for choosing United Imaging. We are dedicated to enhancing your listening experience.

The entire United Imaging series features groundbreaking algorithmic innovations, revolutionizing listening clarity, speech intelligibility, and wearing comfort to provide users with a completely new hearing experience. It incorporates a newly upgraded noise reduction algorithm that effectively distinguishes between essential and non-essential speech sounds, helping you to identify and focus on desired sounds in complex environments. The hearing aid is also equipped with multiple listening programs that respond rapidly to changes in your daily acoustic environment, ensuring consistent clarity. United Imaging also mitigates common device-related interference, such as feedback (whistling) and background noise, evolving the listening performance to be clearer, more understandable, and more comfortable, so you can enjoy listening with confidence.

Please do not hesitate to contact your hearing aid professional. He or she will perform a personalized fitting based on your individual hearing needs and listening preferences to ensure the best possible experience. We also encourage you to read the instructions for use carefully to learn about operating instructions and maintenance, which will help you adapt more quickly to your new hearing aid. If you have any questions not answered in the instructions for use, please feel free to contact us at any time.

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I. Basic Information of Product

Product Name

BTE hearing aids

Model name	Specification
BTE SHW-13	n32/n33/n53/n55/n56/n73/n75/n76/n93/n94/n95/n96
BTE SCW-13	n32/n33/n34/n36/n53/n54/n75/n95/n96

Intended Use

The hearing aid is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

Intended Users

Person with hearing loss using a hearing aid and their caregivers. Hearing care professional responsible for adjusting the hearing aid.

Intended Patient

The target population is primarily the adult population over 18 years of age. This product may also be used with children 36 months of age or older. Individuals with cognitive impairment will require constant supervision by a caregiver.

User Environment

The hearing aid is suitable for the home healthcare environment and due to their portability it may happen that it is used in professional healthcare facility environment like physician oces, dental oces etc.

Indication

Patients diagnosed with mild to profound air-conduction hearing loss requiring amplification.

Contraindications

This product is not suitable for individuals with acute otitis externa, myringitis, chronic suppurative otitis media (during the active discharge phase), acute suppurative otitis media, or a known allergy to any of product materials.

Notes for Hearing Aid Professionals

The professional fitting of hearing aids must be performed by hearing aid professionals with appropriate national qualifications. During the fitting process, special attention must be given to users presenting with any of the following clinical symptoms:

① Congenital or traumatic deformity of the ear; ② History of active drainage

from the ear within the previous 90 days; ③ Sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days; ④ Acute or chronic dizziness; ⑤ An air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz; ⑥ Visible evidence of significant cerumen impaction in the ear canal; ⑦ Pain or significant discomfort in or about the ear.

A qualified hearing aid professional typically possesses the skills to: ① assess a patient's communication needs; ② select, program, and fit appropriate hearing aids; and ③ monitor and validate the effectiveness of the fitting system.

Advice for Users

Do not underestimate hearing loss!

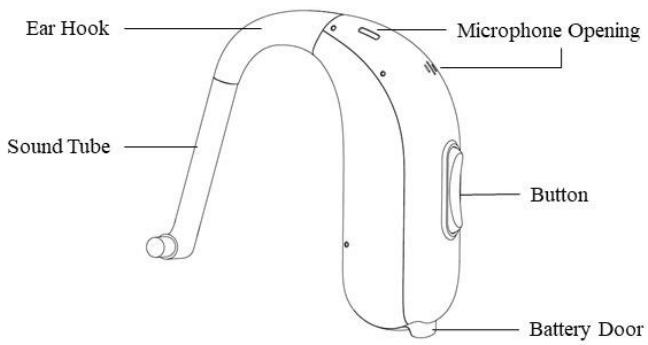
If you notice a decline in your hearing, we strongly recommend visiting a professional hearing center or hospital for a comprehensive hearing examination and assessment. Based on your results, discuss your hearing goals and expectations with your hearing aid professional or doctor, who will help you select a hearing aid that is right for you.

A hearing aid is an assistive listening device designed to help compensate for hearing loss and improve your quality of life. The patient, the intended operator of the hearing aid, for best results, should have the cognitive ability to operate the device scientifically and reasonably under the guidance of a hearing aid professional and put it on consistently.

Putting on hearing aids is one component of aural rehabilitation. Sometimes, additional strategies such as auditory training or lip-reading may also be helpful to supplement your listening. For children using this device, a guardian with aforesaid capacities must provide supervision. After the hearing aid is fitted, it is essential that the child promptly begins professional auditory-verbal therapy.

II. Features and Identification

Hearing instrument



Supporting Accessories (Note: Either a dome or a custom earmould is selected based on user needs.)

Domes (S/M/L)

Custom Earmould
(Custom order required)

List of Accessories

1 Instructions for Use

1 Certificate of Conformity

1 pair of Left/Right Markings

1 set of Cleaning Kit

1 Storage Case

⚠ **Note: Do not use if the product is partially damaged. Please contact an authorized United Imaging Hearing Aid distributor or our customer service center. The type of domes supplied may vary by product model. Please refer to the actual accessories supplied with your device.**

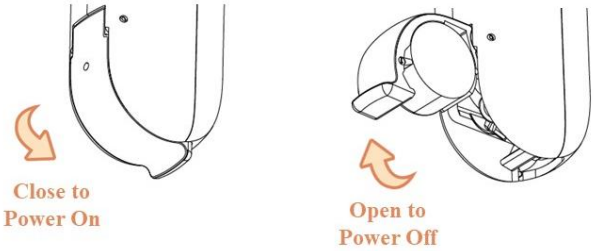
Note:

One box contains only one hearing aid, if you need a pair of hearing aids, you will receive two boxes.

III. Operating Instructions

1. On/Off

1) Open the battery door, insert the correct zinc-air battery, and close the door. The hearing aid will power on, play a ON tone, and activate the default listening program.
2) Open the battery door. The hearing aid will power off and stop working.



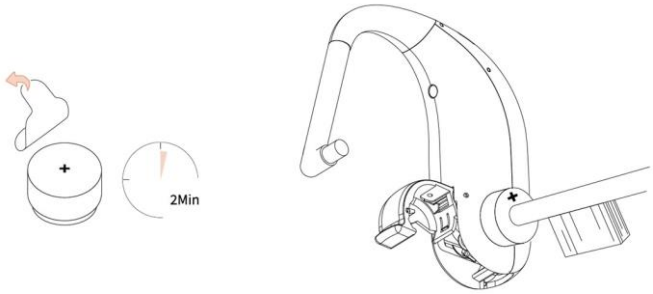
ℹ Tip:

When not using the hearing aid, open the battery door to remove the battery and prevent unnecessary battery drain.

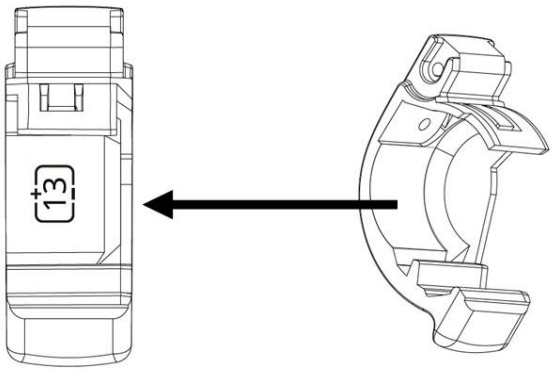
2. Replacing a Battery

1) Open the battery door and remove the used battery, if one is present. You can remove the battery with your fingers or by using the supplied cleaning brush with magnet on the end. Simply touch the magnet to the battery and lift it out.

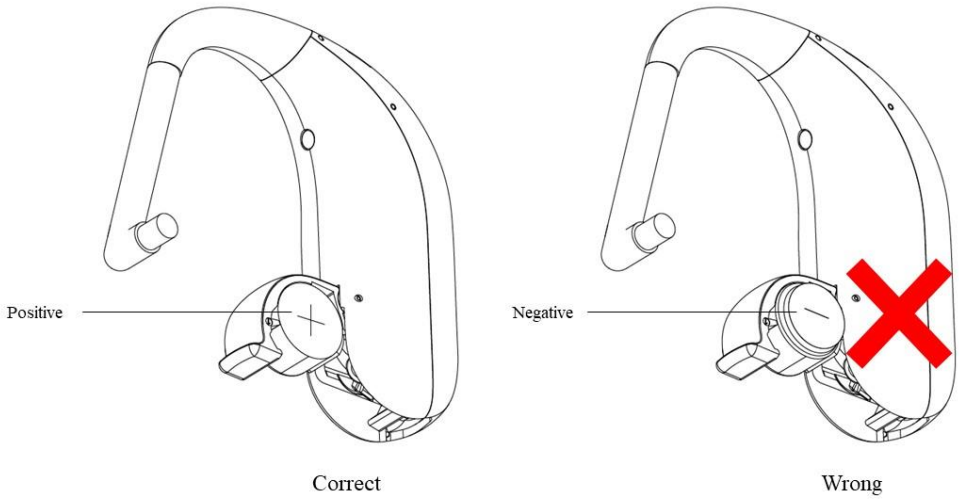
2) Take a new battery and remove its protective tab. Let the battery sit for approximately two minutes to allow it to fully activate with the air (see figure below). For the required battery type, please refer to Chapter VIII “2. Electroacoustic Performance Parameters”;



3) Insert the battery into the battery compartment, ensuring the plus sign (+) on the battery aligns with the plus sign (13+) marked on the compartment and the battery is placed stably;



4) Close the battery door gently. If resistance is felt, do not force it. Check that the battery is inserted correctly.



Tip:

1) Use only a size 13 zinc-air battery. The battery is user-replaceable;
2) Ensure the battery is within its expiration date;
3) When the hearing aid is not in use, open the battery door to power it off and conserve the battery;
4) Waiting approximately two minutes after removing the battery tab before insertion helps ensure a stable power supply;
5) If you will not use the hearing aid for an extended period (more than 7 days), remove the battery to prevent potential corrosion from leakage. Always store the hearing aid in a place that is out of the reach of children.

Warning:

For safety and environmental protection, you must dispose of batteries properly according to applicable regulations. Precautions are as follows:

1) When first learning to change the battery, follow the guidance of your hearing aid professional. Always check that the battery compartment is intact.
2) Keep the battery out of the reach of children.
3) Never change the battery in the presence of infants, children, or individuals with cognitive impairments.
4) Never put a battery in your mouth. Swallowing a battery is extremely dangerous and can be fatal.
5) If a battery is swallowed, seek immediate medical attention.
6) Do not store batteries with medications, as they can be mistaken for pills.
7) Do not dispose of batteries in fire, as they may explode.

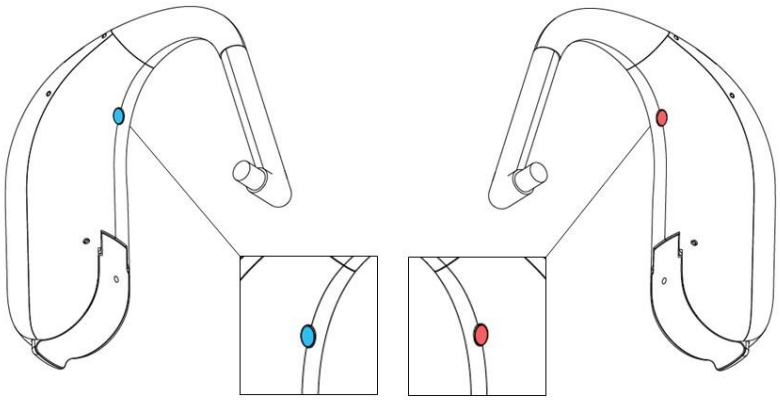
8) Do not leave depleted batteries inside the hearing aid, as leakage can cause corrosion and damage the device.

9) Do not attempt to recharge single-use zinc-air batteries, as this can cause them to leak or explode.

3. Left and Right Ear Markings

Your left and right hearing aids may be programmed differently, so it is crucial to tell them apart. United Imaging hearing aids use a color code to help you: red is for the right ear, and blue is for the left ear. You can find these blue or red markings on either the hearing aid body to identify which is for the left ear and which is for the right.

If you still have trouble telling your hearing aids apart, please contact your authorized United Imaging Hearing Aid distributor for assistance.



Blue = Left Ear Red = Right Ear

4. Attaching the dome or earmould to the hearing aid

1) Hold the sound tube in one hand and the dome or earmould in the other.

2) Slide the dome or earmould over the sound tube.

3) The sound tube and the dome or earmould should fit perfectly together.

5. Putting on a Hearing Aid

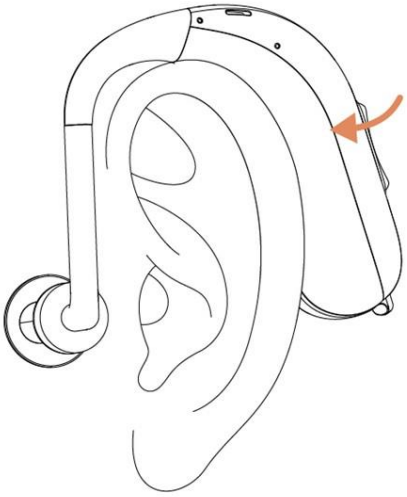
Before putting on your hearing aid, ensure the Ear hook and sound tube are correctly attached to the main body and fitted with the appropriate dome or earmould. Follow these steps to put on your hearing aid:

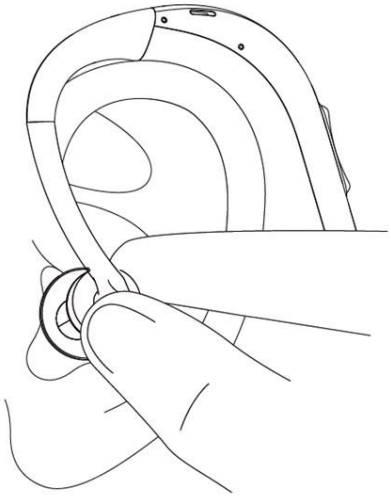
1) Put on the hearing aid on the auricle, with its main body placed behind the auricle (see figure below);

2) With your thumb and forefinger, hold the bend in the sound tube gently. Position the dome (or earmould) at the opening of your ear canal and gently

guide it inside until it rests securely and comfortably, without causing pain and discomfort or feedback (whistling).

3) If the dome does not feel secure or comfortable, try a different size. To ensure optimal performance, we recommend using only genuine replacement domes from our company or an equivalent model. For earmould replacements, please contact your hearing aid professional.



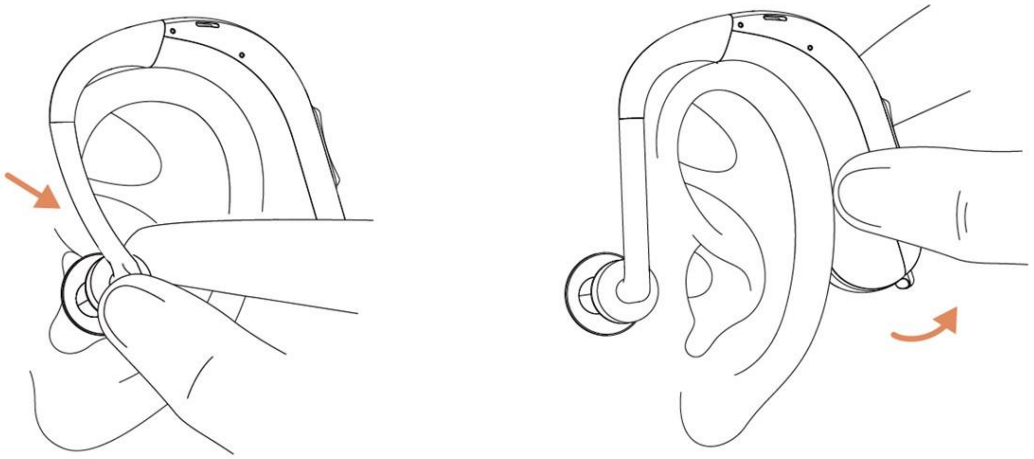


6. Removing a Hearing Aid

To remove your hearing aid correctly, follow these steps (see figure on the right):

1) Grasp the bend of the sound tube with your thumb and forefinger and gently pull the dome out of your ear canal. (If you have a custom earmould, grasp the small removal filament and gently pull the earmould out.) Avoid pulling abruptly or roughly, as this could injure your ear or damage the device.

2) Once the dome is out, lift the hearing aid body from behind your ear.



Tip:

1) It is normal to find insertion and removal a bit tricky at first. With practice, this will become much easier.
2) Using both hands can make the process easier.

Caution:

1) Do not attempt to modify the shape of the hearing aid, domes, or sound tube.
2) If you have difficulty in inserting or removing your hearing aid, please contact your hearing aid professional.
3) If you experience significant discomfort while putting on your hearing aid, such as pain, swelling, or persistent feedback (whistling), please contact your hearing aid professional promptly.

7. Wireless Function

This hearing aid features Bluetooth and can connect wirelessly to iPhones and to Android phones running Bluetooth version 4.2 or higher.

Please consult your hearing aid professional for details on the application software.

8. Multi-Function Button

The button on the hearing aid is a multi-function control. It can be used to adjust volume or switch listening programs, depending on how it has been configured. Please consult your hearing aid professional for details on your specific settings.

IV. Maintenance and Service

Your hearing aid is a precision electronic device. Keeping it clean and dry during daily use is essential for reliable performance. Daily Care and Maintenance:

1) After each use, wipe any oil or moisture from the hearing aid body, sound tube and ear hook with a soft, dry cloth or tissue. Do not use wet cloths or cleaning agents.
2) Do not immerse the hearing aid in water or any other liquid.
3) Avoid dropping the hearing aid onto hard surfaces.
4) Do not expose the hearing aid to heat sources or direct sunlight, such as inside a closed car in the summer, as overheating may cause damage to the hearing aid.
5) Do not put on your hearing aid while showering, swimming, in the rain, or in high-humidity environments like saunas or steam rooms.
6) If your hearing aid is exposed to water or high humidity, turn it off immediately. Place it in a hearing aid dehumidifier (not supplied) and do not use it again until it is completely dry.
7) Remove your hearing aid before applying cosmetics, perfume, shaving cream, hairspray, or sunscreen.
8) In environments with significant temperature changes, condensation may form inside the sound tube, which can affect sound transmission. If condensation is present, contact your hearing care professional for service.
9) If the sound tube shows noticeable discoloration or cracks, contact your hearing care professional for replacement.

Daily Cleaning

Follow these steps for daily cleaning:

1) At the end of each day, wipe the hearing aid body with a soft, dry cloth or tissue; use the small brush supplied to clean the sound tube and the dome or earmould.
2) We recommend using a hearing aid dehumidifier to prevent moisture from damaging internal components.
3) To ensure the best performance, have your ear canals checked regularly for excess earwax, as cerumen impaction can affect your hearing aid effectiveness.

Dome Cleaning

Follow these steps to clean the dome:

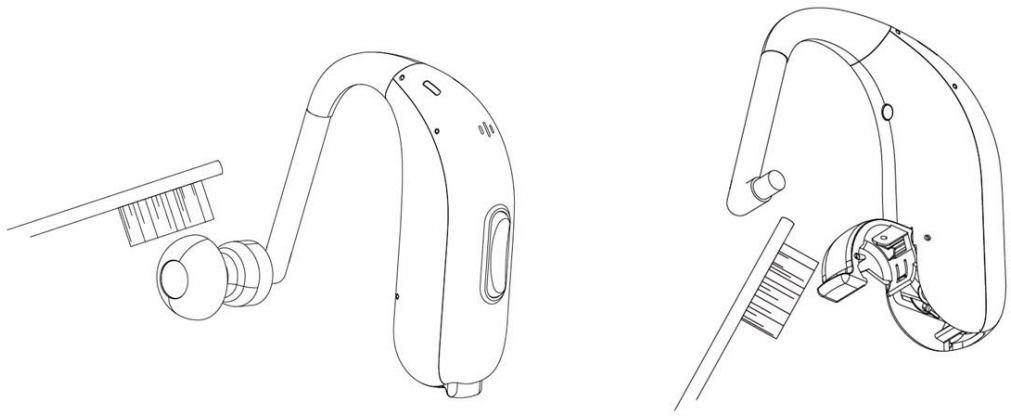
1) Earwax and debris can build up on the dome or earmould over time. Use the small brush or a cleaning cloth provided to remove them. While cleaning,

ensure the sound tube does not come into contact with water or other liquids. Do not use alcohol to clean the dome.

2) If the dome or earmould becomes damaged during normal use, contact your hearing aid professional immediately for a replacement.

Hearing Aid Cleaning

1) After daily use, wipe any earwax or perspiration from the surface of the hearing aid with a soft, dry cloth. You can also perform a more thorough cleaning every 2-3 months using a soft cleaning cloth or a cotton swab to gently wipe the hearing aid surface.
2) Be careful to prevent any liquid from entering the microphone opening or sound tube.
3) If the sound tube or microphone opening appear blocked with debris, use the small brush supplied to gently clean them.
4) Never insert any sharp tools into the sound tube.



Tip: Following these maintenance procedures can help extend the life of your hearing aids and reduce the need for repairs.

V. Troubleshooting

If you experience any of the following problems with your hearing aid, please try these solutions first:

Guidance on Basic Troubleshooting

Manifestation of problems	Reasons	Solutions

Hearing aid silent	Hearing aid out of power	Replace the hearing aid battery.
	Battery malfunction	Reboot the device after replacing the battery. If the problem persists, contact your audiologist or hearing aid professional for servicing.
	The dome or earmould is blocked by earwax, cotton fibers, dust, or other debris.	Clean the dome, or earmould. If the problem persists, contact your audiologist or hearing aid professional for servicing.
Sound intermittent or weak (at microphone opening)	The dome or earmould is clogged by earwax, cotton fibers, dust, or other debris.	Clean the dome, or earmould. If the problem persists, contact your audiologist or hearing aid professional for servicing.
	Moisture inside the sound tube.	Contact your audiologist or hearing aid professional for servicing.
	The microphone is damp or has moisture in it.	Wipe the hearing aid dry and place it in a dedicated dehumidifier; Contact your audiologist or hearing aid professional for servicing.
Hearing aid whistling	The hearing aid, earmould, or dome is not inserted correctly.	Adjust the position and reinsert it;
	Excessive earwax in the ear canal.	Consult a medical professional to have your ear canal examined and cleaned.

If the solutions above do not work or there are other problems with the hearing aid, please contact your hearing aid professional or the United Imaging Hearing Aid Customer Service Center immediately. Do not attempt to repair the device yourself!

VI. Precautions

Precautions

1) A professional hearing examination and assessment should be completed before you are fitted for a hearing aid. The device must be used under the professional guidance of a doctor or hearing aid professional.
2) Users with a history of otitis media should reduce their wearing time as needed to prevent recurrence of otitis media or damage to the eardrum.
3) Do not ingest or inhale any items from the packaging, including the desiccant and cleaning tools.
4) Handle the program and volume control buttons gently. Do not use excessive force.
5) The wireless Bluetooth function uses low-power digital technology and is

unlikely to interfere with other electronic devices. However, if interference occurs, move away from those electronic devices.

6) Avoid exposing the hearing aid to strong electromagnetic interference.
7) We recommend installing security software on any connected devices to ensure a secure operating environment.
8) Protect the hearing aid from moisture, drops, and high temperatures.
9) Do not leave the hearing aid in direct sunlight, near heat sources, or inside a hot car.
10) Avoid dropping the hearing aid onto hard surfaces.
11) Never immerse the hearing aid in any liquid. Do not put it on while showering, swimming, in the rain, or in high-humidity environments like saunas or steam rooms. Always remove your hearing aid before swimming or bathing. After these activities, ensure your ear canal is completely dry before reinserting the hearing aid.
12) Remove your hearing aid before applying cosmetics, perfume, shaving cream, hairspray, or sunscreen.
13) If the hearing aid is accidentally dropped in water or exposed to moisture, immediately wipe it dry and place it in a dedicated hearing aid dehumidifier. Do not use it again until it is completely dry. Or, if you have concerns, contact your hearing aid professional.
14) Keep the hearing aid casing clean and regularly remove earwax from the domes. After each use, wipe the device with a dry cloth or tissue to remove any moisture or oil. Do not use wet cloths or cleaning agents. Store the clean hearing aid in its dedicated dehumidifier.
15) Use a dedicated hearing aid dehumidifier to prevent moisture damage and maintain optimal performance.
16) Schedule regular maintenance and check-ups with your hearing aid professional to ensure your hearing aid remains in excellent working condition.
17) Keep the hearing aid away from pets and children to prevent accidental damage.
18) When not in use, store the hearing aid in its case to protect it, including from insects.
19) The patient must operate all functions of the hearing aid safely, following the guidance of their hearing aid professionals and the instructions for use.
20) The patient must maintain the hearing aid according to the instructions from their hearing aid professionals and the instructions for use.

21) Check first before using the hearing aid in areas where electronics or wireless devices are restricted.

22) The sound tube is a replaceable component. Please contact a professional for replacement.

⚠ Warnings

1) The hearing aid must be selected, fitted, and used under professional guidance. Improper use can cause further hearing damage.

2) Unauthorized modifications to the hearing aid may compromise its basic safety and are strictly prohibited.

3) No maintenance or servicing should be performed on the hearing aid while it is being worn.

4) Do not attempt to service or maintain the hearing aid while it is in use.

5) This device is not intended for children under 36 months of age. Use by children or individuals with cognitive impairments must be supervised by a guardian.

6) High-intensity sound can damage your remaining hearing. For hearing aids with a maximum output exceeding 132 dB SPL, use them with caution and only as advised by your hearing aid professional.

7) Warning for hearing aid professionals: This hearing aid may produce a maximum OSPL90 of 132 dB or higher. Care should be taken when fitting this device to ensure that excessive sound pressure levels are not delivered to the user.

8) Data sheet values were measured with a standardized custom shell. Please note deviation from these values may occur based on individualized acoustic coupling. When children wear hearing aids, the sound pressure level generated in the ear canal may be significantly higher than in adults. It is recommended to measure the RECD to correctly set the target value for OSPL90.

9) If you experience a foreign body sensation, an allergic reaction, or potential cerumen impaction, consult a doctor immediately.

10) Turn off the hearing aid wireless function when on an aircraft.

11) Strong magnetic fields (e.g., during an MRI) or radiation (e.g., during a CT scan) can damage your hearing aid. We advise against putting on your hearing aid in these scenarios.

12) Low-radiation sources such as anti-theft alarms, radio equipment, and mobile phones are generally not expected to affect the hearing aid. However,

interference or a change in sound quality is possible. If this occurs, move away from such electronic devices.

13) Do not use your hearing aid in potentially explosive areas such as mines or oil fields, unless the area is certified as safe for such devices.

14) Do not alter the hearing aid gain settings yourself. Never allow others to use your hearing aid, as it is programmed for your specific needs and could damage their hearing.

15) This hearing aid contains small parts, which may cause choking if swallowed by children. Guardians should pay full attention to prevent this situation. If a part is swallowed, seek immediate medical attention.

16) A trial battery may be included for initial fitting and testing purposes only. If this battery is expired or depleted, please replace it with a fresh one. If you notice battery leakage, do not use the hearing aid, as the fluid can cause skin injury. If battery fluid comes into contact with your skin, wipe the area clean immediately. If you experience any stinging or discomfort, seek medical attention right away. For instructions on how to handle a hearing aid that has been exposed to battery leakage, please contact your hearing aid professional or the United Imaging Hearing Aid Customer Service Center.

17) Do not dispose of the hearing aid or its battery in regular waste.

18) The ME equipment or ME system may be interfered with by other equipment, even if that other equipment complies with corresponding national standards.

19) Please only use accessories and detachable parts that are specified in the instructions for use.

20) Do not use your hearing aid in potentially oxygen-enriched areas such as hyperbaric oxygen chamber or forest fields, unless the area is certified as safe for such devices.

Vigilance

Any serious incident that has occurred in relation to the device should be reported to the local representative of Shanghai United Imaging Microelectronics Technology Co., Ltd. and the Competent Authority of the Member State. A serious incident is defined as any malfunction, deterioration in the characteristics and/or performance of the device, or inadequacy in the device Operations Manual/ labeling which could lead to the death or serious deterioration in the state of health of the user, OR could do so upon recurrence.

VII. Technical Specifications

1. Basic Safety Characteristics

1) Classification according to the type of protection against electric shock: Internally powered equipment;
2) Classification according to the degree of protection against electric shock: Type B applied part;
3) Classification according to the degree of protection against ingress of liquid: IP68;
4) Classification according to the safety degree of product used in the flammable anesthesia gas mixed with air, oxygen or nitrous oxide: not Category AP or APG equipment;
5) Classification according to the use in oxygen-rich environments: This device is not suitable for use in oxygen-rich environments;
6) Classification according to the mode of operation: Continuous operation;
7) Rated voltage and frequency of equipment: 1.45V;
8) Input power: Not applicable;
9) Whether the equipment has defibrillation-proof applied part: No;
10) Whether the equipment has a signal input or output part: Wireless programming;
11) Permanently installed equipment or non-permanently installed equipment: Non-permanently installed equipment;
12) No essential performance of the product;
13) The entire hearing aid is classified as the applied part.

2. Electroacoustic Performance Parameters

Model/specification			$OSPL_{90}$ (dB SPL)		Full-on acoustic gain (dB)		Frequency range (Hz)		Harmonic distortion (%)			Equivalent noise (dB SPL)	Battery current drain (mA)
Model	Specification	receiver	Peak value	HFA	Peak value	HFA	F1	F2	500 Hz	800 Hz	1600 Hz		
BTE SHW-13	n32/n33/n53/n55/n56/n73/n75/n76/n93/n94/n95/n96	UP	140	132	81	69	200	6300	5	1	1	19	1.5
		SP	135	127	76	64	200	6300	2	1	1	19	1.5
BTE SCW-13	n32/n33/n34/n36/n53/n54/n75/n95/n96	UP	137	131	78	66	200	6300	5	2	2	19	1.5
		SP	132	125	73	61	200	6300	3	2	2	19	1.5

Note: Technical specifications are tested according to the EN IEC 60118-0:2024 using a 2cm³ coupler with the device in test mode. With a new battery, the hearing aid provides approximately 37 hours of use with Bluetooth enabled and 92 hours with Bluetooth disabled (Test condition: 23 ± 3°C; 50% ± 5% RH). Actual battery life will vary depending on individual usage and enabled settings.

3. Description on Wireless Network Security

- Data Interface: Communication between the hearing aid and fitting software is based on Bluetooth 5.2 protocol.

- Data Storage Format: JSON.

4. User Access Control Mechanism

To adjust the hearing aid parameters, a wireless programmer establishes a connection between the device (by wireless programming) and the United Imaging fitting software on a computer. Access to the software requires a secure login with username and password.

5. Environmental Conditions

1) Operating Conditions:

Temperature range: -10℃~40℃;

Relative humidity range: 15%~80%;

Atmospheric pressure range: 70 kPa~106 kPa

2) Transportation and Storage:

Temperature range: -25℃~70℃;

Relative humidity range: 10%~93%;

Atmospheric pressure range: 70 kPa~106 kPa

The time required for the ME equipment to warm from the minimum storage temperature between uses until the ME equipment is ready for its intended use when the ambient temperature is 20℃ is 15s.

The time required for the ME equipment to cool from the maximum storage temperature between uses until the ME equipment is ready for its intended use when the ambient temperature is 20℃ is 15s.

6. Disposal

⚠ **Caution**

Used zinc-air batteries can be harmful to the environment. Please collect used batteries and dispose of them at a certified hazardous waste collection facility. Disposing of earmoulds or hearing aids in household waste pollutes the environment. Recycle hearing aids, accessories or batteries according to local regulations. Hearing aid users can also return electronic waste to their hearing care professional for disposal.

VIII. Electromagnetic Compatibility (EMC)

This hearing aid complies the IEC 60601-1-2 radiated emissions requirements for a Group 1 Class B device as stated in CISPR 11.

Declaration - Electromagnetic Emissions
The BTE hearing aids are intended for use in the electromagnetic environment specified

below. The customer or the user of the BTE hearing aids should assure that they are used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The BTE hearing aids use 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 CISPR11	Class B	The BTE hearing aids 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.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance & Declaration — Electromagnetic Immunity			
The BTE hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of the BTE hearing aids should assure that they are used in such an environment.			
Immunity test	**Required test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Not applicable	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BTE hearing aids require continued operation during power mains interruptions, it is recommended that the BTE hearing aids be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz & 60Hz	30 A/m 50Hz & 60Hz	Power f requency magnetic fields/Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic Fields IEC 61000-4-39	CW 8A/m for 30kHz Pluse modulation 2.1kHz, 65A/m for 134.2kHz Pluse modulation 50kHz, 7.5A/m for 13.56MHz	CW 8A/m for 30kHz Pluse modulation 2.1kHz, 65A/m for 134.2kHz Pluse modulation 50kHz,7.5A/m for 13.56MHz	
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic Immunity Concerning Conducted RF & Radiated RF			
The BTE hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of the BTE hearing aids should assure that they are used in such an environment.			
Immunity test	**Required test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	Not applicable	Not applicable	Portable RF communications equipment (including peripherals such as
Radiated RF IEC 61000-4-3	10V/m	10V/m	

	80 MHz to 2.7GHz 80% AM at 1kHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	80 MHz to 2.7GHz 80% AM at 1kHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BTE hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 60118-13	10V/m 0.65GHz to 0.96GHz & 1.4GHz to 2.7GHz (Refer to table 1 of IEC 60118-13:2019)	10V/m 0.65GHz to 0.96GHz & 1.4GHz to 2.7GHz (Refer to table 1 of IEC 60118-13:2019)	

⚠ Caution

The hearing aids are designed to operate in public and residential environments and are designed to comply with international Electromagnetic Compatibility emissions and immunity standards for medical devices.

However, it is still possible that you may experience interference caused by power line disturbances, airport metal detectors, electromagnetic fields from other medical devices, radio signals and electrostatic discharges.

If you use other medical devices or wear implantable medical devices such as defibrillators or pacemakers and are concerned that your hearing aids might cause interference with the medical device, please contact the physician or the manufacturer of the medical device for information about the risk of disturbance.

The hearing aids should not be worn during an MRI procedure or in a hyperbaric chamber.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories and detachable parts 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.

IX. Symbol and Mark Legend

	Manufacturer
EU REP	Authorized representative in the European Community
	Date of Manufacture
MD	Medical Device
	Read instructions before use Note: On the equipment "Follow the instructions for use".
	Warnings and Cautions
+	**Battery positive** Insert the battery into the compartment correctly, aligning the positive terminal as marked.
	Humidity limitation Humidity limitation are indicated adjacent to the upper and lower horizontal lines.
	Temperature limit Upper and lower limits of temperature are indicated adjacent to the upper and lower horizontal lines.
	Atmospheric pressure limitation Upper and lower limits of atmospheric are indicated adjacent to the upper and lower horizontal lines.
	Keep dry
	Non-ionizing radiation Interference may occur in the vicinity of equipment marked with the following symbol.
IP68	**Degree of enclosure protection** 6: Dust-tight; 8: Protection against continuous submersion in water;
SN	Serial number and body number
UDI	Unique device identifier
	Handle with care
	This way up
	United Imaging Group

X. Maintenance Policy

From date of purchase, your hearing aid is covered by a comprehensive warranty.

For specific warranty periods, consult the dealer and manufacturer. The warranty period is calculated from the date of purchase. Any malfunctioning hearing aid must be serviced by a qualified technician. Unauthorized disassembly or repair attempts will void the warranty. The warranty does not cover damage resulting from normal wear and tear, improper use, exposure to chemicals, or circumstances beyond our control (Force Majeure).

Shanghai United Imaging Microelectronics Technology Co., Ltd.
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EU REP

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Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175

CE
0197

Wireless Connection Specifications:

Bluetooth Protocol: Bluetooth 5.2

Main Functions: Data transfer

Modulation Method: GFSK

Frequency Range: 2400–2483.5MHz

Transmission Power: ⩽ 20dBm

Occupied Bandwidth: ⩽ 3MHz

Date of Manufacture: See the product package

Lifetime: 5 years

* As an electronic medical device, the actual lifespan of the hearing aid will vary based on changes in the user's hearing condition and how it is used and maintained. Factors such as excessive earwax, exposure to dusty or humid environments, and improper cleaning will shorten the device's lifespan. While proper maintenance may extend the device's lifespan.

Preparation Date of IFU: December, 2025

XI. FCC Statement

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

Radiation Exposure Statement

This device complies with FCC radiation exposure limits set forth for an

uncontrolled environment and it also complies with Part 15 of the FCC RF Rules.

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.

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