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Cover Page

TUI TUI, Hear the love

In-the-ear Hearing Aids

User guide



Please read this manual carefully before use and keep it for future use

Warning: If you are under 18, do not use this hearing aid without adult supervision.

You should consult a doctor, preferably an ENT (Ear, Nose, and Throat) specialist, as your condition requires specialized treatment. This hearing aid is only suitable for users aged 18 and above.

This hearing aid is intended for users aged 18 and older with moderate to severe sensorineural hearing loss; it may be used only after undergoing pure-tone audiometry and speech-recognition testing for professional fitting. Users under 18 may use this device only after contraindications have been ruled out by an ENT specialist and with the informed consent of a parent or legal guardian, followed by professional fitting. This device requires professional fitting; self-adjustment without proper fitting may impair residual hearing.

Warnings and cautions

When to See a Doctor

If you have any of the following issues, consult a doctor, preferably an ENT specialist:

- Your ears have congenital defects or unusual shapes.
- Your ears were injured or deformed in an accident.
- In the past 6 months, you have seen blood, pus, or fluid coming out of your ears.
- Your ears feel painful or uncomfortable.
- You have excessive earwax, or you suspect something might be in your ears.
- You experience dizziness or a sensation of spinning or swaying (known as vertigo).

- Your hearing has suddenly worsened in the past 6 months.
- The hearing in one of your ears has worsened.
- You hear ringing or buzzing only in one ear.

This hearing aid should not cause pain upon insertion.

If pain or discomfort occurs during insertion or placement, remove it from the ear. To retry, ensure you follow the instructions. If you experience pain or discomfort again, contact the manufacturer or a hearing healthcare professional.

The sound output should not be uncomfortable or painful.

If the sound output is too loud or causes pain, reduce the volume or remove the device. If you consistently need to lower the volume, you may need to further adjust your device.

If something is stuck in your ear, seek medical assistance.

If any part of your hearing aid, such as the ear tip (dome), becomes stuck in your ear, and you cannot easily remove it with your fingers, seek medical help promptly. Do not attempt to use tweezers or cotton swabs, as they may push the object further into your ear, potentially causing serious consequences to your eardrum or ear canal.

What to Expect When You Start Using Hearing Aids:

Using a hearing aid can be beneficial for individuals with hearing loss. However, it's important to understand that it won't restore normal hearing, and you may still encounter some difficulties hearing in noisy environments. Additionally, hearing aids do not prevent or improve conditions that lead to hearing loss.

People starting to use hearing aids may need a few weeks to adapt to them. Similarly, many individuals find that training or counseling can help them extract more useful information from the device.

If you have hearing loss in both ears, you may experience more benefits from using hearing aids, especially in challenging situations that can be tiring—such as noisy environments.

Handling of Hearing Aids After Exceeding Their Intended Service Life:

The hearing aid has a service life of five years. Once this period is exceeded, replace it promptly

with a new device to prevent diminished performance from compromising hearing effectiveness or worsening hearing loss.

Product Introduction

Thank you for choosing the TUI TUI hearing aid. We recommend using the hearing aid every day.

Note:

Before using the hearing aid, please read this user guide carefully. You can also visit www.eartech.cn to learn how to wear the hearing aids, pair them with your mobile device, and download additional applications.

Intended Use

This hearing aid is designed to amplify sounds for individuals aged 18 and above with moderate to severe hearing impairment.

User Profile

The hearing aid is suitable for use by adults aged 18 and above.

Therapeutic Indications

Designed for individuals experiencing moderate to severe hearing impairment.

Clinical Information

These devices have undergone clinical assessments for equivalency and have been compared with similar devices on the market serving similar purposes. They compensate for hearing loss by amplifying and delivering sound to the ears.

If you have any inquiries, please contact local customer support. For contact information, please refer to the back page.

About hearing aids

Hearing aid models:

☐Sara 1; ☐Sara 2; ☐Sara 3; ☐Sara 4; ☐Sara 5; ☐Sara 6; ☐Sara 7; ☐Sara 8; ☐Sara 9; ☐Sara 10

Battery Type:

Lithium-ion rechargeable battery

Charging

☒Allow ☐NOT Allow

Serial number (left side):

Serial number (right side):

Product shelf life:5 years

Date of purchase:

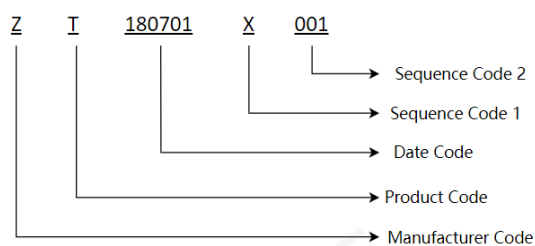
Product Components:

Cables: Charging cable、Tube(Receiver wire)

Sensors: Microphone、Signal processor、Receiver、Multi-function button

Accessories: dome、Cleaning tools (cloth and brush)、Charging box、Wax filter

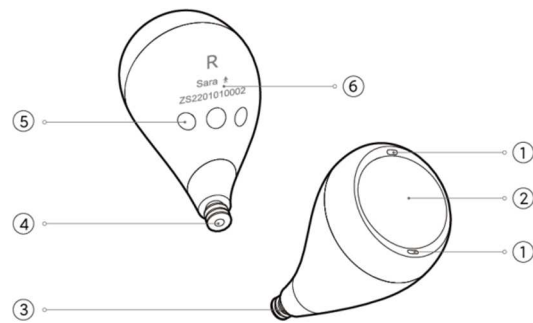
The product' s serial number is unique and fully traceable. It consists of 12 digits or letters, with the following meaning:



Hearing aid over view

Device models: Dion TWS 3

Product Component Description for Dion TWS 3



- ① Microphones
- ② Multi-function button
- ③ Receiver
- ④ Indicator lights
- ⑤ Charging contacts
- ⑥ Serial number

Note: In other contexts, you might encounter the terms "ear tip" or "earpiece" used interchangeably with "dome," but these terms carry the same meaning.

Replacing Parts and Optional Accessories

Contact support for additional information and ordering. For contact information, please refer to the back page.

Dome



Tulip Dome



Closed Dome



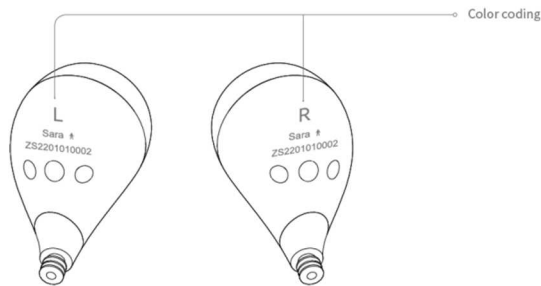
Open Dome



Sleeve Dome(S) Sleeve Dome(M) Sleeve Dome(L)

Note: Only use domes provided by TUI TUI. For instructions on how to replace the dome, refer to 'Replacing Hearing Aid Domes,' page 17.

Receiver



The receiver comprises a connector for attaching to the hearing aid, a wire, the receiver unit itself, a replaceable dome, and a replaceable wax filter.

*Your receiver is color-coded. Left = Blue. Right = Red.

Using Your Hearing Aid

Battery Performance

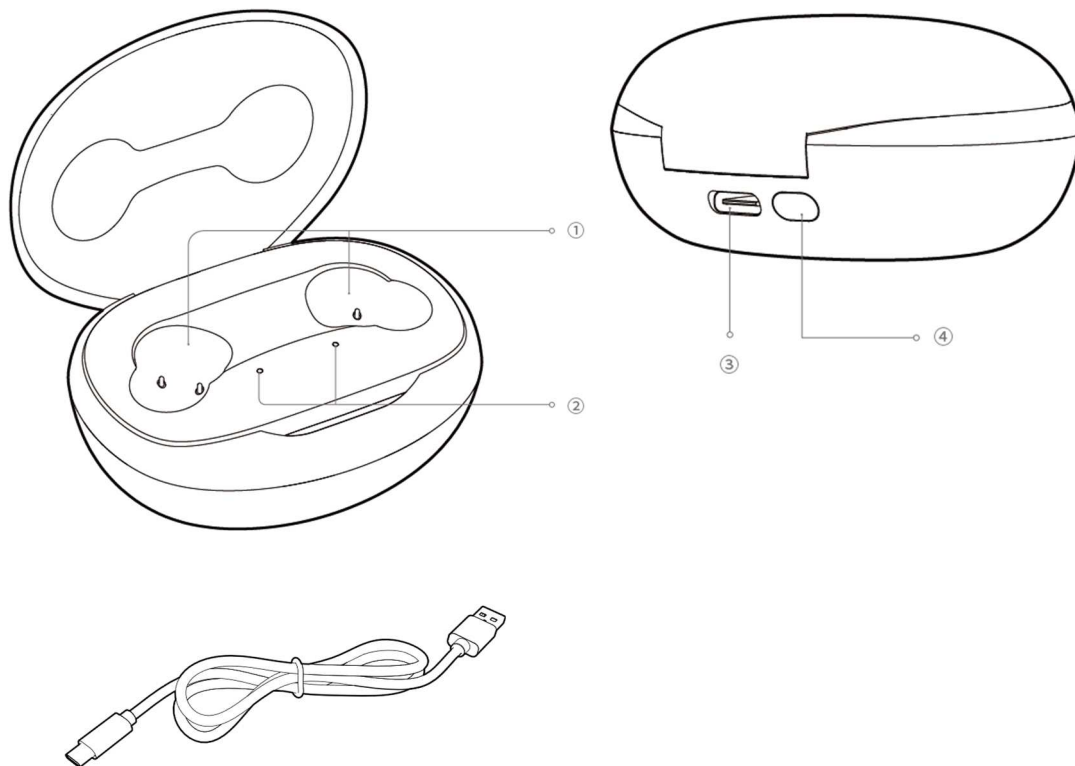
1. Typical operation time: approximately 11 – 12 hours of continuous use on a single full charge (measured in a quiet daily-use environment at medium volume).
2. Typical service life of the internal power source: under normal use and maintenance, the lithium-polymer battery retains $\geq 80\%$ capacity after about 700 charge/discharge cycles; with one charge per day, this corresponds to an expected lifetime of 2 – 3 years.
3. Behaviour of the equipment while charging: the hearing aid automatically powers off when placed in the charger. The indicator remains solid orange during charging and turns solid green when fully charged. No audio output is provided while charging, ensuring user safety.

Battery Warning

Warning:

4. Regularly check the battery level of the hearing aid and replace the batteries or recharge in a timely manner. Avoid waiting until the battery is completely drained before replacing or recharging, as this may affect the normal use of the hearing aid.
5. Rechargeable hearing aids are powered by a non-removable rechargeable lithium-ion battery. Contact or ingestion can be severely harmful. Never place rechargeable hearing aids in your mouth.
6. Keep your rechargeable hearing aids away from pets, children, and individuals with cognitive, intellectual, or mental health challenges.
7. Never swallow lithium-ion batteries or place them in any part of your body, as this may cause fatal injuries within two hours or less. If a lithium-ion battery is swallowed or placed in any part of the body or if a rechargeable hearing aid is swallowed, seek medical attention immediately.
8. If the casing of the rechargeable hearing aid is damaged, the rechargeable battery inside may leak. In this situation, do not attempt to use the hearing aid – contact support. For contact information, please refer to the back page.
9. Battery leakage can cause chemical burns. If you are exposed to materials leaked from the battery, rinse immediately with warm water. If you experience chemical burns, redness, or skin irritation due to battery leakage, seek medical attention.
10. Batteries are environmentally harmful. Therefore, never attempt to burn them. Dispose of your used rechargeable hearing aids according to the regulations in your country.
11. For safety reasons, only use the charging box provided with the hearing aid.
12. When traveling, consult your airline about transportation rules for hearing aids and charging box.

Charging box



Hearing aid charging bay

Charging box battery light

Charging box cableport

Charging box cable

Adapter Specifications

Input: 100 – 240 V AC, 50/60 Hz, 0.35 A

Output: 5 V DC $\pm 5\%$, 1 A (USB-C)

Must comply with IEC 60601-1 medical safety requirements

Port and Cable

USB-C female receptacle; supplied USB-C cable rated for ≥ 5 V/1 A

Charging box Battery

Type: 3.7 V, 400 mAh Li-polymer, non-removable

Cycle life: ≥ 500 cycles with $\geq 80\%$ capacity retention

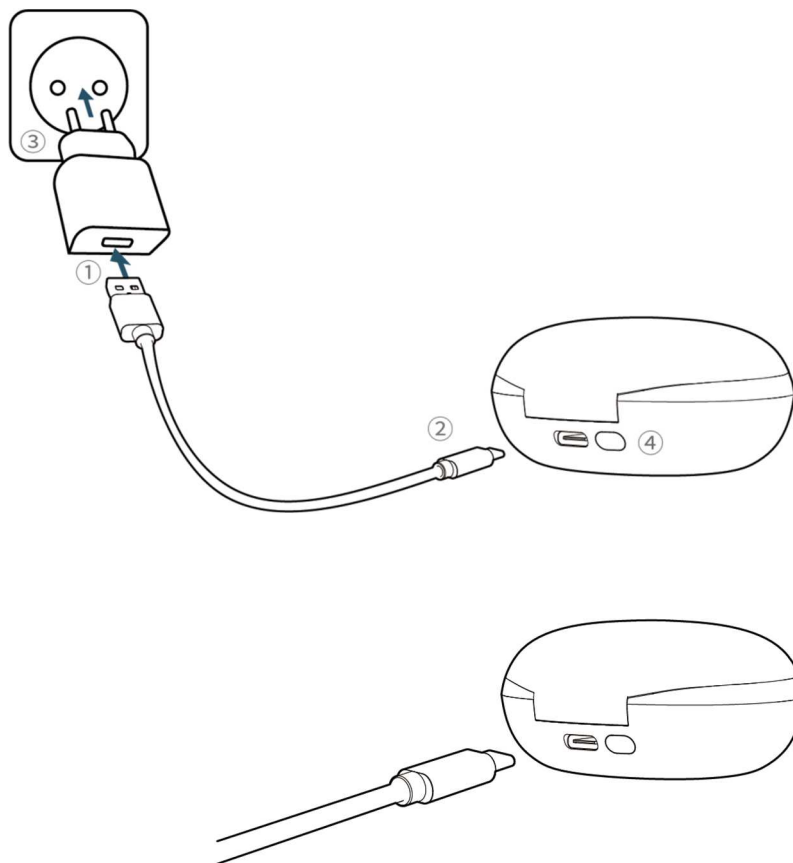
Operating & Storage Conditions

Charging / use: $+5^{\circ}\text{C} - +40^{\circ}\text{C}$, 15 % - 85 % RH

Storage / transport: $-10^{\circ}\text{C} - +40^{\circ}\text{C}$, $\leq 90\%$ RH

Preparing the charging box

Connecting the power supply



1. Plug the larger end of the charging cable into the power supply.
2. Plug the smaller end into the USB port on the charging box.

3. Plug the power supply into a power outlet.
4. The indicator light turns green or orange when the charging box is connected to a power source.

Power supply specification

Power supply output voltage : 5 VDC +/-10%, current 1 A

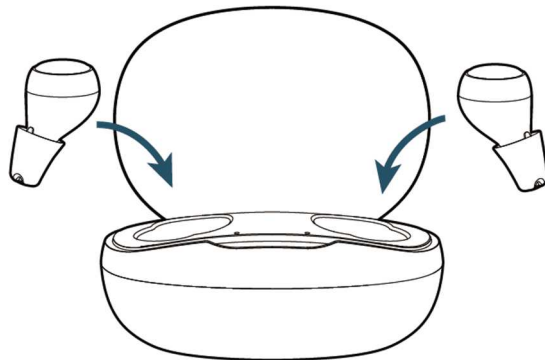
Charging box input voltage : 5 VDC +/-10%, current 1 A

USB cable specifications: 5 V min. 1 A, USB-A to USB-C, maximum length 1 m

Charging the hearing aids

1. Insert the hearing aid into the charging inserts.

Make sure the left and right hearing aid markings match the left (blue), right (red) indicators next to the charging inserts. The hearing aids will automatically be switched off when inserted into the charging box.



2. The indicator light will show the charging state of the battery until the hearing aid is fully charged.

When fully charged the indicator light will remain on, i.e. solid green light.

The charging process will automatically stop when the batteries are fully charged, so the hearing aids can be safely left in the charging box. It can take up to 3 hours to charge the hearing aids. The charging box covers can be closed while charging.

Charging times

3. Remove the hearing aids from the charging inserts by

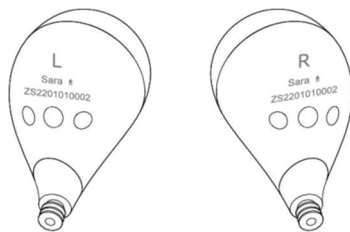
- 1) pulling the hearing aids gently toward yourself and
- 2) lifting them out of the charging box.

NOTE:

Do not hold the tubes to remove the hearing aids from the charging box as this can damage the

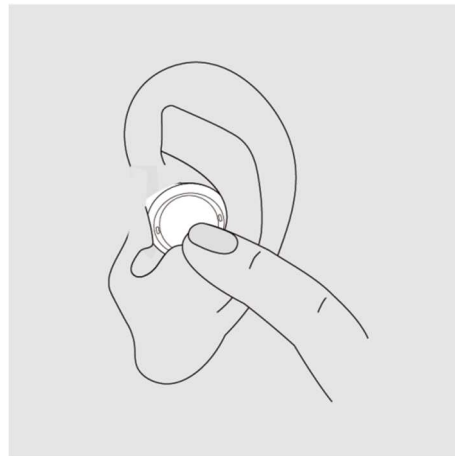
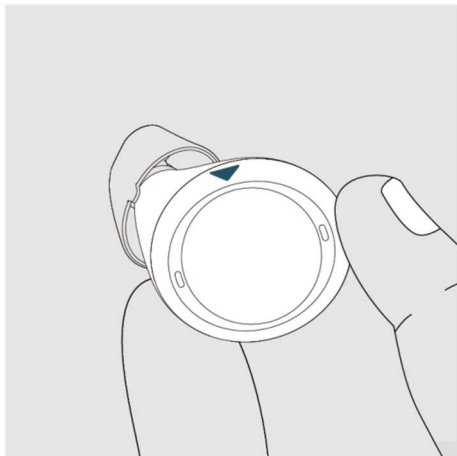
Wearing Hearing Aids

How to Distinguish Between the Left and Right Ear

**NOTE:**

Your two hearing aids may have different programs. Do not exchange them, as it could potentially harm your hearing. Your hearing aids are color-coded: Left = L Right = R.

Insert the receiver dome into your ear



Hang the hearing aid
beside your ear.

**Push the dome far enough
into your ear canal . You can
check in a mirror.**

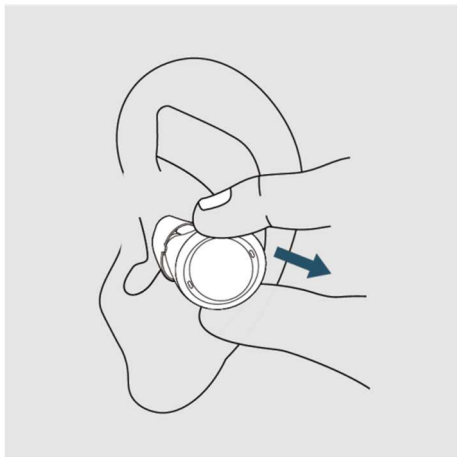
NOTE:

To avoid feedback, ensure that the wire and dome fit correctly in your ear. If you continue to experience whistling, refer to the troubleshooting guide for other possible causes and solutions.

If the receiver wire of the hearing aid is not snug against the side of your head, try using a smaller dome size (for dome replacement, see page 32). If the hearing aid wire is not snug against the side of your head, you may need a new receiver length (see "Replacing the Receiver," [page 39](#)).

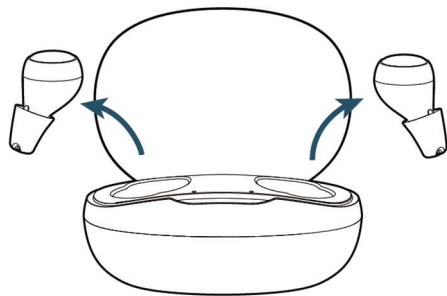
If you still cannot achieve a proper fit, please contact a hearing aid professional or service provider. For contact information, refer to the last page.

Removing the Hearing Aid

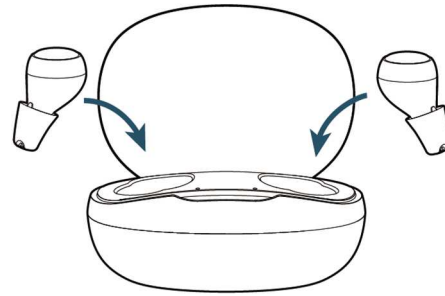


Lift the hearing aid off your ear.

Using the Hearing Aid



Power on



Power off

Turning Your Hearing Aid On and Off

When the hearing aid is charged, it will automatically turn on after being taken out of the charging box.

After placing the hearing aid in the charging box, the corresponding indicator light will light up. The hearing aid will automatically shut down and charge.

Multi-function button features

Call mode: double-tap to “answer/end call” ; press and hold to “decline”

Music mode: double-tap to “play/pause”

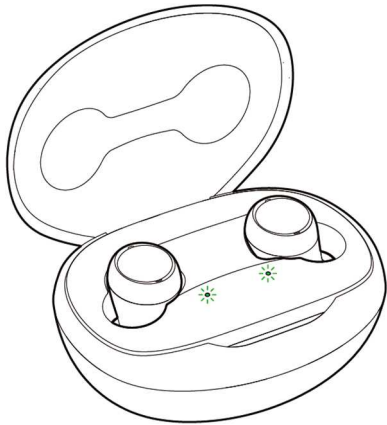
Press and hold to wake “voice assistant”

Indicator Light Guide:

1. Hearing aid



When the hearing aid's internal battery is $\leq 80\%$ and it is placed in the charging box, the orange indicator lights up, indicating that the hearing aid is charging.



When the hearing aid's internal battery is $\geq 80\%$ and it is placed in the charging box, the green indicator lights up, indicating a sufficient charge level.

2. Charging box

While charging the box, a green light indicates $\geq 80\%$ battery, and an orange light indicates $\leq 80\%$ battery.

Volume control:

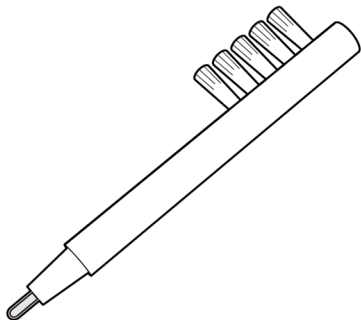
Volume can be adjusted and controlled via the companion mobile app.

Cleaning and Maintaining Your Hearing Aid

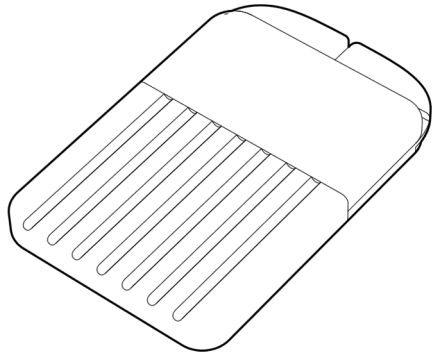
Cleaning Tools

These cleaning tools come with the hearing aid:

1.A brush with a battery magnet



2.Wax filter



General Instructions for Care and Maintenance

Note: To ensure the highest quality experience and the longest lifespan of your hearing aids, cleaning and caring for them is crucial. Keeping your hearing aids in perfect working condition is easy by following these steps:

1. Turn them off when you remove the hearing aids.
2. Wipe them with a soft cloth after removing the hearing aids to keep them clean and dry.
3. If you use a drying agent, only use the recommended product.
4. Remove the hearing aids before using cosmetics, perfume, aftershave, hair spray, lotion, etc.
These products can damage your hearing aids.
5. Never immerse the hearing aids in liquid.
6. Keep your hearing aids away from excessive heat and direct sunlight.
7. Avoid swimming, showering, or using steam baths while wearing the hearing aids.
8. Prevent the device from exposure to a significant amount of dust.

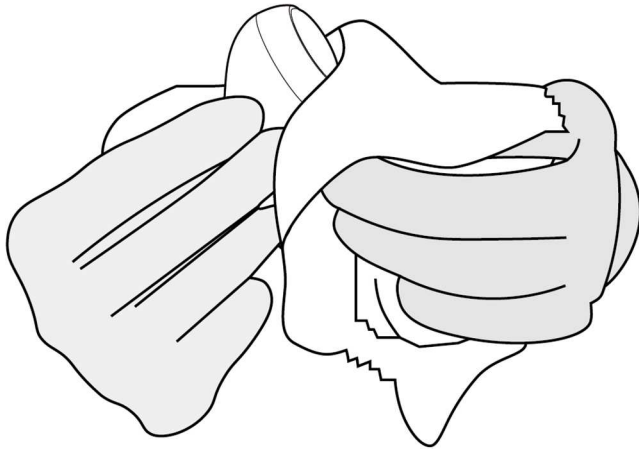
Caution

Repeated cleaning during the expected service life will not result in loss of basic safety performance. Clean the hearing aid strictly according to the instructions; never use alcohol or other solvents, as they may damage the device and cause skin reactions. Earwax or other residues may also lead to infection.

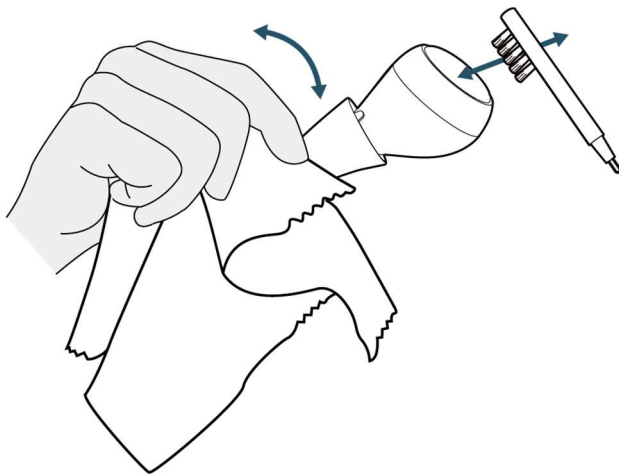
Daily Care and Maintenance

It is essential to keep your hearing aids clean and dry every day and to regularly clean any earwax buildup. Use the provided cleaning tools.

1. Wipe your hearing aids with the cloth.



2. Swipe the small brush across the microphones.

**Note:**

Never attempt to insert the bristles of the small brush or the cleaning wire into the microphone inlet. This may damage your hearing aids. Do not wash your receiver wire and dome with water.

Wipe your receiver and dome with a soft, dry cloth.

Over time, the receiver wire may become stiff, brittle, or discolored. If you feel that your receiver wire needs replacement, please contact your local dealer or hearing care professional.

Replacing the Dome of the Hearing Aid:

Every three months or sooner, you should replace the dome of your hearing aid. For example, if a dome is filled with earwax, replace it with a new one. If the hearing aid sounds quieter, it may indicate the need for a new dome. Refer to "Replacing the Wax Filter," page 17, for additional information.

If you are unsure of the size of your dome, try installing different sizes, testing each one on the receiver and finding a size that fits comfortably in your ear.

Note:

Incorrect dome replacement when removing the hearing aid may cause the dome to come off.

If you lack confidence in performing this task, please contact enhanced support. Refer to the back page for contact information.

Caution:

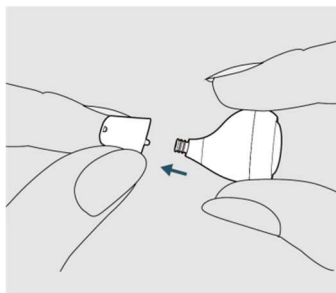
If you suspect there is a dome in your ear, consult a healthcare professional. These objects may be harmful to your ear and could lead to an infection.

Use accessories only intended for hearing aid use.

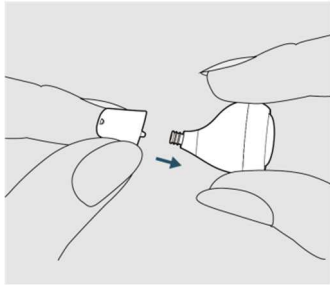
Standard domes

The illustration depicts an open dome, but the procedure is the same for all other domes. Follow these instructions to replace your dome.

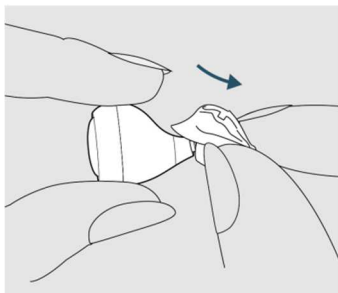
1. Remove the used dome from the receiver, and discard it. This may require some force.



2. Push the new dome over the ribbed end of the receiver.



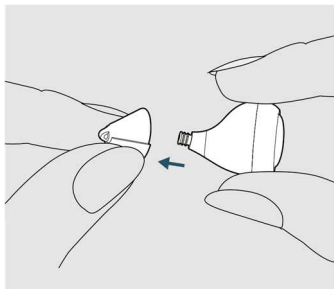
3. Carefully lift the bottom of the dome, ensuring it is securely installed, and verify that the collar completely covers the ribbed end of the receiver.



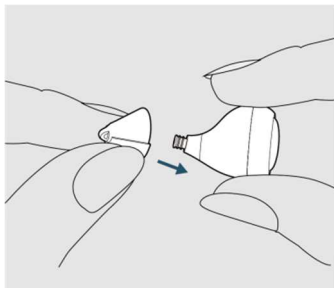
Tulip Dome

To replace the tulip dome, follow these instructions:

1. Remove the used dome from the receiver and discard it. This may require some force.

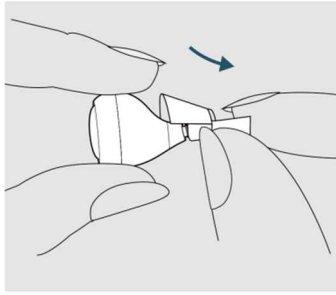


2. Push the tulip dome onto the ribbed end of the receiver, with the largest petal facing backward.



3. Ensure that the tulip dome by checking that the larger petal is facing forward. Confirm secure

installation by verifying that the collar completely covers the ribbed end of the receiver.



The illustration demonstrates a correctly installed tulip dome. Ensure the larger petal is positioned outside the smaller petals.

Replacing Earwax Filters

Earwax filters are located at the innermost end of the receiver.

Earwax filters help keep earwax away from the components of the hearing aid. It is essential to replace them regularly, depending on how much earwax your ears produce.

You will need your box of earwax filter tools.

Note: Do not use the hearing aid without installing the earwax filter. Using a hearing aid without an earwax filter can cause permanent damage to the receiver.

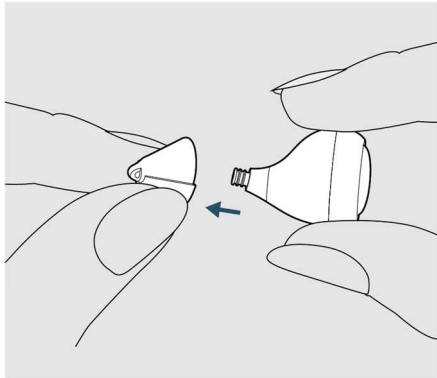
Earwax Filter Tool



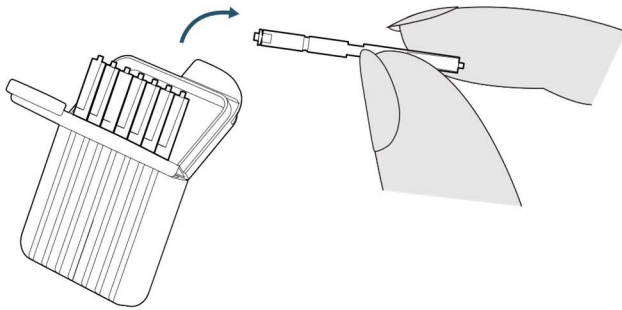
The earwax filter tool serves two functions: one for removing the used filter from the tip, and the other for replacing it with a new white filter.

Removing the old wax filter

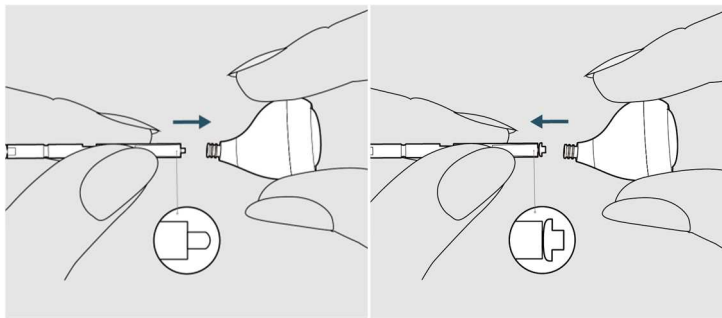
1. Remove the dome from the receiver



2. Open the earwax filter box and take out one tool. Each tool has a small hook at one end and a new earwax filter at the other end.

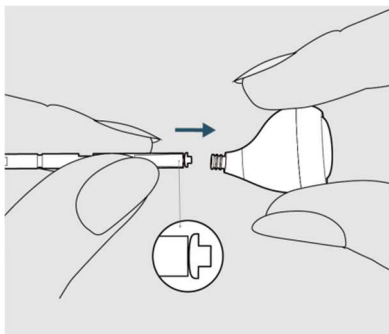


3. Insert the disassembly tip into the used earwax filter, then pull the tool straight out. It is crucial to pull straight, not at an angle.

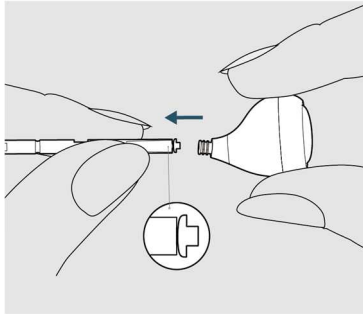


Inserting the new wax filter

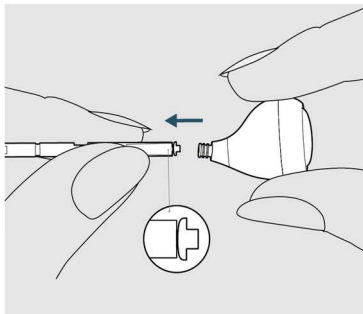
1. Insert the other end of the tool into the sound outlet (end for replacing the filter).



2. Gently press the replacement part directly into the sound outlet until the outer ring makes contact with the sound outlet.



3. Pull the tool straight out. Your new earwax filter will remain in place. Reinstall your dome or a replacement dome.



Note: If you lack confidence in performing this task, please contact enhanced support. Refer to the back page for contact information.

General Warnings and Precautions

Warning:

Building upon general warnings, the following supplementary warnings are provided:

- Do not allow children or individuals with cognitive, intellectual, or psychological impairments to use the hearing aid unsupervised. Hearing aids contain small parts that can be dangerous if swallowed. Seek immediate medical attention if any part of the hearing aid is swallowed.
- Do not wear hearing aids during radiation exposure. Certain types of radiation, such as magnetic resonance imaging (MRI) or CT scanners, can affect the settings of the hearing aids,

leading to malfunctions and potential damage to your hearing.

- Other types of radiation, such as theft alarms, room monitoring systems, mobile phones, metal detectors, and radio devices, will not damage your hearing aids. However, they may temporarily affect the audio quality of your hearing aids and produce unwanted sounds.
- Do not use your hearing aids and charging accessories in explosive areas (areas with explosive hazards such as mines or industrial zones, oxygen-rich environments, or areas handling flammable anesthetics) or in areas where the use of electronic devices is prohibited.
- Do not attempt to dry the hearing aids in ovens, microwaves, or other heating devices. This may cause them to melt and could result in burns to your skin.
- Modifying this equipment is not allowed, as it may damage your ears or hearing aids.

Caution:

- Use hearing aids as recommended. Incorrect usage may damage your hearing.
- Do not use damaged or modified hearing aids. They may not function properly and could harm your hearing, causing scratches or ulcers.
- Use only accessories, ear tips/ear-molds, batteries, and charging cables specified or provided by the manufacturer. Do not use non-original or uncertified accessories.
- Use only certified power adapters.
- Do not attempt to modify the shape of your hearing aids or accessories. This may cause skin reactions or sharp edges, leading to scratches or ulcers.
- The programs on your two hearing aids may be different. Do not interchange them, as it may damage your hearing. Your hearing aids are color-coded; left = blue, right = red.
- If your hearing aids come into contact with your ears or head, and you experience pain or injury, continuing to use the hearing aids may worsen the situation or hinder healing. Please consult a hearing care professional for assistance or seek prompt medical attention. Do not allow others to use your hearing aids, as it may damage their hearing.
- When using wireless functions, your hearing aids will use low-power digital coding transmission to communicate with other wireless devices. Other electronic devices may also

be affected. In such boxes, keep the hearing aids away from the affected electronic devices.

- Do not place hearing aids next to or stacked with other electronic devices, as this may cause the devices to malfunction.
- Staying away from interference sources, using original accessories, and promptly placing the hearing aid back in the charging box when not in use can help avoid electromagnetic interference with the basic safety and performance of the hearing aid.
- Situations that may occur due to electromagnetic interference causing the basic performance of hearing aids to be lost or degraded include: The hearing aid may produce noise, whistling, or distortion, which affects the clarity and quality of the sound. The amplification function of the hearing aid may be affected, resulting in unstable sound output or insufficient gain. In extreme boxes, electromagnetic interference may cause the hearing aid to fail completely and not function properly. If the above situations occur, please consult relevant professionals or return the product for repair.
- To avoid electromagnetic interference, the following measures should be taken: First, keep away from strong electromagnetic sources, such as large medical equipment, radio transmitters, or industrial electromagnetic devices to prevent audio-signal interference or performance degradation. Second, ensure ear tips or ear molds are properly fitted and sealed, minimizing acoustic feedback and electromagnetic coupling through any gaps. Third, clean the hearing aids regularly and store them correctly. Earwax and moisture can reduce shielding effectiveness and increase noise, while high temperature and humidity may oxidize shielding layers. Therefore, place the devices in a dry environment and perform weekly cleaning and maintenance.

Troubleshooting

Problem	Causes	What to do
NO SOUND	NOT boot(no boot prompt tone)	Long press the button
	Low battery	Put the hearing aid into charging box
	Speaker blockage	Cleaning speaker
LOW VOICE	Improper wearing of earplugs	Wearing earplugs correctly
	The ear fill dirty	Clean ear plugs
	Speaker dirty	Clean speaker
	Too many cerumen in ear canal	Clean ear canal and seek medical advice if necessary
	Hearing loss	Consult a surveyor
SQUEAL	Improper wearing of earplugs	Wearing correctly
	Too many cerumen in ear canal	Clean ear canal and seek medical advice if necessary
	Improper setting of hearing aids	Consult a surveyor
DISTORTION OF SOUND	Low battery	Install sufficient batteries and fill the battery compartment
	Wearing wrong earplugs	Consult a surveyor
	Improper setting of hearing aids	Consult a surveyor
	Hearing aid failure	Consult a surveyor

*If the above solution does not solve your problem, please consult your technician. If you need to repair the circuit or component, please send it to the manufacturer for repair.

Service and warranty

Local warranty

Please check the hearing care professional from which you purchased your hearing aids for the local warranty terms.

International warranty

Eartech hearing aid offers a one-year limited international warranty, effective from the date of purchase. This limited warranty covers manufacturing and material defects in the hearing aid itself, but excludes accessories such as batteries, tubes, Domes, external receivers. Warranty is only valid on presentation of proof of purchase. The international warranty does not affect any legal rights you might have under applicable national legislation on the sale of consumer goods.

Warranty limitation

This warranty does not cover damage from improper handling or care, exposure to chemicals or undue stress. Damage caused by third parties or non-authorized service centers renders the warranty null and void. This warranty does not include any services performed by a hearing care professional in their office.

Regulatory and legal information

Product structure and composition:

The rechargeable behind-the-ear hearing aid consists of a shell, a microphone, a signal processor, a receiver and an Dome.

Operating principle:

Hearing aids are essentially sound amplifiers; the sound is amplified in some way, and it is some way that people with hearing loss can effectively use themselves to participate in the hearing.

The microphone receives the external sound of the hearing aid, and the analog-to-digital (ADC) converter converts it into a digital signal. The multi-channel digital signal processor(DSP) processes the digital input signal and outputs a direct digital drive (DDD), which drives the receiver sound. Through the programming interface, use the special testing and debugging software to set according to the user's empathy for the hearing aid, save the setting value in the memory, and save some parameters and program segments that control the working mode of the DSO.

Product intended use:

After the test, it is provided to the patients with hearing loss compensation.

Contraindication:

Dion series products are not recommended for people with acute otitis externa, tympanitis, chronic suppurative otitis media, and acute suppurative otitis media.

Voltage range:

DC 3.7 V (+0.1/ -0.1 V) Apply to Sara 1

	Neighbor compatibility At the following field strength, IRIL=55dB The field strength is expressed in terms of V/m(*)	
	0.8-0.96	1.4-2.0
GHz		
Microphone mode	3V/m	2V/m

Electromagnetic compatibility Specification:

In accordance with IEC 60601-1-2:2020+RED "electroacoustic hearing aids - Part 13: Electromagnetic Compatibility (EMC)" adjacent compatibility requirements.

*Note: The test field strengths given are unmodulated carrier values.

Operating, transport and storage conditions

Transportation and storage

Ambient temperature range: $-10^{\circ}\text{C}\sim 40^{\circ}\text{C}$

Relative temperature range: $\leq 80\%$

Atmospheric pressure: 860hPa ~ 1060hPa

Normal operating conditions:

Environment temperature: $-10^{\circ}\text{C}\sim 40^{\circ}\text{C}$

Relative humidity: $\leq 80\%$

Atmospheric pressure: 860hPa ~ 1060hPa

nominal voltage: DC 3.7 V (+0.1/ -0.1 V)

A special note on howlers:

One of the most common problems that new users of hearing AIDS encounter for the first time is "squealing", which is hearing aids emit loud noises, especially when the volume is turned on higher. The noise comes from the domes that are not completely plugged, and the ear canal cannot be closed. The hearing aid amplifies the leakage sound, which is then amplified by the hearing aid to generate noise.

Technical description:

Classification of hearing aids:

1. According to the type of shock: Internal power equipment;
2. According to the degree of shock: Type B application equipment;
3. According to the degree of protection of harmful liquid: IPX0, conventional device ;
4. According to the degree of safety in the presence of flammable anesthetic gas mixed with air or with oxygen or nitrogen oxide: Equipment not to be used in the presence of a flammable mixture of anesthetic gas and air or a mixture of oxygen or nitrogen oxide
5. According to the operation mode: continuous operation

External link device

1. If the mains power the external equipment connected to the product, it must comply with IEC 60601-1:2020 or equivalent safety standards.
2. Connect only to external equipment that complies with international safety standards.

Technical specification:

Model	OSPL90		Full range sound gain (mean athigh frequ ency)	Equivalent input noise (dB)	Total harmonic distortion			Frequency response range (Hz)
	Maximum saturated sound pressure level (dB)	High frequency mean (dB)			500Hz	800Hz	1600Hz	
Sara 1	$\leq 108+3$	105 ± 4	25 ± 5	$\leq 26+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	600—5000
Sara 2	$\leq 108+3$	105 ± 4	25 ± 5	$\leq 26+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	600—5000
Sara 3	$\leq 108+3$	105 ± 4	25 ± 5	$\leq 26+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	600—5000
Sara 4	$\leq 110+3$	106 ± 4	30 ± 5	$\leq 25+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	500—6500
Sara 5	$\leq 110+3$	106 ± 4	30 ± 5	$\leq 25+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	500—6500

Sara 6	$\leq 110+3$	108 ± 4	30 ± 5	$\leq 25+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	500—6500
Sara 7	$\leq 108+3$	103 ± 4	27 ± 5	$\leq 26+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	600—5000
Sara 8	$\leq 108+3$	103 ± 4	27 ± 5	$\leq 26+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	600—5000
Sara 9	$\leq 110+3$	108 ± 4	30 ± 5	$\leq 25+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	500—6500
Sara 10	$\leq 110+3$	108 ± 4	30 ± 5	$\leq 25+3$	$\leq 4+3$	$\leq 4+3$	$\leq 4+3$	500—6500

Software Version Description:

Model	Software version number	Software Release
Sara 1	4.2.0	4
Sara 2		
Sara 3		
Sara 4		
Sara 5		
Sara 6	6.4.0	6
Sara 7		
Sara 8		
Sara 9		
Sara 10		

Test Levels

Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions

ITE Hearing Aids		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The models Sara 1, Sara 2, Sara 3, Sara 4, Sara 5, Sara 6, Sara 7, Sara 8, Sara 9, Sara 10 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 models Sara 1, Sara 2, Sara 3, Sara 4, Sara 5, Sara 6, Sara 7, Sara 8, Sara 9, Sara 10 are suitable for use in allestablishments, 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2: Guidance & Declaration - electromagnetic immunity

Guidance & Declaration — electromagnetic immunity			
ITE Hearing Aids			
Immunity test	IEC 60601-1-2 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	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line	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	<5 % U_T (>95% dip in U_T) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95% dip in U_T) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Sara 1, Sara 2, Sara 3, Sara 4, Sara 5, Sara 6, Sara 7, Sara 8, Sara 9, Sara 10 require continued operation during power mains interruptions, it is recommended that the models Sara 1, Sara 2, Sara 3, Sara 4, Sara 5, Sara 6, Sara 7, Sara 8, Sara 9, Sara 10 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m	Power frequency magnetic fields/ Proximity magnetic fields should be at levels characteristic of a typical

IEC 61000-4-8			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.			

Table 3: Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

Guidance & Declaration - Electromagnetic immunity			
ITE Hearing Aids			
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF IEC 61000-4-3	3&10 V/m, 80 MHz to 2.7 GHz	3&10 V/m, 80 MHz to 2.7 GHz	Portable RF communications equipment (including peripherals such as antenna cables and

	0.65-0.96GHz, 1.4-2.7GHz Test specifications for mobile digital wireless on equipment (Refer to IEC 60118- 13:2019)	0.65-0.96GHz, 1.4-2.7GHz Test specifications for mobile digital wireless on equipment (Refer to IEC 60118- 13:2019)	external antennas) should be used no closer than 30 cm (12 inches) to any part of the models Sara 1, Sara 2, Sara 3, Sara 4, Sara 5, Sara 6, Sara 7, Sara 8, Sara 9, Sara 10 , including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1- 2:2014+A1:20 20)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1- 2:2014+A1:20 20)	If higher IMMUNITY TEST LEVELS than those specified in Table 9 are used, the minimum separation distance may be lowered. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = [6/d] \times P^{1/2}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

Radio Frequency Electromagnetic Energy

The audiometric test frequencies for patients receiving ME equipment are divided into: 250Hz, 500Hz, 1000Hz, 2000Hz, 4000Hz, and 6000Hz. The preferred test frequencies are generally chosen

based on the patient's hearing loss condition.

FCC statement

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.

FCC Caution:

FCC RF exposure information (SAR)

This device meets the government's requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

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

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 Radiation Exposure

This equipment complies with FCC exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located operating in conjunction with any other antenna or transmitter.

FCC RF exposure information (SAR)

This device meets the government's requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

Left ear FCC ID:2A5WV-SARAL-EARTECH

Right ear FCC ID:2A5WV-SARAR-EARTECH

Operating frequency range:2402-2480MHz

Maximum RF Output power: <10dBm

Network Security Instructions

JRE: DSP Chip

Security software: No security software is available

Data domain device interface:

TCP: Bluetooth

Dion series: Bluetooth transmission data modify hearing aid gain parameters, data storage format is binary, hearing aid can also accept music, call and other voice data for real-time playback, without storage.

Information and description of symbols

 This symbol indicates the pending European conformity approval of relevant regulations and directives. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned regulation and directive.

 The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Sonova AG is under license. Other trademarks and trade names are those of their respective owners.

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 Indicates the medical device manufacturer, as defined in the Medical Device Regulation (EU) 2017/745

 Indicates the date when the medical device was manufactured

 Indicates the manufacturer's serial number so that a specific medical device can be identified.

 This symbol indicates that it is important for the user to read and consider the relevant information in this user guide.

 This symbol indicates that it is important for the user to pay attention to the relevant warning notices in these user guides.

IP22 means the device enclosure and supplied carrying box protect against solid objects ≥ 12.5 mm and vertically dripping water; they are not dust-tight and are not protected against water jets or immersion.



The symbol with the crossed-out garbage bin is to remind you that this CROS device and the charging box may not be disposed of as regular household waste. Please dispose of old or unused hearing aids and charging boxes, at waste disposal sites intended for electronic waste, or give your hearing aid and charging boxes to your hearing care professional for disposal. Proper disposal protects the environment and health.



The temperature during transportation and storage: -20° to $+60^{\circ}$ Celsius (-10° to $+40^{\circ}$ centigrade).



Humidity during transportation: Up to 80% (non condensing). Humidity during storage: 0% to 80%, if not in use.



Atmospheric pressure during transportation and storage: 86kPa to 106kPa



Keep dry during transport.



This symbol indicates that the products described in these user instructions comply with the requirements of the Category B application part of EN 60601-1. Hearing aid surfaces are designated as Class B Applied Parts.

Packing list

Title	Amount
Hearing aid	2
User guide	1
Certification	1
Warranty card	1

Dome	6
Charging box	1

Registration information

Name of registrant/manufacture: Shenzhen Eartech Company Limited.

Domicile of registered person/manufacture: 516, Building 4, Tusincere Science Park,
Longcheng Street, Longgang District, Shenzhen, Guangdong, China

Contact information of the registrant/manufacture:

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Tel: +86(0755)28709006

Postcode: 518116