

Bone Conduction Hearing Aid

User Manual

Applicable model: XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3

Shenzhen Magnet Technology Co., Ltd

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WARNING: People younger than 18 should go to a doctor before using this. People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.

Warning to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

Cautions and notices for users:

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over

noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them “adverse events,” and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

Note: Hearing loss in people younger than 18

- People younger than 18 should see a doctor first, preferably an ear-nose-throat doctor (an ENT), because they may have different needs than adults.
- The doctor will identify and treat medical conditions as appropriate.
- The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won’t treat on its own.

Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person’s ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person’s individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

Preface

This user manual contains important information essential for the safe and proper use of the device.

The user manual is an integral part of the product. Therefore, all personnel must carefully read this user manual before using this product.

The user manual should be handed over to any subsequent user or owner of this product.

Reproduction, photocopying, digital processing, or duplication of this manual is strictly prohibited without the consent of Shenzhen Magnet Technology Co., Ltd.

This product is safe and reliable when used as intended, except in cases of hazards caused by special factors such as failure to follow the manual or use for other purposes. Therefore, please adhere to the following regulations during use to prevent accidents.

This product must be operated in accordance with the manual.

Equipment maintenance must be carried out by the technical staff of Shenzhen Magnet Technology Co., Ltd or by personnel authorized for operation.

If there are any other operation-related issues not mentioned here, please contact Shenzhen Magnet Technology Co., Ltd promptly.

The contents of the manual may be modified without prior notice.

Please keep this manual readily accessible for future reference.

Tips:

To obtain the electronic version of the User Manual, please refer to the following link:

<https://www.fi-stave.com/Customer/FileDownloadVerifyPass?fileid=2978792&type=img>

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1 Indications for use

Bone Conduction Hearing Aid (models: XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3) is wearable sound-amplifying device intended to compensate impairments in personal hearing. The fundamental operating principle is to receive, amplify, and transfer sound via the skin and the bone of the skull to the inner ear of a hearing impaired person. The amplification suits the needs of a mild to a moderate hearing loss. They require individual fitting in performance executed by a hearing aid professional. The device is intended for adults and children (≥ 12 years).

2 Safety Precautions

2.1 Contraindications

Patients must not use the bone conduction hearing aid:

- 1) Loss of auditory nerve.
- 2) Sudden or rapidly worsening hearing loss.
- 3) Recent sudden tinnitus or tinnitus in one ear.
- 4) Unexplained deafness in one ear or significant asymmetric deafness.
- 5) Pain in either ear.
- 6) Poor physical condition
- 7) Uncontrollable emotional state.
- 8) Hearing loss is not covered by the adjustment range of the device.

2.2 Warnings

- 1) Bone conduction hearing aids do not repair the user's previous hearing or prevent or improve hearing damage due to organ conditions. In most cases, infrequent use of hearing aids also does not provide the most benefit to the user. The use of hearing aids is only part of hearing rehabilitation and is complemented by auditory training and lip-reading instruction.
- 2) When using bone conduction hearing aids, first exclude the reaction of particularly allergic patients to the materials of this device.
- 3) Striking the head area where a bone conduction hearing aid is worn may cause personal injury or damage to the device, resulting in malfunction.
- 4) Do not do magnetic resonance imaging (MRI) scans while you are wearing this device. If you wear this device into a MRI scanning room, or undergo an MRI scan, you may suffer serious injury. This device should be removed prior to an MRI scan.
- 5) Do not put your bone conduction hearing aids in an incinerator or in a fire.
- 6) Do not dispose of the built-in battery of the product at will, and do not throw the battery into the fire.
- 7) The accessory of this device contains magnets that can have an effect on a pacemaker or implantable cardioverter defibrillator device. Therefore, the magnetic portion of the bone

conduction hearing aid attachment should be kept away from the pacemaker or implantable cardioverter defibrillator.

- 8) Make sure that the components of the bone conduction hearing aid are kept away from magnetic data storage media or magnetic electronic devices. bone conduction hearing aid accessories contain magnets that can cause potential damage to magnetic data storage media and magnetic electronics.
- 9) To avoid damaging the device, ensure that bone conduction hearing aids are stored at all times in a environments with a temperatures not lower than 0 °C or not higher than 38 °C and humidity less than 80% RH.
- 10) Bone conduction hearing aids should be removed before an X-ray scan of the head or neck.
- 11) During radiation therapy, please remove the bone conduction hearing aid.
- 12) Portable or removable radio frequency communication devices can affect the performance of bone conduction hearing aids. Do not bring bone conduction hearing aids near other unknown Bluetooth devices, as this may trigger automatic communication between them. Bluetooth modulation type: GFSK, pi/4-DQPSK, 8-DPSK; Transmit power: 4.5dB; range: 2400MHz~2480MHz.
- 13) Bone conduction hearing aids may trigger airport metal detectors. When passing through security at the airport, you should remove the bone conduction hearing aid.
- 14) Do not use bone conduction hearing aids when participating in contact sports. Because hard physical contact with the device or hitting the device may cause damage or malfunction of the device, and may also cause injury to the user.
- 15) Bone conduction hearing aids should only be cleaned as directed in this user manual, and other common household cleaners or methods such as washing machines, bleach, ammonia, or jet cleaners may damage the device.
- 16) To avoid damage to the package box or bone conduction hearing aids, do not use household soap to clean the device or rinse/soak the device in water, do not wash the inner box in the dishwasher. If the inner box is wet, whatever the reason, make sure to air dry the inner box thoroughly before placing the bone conduction hearing aid in the box.
- 17) The protection class of Bone conduction hearing aids is IP32, but should not be worn in heavy rainy weather, bathing, while taking a bath, showering, diving, or in other environments that may expose them to large amounts of moisture. Exposure of bone conduction hearing aids to moisture may cause damage.
- 18) Protect your bone conduction hearing aids from shock or vibration and drop your bone conduction hearing aids.
- 19) Do not expose bone conduction hearing aids to strong sunlight unless you are wearing them.
- 20) When removing the device, please turn it off first. If you don't use your bone conduction hearing aids for a long time, you should fully charge them and put them in the box in a turned off state.
- 21) After removing the device, it is recommended to put it in a box containing desiccant, away from light, high temperature and high humidity environments, and avoid falling.

- 22) The power on and off buttons and volume buttons should be used correctly, and the switch should be opened and closed as gently as possible to avoid excessive force and pulling, which may cause damage to the device.
- 23) Bone conduction hearing aids do not contain latex in parts or packaging.
- 24) When not in use, bone conduction hearing aids should be turned off, which is beneficial for extending the life of the battery.
- 25) If you do not turn off your bone conduction hearing aid when you remove it, the product will produce a vibrating whistling sound that will drain the battery. Therefore, when not wearing it, the device should be turned off and then removed.
- 26) Keep the outer surface of the device clean, and remove the bone conduction hearing aid and its accessories when using hair styling agent or hairspray.
- 27) In addition to transducers and cables sold by manufacturers of bone conduction hearing aids as spare parts for internal components, the use of unspecified accessories, transducers and cables may result in increased emission or decrease in immunity of bone conduction hearing aids.
- 28) Bone conduction hearing aids should not be used in close proximity or stacking with other devices, and if they must be used in close proximity or stacking, they should be observed to verify that they can function properly under the configuration in which they are used.
- 29) Use of non-specified accessories, transducers, and cables with bone conduction hearing aids may result in increased bone conduction hearing aid emissions or decreased immunity.
- 30) The internal battery is not replaceable.
- 31) If hearing aids need to be fitted, please have them operated by a professional fitter or doctor.
- 32) Modification of this equipment is not permitted.
- 33) Inexperienced responsible parties must contact their local authorities to determine the appropriate way to properly dispose of discarded components and accessories that may be biohazardous.

2.3 Precautions

- 1) The patient is an intended operator.
- 2) When removing from minimum/ maximum storage temperature, it is recommended to recover for 2 hours before use.
- 3) Keep the bone conduction hearing aids out of reach of small children, people with cognitive impairment (other than the patient), pets or pests to avoid injury.
- 4) Do not modify the settings or other components of the bone conduction hearing aid. Unauthorized modifications to the bone conduction hearing aid can damage your hearing.
- 5) Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair, if necessary. But do not modify the equipment by yourself or any other unauthoritative organization. Unauthorized changes or modifications could void the user's authority to operate the device.
- 6) Never wear your bone conduction hearing aid in areas with an explosion risk or in oxygen-rich environments.

- 7) If you experience pain in the front or upper part of the ear, for example due to pressure points, talk to your hearing aid specialist or doctor immediately.
- 8) If the sound impression you receive from the bone conduction hearing aid changes, please contact your hearing aid specialist immediately.
- 9) Be aware that hearing programs that use the directional microphone mode reduce background noises. Warning sounds or noises from behind will be only very weak.
- 10) Never use liquids to clean the microphone inputs. They will lose their special acoustic properties if you do.
- 11) Protect your bone conduction hearing aid from heat.
- 12) Do not dry the bone conduction hearing aid in the microwave.
- 13) Though the device has pass the biocompatibility testings, it is still possible to cause a potential allergic reaction depending on the individual's skin condition.
- 14) Your bone conduction hearing aid must not be worn by anyone else. There is a danger it this could damage their hearing.
- 15) If the patient is unable to operate the bone conduction hearing aid her/himself, the device must be operated by the responsible person. Never leave the persons listed above with the hearing aid without supervision.
 - When using children's hearing systems, it must be ensured that children do not pull the headband over their neck. There is a risk of suffocation resulting from strangulation with the headband.

3 Key to symbols

The following symbols are displayed on the device and packaging:

	Warning		Fragile, handle with care
	Type BF applied part		Keep away from sunlight
	Non-ionizing electromagnetic radiation		Keep dry
	This way up	IP32	1 st numeral - solid foreign objects: Protected against solid foreign objects of 2,5 mm Ø and greater 2 nd numeral - water: Protected against spraying water
Rx only	Prescription use Caution: Federal law restricts this device to sale by or on the order of a physician.		“WEEE (Waste Electrical and Electronic Equipment)”. The waste products should be handled legally.
	Refer to instruction manual/ booklet		Serial number

	Date of manufacture		Batch code
	Manufacturer		General warning sign
	FCC certification		Direct current

4 Structural composition

The following is the basic composition of bone conduction hearing aid, which mainly consists of a bone conduction (output) transducer, control box (including an input transducer and a signal conditioning unit), battery (an internal rechargeable lithium-ion polymer battery), and headband (with built-in wiring), as shown in figure 1.

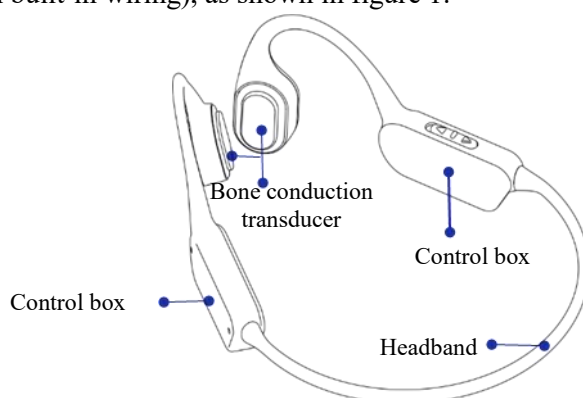


Figure 1. Basic composition of bone conduction hearing aids

The structure of the bone conduction hearing aid control box includes: power (on/off) button, left ear volume buttons “L-” and “L+”, right ear volume buttons “R-” and “R+”, indicator light, microphone pickup hole, and charging port.

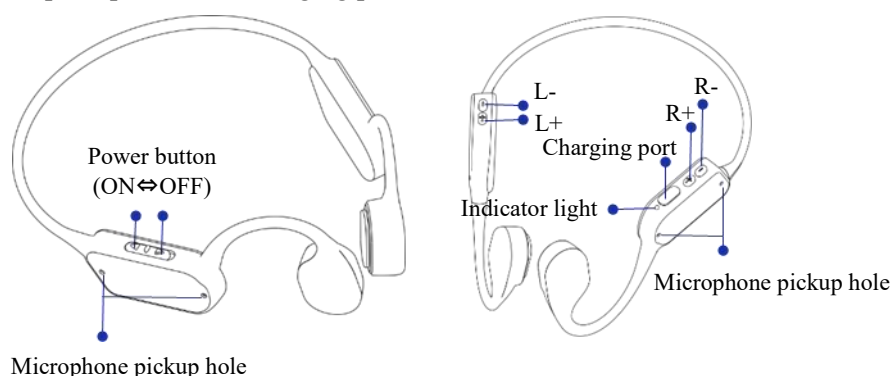


Figure 2. Structure of the bone conduction hearing aid control box

5 Packing List

After opening the package, please check whether the items you receive fully contain the following items. If there are any omissions, please contact the distributor or the manufacturer.

Packing List			
No.	Accessory	Quantity	Remark
1	Bone conduction hearing aid	1	
2	User Manual	1	
3	Warranty Card	1	
4	After-sales Service Commitment Letter	1	
5	Charge Cable	1	

6 Technical Specifications

Product name	Bone Conduction Hearing Aid		
Model	XTS-AISW-D1	XTS-AISW-D2	XTS-AISW-D3
Dimensions	114 x 93 x 45 mm		
Weight	35g		
Structural type	Integrated		
Channel	Dual-channel		
Wired or wireless	Wireless		
Bluetooth version	V5.3		
Power supply	Built-in rechargeable polymer lithium battery (210mAh), the maximum temperature allowed is 45 °C		
Rated voltage	DC3.7V		
Typical continuous working time	13 hours		
Charging time	2~2.5 hours		
Performance			
Type of Protection	BF Type		
IP Classification	IP32		
Design serial number	D1	D2	D3
Output power	High power	Medium power	Low power
Bluetooth	Yes		
Embedded software release version	V1.00		
Maximum OFL90 (dB) (Tolerance: +3dB)	106	105	104
High-frequency average OFL90 (dB) (Tolerance: ±4dB)	101	99	97
Maximum Gain (dB)	29.7	27.8	29.9
Full-on Gain (High-Frequency Average) (dB) (Tolerance: ±5dB)	26.5	25.0	23.5
Equivalent Input Noise Level (dB) (Tolerance: +3dB)	11	13	15
Total Harmonic Distortion (THD) (Tolerance: +3%)	1.5%	1.5%	1.5%
Frequency response range (Hz)	400~5850		

Other technical characteristic	● Independent volume control for left and right channels ● Automatic noise reduction ● Acoustic feedback control ● Programmable digital hearing aid system ● 3 selectable parameter modes that can be switched cyclically (chosen freely by the user) ● 16 channels ● 16 frequency bands ● Battery low-level prompt ● Supports Bluetooth function (for non-medical purposes)		
Saturation output curve (Saturation Sound Pressure Level (SSPL) 90 curve)	101dB	99dB	97dB
Frequency response curve	The starting point of automatic gain control is 40dB to 80dB. Dynamic output characteristics: Rise time is ≤80ms, recovery time is ≤460ms.		
Operate environmental conditions			
Temperature	-10 °C~40 °C		
Relative Humidity	≤80%		
Atmospheric pressure	700hPa~1060hPa		
Product service life	Product life time: 3 years		
	Battery lift time: The charge and discharge cycle is 1,500 times		

7 Instructions for use

7.1 How to wear/ remove the hearing aids

- 1) Wear it as shown in the figure 3 below:

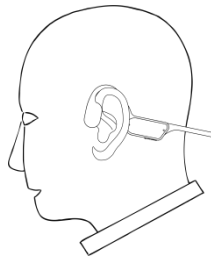


Figure 3. Wearing diagram

- 2) Turn the power button to the “ON” position to turn on the device.



◆ Be sure to wear it before turning on the device. Remove it first before shutting down. Do not wear it and keep it in shutdown state during charging. Otherwise, a loud howling sound may occur and damage the product itself.

	◆ During use, the bone conduction transducer should be attached to the skull. Do not put the microphone close to the ear cartilage or into the ear canal. Otherwise, a loud howling sound may occur and damage the product itself.
	◆ The hearing of the left and right ears is different for different users. During use, users need to adjust the volume of the left and right channels independently to achieve the best balance.

- 3) After confirming that the bone conduction hearing aid has been turned off, remove the headband and store the product.

7.2 Operation instructions

It is recommended to optimize the listening mode parameters according to the following steps when using it for the first time.

1) Power on

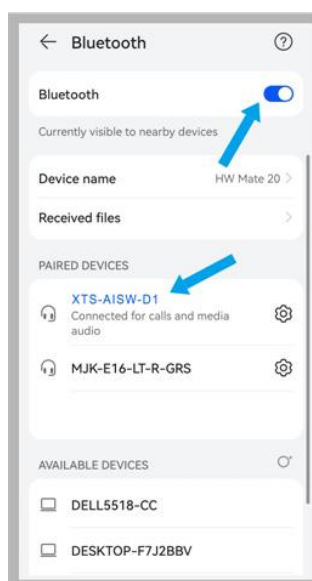
After properly wearing the bone conduction hearing aid, slide the power button to the “ON” position. Upon startup, a “power-on” tone will sound, and the device will enter Bluetooth pairing mode: the orange and blue indicator lights will alternate flashing. If no Bluetooth connection is established within the timeout period (60 seconds), all indicator lights will turn off.

2) Volume adjustment

Adjust the “L-” and “L+” buttons on the left ear and the “R-” and “R+” buttons on the right ear respectively in sequence to select the volume suitable for the user's left and right ears.

3) Bluetooth connection

Open the Bluetooth window of your mobile phone or other device, find the product name of the hearing aid model XTS-AISW-D1, XTS-AISW-D2, and XTS-AISW-D3 (e.g., XTS-AISW-D1), and click “Pair”:



- When the Bluetooth is connected or fails to connect within the time limit, both the orange light and the blue light will turn off.
- After connecting to the mobile phone via Bluetooth, if there is an incoming call, press the “R+” button briefly to answer it, or long press the “R+” button for 2 seconds to reject it. During the call, press the “R+” button briefly to hang up the call.
- When playing music:
 - Double click the “L+” button to play or pause the music;
 - Double click the “R+” button to play the next music;

- Double click the “R-” button to play the previous music.

4) Hearing Aid Mode Adjustment:

Hold down the “R-” button for 2 seconds and then release. The device will output a “Mode x” notification (where “x” represents numbers 1~3). Users can then select the optimal scenario mode (Mode 1: Noisy environment, Mode 2: Conventional environment, mode 3: Quiet environment) based on their hearing needs. The bone conduction hearing aid will automatically save this mode for future adjustments.

5) Power off

Switch the Power button to “OFF” position, and the orange light will be on for 1 second and the device will announce “OFF” sound, then shut down.

Please remove the hearing aid after turning it off.

6) Charging the device

- It is suggest to use a power adapter (input: 100-240V~50/60Hz, not less than 0.5A; output power is d.c.5V, not less than 0.5A) that complies with IEC 60601-1: 2005 + A1:2012+A2:2020 and a standard USB charging cable for charging.
- This product needs to be charged in the power off state. Unplug the USB plug before connecting the charging cable. Charge according to the diagram:

Caution: Do not use the device when charging.

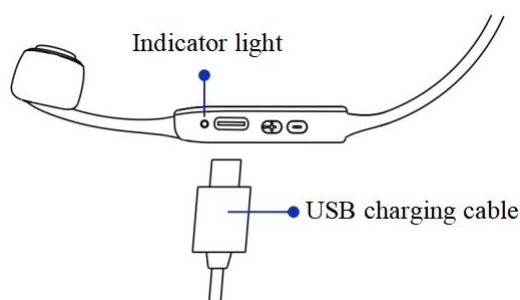


Figure 4. Charging diagram

7) Indicator light and battery status

Status of the hearing aid	Battery status	Indicator light status
Power-on operation	Battery full	The orange and blue indicator lights will alternate flashing and the device will sound “power on” prompt.
Device working	Battery full	The Bluetooth is going to connect: Alternating orange and blue indicator lights flash; when fails to connect within the time limit, both turn off. Bluetooth connected: All indicator lights are off.
Device working	Battery low	The indicator light flashes orange and the device will say “low power” prompt.
Mode switch	Battery full	Output the "Mode x" prompt tone (“x” represents the numbers 1 to 3)
Power off for charging	During charging	Keeps lighting up in orange
Power off for charging	Full charged	The indicator light is off.

Note:

After connecting the phone through Bluetooth, the percentage of the device's power information can be displayed on the phone.

8 Cleaning instructions

Clean the bone conduction hearing aid when there is dirt on it.

- 1) Please turn off the bone conduction hearing aid before cleaning.
- 2) When cleaning your bone conduction hearing aid, please wipe it with a soft cloth or use a disinfected cotton swab for cleaning.



- 3) When wiping, it is recommended to use neutral solvents.
- 4) After cleaning, please conduct visual inspection to check whether the device is visually clean, if it's not, please repeat the above cleaning steps.
- 5) If the bone conduction hearing aid is soaked in water:
 - Immediately close the bone conduction hearing aid;
 - Put the bone conduction hearing aid in a container with desiccant for 12 hours.
 - If the product is still not working properly, please contact your distributor or manufacturer.



Caution:

- 1) The protection class of the device is IP32. It should not be worn in heavy rain, when bathing, showering, diving, or other environments where it may be exposed to large amounts of water.
- 2) Bone conduction hearing aids may be damaged by contact with water.
- 3) To avoid damage to the inner packaging or bone conduction hearing aid, do not use household soap, rinse/soak in water, and do not wash the inner packaging in the dishwasher.
- 4) If the inner case is wet, for whatever reason, ensure that the inner case is thoroughly dried before placing the bone conduction hearing aid in the inner case.

9 Storage and transportation requirements

9.1 Storage

Daily storage: bone conduction hearing aids come with packaging boxes, which can be used for storage when the device is not in use.

Long-term storage: The device should be kept in a well-ventilated room free from corrosive gases, with a environment conditions:

Storage environmental conditions	
Temperature	0 °C~38 °C
Relative Humidity	≤80%
Atmospheric pressure	700hPa~1060hPa

9.2 Transportation

Bone conduction hearing aids should be protected from direct sunlight and rain during transportation, with a environment conditions:

Transport environmental conditions	
Temperature	-10 °C~45 °C
Relative Humidity	≤93%
Atmospheric pressure	700hPa~1060hPa

10 Troubleshooting & Maintenance

Below summarizes the most common problems you could encounter with the device. If you are unable to solve the problem with the information below, please contact Shenzhen Magnet Technology Co., Ltd:

Problem	Possible causes	Solution
The power indicator light does not illuminate.	The battery is severely undercharged.	Charge the product in OFF mode.
No sound output	The volume was too low	Adjust the left and right volume buttons “L+” or “R+”.
After the “ON” prompt sound is output, the “OFF” prompt sound is immediately output.	The battery is undercharged.	Charge the product in OFF mode.
The sound was too low	Low volume, pickup hole blocked.	Check for a blocked pickup hole and adjust the volume buttons “L+” or “R+”.
Not fully charged, the indicator light is always orange.	The external charger is of poor quality and the driver is not enough.	Please use a power adapter that complies with IEC 60601-1:2005 + A1:2012+A2:2020. The output power of the power adapter is d.c.5V, not less than 0.5A
Chirping when operating	Wearing steps are wrong	Wear it before turning on the machine
		When not in use, turn off the power first and then remove it
Chirping when in use	Wearing it on the wrong position	Adjust the position of the bone conduction microphone according to the wearing diagram (note that the position is not the entrance of the ear canal)

No prompt tone on button	The button is pressed too frequently	Press the button at least 2 seconds apart
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Users can carry out routine maintenance on battery performance. When the device is not in use for extended periods, please fully charged it before storing, and keep it in its original packaging material. Avoid prolonged exposure to direct sunlight, lint, and dust. But recharge at least once every six months.

If the product's essential performance fails (high-frequency average OFL₉₀), three possible scenarios exist: excessive volume, insufficient volume, or no sound output. Please confirm whether the product's battery level is normal (no low-voltage prompt), volume controls are functioning correctly, and the volume is not set to the minimum level. After turning off and restarting the device, if the issue still exists, charge the product fully and restart it again.

If essential performance fails and cannot be restored through the above steps—specifically, if the issue occurs once and remains unresolved—contact the manufacturer's after-sales service department for factory testing and repair.

Users are advised to verify the essential performance of the device every six to twelve months and concurrently retest bilateral hearing.

The hearing aid function and Bluetooth functionality (if applicable) of this product are safe for patient use.

Inexperienced operators may perform maintenance-related cleaning, trial fitting, or trial operation of this product. Below are descriptions of potential impacts on the product for each of these three operations.

First, inexperienced users may perform maintenance tasks such as wiping the device with a soft cloth or disinfectant cotton swabs without following the recommended instructions. All skin-contact components are made of stable silicone material and meet IP32 protection standards. Such actions will not cause unacceptable or irreversible damage to the device's basic safety or essential performance; however, please avoid immersing the device in solvents or water.

Second, inexperienced users may attempt trial wear, typically by pulling apart the headband and placing it on the head. The headband incorporates pre-shaped, memory-alloy titanium components. Even if bent or stretched, the headband automatically returns to its factory shape upon release. Such actions will not cause unacceptable or irreversible damage to the product's fundamental safety or performance.

Third, inexperienced users may attempt trial operations, typically falling into three categories:

- (1) Failing to follow the manual's steps for wearing and removal, such as powering on before wearing or powering off before removal. This only affects user experience—for example, powering on before wearing may cause sound output, impacting the wearing experience—but does not cause unacceptable or irreversible damage to the product's fundamental safety or performance.
- (2) Incorrect placement, such as positioning the bone conduction transducer at the ear canal opening instead of the location shown in Figure 3 on page 10. This only affects user experience — e.g., minor whistling due to sound leakage from the transducer — and improves when properly positioned. It does not cause unacceptable or irreversible damage to the product's fundamental safety or performance.

- (3) After wearing the device, adjust the gain using the volume buttons. Regardless of whether the product is powered on or off, the power switch and volume up/down buttons can be freely operated. This allows restoring the user's volume settings and does not cause unacceptable or irreversible effects on the product's basic safety or essential performance.

11 Disposal



Since this product is a medical device, it cannot be treated as general household waste when its service life ends. It should be disposed of in accordance with the laws and regulations of the region. Inexperienced responsible parties must contact their local authorities to decide on the proper disposal of discarded potentially biohazardous components and accessories.

12 Cybersecurity and Interoperability Instructions

12.1 Cybersecurity Information

1) Product Description and Recommended Controls

a. Applicable Environment:

This device is primarily used in hospitals, clinics, and home environments, with functionality limited to transmitting audio data and updating device configurations via Bluetooth interface. Users are recommended to deploy certified antivirus software, firewalls, and security monitoring software to enhance the protection of the overall network environment.

b. Password Requirements:

The device is shipped without a default password. Pairing and connection with Bluetooth devices (such as smartphones or computers) must be performed before first use.

2) Implementation Flowchart

To facilitate user implementation of cybersecurity control measures, the product provides a risk management flowchart as follows:

- Identify potential threats
- Assess risk levels
- Implement security control measures (e.g., Bluetooth pairing, password updates, anomaly detection)
- Real-time monitoring and anomaly logging
- Regular review and update of control measures

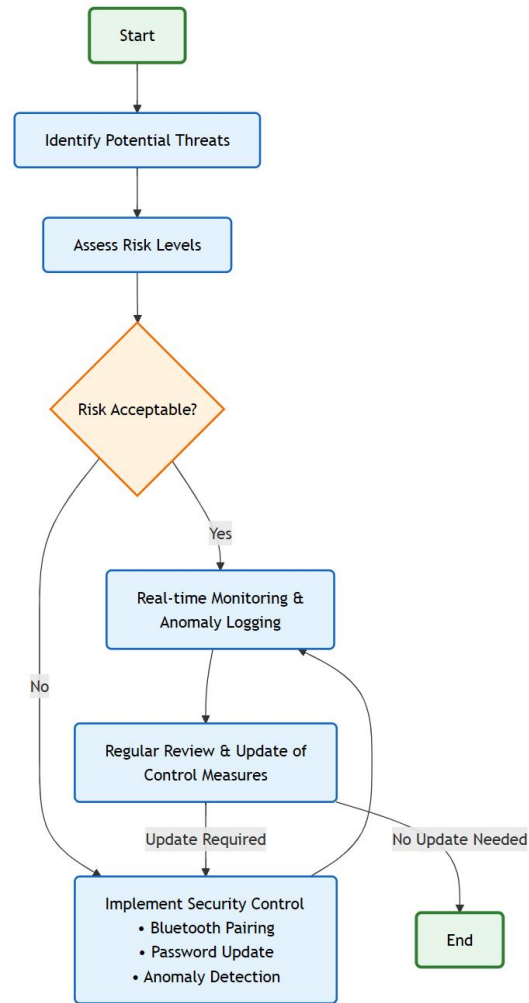


Figure: Cybersecurity Risk Management Flowchart. This diagram illustrates the iterative process for implementing and maintaining the security controls described

3) Network Ports and Interfaces List

This device only has the following data communication interface:

a. Bluetooth Interface

- Function Description: Supports bidirectional audio data transmission and device pairing
- Communication Protocol: Compliant with Bluetooth 5.3 standard
- Encryption Method: Utilizes embedded AES-256 encryption within Bluetooth protocol
- Data Transmission Rate: Up to 2Mbps
- Security Control Measures:
 - Only allows connection with paired devices; unauthorized data incoming/outgoing is automatically rejected
 - Device unique identifier authentication during pairing ensures link integrity
 - When abnormal pairing or data transmission is detected, events are automatically logged and local alarms are triggered

- 4) Supporting Infrastructure Requirements and Fault Response
 - a. Basic Requirements:
 - Mobile devices used by users must support Bluetooth 4.2 or above.
 - b. Fault Response Measures:
 - Users should disconnect current connections, check device and mobile terminal configurations, and restart the device if necessary
 - In case of cybersecurity incidents (e.g., unauthorized access or data tampering), users should isolate the device according to the predetermined emergency response procedure and contact manufacturer technical support.
- 5) SBOM (Software Bill of Materials)
 - To obtain SBOM, please contact: Email: bing@fi-stave.com
- 6) Software/Firmware Download and Update Procedures
 - User updates are not provided
- 7) Abnormal Condition Response

When the device detects abnormal conditions (e.g., illegal Bluetooth pairing attempts, abnormal data transmission, or configuration changes), it is recommended to disconnect or restart the device. If incidents persist, users should isolate the device according to the predetermined security emergency plan and report to the manufacturer and relevant regulatory authorities.
- 8) Critical Function Protection and Configuration Management

The device has a built-in backup mode that can automatically save and restore user configuration parameters when anomalies occur.

Except for the Bluetooth data transmission port, other interfaces (such as USB) remain locked by default when not in use.
- 9) Factory Security Configuration and User-Configurable Changes
 - a. Factory Security Configuration:

The device is initially configured with highest security mode (Bluetooth connections limited to authenticated devices only)
 - b. User Change Risk Warning:

The device allows users to modify partial Bluetooth pairing list
- 10) Lifecycle Management (EOL/EOS) Description
- 11) Device Support Deadline: 3 years

Device Secure Decommissioning and Disposal

 - No sensitive data
- 12) Software Update and Maintenance Operation Instructions
 - a. Update Operations:
 - Firmware updates are manual mode only and must be performed by authorized personnel trained by the manufacturer
 - After updates, the device automatically executes critical function verification (including audio response and Bluetooth stability tests)
- 13) Offline/No-Internet Operation Instructions

When cloud or internet is unavailable, the device supports core functions locally:

- Basic bone conduction hearing mode, volume adjustment, and preset modes can be executed through local control.
- All configurations and user settings are stored locally; users can manually synchronize latest configurations and patch updates after network recovery.

12.2 Interoperability Information

1) Interface Purpose and Expected Connection Requirements

This product only configures a Bluetooth interface for connecting to mobile applications (version 4.2 or higher required) to achieve device monitoring, configuration management, and firmware updates.

- Intended Users:

- Patients or home device users: Achieve basic device settings and status monitoring through the application
- Medical personnel: Understand interface fault and anomaly reporting operations

2) Interface Technical Specifications

Bluetooth interface detailed parameters:

- Protocol: Bluetooth 5.3
- Encryption Algorithm: AES-256
- Data Transmission Rate: Up to 2Mbps
- Security Measures: Only allows connection from successfully paired devices, with integrity verification and authentication for data transmission
- Logging: Detailed records of interface anomalies and connection failure events for forensics and subsequent security analysis

3) Fault Handling and Fault Tolerance Scheme

- When Bluetooth connection anomalies or error commands occur, the device automatically disconnects and enters offline mode
- After faults occur, users should refer to fault response measures in this manual, disconnect abnormal interfaces, restart the device, and contact technical support if problems persist

4) Recommended Usage and Interface Settings

- It is recommended to use the device only on trusted, non-public, non-unencrypted networks
- Users are advised to use manufacturer-certified mobile devices and ensure the mobile application is the latest version

13 EMC Statements

All types of electronic equipment may cause electromagnetic interference to other equipment through the air or the cable connected with it. The term EMC (electromagnetic compatibility) refers to the ability of a device to be unaffected by electromagnetic interference from other devices and not to affect other devices through similar electromagnetic radiation.

To fully achieve the specified EMC performance, users should follow the detailed described in the service manual to properly install the product.

The Bone Conduction Hearing Aid is suitable for home healthcare environment.



WARNING:

- Do not use the product near by active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Portable RF communications 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 RF Generators, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- RFID equipment may interfere with the device and lead to performance degradation, caution should be paid when use the device around RFID equipment.
- 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, 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.

No.	Name	Cord length(m)	Whether to block	Remark
1	Charge cable	0.8m	No	/



CAUTION: This device that is used may emit some radio frequency energy. This device may cause radio frequency interference to other medical, non-medical and radio communications' device. To effectively prevent such interference, this product conforms to the radio frequency emission limit specified in IEC60601-1-2 standard for class A of group 1. However, the company does not guarantee that there will be no interference in individual installation environments.

The hearing aid is connected to the mobile phone with Bluetooth signal, and the frequency range of transmission and reception is 2400Mhz~2480Mhz; Modulation type: GFSK, pi/4-DQPSK, 8-PSK; Bluetooth signal transmission power: less than 10mw)

13.1 Electromagnetic Emission

Guidance and Manufacturer's Declaration – Electromagnetic Emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A

Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies
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13.2 Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
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
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz	3 V 0,15 MHz – 80 MHz

	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mains voltage prior to application of the test level.		

Guidance and Manufacturer's Declaration - IMMUNITY to proximity fields from RF wireless communications equipment						
Immunity Test	IEC60601 test level					Compliance level
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)	
Radiated RF IEC61000-4-3	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1700 – 1990	GSM 1800; CDMA 1900;GSM 1900; DECT;	Pulse modulation 217 Hz	28	28
	1845					

	1970		LTE Band1,3,4,25; UMTS			
	2450	2400–2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450,LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Guidance and manufacturer's declaration –proximity magnetic fields				
Immunity Test	IEC60601 test level			Compliance level
Proximity magnetic fields IEC 61000-4-39	Test frequency	Modulation	IMMUNITY TEST LEVEL(A/m)	
	30kHz	CW	8	8
	134,2kHz	Pulse modulation 2,1 kHz	65	65
	13,56MHz	Pulse modulation 50 kHz	7,5	7,5

13.3 Test summary according to IEC TS 60601-4-2

The Bone Conduction Hearing Aid was tested according to the recommendations of IEC TS 60601-4-2:2024, Medical electrical equipment - Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

The maximum recovery time following a TRANSIENT phenomenon: 460ms

Phenomenon	Basic EMC standard	Immunity test level	Performance criteria
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	±4KV contact ±2kV,±4kV,±8kV air	Criterion B
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz to 2,7GHz 80%AM at 1kHz	Criterion A
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 1	Criterion A

RATED power frequency magnetic fields	IEC 61000-4-8	3A/m,50Hz or 60Hz	Criterion A
Electrical fast TRANSIENTS/ bursts	IEC 61000-4-4	±1kV 5kHz or 100kHz Repetition frequency	Criterion B
Surges	IEC 61000-4-5	±0,5kV, ±1kV	Criterion B
Conducted disturbancesinduced by RF fields	IEC 61000-4-6	3 V 0,15 MHz to 80 MHz 80 % AM at 1 kHz	Criterion A
Voltage dips	IEC 61000-4-11	0%UT; 0,5 cycle At 0°and 180°	Criterion B
	IEC 61000-4-11	70%UT; 25/30 cycle Single phase: at 0°	Criterion C
Voltage interruptions IEC 61000-4-11	IEC 61000-4-11	0%UT; 250/300 cycle	Criterion C
NOTE: a) Criterion A: The ME EQUIPMENT or ME SYSTEM should continue to meet the performance criteria during and after the following tests, without the need for OPERAT or intervention tore store operation. This also applies to tests for other continuous phenomena that might be applicable to the ME EQUIPMENT or ME SYSTEM. b) Criterion B: The ME EQUIPMENT or ME SYSTEM should continue to meet the performance criteria after the following tests, without the need for OPERAT or intervention to restore operation. The MANUFACTURER should specify in the instructions for use the maximum recovery time. While operation as intended during the test is desirable, some degradation is acceptable. This also applies to tests for other TRANSIENT phenomena that might be applicable to the ME EQUIPMENT or ME SYSTEM. c) Criterion C: The ME EQUIPMENT or ME SYSTEM should continue to meet the performance criteria after the following tests. OPERAT or intervention is allowed to restore operation.			

Table 1.

Test frequency MHz	Band ^{a)} MHz	Service ^{a)}	Modulation ^{b)}	IMMUNITY TEST LEVEL V/m
385	380 to 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	6
450	430 to 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	9
710	704 to 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	3
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	9
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	9
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, W LAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	9
5 240	5 100 to 5 800	W LAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	6
5 500				
5 785				
NOTE If applicable to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM can be reduced to 1 m. The 1 m test distance is specified in IEC 61000-4-3.				
^{a)} For some services, only the uplink frequencies are included.				
^{b)} The carrier should be modulated using a 50 % duty cycle square wave signal.				
^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used, because while it does not represent actual modulation, it would be worst case.				

14 FCC Declaration

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.

NOTE: “Harmful interference” is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

CAUTION: To comply with the limits of the Class B digital device, pursuant to Part 15 of the FCC Rules, this device is to comply with Class B limits. All peripherals must be shielded and grounded. Operation with non-certified peripherals or non-shielded cables may result in interference to radio or reception.

14.1 FCC RF Radiation Exposure Statement

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

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

14.2 FCC Caution

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

15 After-sales and Warranty Services

The bone conduction hearing aid (with internal power supply) is expected to have a service life of 3 years depending on the product's purpose, wear and tear, and damage. If the bone conduction hearing aid cannot produce enough vibration or the sound is highly distorted, please contact us for repair or replacement of the device.



Shenzhen Magnet Technology Co., Ltd

No.901, Building 9 of Zhongyuntai Industrial Park, Songbai Rd., Tangtou Community, Shiyan St., Bao'an Dist., Shenzhen, China

After-sales Service: Shenzhen Magnet Technology Co., Ltd

Address: No.901, Building 9 of Zhongyuntai Industrial Park, Songbai Rd., Tangtou Community, Shiyan St., Bao'an Dist., Shenzhen, China

Postal code: 518108

Tel: +86 0755-82598747

Email: bing@fi-stave.com

Annex 1 - After-sales Commitment

After-sales Commitment

1. According to the national three-guarantee policy, the warranty period is 12 months, and the warranty period is free of charge during the warranty period, and the warranty date is calculated according to the sales date indicated on the product invoice.
2. If the product fails within 7 days from the date of sale, consumers can choose to return, exchange or repair.
3. Within 15 days from the date of sale, if the product fails, consumers can choose to replace or repair it.
4. As long as the goods sold meet the warranty conditions during the warranty period, they can enjoy repair services, but the following situations are not covered by the warranty:
 - ① Product appearance;
 - ② Damage caused by wrong or improper use;
 - ③ Intentional damage;
 - ④ It has been disassembled or repaired by others;
 - ⑤ Damage caused by force majeure factors (such as lightning, fire, flood and other natural disasters);
 - ⑥ The product exceeds the warranty period;
 - ⑦ The model or number on the invoice or the three-guarantee voucher record is inconsistent with or altered with the physical product.
5. Products that exceed the warranty period will be borne by the user for material costs, repair costs and round-trip costs.
6. After-sales commitment is an important document for product assurance, please keep it properly.

Annex 2 - Warranty card

Warranty card

Dear Users,

Hello! Thank you for purchasing the products of Shenzhen Magnet Technology Co., Ltd. To better serve you, please read carefully, fill in and keep this warranty card properly after purchasing the product.

Contact person		Contact number	
Date of purchase		Contact address	
Product model		Product serial number	
Product after-sales records	Date	Causes of failure	After-sales processing
Product after-sales records			
Product after-sales records			
Product after-sales records			

Warranty Description:

If the product has quality problems and needs to be repaired, please send this warranty card and the purchased product to our after-sales maintenance office properly.

Precaution:

1. From the date you purchase this product, if you use it according to the instruction manual, if there is a non-human quality problem within one year, our company will provide free maintenance. If maintenance is required after one year, our company needs to charge maintenance cost and material cost.
2. During the warranty period, the company will charge maintenance costs and material costs for maintenance of quality problems caused by non-product quality reasons, such as improper use, improper storage, crushing and smashing, unauthorized dismantling of the machine, etc.
3. Please present the original warranty card and valid invoice when warranty.
4. The warranty period of this product is one year.