

Patient Instructions for Use (IFU)
& Information Guide
For the SoundBite® Hearing System
by Sonitus Medical

Welcome

Congratulations on your choice of the SoundBite® Hearing System from Sonitus Medical. You are now ready to use Sonitus Medical's highly advanced bone conduction sound processor, featuring sophisticated signal processing and wireless technology.

This manual provides comprehensive tips and advice on the best way to use and care for your SoundBite® device. By reading this manual and then keeping it handy for future reference, you will ensure that you get the most benefit out of your SoundBite® device.

Manual of SoundBite® Hearing System G4 Table of Contents

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1. Indications for Use

The SoundBite Hearing System is a non-surgical and removable bone conduction hearing device designed to transmit sound through the teeth.

1.1 Intended use of product

The SoundBite Hearing System is intended for patients 18 years and older with the following indications:

- Patients with moderately severe, severe, or profound sensorineural hearing loss in one ear and normal hearing in the other ear (i.e. single sided deafness or "SSD"). Normal hearing is defined as a pure tone average (PTA) air-conduction (AC) hearing threshold (measured at 0.5, 1, 2, and 4 kHz) of better than or equal to 25 dBHL.
- Patients with conductive hearing loss where the pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 4 kHz) is better than or equal to 25 dB HL.

Additionally, use of SoundBite is intended for patients with:

- At least two contiguous molar or premolar teeth with no untreated tooth decay. Patients with tooth decay present are to first have restorations before being fitted for SoundBite;
- Healthy attachment to those teeth with tooth pockets limited to no more than 5mm;
- No mobile teeth;
- Bone loss no greater than a 34% average on the mesial and distal sides of the tooth as measured on X-ray on the teeth on which the device will be worn.

Note

The Physician must review the patient IFU with the patient as part of the fitting process.

1.2 Contraindications

- The SoundBite® Hearing System and all portions of it are contraindicated for use in an MRI Environment and should be removed prior to MRI exposure.
- The SoundBite® Hearing System is not to be used in patients with known hypersensitivity to any of the components including allergies to polymers.
- The SoundBite® Hearing System is contraindicated for vulnerable populations that are unable to use their hands such as paraplegics or others that are unable to comply with the warnings in the product's labeling.

1.3 Product composition

The SoundBite® Hearing System mainly consists of a behind-the-ear device (BTE), an In-the-mouth unit (ITM) and a charging system.

Behind-the-ear (BTE) Microphone unit

The BTE unit is worn on the ear that has the most hearing loss. A small tube connects the BTE unit to a microphone that is attached to a flexible ear dome and positioned in your ear canal. The BTE unit contains a signal processor that processes sound and transmits the signal wirelessly to your In-the-Mouth (ITM) device. It is removable and rechargeable when docked in the Charger.

When fully charged, the BTE unit has an average of 10 hours of operational battery life.

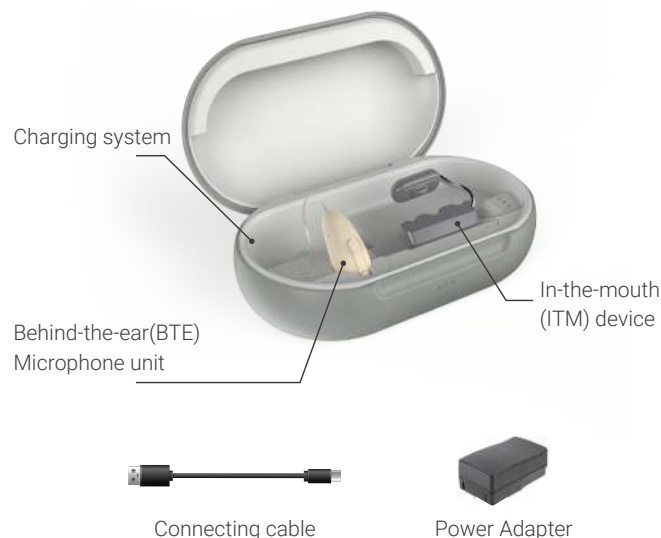
In-the-mouth (ITM) device

The ITM device is individually made and worn on your upper molars on one side of your mouth. The ITM device receives the wireless signal from the BTE unit, and converts the sound signals into tiny vibrations that are sent via your teeth, to your skull, and ultimately to your working inner ear. It is removable and rechargeable when docked in the Charger.

When fully charged, each ITM device has an average of 8 hours of operational battery life.

Charging system

The G4 SoundBite® Hearing System is with charging system. The accessories include power adapter and connecting cable, which can charge both ITM and BTE, and can be fully charged within 4 hours.



Warning

Use only the system Charger and power adapter provided. Other power adapters may look similar but may cause damage to your SoundBite® device

2. Operation instructions

2.1 Charging batteries

1. Connect the power adapter, cable and charger case, and switch on the power supply.
2. (As shown in the right), the LED indicator on the outside of case is flashing, which indicates power on.
3. Ensure that BTE and ITM dry.
4. Snap BTE and ITM into the slot of charging dock respectively (as shown in the right figure).
5. When the indicator light corresponding to the light flash, it indicates that the device is charging; when the corresponding three lights is on, it indicates that the charging of device is completed.
6. After the power is exhausted, it can be fully charged within 4 hours.
7. If the light is not on, make sure that the device is placed correctly in the charging dock.



Visual indicators (all light flashes are white)

Light	One light flash ○	The second light flash ●○	The third light flash ●●○	Three lights on ●●●	All three lights flash ○○○
Charger battery LED indicator	Low Battery Less than 30%	Battery Less than 60%	Battery Less than 90%	100% fully charged	Charger failure
ITM dock LED indicator					ITM failure
BTE dock LED indicator					BTE failure

i Attention

- Illustrations shown here demonstrate proper orientation of ITM and BTE
- Each device will snap into place.
- If lights do not illuminate, please ensure that devices are fully seated in dock
- Be sure that the ITM is dry before placing it in the Charger. Do not insert a wet ITM, wet finger, or any other wet instrument into the charger dock.

2.2 Use of BTE and ITM

1. Once the ITM and BTE are fully charged (three indicator lights are on), remove them one at a time from the Charger.
2. Snap the ITM device on upper back teeth in the correct orientation for a snug fit.
3. Place the BTE unit on impaired ear as shown, with the BTE unit resting comfortably behind your ear and the dome just inside the ear canal.
4. Both BTE and ITM shall be comfortable to wear. If you feel uncomfortable, please re-wear or consult a hearing care professional.
5. The ITM device and BTE unit will link automatically when you put them on and immediately begin to transmit sound. The ITM and BTE remain on until the batteries are exhausted or they are placed in the charger.
6. Your SoundBite device can be fitted with up to four programs suitable for different listening environments.

Note

You can also change program and adjust the volume directly from Smart phone APP, for full compatibility details and more information visit www.sonitus.com.

Beeps (the beeps are only audible to the ITM)

Function on the device	Audible indicator	What it means
Short press the top/bottom of the volume button	● 1 beep	Volume level increased/ decreased by one step;
Short press the top/bottom of the volume button	None reaction	Volume limit reached;
Press and hold top/ bottom of the volume button for more than 3 seconds to change the program once	●●●● 1-4 beeps	Change program. Number of beeps indicates the number of the current program. 
No press any button	●●● 3 sequential beeps	Low battery warning

Attention

- If BTE and ITM are placed in a distance within 23 cm, the connection will be established. It may give whistling.
- When BTE or ITM is inserted into the slot of charging dock, it will enter the standby state for power saving (stop whistling).
- Do not wear ITM when going to sleep.

2.3 System reset

When the BTE unit or ITM device is reinserted into its Charger dock, the device will reset itself after 10 seconds. This reset feature may be useful if the link between ITM and BTE is unexpectedly lost or should any unusual sounds or other conditions appear.

Note

System reset can be realized regardless of external power connected or not.

This method can be used to reset the device in case of disconnection, abnormal sound and other conditions during use.

2.4 Low battery indicator

When the BTE unit or ITM device battery is low, you will hear three sequential beeps that indicate you need to charge your device.

Note

To maximize battery life, place the ITM and BTE devices correctly into their charger docks when they are not in use.

2.6 Eating While Wearing Your In- The-Mouth (ITM) Device

So that you may fully participate in social situations, the ITM device is designed so that it may be worn at your discretion while eating. For safety, the device is designed to be large enough to prevent accidental swallowing. Nonetheless, extra caution should be taken to avoid swallowing the ITM. Be sure to rinse the ITM device after each meal. Prior to eating with the ITM device in your mouth you should carefully read the General Warnings and Precautions section of this manual.

2.7 Signal interference

The SoundBite® Hearing System contains a wireless radio link that allows the BTE unit to transmit audio picked up from the impaired ear and transmit it to the ITM device. The low power wireless technology is designed to allow an operating range within the proximity of the head.

As with any wireless system, SoundBite® may be susceptible to interference from other common radio frequency (RF) devices, such as hand-held computer devices or mobile phones. Consult the Warnings and Precautions sections for more information. If the system encounters RF interference, the wireless link between the BTE and ITM may be affected, resulting in no audio output. The link will be reestablished automatically once the interference is removed and audio will resume. If the system does not recover, you may need to perform a System Reset before putting the devices back on.

The system has been tested and complies with all applicable wireless and safety standards and has been tested for interference with

typical RF devices. Consult the Technical Description for more detail regarding the wireless technology, testing performed on the system, compliance statements and additional electromagnetic guidance.

2.8 Waste disposal

Discards concerning this product, such as metals, electronic components and non-degradable substances, as well as the product end of life, would pose risks to the environment and health if not disposed properly. Please dispose in accordance with the local regulations.

3. Cleaning and Daily Care

Make sure that your SoundBite® Hearing System is properly maintained on a daily basis.

3.1 Cleaning your ITM Device

- Rinse the ITM thoroughly after each meal;
- Clean the ITM daily within 24 hours of removal;
- Soak the ITM in warm water (enough to cover the device) and antibacterial denture cleaner (e.g. Efferdent® Antibacterial Denture Cleanser) for at least 15 minutes, Do not soak ITM in denture cleaner overnight;
- Brush for at least 1 minute to remove food particles using a soft bristle toothbrush and warm water;
- Rinse the device with warm water;
- Dry with a clean, soft lint-free cloth;
- Be careful not to drop the ITM to avoid damage;

Note

- Do not clean the ITM with denture cleaner more than once per day;
- Do not use mouthwash or alcohol-containing detergent to clean ITM;
- Do not wash ITM in dishwasher, microwave oven or boiling water;
- Do not use oral irrigator or dental ultrasonic equipment to clean ITM;
- Do not take drugs orally when wearing ITM;

3.2 Cleaning your BTE unit

- Clean BTE and its components daily;
- Wipe BTE, microphone and earplug with a soft and damp cloth;
- Inspect the microphone and dome for earwax, and if earwax is found, clean with wax loop or pipe cleaner;

Note

- Remove the BTE before applying hair products to avoid staining or soiling the BTE
- Do not rinse the BTE underwater as this may damage the device
- Microphone tubes and domes may be replaced when they become stiff, brittle or discolored. To replace a dome, peel it gently from around the microphone barrel
- DO NOT pull excessively on the microphone tube
- If the dome comes off in your ear and you are unable to remove it safely, contact your treatment provider immediately.

3.3 Cleaning your Charger

- Wipe the exterior Charger surfaces with a damp cloth as necessary
- Remove the ITM charging dock tray (ITM tray) by pinching the finger rests and lifting up as shown
- Clean the ITM tray daily with antibacterial denture cleaner

3.4 Cleaning the ITM tray

- Clean following the directions on the denture cleaner label
- Brush for 1 minute to remove food particles using a soft bristle toothbrush and water.
- Ensure brush reaches corners of charger tray including gold metallic contacts
- After cleaning, rinse the tray under running water
- Dry with a clean lint-free cloth after cleaning
- Do not soak ITM tray in denture cleaner overnight
- Do not clean with denture cleaner more than once per day

- i** Be sure that the Charger is unplugged before cleaning. Be sure that the Charger docks are dry before plugging the Charger back into the wall.



4. Troubleshooting

If the problem persists, please contact the customer service center of Sonitus Medical or your hearing health expert.

Problem	Measure
No sound	1. Plug ITM and BTE into the charging dock for 10 seconds to reset the system. Then take out and bring them closer together to establish a connection, and you will hear a whistling. 2. If the whistling is not heard and the connection is not established, plug ITM and BTE into the charging dock for 20 minutes and repeat the step "1". 3. Make sure there is no gap at the connection between BTE and microphone, and the transparent connecting tube is not damaged.
Sound output is too low, or clicking or humming is heard	1. Inspect the transparent connector between your BTE and the microphone tube. If you see damage, contact Sonitus Medical Customer Service for a replacement microphone. 2. Inspect the end of the BTE microphone tube where the ear dome is attached to confirm that the open slots are unobstructed. If earwax is found, clean with wax loop or pipe cleaner.
Short working time of ITM or BTE	1. Before wearing them, ensure that ITM and BTE devices are fully charged by leaving them in the charger until the indicator three lights all illuminated. 2. If you carry your devices during the day for later use, we recommend that you place correctly them in the charger slots, which will power down the devices and preserve battery life. 3. The SoundBite® Hearing System battery life is dependent on the sound environment. Reducing time spent in noisy environments can slightly extend battery life.
Whistling when wearing	1. Whistling may occur in a closed environment, in a small space, or near a hard reflective surface. Adjust your position to eliminate whistling. 2. Make sure the microphone earplug is not inserted too deep into the ear canal. 3. Place ITM and BTE on the charging dock for 10 seconds to reset the system and then re-wear. If the whistling is frequent or persistent, it may require help from a hearing health expert.
ITM fit is uncomfortable	If the ITM fit is too tight or causes discomfort, you should make an appointment with your clinician for an adjustment. If you sense a sore spot in the soft tissue of your mouth from wearing the ITM, please contact your SoundBite® Partner Dentist.
Light of charging dock not on or flash	1. Check the charger power indicator light to ensure it is one light flash or three lights on when the unit is plugged in. If not, remove and reconnect Charger power adapter or try a different electrical outlet. 2. If the dock indicator lights do not illuminate or flash on and off, inspect BTE, ITM, and ITM Tray contacts for debris and ensure that the devices snap securely into the charger docks according to the instructions provided.

5. Warnings and Cautions

5.1 Warnings

1. The SoundBite® Hearing System and all portions of it are contraindicated for use in an MRI Environment and should be removed prior to an MRI exam or MRI Exposure. Keep the SoundBite® Hearing System components away from strong magnetic fields.
2. If the ITM device is swallowed, seek emergency medical care immediately. Ask the emergency professional to contact your treatment provider for information regarding the SoundBite® device.
3. Do not use alcohol or drugs while wearing the device as alcohol and drug use can affect your gagging reflex and could increase the chance that you could swallow the ITM device.
4. If your mouth or the skin in or behind your ear gets sore or irritated, please contact your treatment provider
5. Do not play sports while wearing the device because physical contact with your mouth may damage your teeth and the device attached to those teeth.
6. Be sure that the ITM device unit is dry before placing it in the charger. Do not put a wet device, wet finger, or any other wet instrument into the charger or charging dock.
7. The ITM device and BTE unit components of the SoundBite® Hearing System contain batteries that, in some rare occurrence, could malfunction in a way that may potentially cause discomfort or pain due to electrical current flow. If you notice any discomfort or pain due to electrical current, immediately remove all components of the system and contact your treatment provider and Sonitus Medical.
8. Keep all components out of the reach of children, pets, or anyone who might swallow them or otherwise be at risk of being harmed by the device. If any component is swallowed, seek emergency medical attention immediately.
9. BTE and ITM are matched and customized for individuality and not applicable to others. Otherwise, it may cause harm.
10. If ITM is bitten by force inadvertently, please stop using it and contact a hearing care professional.
11. Only the components of the matching charging system (power adapter, charging line, charging dock or pocket charger) can be used. Even other power adapters look similar, but may cause damage to the product.
12. Portable and mobile radio frequency communication equipment may affect BTE and ITM.
13. Do not cross-use with other hearing equipment. If necessary, consult a hearing health expert.
14. Do not disassemble the product. Do not place the product in an environment with temperature higher than 60ℳ. Do not place the product in an incinerator that decomposes waste by thermal energy for disposal.
15. Make sure to clean the charging dock with power off. Make sure the power adapter is dry before inserting it into the socket.

5.2 Precautions

1. Do not wear BTE when showering, bathing or swimming.
2. Do not throw BTE and ITM to avoid damage. Handle with care.
3. Keep BTE and ITM away from exposure to high temperature or long-term sunshine.
4. If you have a history of recurrent dizziness or similar symptoms when wearing the hearing system, stop wearing it and consult a hearing health expert.
5. Approaching radiation devices such as X-ray machine or computed tomography (CT) may affect the working effect temporarily. Please remove BTE and ITM.
6. Do not stay in the area of electromagnetic security system such as burglar alarm system and metal detector security system for a long time to prevent interference with the hearing system.
7. At some security checks, such as near the airport security check system, remove all parts of the hearing system and inform the security personnel if necessary.
8. Do not disassemble any parts after the product has been adapted by the hearing health expert. Any change or maintenance of the product must be conducted by the Company's designated and certified agent.
9. If any part of the product fails or is damaged, stop using it and contact a hearing health expert.
10. If you wear an ITM to eat, the following precautions are recommended:
 - Start with soft foods and chew with the side opposite to ITM as much as possible.
 - Food that is too sticky or too hard is not easy to chew.
 - Sticky food and chewing gum may cause difficult to clean ITM, and may also affect its function.
 - Most foods and drinks are not harmful to ITM. After eating, ITM should be cleaned thoroughly to ensure its normal operation and maintain oral hygiene.
11. Please use the designated cleaning products to clean, and avoid other detergents which may cause damage to ITM.
12. The Company has not claimed that the mobile phone can be used in conjunction with the SoundBite® Hearing System.
13. The multiple systems in distance less than 30cm may interfere with each other.
14. Some devices, including computers, burglary protection systems and mobile phones, may interfere with the SoundBite® Hearing System even if they meet the radiation requirements of the International Special Committee on Radio Interference (CISPR).

6. Symbolic information and explanation

	Manufacturer		Attention! Consult the attached documents		Dispose of in accordance with WEEE
	Consult the instructions		Serial number		Upper and lower temperature limits to be marked near the upper and lower horizontal lines.
	Direct Current		UDI		Humidity limits to be shown near the upper and lower transverse lines.
	Non-ionizing radiation		Alternating Current		Atmospheric pressure limit to be shown near the upper and lower transverse lines.
	BF type application part		MR unsafe		Important information on operation and product safety
	Class II equipment		Non-sterile		Keep dry
	No latex		Indoor use only		

7. Technical Description

Dimensions:

ITM 35 x 28 x 25mm (approximately)

BTE 15 x 9 x 30mm

Charger 60 x 30 x 100mm

Weight:

ITM 5g

BTE 1.5g

Charger 75g

7.1 Classification of electrical safety

Charger	CLASS II	
ITM and BTE	INTERNALLY POWERED EQUIPMENT TYPE BF	
ITM	IPX7	
BTE	IPX2	

1. By degree of safety when using flammable anesthetic gas mixed with air or oxygen or nitrous oxide: device that cannot be used when there is flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide.
2. By operation mode: uninterrupted operation.
3. By disinfection and sterilization method: subject to manufacturer's regulations.

7.2 Ambient Conditions

Working conditions:

Power supply voltage and frequency: 100-240 VAC, 50/60 Hz;

Rated input: 0.2A.

Charger and BTE: 0°C to 40°C (32 °F to 104 °F) @ 5~95% Rel. Humidity;

ITM: 10°C to 40°C (50 to 104 °F) @ up to 100% Rel. Humidity;

Atmospheric pressure: 70kPa~106 kPa.

Storage and transport conditions:

-20°C to 45°C (-4 °F to 113 °F) < 85% Rel. Humidity;

Atmospheric pressure: 61 kPa~101 kPa.

7.3 Wireless technology

- Type: Near Field Magnetic Induction (NFMI)

Operating frequency: 10.597MHz

Bandwidth of receiver: 380kHz

Modulation type: CPFSK

Channel data rate: 298 kbps

Wireless range: 25cm(10 inches)

Effective radiated power: < -10dBm

- Security

Safety features of wireless technology for SoundBite® Hearing System include: SoundBite®

Patient-specific information is not stored in BTE or ITM.

The wireless signal of SoundBite® Hearing System is only close to the user's head, so any interference to the system requires a very close distance.

Audio sent over wireless connection is all compressed by ITU G.722 code.

• RF exposure

The SoundBite® Hearing System is tested to conform to IEEE C95.1 the IEEE Safety Level Standard for Human Contact with 3 kHz ~ 300 GHz RF Electromagnetic Fields to ensure that the system will not produce unsafe radiation levels to patients.

• FCC Compliance Statement

FCC ID: 2AUH802

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by Sonitus Medical 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.

7.4 Acoustic performance

OSPL90 loudest output (dB re. 1 uN): max. < 135dB,
System frequency response range (Hz): 1200Hz-8200Hz,
Total harmonic distortion + Noise (dB)

1000Hz (≤)	1500Hz (≤)	4000Hz (≤)	6000Hz (≤)
-20dB	-15dB	-15dB	-15dB

Equivalent input noise (dB re. 1 uN) (≤): 32 dB.

7.5 External power supply

External equipment connected to this product must meet IEC60601 or equivalent safety standards if mains power is used.

7.6 IP classification description

classification	Brief description	Definition
IPX0	Non-protected	—
IPX2	When the vertical planes of the ear-back machine are inclined at 15 degrees, the vertical drip should have no harmful effect.	Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical.
IPX7	Strong spraying of water in all directions has no harmful effect to ITM.	Ingress of water in quantities causing harmful effects shall not be possible when the enclosure is temporarily immersed in water under standardized conditions of pressure and time.

8. Warranty

This product has been reasonably controlled in the design and manufacturing process. Under normal wearing conditions, BTE and ITM have a warranty period up to 2 years. In your contract, it is clear when replacement and maintenance can be carried out due to manufacturing defects.

8. EMC Compliance Statement

The SoundBite® Hearing System has passed the compliance test of electromagnetic emission.

List of all cables used in the SoundBite® Hearing System				
Cable type	Cable description	Max. cable length	Cable type	Cable model
USB Type C	USB cable, charging cable, used with pocket charger	1m	Various	Various
 Warning: Use of accessories, sensors and cables other than those specified by our Company may result in increased electromagnetic radiation or decreased electromagnetic radiation immunity of the product.				

Guidance and Manufacturer's Statement - Electromagnetic Emission		
The SoundBite® Hearing System is expected to be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in this electromagnetic environment:		
Launching test	Compliance Level	Electromagnetic Environment - Guidelines
RF emissions CISPR 11	Group 1	The SoundBite® Hearing System only uses radio frequency energy for its internal function. Therefore, RF radiation is very low and will not cause interference to nearby electronic equipment. The SoundBite® Hearing System is suitable for all places, including family houses and buildings directly connected to the public low-voltage power supply network for civil buildings.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Compliant	

Guidelines and Manufacturer's Statement - Electromagnetic Immunity

The SoundBite® Hearing System is expected to be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in this electromagnetic environment:

Immunity test	Basic EMC standard or test method	Home healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80%AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances".
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m; 50 Hz or 60Hz
Electric fast transients bursts	IEC 61000-4-4	±2kV 100kHz repetition frequency
Surges	IEC 61000-4-5	Line to line: ±0.5kV, ±1kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V in 0.15 MHz - 80 MHz 6 V in ISM and/or amateur radio bands between 0.15 MHz and 80 MHz
Voltage dips	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 sine phase at 0°
Voltage interruptions	IEC 61000-4-11	0% UT: 250/300 cycle

U_T: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz

Recommended separation distances between portable and mobile RF communications equipment and this device

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This SoundBite® Hearing System has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this SoundBite® Hearing System as recommended below.

Test frequency(MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460 RFS 460	FM ±5 kHz Deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE B	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

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

Note 1: At frequency points of 80 MHz and 800 MHz, the formula of higher frequency band is used.

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



Warning: SoundBite® Hearing System may not be used close to or superimposed on other devices. If it must be close to or superimposed in use, it shall be observed and verified that it can operate normally under the configuration applied.

10. Parts List

Part name	Number	
In-the-Mouth "ITM" hearing device	1	Standard
Behind the ear "BTE" microphone unit	1	Standard
Charger	1	Standard
Power Adapter	1	Standard
Cable	1	Standard
Instructions	1	Standard
Warranty card (include certificate of quality)	1	Standard

Manufacturer: Sonitus Medical (Shanghai) Co., Ltd.

Address: Room 501, No. 11, Lane 500, Furonghua Rd., Pudong New Area, Shanghai, China

Tel: (86) 021-60879088 Zip: 201318

Date of Production: See product package

Service life: 5 years

Preparation date of manual: Feb of 2023

Revision: 01

This Manual only lists general information. If you have any questions and/or demand about this Manual, please contact your hearing care professional or customer service of Sonitus Medical.

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