

Patient Instructions for Use (IFU) & Information Guide

For the SoundBite™ Hearing System by Sonitus Medical

MP-11-0002 Rev 1.doc

Nov 7, 2010

User Assistance information

For information regarding the proper use of the SoundBite Hearing System, contact the prescribing physician.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

SoundBite Hearing System Components:

1. SoundBite[™] In-the-Mouth “ITM” hearing devices (2)
2. Behind the Ear “BTE” microphone unit (1)
3. Carrying Cases (2: One for the ITMs and one for the BTE)
4. System Charger (2)



Warnings



Keep the SoundBite Hearing system components away from strong magnetic fields. The ITM and BTE must be removed prior to undergoing an MRI exam.



If the ITM is swallowed, seek emergency assistance immediately and ask the emergency professional to contact your treatment provider for information regarding the SoundBite ITM device.



Do not consume alcohol while wearing the device or wear the device while under the influence of alcohol or drugs, as it could decrease your normal gagging reflex and increase the possibility of swallowing the ITM device.



If you experience persistent soreness or inflammation in your mouth or behind/in your ear please contact your treatment provider.



Under certain conditions, the SoundBite ITM and BTE units may heat up to a temperature of 44.1°C. If the units become unusually warm while wearing them, you should remove them immediately, discontinue use and contact your treatment provider.



Do not play sports while wearing the device as athletic or physical contact may damage your teeth.



Assure that the ITM is dry before placing it in the charger.



All components should be kept 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 attention from a medical provider immediately.



Do not allow others to wear or use either component to avoid damage to your device and potential harm to others.



The SoundBite system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.



Portable and mobile RF (radio frequency) communications equipment may affect the performance of your BTE (behind-the-ear) and ITM (in-the-mouth) devices.



The SoundBite system should not be used adjacent to or stacked with other equipment. If adjacent or stacked used is necessary, the SoundBite System should be observed to verify normal operation in the configuration in which it will be used.



Do not disassemble the BTE or ITM, expose to heat above 140°F (60°C) or dispose of by incineration.

Precautions

- Protect the BTE microphone unit from excessive moisture as this may damage the device. Remove the unit before showering, bathing, or swimming.
- Dropping risk of damage – do not drop the device as this may cause damage. Take care to properly handle the device, as incorrect handling or dropping the device(s) may cause malfunction and/or permanent damage to the components.
- Protect the devices from excessive heat as this may cause damage; do not leave near windows or in a car.
- If you have a history of recurrent dizziness and these symptoms are present while wearing the device, you should discontinue use of the device and consult with your treating physician.
- Although it will most likely not cause damage to the device, X-Ray type radiation including CT scans or airport security terminals may temporarily cause the device to improperly perform. It is recommended that all components are removed prior to any such scanning procedure.
- Modifications or changes to all components are not allowed by any party other than those appointed and approved by Sonitus Medical, Inc.
- If any component of your system fails to operate or if it is damaged, contact your treatment provider.
- The following precautions should be noted if the ITM is worn while eating:
 - Start slowly by eating softer foods. Consider chewing on the opposite side of your mouth from where the ITM device is placed.
 - Some foods may be difficult to eat because they are too sticky or hard to chew while wearing your device.
 - Certain sticky foods and chewing gum may adversely affect the ability to clean the ITM device and its function.
 - Food and beverages will not harm the device. But be sure to clean it thoroughly after each time you eat for optimal performance and to maintain oral hygiene.
- Use only the battery charger and AC wall adapter provided. Other chargers may look similar but may cause damage to your SoundBite device.
- Never use household cleaning products such as detergents, bleach, etc. to clean your devices as these agents may cause damage to the device

User's Manual for the SoundBite Hearing System

System Description

The SoundBite Hearing System is a non-surgical and removable bone conduction hearing device designed to imperceptibly transmit sound via the teeth. The SoundBite system consists of:


- A small BTE (behind the ear) microphone unit worn on the poorer ear
- Two (2) easy to insert and remove ITM (in the mouth) hearing devices
- A system charger provided to recharge the batteries in the BTE and ITM. The system charger consists of a standard power outlet AC wall adapter that has docks to simultaneously recharge two ITM hearing devices and the BTE microphone unit.

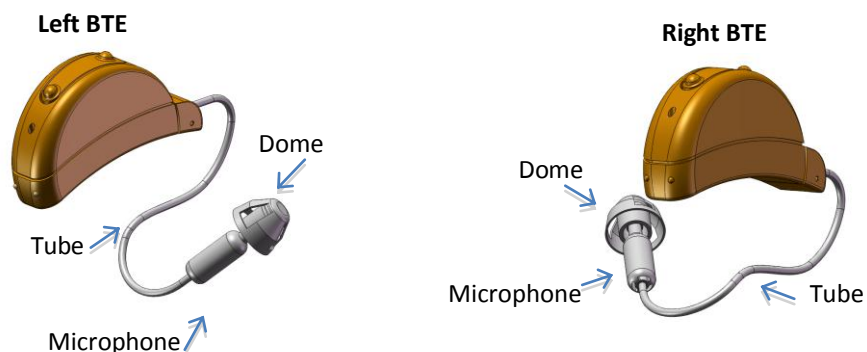
BTE (Behind the Ear) Microphone Unit

The BTE microphone unit is pictured below. It has an open fit dome containing the primary microphone, which is placed in the canal of the poorer ear. The dome is connected to the BTE by a discreet translucent tube. This design allows the patient to take advantage of the natural acoustic benefits provided by shape of his or her own ear.

The BTE uses a digital signal processor to process the sound and a wireless chip to transmit the signals to the hearing device worn in the mouth.

The BTE device is designed to be used on the poorer ear which can be either the left or right ear of the patient. The microphone assembly comes in 8 configurations, 4 sizes for each side. The microphone assembly snaps onto the top of the BTE housing and is secured in place by a pin, which can be inserted with a standard tool.

 Do not disassemble the BTE, expose to heat above 140°F (60°C) or dispose of by incineration.



SoundBite ITM (In the Mouth) Hearing Device

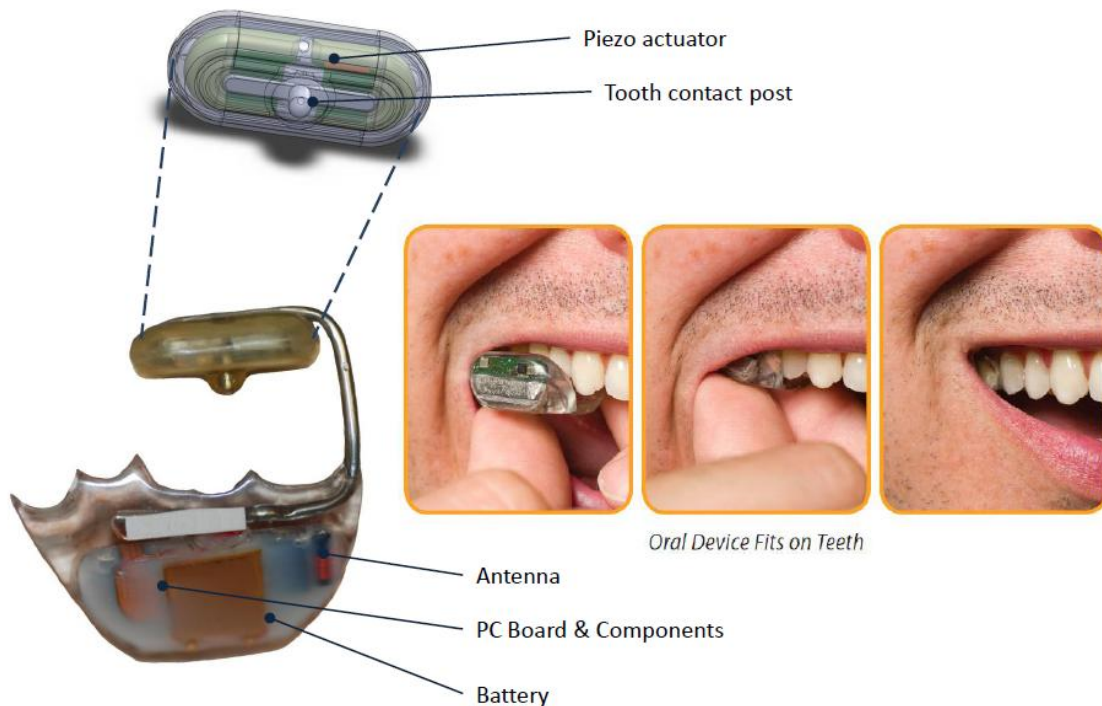
The ITM intraoral device (pictured below) is custom made to fit around two of either the upper left or right molars (back teeth). It does not require any modifications to the teeth, and is easily inserted and removed by the wearer.

The ITM contains the electronics including circuit boards, a sealed, flat, rechargeable battery, a wireless chip that picks up sound transmissions from the BTE, and a small vibrating component (called a piezoelectric actuator) that converts those signals into imperceptible vibrations that are sent via the teeth, through the skull bones, and ultimately to the cochleae. All of these miniaturized components are hermetically sealed inside a dental grade acrylic that has been safely used in dental applications for many years.

The ITM is designed with a rechargeable battery that is recharged through direct contact charging with the two round gold contacts. Both sides of the device are mounted on a bent stainless steel wire which acts as a spring clip applying the necessary retentive force to hold the device to the teeth.



Do not disassemble the ITM, expose to heat above 140°F (60°C) or dispose of by incineration.



System Charger

The system charger consists of a standard power outlet AC wall adaptor, 2 docks for the ITM devices, and 1 dock for the BTE unit to recharge. It is designed to deliver direct contact charging to all components through their gold contacts.

The charger has 4 LEDs: one for the power source cable that lights up green when plugged in; and one for each of the 3 component charging docks that lights up orange when charging and green when the charge is complete.

The ITM hearing devices each have a 6 to 8 hour operational battery life when fully charged. The BTE microphone unit has a 9 to 11 hour operational life when fully charged. It takes approximately 2½ hours to recharge the components from a completely depleted state.



Assure that the ITM is dry before placing it in the charger.

CAUTION

Use only the battery charger and AC wall adapter provided. Other chargers may look similar but may cause damage to your SoundBite device.

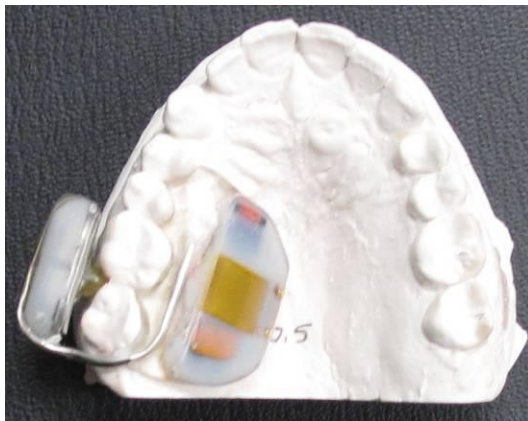
System Charger



How to use the SoundBite Hearing System

Place the BTE microphone unit on your impaired ear as instructed by your hearing professional.

- Snap the ITM hearing device onto the upper back teeth as instructed by your hearing/dental professional so that it remains snugly in place. The ITM device is custom designed to your teeth for optimal comfort and sound transmission. If the device is uncomfortable, it is likely not seated properly for optimal performance.
 - Be sure it's on the correct side of your mouth with the wire behind your farthest back tooth.
 - The smaller side of the device should be in contact with the outside of your teeth (the side of your teeth that contacts your cheek).
 - If the ITM device is loose, rocking, or easily dislodged with your tongue it is not seated properly.



ITM worn **CORRECTLY** on Upper teeth



ITM worn **INCORRECTLY** on Upper teeth

- When the ITM device is brought close enough to the BTE – within about 8 inches, the BTE and ITM units will automatically link and the hearing system will begin to transmit sound. If the two components go outside of that range, the system will stop working until the two components are brought back within range.
 - **NOTE:** Whenever you switch from one ITM device to the other, the system will need to be reset by placing the BTE unit back in the charger for 10 seconds. This reset will allow the BTE unit to link with the other ITM device.
- When undocking the SoundBite system from the charger the wireless link is initialized and active, and it will remain active until the SoundBite system is docked in the charger, powered down using the power saver caps, or the BTE runs out of battery power.
- The system is designed to be worn during waking hours only, including while eating and drinking.

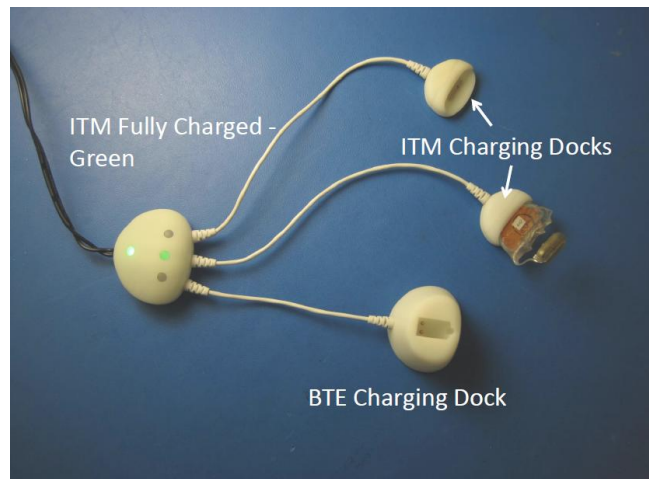
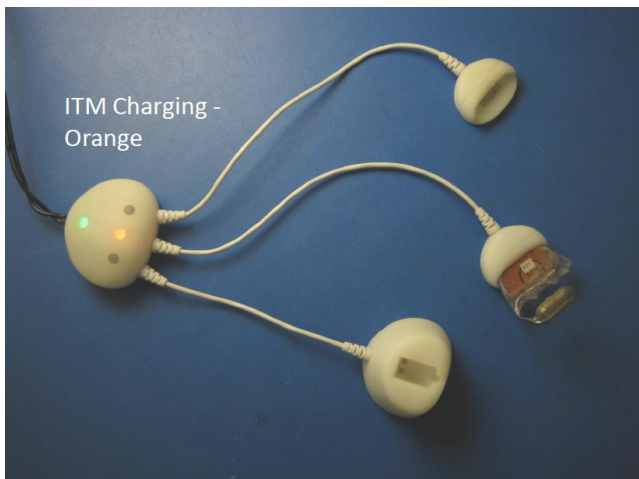
Battery Life and Recharging

- When fully charged, one ITM device is designed to work normally for at least 6 to 8 hours and the BTE for approximately 9 to 11 hours depending on the level of noise in your environment (louder environments shorten the battery life).
- When one or the other components becomes low on power, one time only you will hear an indicator tone or “ding” similar to a door bell. This tone indicates that at least one of the components is low in power and requires recharging. If this tone is ignored, shortly afterward a continuous “shush” or “ssss” or “clipping” sound will begin and continue until the power is completely depleted. If still not recharged, the system will eventually shut off.
- To recharge the system, place the components on their appropriate docks on the System Charger. There are two docks for the ITM devices and one dock for the BTE.



Assure that the ITM is dry before placing it in the charger.

- There are four lights on the charger: one that indicates the charger is plugged into a power source; one for the BTE unit; and two for the ITM devices. When each component is charging, a corresponding indicator light for that component will light up orange. When charging is complete, the indicator light will change to green, at which time the component is fully charged.
 - **NOTE:** When a component that has been completely depleted of power is placed on the charger, the indicator light will initially light up green and then turn orange after about two minutes of charging.



- Be sure to orient the ITM devices and BTE unit correctly when inserting them into their charger docks. The side of the ITM device that should be inserted into the charger dock is the side with the two gold contacts. They must be oriented correctly. If the lights do not light up, try flipping the component 180 degrees.
- To fully recharge the components from a zero charge remaining state, it will take approximately 2½ hours of continuous recharging.
- **NOTE:** The system does not have an on and off switch, so when either device is removed from the Charger, it will immediately begin using power (even when the ITM device is not in your mouth and the system is not linked).

Tips for Best Use and Troubleshooting

- **Keep one ITM device on the charger while wearing the other one:** This way you can retain the full or current charge on the ITM device not in use. This way you can wear the ITM devices in sequence.
 - For example, the first ITM device can be worn during the first several hours of the day while the second ITM device is stored on the charger. When the second ITM device is needed and removed from its charger dock to be worn, it will still have its full battery life remaining.
 - To avoid finding both of your ITM devices to be with zero power, it is recommended that the ITM device not being worn be kept on the charger in order to keep one device charged at all times.
- **System Reset** feature:
 - Each time a component is reinserted into its System Charger dock, the system is reset after about 10 seconds. This feature comes in handy to resolve any unusual conditions that may arise from time to time while wearing the device, such as:
 - Feedback or unusual noises such as hissing, buzzing, etc.
 - Suddenly losing the link between the ITM device and the BTE microphone unit
 - If you experience any unusual or unexpected sounds or issues with the link between the ITM device and BTE unit, it is recommended to employ the System Reset feature by putting the ITM device and the BTE unit back on the charger and waiting 10 seconds.



Assure that the ITM is dry before placing it in the charger.

- **Use of the SoundBite Hearing System in Noise** – When using the device in noisy environments you may find that you need to orient yourself differently to optimize sound delivery. A typical orienting strategy such as positioning the better ear to the speech and the poorer ear to the noise may actually be less effective than facing the speech source so that the noise comes from the side of the normal ear. The latter strategy takes advantage of the head shadow effect which decreases the level of the noise relative to the speech at the aided ear compared to the unaided ear. The signal at the aided ear is transmitted via bone conduction to the better ear. We recommend you consult with your prescribing provider on this topic.


- **Eating with your ITM hearing device on** – So that you may fully participate in social situations in which food is served, the ITM hearing device is designed so that it may be worn at your discretion while eating. For safety, the device is designed to exceed the maximum size of an object capable of being accidentally swallowed by an adult. Nonetheless, extra caution should be taken to avoid swallowing the ITM. The device is also designed to withstand crushing forces that greatly exceed the capability of an adult’s maximum bite force. Be sure to rinse the ITM after each meal. Prior to eating with the ITM hearing device in your mouth you should carefully read the **Warnings and Precautions** section of this manual.
- **Signal Interference with your Hearing System** – The SoundBite Hearing System contains a wireless radio link that allows the BTE to transmit audio picked up from the impaired ear and transmit it to the ITM device. The wireless technology used to achieve this functionality is Near Field Magnetic Induction (NFMI), which is a short-range wireless technology that in the SoundBite implementation allows for transmission of up to 12 inches. The system has been tested to and complies with IEC60601-1-2 and FCC CFR47 Part 15.209 and has been tested for interference with commonly used wireless devices.

CAUTION	Some devices, including hand-held computer devices, induction cooking appliances, retail store alarm system and mobile telephones may cause unforeseen interference with the SoundBite System.
CAUTION	SoundBite systems may interfere with each other if they are within range of approximately 2 inches or less.

Should any unusual sounds or other conditions become present, first try a system reset and then if the problem persists, recharge the components if necessary. If the problem still persists, contact your treatment provider. Refer to additional information and warnings regarding electromagnetic compatibility in the Technical Description.

Cleaning & Daily Care

Proper daily care is essential to keep all the components of your hearing system functioning properly.

	Assure that the ITM is dry before placing it in the charger.
CAUTION	Dropping risk of damage – do not drop the device as this may cause damage. Take care to properly handle the device, as incorrect handling or dropping the device(s) may cause malfunction and/or permanent damage to the components
CAUTION	Never use household cleaning products such as detergents, bleach, etc. to clean your devices as these agents may cause damage to the device

ITM Cleaning

The ITM device is to be cleaned daily using an antibacterial denture cleanser (such as Efferdent® Antibacterial Denture Cleanser) found at local pharmacies by following the directions on the label. The device is to be dried with a clean, soft tissue. If needed, food particles can be removed from the device prior to cleaning using a soft-bristle toothbrush and water.

- Avoid placing the device in a dishwasher, microwave, or in boiling water as this will damage the device. Oral irrigators, mouthwashes, and denture ultrasound devices should not be used.
- Do not take oral medications while wearing the device as some medications may coat or adhere to the device.
- Rinse the ITM after each meal.

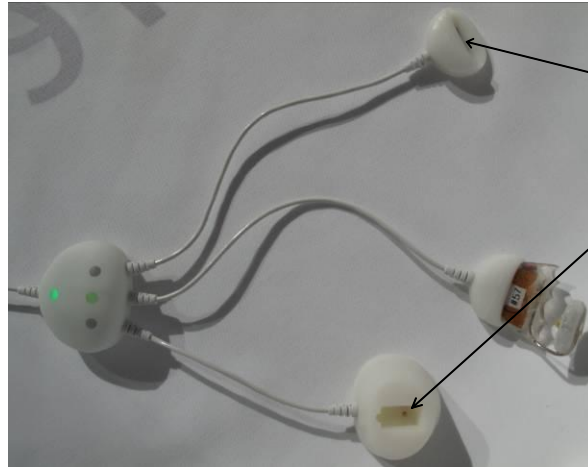
BTE Cleaning

Similar to other manufacturer's recommendations for other ear-worn devices such as hearing aids, the BTE Microphone Unit is to be cleaned daily by first carefully wiping it down with a soft damp cloth or tissue. Then inspect the portion of the hearing aid that fits down into the ear canal. If earwax is observed accumulating at the end, it is to be removed using a soft tool such as a wax loop or pipe cleaner. The portion that goes behind the ear may be washed with a mild antibacterial soap and water on a damp cloth and air dried.

- You should have the tubes and domes replaced by your hearing professional approximately every three to six months, or when they become stiff, brittle, or discolored. Clean the domes daily with a damp cloth. You should also clean the tubes periodically with a damp cloth.
- To help prevent soiling, remove the BTE prior to applying hair products such as gels, sprays, or dyes.
- Do not submerge the BTE as this may damage the unit.
- If the dome comes off in your ear and you are unable to remove it safely, contact your treatment provider immediately.

Charger Cleaning

The System Charger should be unplugged before cleaning. Clean the ITM charger docks before each use (reset or charge) by thoroughly wiping the surfaces with a cotton swab wetted with 70% isopropyl alcohol (available at local pharmacies) and allow to air dry. Be sure to get the cotton swab inside the recessed portions of the charging docks as shown below (including the electrical contact points within) of both ITM docks during cleaning.



Be sure to clean inside recessed portions of ITM charging docks including electrical contacts.

Carrying Case Cleaning

The Carrying Cases are made of plastic and can be cleaned with an antimicrobial dishwashing soap and water and/or in the top rack of a dishwasher.

Follow-up Visits with your Prescribing Physician and Dentist

It is recommended that you see your proscribing physician after the first 30-days of use to assess how you are adapting to the device and to make any device adjustments that may be necessary. It is also recommended that you see a dentist at least every six months and your proscribing physician for an audiological exam at least once per year as a user of this device.

Technical Description

Dimensions

ITM 35 x 35mm (approximately)
 BTE 16 x 8 x 31mm

Weight

ITM 3g
 BTE 7g

Power Requirements

Battery Charger Input: 100 – 240 VAC, 50-60Hz, 0.2A
 Battery Charger Output: 5.0 VDC, 0.6A



Operating Conditions

Charger and BTE: 0° to 40°C (32° to 104°F) @ 5 – 95% Rel. Humidity
 ITM: 10°C to 40°C (50° to 104°F) @ up to 100% Rel. Humidity

Storage Conditions

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

Device Classification

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

Wireless Technology

Type: NFMI (Near field magnetic induction)
 Frequency: 10.597MHz
 Modulation type: CPFSK
 Channel data rate: 298 kbps

Quality of Service:

The SoundBite hearing system continuously monitor the audio quality on the incoming audio stream from the BTE and allows for just 0.1% error in the audio output to ensure a high fidelity audio stream being delivered to the patient. Further the SoundBite hearing system ensures a constant delay between the incoming audio from the BTE and the delivered audio to the patient through the ITM.

Security:

The SoundBite system wireless technology is very secure as:

- No patient specific information is stored inside either the BTE nor the ITM
- The wireless link of the SoundBite system is merely 12 inches so any intruder to the SoundBite system is required to be in close range
- All audio send across the wireless radio link is encoded

Human Safety:

The SoundBite system has been tested to comply with IEEE C95.1 “IEEE standard for Safety Levels with respect to Human Exposure to Radio Frequency Electromagnetic fields, 3kHz 300GHz” to ensure the SoundBite system does not expose patients to unsafe levels of radiation.

FCC Compliance Statement

FCC ID: YTESM03

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.

Electromagnetic Compatibility Compliance Statement

The following accessories supplied with the SoundBite system have been tested for electromagnetic emissions compliance.


List of all cables utilized with the SoundBite system				
Cable Type	Cable Description	Maximum Cable Length	Cable Manufacturer	Cable Model Number
Charger System 2-conductor shielded cable	34 AWG 16/46 TC, 10 PVC, SH, PVC GRY	6 feet	New England Wire Technologies	N21-46T+00001-9A
 Warning: Use of accessories, transducers and cables other than those specified by Sonitus Medical, Inc. may result in increased EMISSIONS or decreased IMMUNITY of the SoundBite system.				

Guidance and manufacturer's declaration – electromagnetic emissions		
The SoundBite® system is intended for use in the electromagnetic environment specified below. The customer or user of the SoundBite system should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The SoundBite system uses 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 CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The SoundBite system is intended for use in the electromagnetic environment specified below. The customer or user of the SoundBite system should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	± 2 kV for power supply lines ± 1kV for input/output lines	± 2 kV for power supply lines N/A ^a	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 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 SoundBite System requires continued operation during power mains interruptions, it is recommended that the SoundBite System be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			
^a The SoundBite system does not contain signal and interconnecting cables greater than 3m			

Guidance and manufacturer’s declaration – electromagnetic immunity

The SoundBite system is intended for use in the electromagnetic environment specified below. The customer or user of the SoundBite system should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the SoundBite System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SoundBite system is used exceeds the applicable RF compliance level above, the SoundBite system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SoundBite system.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SoundBite System

The SoundBite system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SoundBite system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SoundBite system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.39
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warranty

Sonitus Medical, Inc. warrants that reasonable care has been taken in designing and manufacturing this product to a high quality standard. The expected life span for each ITM is 3 years. The ITMs and BTE are under Warranty for a period of 3 years during which time they are guaranteed to be replaced or repaired for manufacturing defects under normal wear conditions.

Manufacturer Contact Information

Sonitus Medical, 1825 S. Grant Street, Suite 350, San Mateo, CA 94402

Phone: (650) 838-0325 - www.sonitusmedical.com