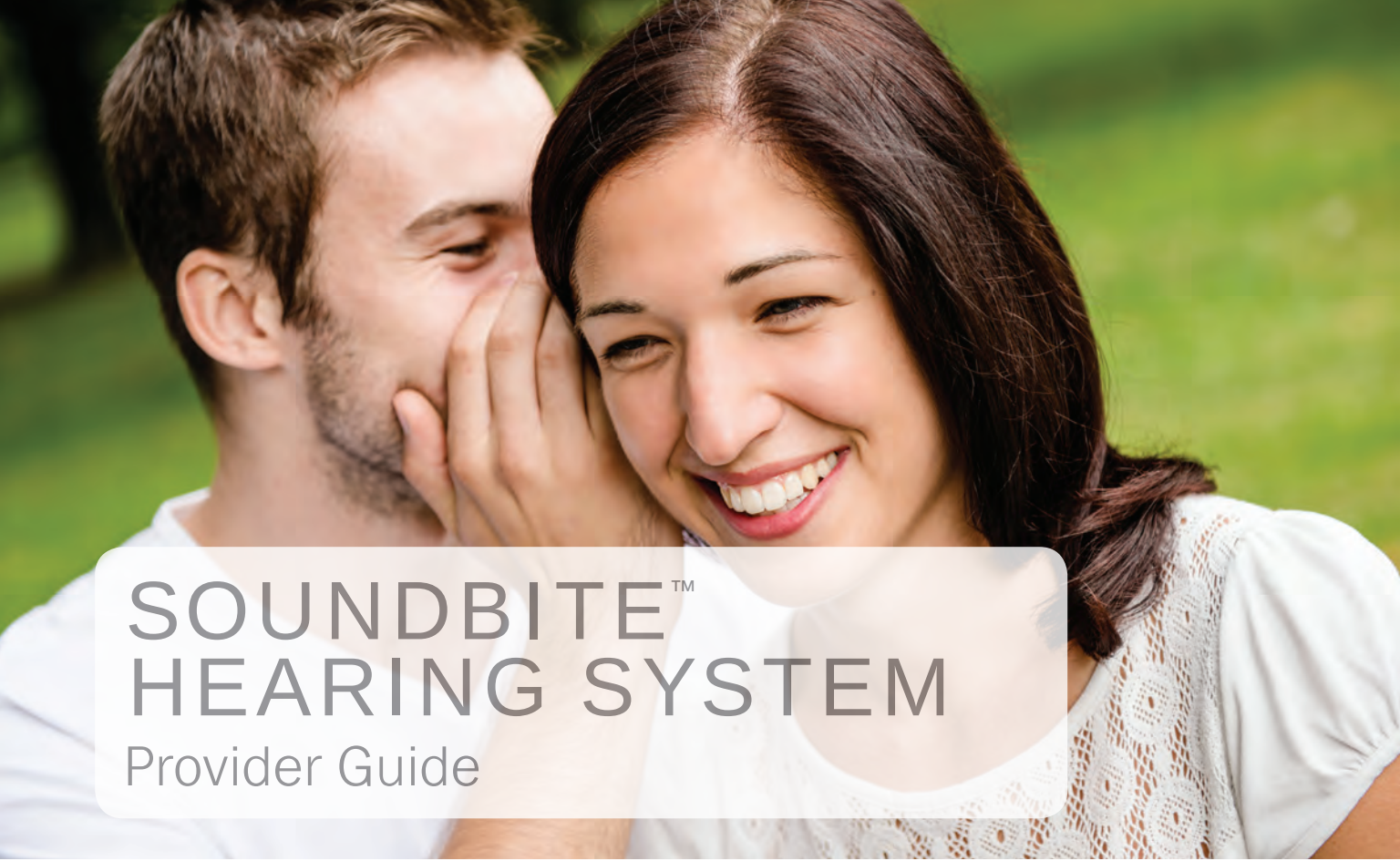

SOUNDBITE™ HEARING SYSTEM

Provider Guide

The treating clinician must review the user manual with the patient as part of the fitting process. Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed physician, or properly licensed practitioner.

SoundBite™ BY SONITUS MEDICAL

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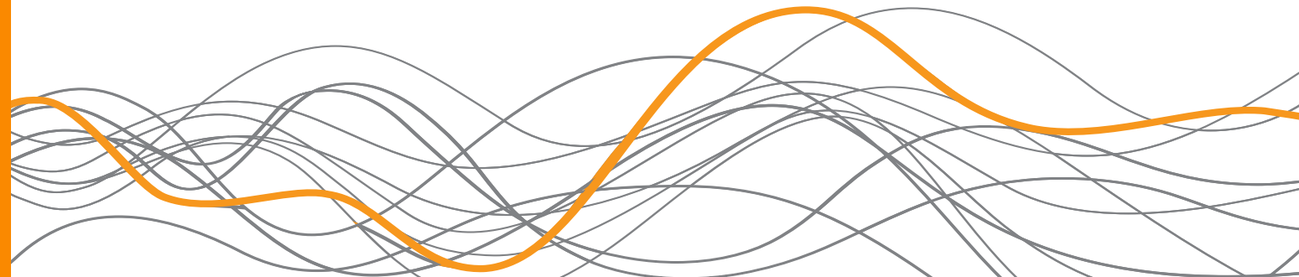
PLEASE NOTE:

Instructions for Use are updated periodically. Check www.SonitusMedical.com for the current version of this document. If an additional paper copy of this Instructions for Use is desired, please contact customer service.



INDICATIONS FOR USE

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 3 kHz) of better than or equal to 25 dB HL
- Patients with conductive hearing loss where the PTA bone conduction hearing threshold (measured at 0.5, 1, 2, and 3 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 5 mm
- 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

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 should not 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 such as paraplegics who are unable to use their hands or others who are unable to comply with the warnings in the product's labeling.

SYSTEM DESCRIPTION

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

The System consists of the following:

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 placed in the canal of the patient's ear. The microphone location takes advantage of the natural acoustic sound provided by the shape of the ear. The BTE unit processes sound and transmits the signal wirelessly to the In-the-Mouth (ITM) device. The BTE unit is removable and rechargeable when docked in the System Charger. When fully charged, the BTE unit has a minimum of 15 hours of operational life. The BTE can be carried in the small travel case provided.

In-the-Mouth (ITM) hearing device

The ITM device is individually made and placed on the patient's upper molars on one side. The ITM device receives the wireless signal from the BTE microphone unit and contains a small component that converts the signal into tiny vibrations that are sent via the patient's teeth to the skull and then to the patient's inner ear. All components are protected by a watertight seal inside a plastic housing. The ITM device is also removable and rechargeable when docked in the System Charger. When fully charged, the ITM device has an average of 12 hours of operational life. The ITM can be carried in the small travel case provided.

System Charger including power adapter

The Charger has docks to simultaneously recharge the batteries in the ITM device and BTE unit and is provided with a special AC power adapter for connection to the electrical outlet. The charger delivers direct contact charging to all components through their gold contacts. LED lights indicate connection to the power source and individual components, as well as the charge status of the components. It takes a minimum of 3.5 hours to fully recharge the ITM device and BTE unit from a completely depleted state.

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

Programming Software, Box and Cable

Each SoundBite Hearing System is custom programmed for the patient using the SoundBite programming software provided. Software can be installed onto a computer with a 32-bit or 64-bit Windows operating system, guided by prompts that will appear automatically on the screen. For programming, the BTE unit is docked in the boot of the Programming Cable attached to the Programming Box, which is plugged into the computer via its standard USB port on the other end. The SoundBite Hearing System is also compatible with programming via the HI-PRO and HI-PRO2 USB.

WARNINGS (For Users)

- 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.
- 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.
- 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.
- If your mouth or the skin in or behind your ear gets sore or irritated, please contact your treatment provider.
- 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.
- 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.
- 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.

- 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.
- Do not allow others to wear or use either component to avoid damage to your device and potential harm to others.
- If the ITM device experiences a hard bite, stop using the system and contact your treatment provider.
- Use only the system charger and power adapter provided. Other power adapters may look similar but may cause damage to your SoundBite Hearing System.
- The SoundBite Hearing System needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the Technical Description.
- Portable and mobile Radio Frequency (RF) communications equipment may affect the performance of your BTE unit and ITM device.
- The SoundBite Hearing System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the SoundBite Hearing System should be observed to verify normal operation in the configuration in which it will be used.
- Do not take the units apart; do not expose them to heat above 140°F (60°C); do not dispose of them in an incinerator that uses heat to destroy waste.
- Be sure that the Charger is unplugged before cleaning. Be sure that the Charger docks are dry before plugging Charger back into the wall.

PRECAUTIONS (For Users)

- Avoid getting the BTE microphone unit very damp, moist or wet. Remove the unit from behind the ear before showering, bathing, or swimming.
- Do not drop the device as this may cause damage. Be sure to handle the device carefully to keep it in good working order.
- Protect the devices from very high temperatures. Do not leave any system parts near windows or in a car.
- If you have a history of repeated dizziness and these symptoms occur while wearing the device, you should stop wearing it and consult with your physician.
- Remove all components of the SoundBite Hearing System before being exposed to X-ray equipment or radiation machines such as Computer Tomography (CT) scans. These special types of x-ray equipment are not likely to damage your device but may temporarily affect how well the device works. It is recommended that all components are removed prior to any such scanning procedures.
- Do not linger in areas where electromagnetic security systems such as anti-theft alarm systems (also known as electronic article surveillance [EAS]) and metal detector security systems are present and do not lean on such systems while wearing SoundBite.
- At certain security checkpoints, such as near airport security systems, remove all components of the device and alert security personnel of the device as necessary.
- Any modifications or changes to your device must be made by a party or agent appointed and approved by Sonitus Medical, Inc.

- If any component of your system fails to operate or if it is damaged, stop using the device and contact your physician.
- The following precautions should be taken if the ITM device is worn while eating:
  - Start slowly by eating softer foods. Consider chewing on the opposite side of your mouth from where the device is placed.
  - Some foods may be difficult to eat because they are too sticky or hard to chew while wearing your device.
  - Avoid eating sticky foods and chewing gum because they make it difficult to clean the ITM device and can affect its function.
  - Most food and beverages will not harm the device. But be sure to clean the device thoroughly each time after you eat to make sure the device works correctly and you maintain good oral health.
- Never use household cleaning products such as bleach to clean your devices as these agents may cause damage to the device.
- Sonitus Medical makes no claims regarding the use of cell phones with the SoundBite Hearing System.
- SoundBite Hearing Systems may interfere with each other if they are within range of approximately 12 inches or less.
- Some devices, including hand-held computer devices, retail store anti-theft systems and mobile telephones may cause interference with the SoundBite Hearing System, even if those devices comply with CISPR emission requirements.

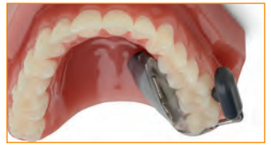
FITTING AND PROGRAMMING SOUNDBITE

Prior to your patient's appointment for fitting and programming, create a new patient record in the SoundBite programming software and gather the recommended supplies listed below.

Device Fitting	Device Programming	
1. SoundBite Hearing System (BTE Unit, ITM Device, Charger, Travel Case) **2. Optional Supplies** (gloves, mouthwash and small cups, tissues)	**Sound Field Testing:** • Calibrated Standard Audiometer • Calibrated Supraaural (TDH series) or Circumaural (Sennheiser HDA 200) Headphones	**SoundBite Programming:** • SoundBite Programming Software • Programming Box (SoundBite or HI-PRO) • SoundBite Programming Cable • External Computer

Device Fitting

ITM FIT



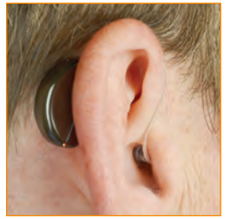
To ensure optimal sound transmission and a comfortable fit, confirm that the ITM device is properly oriented, with the small side of the device positioned on the outer (cheek side) tooth surface and the stainless steel wire positioned behind the patient's back upper molar, then snap into place.

If the ITM device is loose or uncomfortable, it may not be positioned properly or may need to be adjusted (See Instructions for Dental Professionals).

BTE FIT

Use the microphone sizing tool to select the appropriate microphone tubing size and connect the microphone to the BTE body by snapping in place. Select the appropriate size dome and connect to the microphone body.

Place the BTE microphone unit on the most impaired ear, taking care to ensure proper placement:



- The BTE unit should rest comfortably behind the patient's ear.
- The microphone tube and dome should be sized so that the tube provides a good cosmetic fit and avoids contact with the ear anatomy (e.g. tragus) to the extent possible, with the dome positioned flush with the opening of the ear canal. Unlike with hearing aids, it is not necessary to position the SoundBite microphone/dome deep within the ear canal.

Once placed in position on the patient, the BTE and ITM devices will automatically link and begin to transmit sound. In some cases, it may be necessary to bring the BTE and ITM to within 7 inches to initiate link prior to positioning on the patient.

Device Programming

The SoundBite Hearing System is programmed using proprietary software that stores settings on the BTE unit. The frequency bandwidth of the SoundBite Hearing System spans 250 Hz to 8000 Hz, controlled by settings for 8 discrete frequency bands. Programming is performed by adjusting the output of the SoundBite Hearing System in each of these frequency bands so that the patient perceives equivalent sound levels for both ears. This process accounts for any individual differences in the sound conduction pathway from the tooth to the cochlea.

Program the SoundBite Hearing System in 3 steps:

STEP 1: AIDED THRESHOLD TESTING

In this step, you will establish objectives for device programming and determine what (if any) adjustments are necessary from factory default settings. After initial device fitting, record Target Thresholds (from a recent audiogram) for the impaired ear using the Aided Threshold Testing Worksheet.

- Target Thresholds for Single-Sided Deafness patients: Use Thresholds from better ear
- Target Thresholds for Conductive Hearing Loss patients: Use Bone Threshold values of affected ear

In the sound booth, with the SoundBite BTE and ITM in position on the patient, place the audiometer headphones over the ears. Use the Hughson-Westlake method of testing to obtain Aided Threshold scores for the impaired ear. Record Aided Threshold values on the Worksheet.

STEP 2: SOUNDBITE DEVICE PROGRAMMING

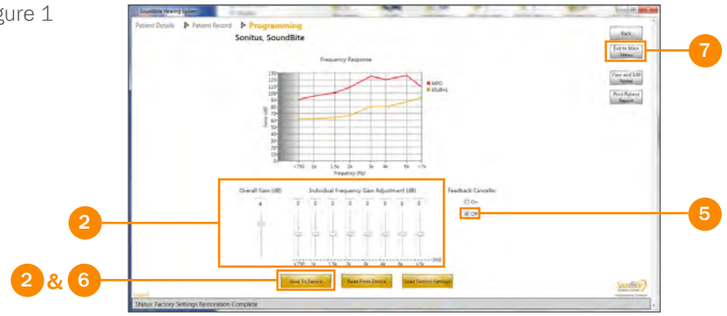
Use the Aided Threshold results to customize SoundBite Hearing System settings for optimal results.

After removing the BTE unit from the patient, dock the BTE in the boot at one end of the programming cable, with the other end connected to the programming box and computer. If Aided Threshold Testing values are not within 10dB (without being better than) the Target Thresholds, adjust the overall gain or the gain in individual frequency bands to program the device as follows:

1. Launch programming software and connect BTE unit to the programming cable. Navigate to programming page and software will link to the BTE unit.
2. Adjust and save settings: Change gain in individual frequency bands or the overall gain (across all frequencies). Click “Save to Device” to transfer desired settings to the BTE unit.
3. Check clinical results of changes: Reposition the BTE unit on your patient in the sound booth and repeat Aided Threshold Testing with the adjusted settings.

Please note: Adjustments can be completed in as small as 1-decibel increments across frequencies and the Overall Gain control can be used to add gain across the entire frequency range (Figure 1).

Figure 1



STEP 3: FINAL PROGRAMMING

Confirm final customized settings and add stable gain by activating an advanced feedback-canceling algorithm to reduce the chances of post-fitting feedback.

4. Reconnect BTE to programming boot.
5. Check the “On” box to enable Feedback Canceller. Once enabled, the system will automatically detect and make adjustments to eliminate feedback within a few seconds.
6. Click “Save to Device” to save the patient’s configuration.
7. Click ”Exit To Main Menu” and remove the BTE unit from the programming cable.

INSTRUCTIONS FOR DENTAL PROFESSIONALS

DENTAL EXAM

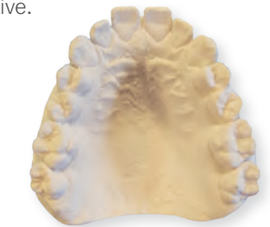
A minimum of two contiguous molar or premolar teeth are required to support the ITM device for retention, comfort and function. The ITM device is made only for the upper teeth.

SoundBite should only be worn on healthy teeth, healthy restorations and healthy gums. All dental disease should be treated prior to taking impression, and all restorations should be serviceable. X-rays within the last 6 months should be available and a dental cleaning within the past 6 months is advisable.

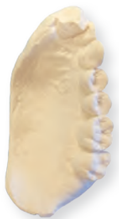
DENTAL MODEL

A full upper model is preferred. However, a quadrant model that captures the midline is also acceptable, using the COE-99 tray. Dental models poured from an alginate impression are preferred.

To return the model to Sonitus Medical, please use provided packaging material. Models should capture dentition as accurately as possible and be free of defects. Sonitus Medical will inspect each model and will request another model if one is defective.



Good Full Arch Model



Good Quadrant Model

Incomplete Quadrant Model

DEVICE ADJUSTMENT, IF NECESSARY

You must have clear sight into the mouth to evaluate fit and retention. Do not perform any adjustments if you have not been trained to do so. The ITM device is much like a retainer or partial denture and can be adjusted similarly. Please note the following:

- DO NOT do any grinding on the metal surfaces or gray surfaces
- DO NOT crimp the metal tube
- The ITM device can be tightened with three prong pliers using very light forces
- Occlusal adjusting can be performed on clear acrylic

Acrylic Section

PLEASE NOTE:

Impressions must be handled and disinfected according to the Center for Disease Control's (CDC) recommendation: Guidelines for Infection Control in Dental Health-Care Settings (2003 or latest edition). The impression should be cleaned before organic soil dries on it and before disinfecting it. Disinfect using an EPA-registered hospital disinfectant with a tuberculocidal claim, and thoroughly rinsing it after it's soaked in the disinfecting solution. Call Sonitus Medical if you have questions about recommended dental materials.

WARNING: The impression must be disinfected according to the CDC guidelines listed above before submission.

OTHER INFORMATION

CLINICAL EVIDENCE

The safety and efficacy of the SoundBite Hearing System have been established in numerous peer-reviewed publications, which are listed on www.sonitusmedical.com.

CLEANING AND CHARGING

Using the instructions provided with each SoundBite Hearing System User Guide, review cleaning and charging instructions with your patients. Remind your patients that proper daily care of the SoundBite Hearing System is essential to ensure it operates well. The ITM device is analogous to a retainer or a partial denture. It is designed for eating and for wearing during awake hours.

SIGNAL INTERFERENCE

The SoundBite Hearing System contains a wireless link that allows the BTE unit to transmit sound retrieved from the impaired ear to the ITM device. The system has been tested to applicable regulatory standards, and for interference with commonly used wireless devices. Should any unusual sounds or other conditions appear, try to reset the devices by temporarily placing in the charger and then relinking, or recharge the devices if necessary. Refer to the Technical Description for more detail.

DISPOSAL INSTRUCTIONS

The ITM and BTE contain rechargeable lithium ion batteries. Dispose of them according to local regulations.

SYMBOLS

Explanation of Symbols Used on Equipment and Accompanying Instructions

	Consult Instructions for Use		Storage and transport limits		Manufactured by
	Caution, consult accompanying documents		Keep dry		Latex free
	Magnetic Resonance (MR) Unsafe		Non-sterile		Direct current
	Contents of package/box		Dispose of in accordance with local regulations		Lot number
	Type BF applied part		Do not use if package is damaged		Serial number
	Non ionizing radiation		Alternating Current		Prescription use only
	Catalog number		CE Mark		Authorized Representative
	Class II equipment		Indoor use only		Storage and transport relative humidity limits
	Storage and transport atmospheric pressure limits				

SOUNDBITE HEARING SYSTEM TECHNICAL DESCRIPTION

POWER REQUIREMENTS

Power Supply Input: 100 – 240 VAC, 50-60Hz, 0.4A Power Supply Output: 5.0 VDC, 1A

Compatible with: Mepos UE08WCP-050100SPA; Franmar FRM06-S05-Z

DEVICE CLASSIFICATION

Battery Charger	Class II	
ITM and BTE	Internally Powered Equipment Type BF	
ITM	The ITM rated IP27 is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which is it exposed to immersion up to 1 meter.	
BTE	The BTE rated IP22 is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water	

WIRELESS TECHNOLOGY

Type: NFMI Frequency: 10.597MHz Receiver BW: 380kHz

Modulation type: CPFSK Channel data rate: 298 kbps Wireless range: 10 inches (25 cm) Effective Radiated Power: <0.1 mW

Quality of Service

The SoundBite Hearing System continuously monitors 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 Hearing System wireless technology security features include:

- No patient-specific information is stored inside the BTE or the ITM.
- The wireless link of the SoundBite Hearing System is only in proximity to the head so any intruder to the SoundBite Hearing System is required to be in close range.
- All audio transmitted across the wireless link is compressed with an ITU G.722 encoding.

RF Exposure

The SoundBite Hearing 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 to 300GHz" to ensure the SoundBite Hearing System does not expose patients to unsafe levels of radiation.

FCC Compliance Statement

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

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 Hearing System have been tested for electromagnetic emissions compliance.

List of all cables utilized with the SoundBite Hearing System				
Cable Type	**Cable Description**	**Max Cable Length**	**Cable Type**	**Cable Model Number**
2-conductor 34AWG shielded cable	BTE Programming Cable	7 feet	New England Wire Technologies	3340
USB Type A to Type B 28AWG 1P + 28AWG 2C, Shielded	Programmer USB Cable	6 feet	Various	Various
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 Hearing System.				

Guidance and manufacturer's declaration – electromagnetic emissions		
The SoundBite Hearing System is intended for use in the electromagnetic environment specified below. The customer or user of the SoundBite Hearing 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 Hearing 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	The SoundBite Hearing System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The SoundBite Hearing System is intended for use in the electromagnetic environment specified below. The customer or user of the SoundBite Hearing 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 +/- 1 kV for input/output lines	+/- 2 kV for power supply lines	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	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 battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency 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.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The SoundBite Hearing System is intended for use in the electromagnetic environment specified below. The customer or user of the SoundBite Hearing 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 Radiated RF IEC 61000-4-3	3 Vrms; 150 kHz to 80 MHz 3 V/m; 80MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SoundBite Hearing System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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). 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] Interference may occur in the vicinity of equipment marked with the following symbol:
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 Hearing System is used exceeds the applicable RF compliance level above, the SoundBite Hearing 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 Hearing 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 Hearing System

The SoundBite Hearing System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SoundBite Hearing System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SoundBite Hearing 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.

FOLLOW-UP VISITS

TREATING CLINICIAN: A 30-day appointment is recommended to assess how your patient is adapting to the device and to make device adjustments, if necessary. Once a year, an audiological exam for your patient is recommended.

TREATING DENTIST: A 6-month appointment is recommended for your patient.

OPERATING CONDITIONS

Charger and BTE: 0°C to 40°C (32°F to 104°F) @ 5-95% Rel. Humidity
ITM: 10°C to 40°C (50°F to 104°F) © up to 100% Rel. Humidity
70 kPa to 106 kPa Atmospheric Pressure

STORAGE AND TRANSPORT CONDITIONS

-20°C to 45°C (-4°F to 113°F) © <85% Rel. Humidity
61 kPa to 101 kPa Atmospheric Pressure

WARRANTY

Reasonable care has been taken in the design and manufacture of this product. Under normal wear conditions, the BTE unit and ITM device are under warranty for up to 3 years, as specified by each user's contract during which time they will be replaced or repaired for manufacturing defects.

CE 0843 EC REP

EC Representative Contact Information:
Emergo Europe, Molenstraat 15, 2513 BH
The Hague, Netherlands

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme avec Industrie Canada exempts de licence standard RSS (s) . Son fonctionnement est soumis aux deux conditions suivantes : (1) cet appareil ne peut pas provoquer d'interférences , et (2) cet appareil doit accepter toute interférence , y compris les interférences qui peuvent causer un mauvais fonctionnement de l'appareil.

CAN ICES-3 (B)/NMB-3(B)

Manufactured By:

Sonitus Medical

1900 Alameda De Las Pulgas, Suite 200
San Mateo, CA 94403 USA
Phone: 866 816 2076
Fax: 650 838 0326
www.sonitusmedical.com
www.soundbitehearing.com

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