Manual of SoundBite Hearing System G3/G3S

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1. Product Description

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 dB HL.
- 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.

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, and the portable box is optional.

Behind-the-ear (BTE) 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 14 hours of operational battery life. If desired, the BTE can be carried in the small travel case provided.

In-the-mouth (ITM) hearing 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 12 hours of operational battery life. If desired, the ITM can be carried in the small travel case provided.

Charging system
The G3/G3S Soundbite Hearing Systems are with different charging systems.
The G3 Soundbite Hearing System is with charging dock V1.0 and the G3S Soundbite Hearing System is charging dock V2.0 (pocket charger). Both sets of accessories include power adapter and connecting wire, which can charge both ITM and BTE, and can be fully charged within 5 hours.

Charging system V1.0

Charging system V2.0 (pocket charger)

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

2.1.1 Use of charging system V1.0

① Connect the power adapter, connecting wire and charging dock, and switch on the power supply.
(As shown in the right), the power indicator on the right side of charging dock is green, which indicates the power on.

② Ensure that BTE and ITM dry.

③ Snap BTE and ITM into the slot of charging dock respectively (as shown in the right figure).

- Orange light of corresponding indicator indicates charging and green for full.
- After the power is exhausted, it can be fully charged

Orange or green LED lights on

within 5 hours.

• If the light is not on, make sure that the device is fully seated in the charging dock.

2.1.2 Use charging system V2.0 (pocket charger)

① Connect the power adapter, connecting wire and pocket charger, and switch on the power supply.

(As shown in the right), the power indicator on the left side of pocket charger indicator is white, which indicates power on.

② Ensure that BTE and ITM dry.

③ Snap BTE and ITM into the slot of charging dock respectively (as shown in the right figure).

• When the indicator light corresponding to the indicator light position flicks white light and shade, it indicates that the device is charging; when the corresponding indicator light is white, it indicates that the charging of device is completed.

• After the power is exhausted, it can be fully charged within 5 hours.

• If the light is not on, make sure that the device is fully seated in the charging dock.

ⓘ 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 wetinstrument into the charger dock.

2.2 Use of BTE and ITM

① Once the ITM and BTE are fully charged (indicator lights are green), 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 health care expert.

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.

ⓘ 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 Use charging dock for the first time

Remove O-Ring and Shut-off Clip from ITM tray and discard. Place ITM tray in Charger.

2.4 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.

2.5 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.

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 depose 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

ⓘ
Do not clean the ITM with denture cleaner more than once per day.

- Do not use mouthwash or alcohol-containing detergent to clean ITM
- Please 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 wet cloth.
- Inspect the microphone and dome for earwax, and if earwax is found, clean with wax loop or pipe cleaner

ⓘ
- 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

ⓘ 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.

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 or pocket charger 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 or pocket charger 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. 4. Remove the microphone from BTE and reconnect BTE and ITM. If you hear a weak and intermittent ticking, please contact the customer service center of Sonitus Medical to replace the microphone.
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 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 lights turn green. 2. If you carry your devices during the day for later use, we recommend that you leave them in the travel case, 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 power indicator light to ensure it is green 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.

4. Warnings and Cautions

4.1 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 health expert.
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. Only HI-PRO and HI-PRO2 programming equipment provided by our Company can be used for programming.
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 60℃. 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.

4.2 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.

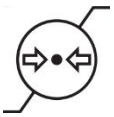
11 Please use the designated cleaning products to clean, and avoid other detergents which may cause damage to ITM.

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).

5. Symbolic information and explanation

	Manufacturer		Consult the instructions
	Attention! Consult the attached documents		Important information on operation and product safety
	Serial number		Batch code
	DC		AC
	Non-ionizing radiation		MR unsafe
	BF type application part		Class II equipment
	Indoor use only		Keep away from rain
	Upper and lower temperature limits to be marked near the upper and lower horizontal		Humidity limits to be shown near the upper and lower transverse lines.
	Atmospheric pressure limit to be shown near the upper and lower transverse lines.		This symbol indicates that the product may not be discarded as domestic waste. Please give the old or unusable products to the waste disposal station for disposal as electronic products, or to your hearing health expert for disposal. Reasonable disposal will protect the environment and health.

6. Technical Description

6.1 Classification of electrical safety

1. Classification by type of electric-shock prevention:
   a) Charging system: device powered by external power supply--Class II,
   b) ITM and BTE: device powered by internal power supply.
2. By degree of electric-shock prevention: BF type device.
3. By degree of protection against harmful liquid intake: IPX7 for ITM, IPX2 for BTE, and IPX0 for the charging system.
4. 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.
5. By operation mode: uninterrupted operation.
6. By disinfection and sterilization method: subject to manufacturer's regulations.

6.2 Ambient Conditions

Working conditions:
Power supply voltage and frequency: 100-240 V ~ 50/60 Hz;
Rated input: 0.2A.

Charging system and BTE: 0℃~40℃ (32 ℉~104 ℉) @ 5~95% relative humidity;
ITM: 10℃~40℃ (50~104 ℉) up to 100% relative humidity;
Atmospheric pressure: 70 kPa～106 kPa.

Storage and transport conditions:
-20℃~45℃ (-4 ℉~113 ℉) < 85% relative humidity;
Atmospheric pressure: 61 kPa~101 kPa.

6.3 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

- Service quality:

The dental conduction hearing system monitors the audio quality of the input audio stream from BTE continuously, and the audio output only allows an error rate of 0.1% to ensure that the HI-FI audio stream is sent to the patient. In addition, the system ensures that the input audio from BTE keeps a fixed delay with the voice to be sent to the patient via ITM.

- Security

  Safety features of wireless technology for SoundBite Hearing System include:

  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.

6.4 Acoustic performance

- 0SPL90 loudest output (dB re. 1 uN): max. < 135dB,
  System frequency response range (Hz): 250-8000,
  Total harmonic distortion + Noise (%)

1000Hz (≤)	1500Hz (≤)	4000Hz (≤)
1%	1.5%	3.2%

  Equivalent input noise (dB re. 1 uN) (≤): 52 dB.

6.5 External power supply

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

6.6 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.

7. 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 3 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 A- mini type	USB cable, charging connector, used with charging dock	1.5m	Various	Various
USB A- Type- C	USB cable, charging cable, used with pocket charger	1.5m	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.
RF emissions CISPR 11	Class B	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.
Harmonic emissions IEC61000-3-2	Class B	
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% U_T: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°

		0% U_T: 1 cycle and 70% U_T: 25/30 cycles sine phase at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T: 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.

9. Parts List

Part name	Number	
Instructions	1	Standard
Certificate of quality	1	Standard
User delivery table	1	Standard
Quick operating guide	1	Standard
Portable box	1	Optional

CE2460

EC REP **EC Representative:**

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Date of Production: See product package
Service life: 3 years

Preparation date of manual: August of 2018
Revision: xx

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

MP-11-0142-01B

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 the manufacturer could void the user's authority to operate the equipment.

The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

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.

This device complies with FCC RF radiation exposure limits set forth for an uncontrolled enviroment.

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