Sonu

by Sound Health Systems

Rapid Non-Pharmaceutical Relief from Nasal Congestion

USER MANUAL

Sound Health Systems reserves the right to change or improve its products and accompanying technical literature without specific notice.

Model name: SHS-HW-001A & SHS-HW-001B

Brand name: SONU

Manufactured for:

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Los Altos, CA 94024

Web: www.soundhealth.life

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About This Manual

This manual provides the information necessary for you to effectively use Sonu.

- Please follow all manufacturer recommendations
- If you have any questions, please email customer support at support@soundhealth.life

1. Product Overview

- Sonu is a non-invasive, over-the-counter (OTC) device indicated for the treatment of moderate to severe nasal congestion due to allergic and non-allergic rhinitis, through the delivery of sound, or acoustic vibrational energy, to the sinus cavities and nasal passages. It consists of an adjustable, wearable Headband integrated with two acoustic bone-conduction transducers and a smartphone application (App) that connects to the Headband using Bluetooth technology.
- The App captures the patient's 3-dimensional facial features using the smartphone camera, estimates the resonant frequencies of their nasal cavities and sinuses (using an Artificial Intelligence (AI) / Machine Learning (ML) algorithm that has been trained to correlate craniofacial measurements with sinus dimensions) and delivers patient-specific, acoustic resonant vibration through bone conduction transducers in the wearable headband.
- Moderate Congestion is defined as "Definite awareness of symptom; bothersome but tolerable," and Severe Congestion is defined as "Symptom hard to tolerate; interferes with daily activity."

2. Product Functions

- The Sonu Band is battery-powered. The battery is rechargeable and integrated with the bone conduction transducer assembly.
- The Band only includes a USB type C cable for charging.
- During charging, the Band does not function as a medical device (Bluetooth is disabled and band cannot be used as a medical device when it is charging)
- The Band can be charged via a DC power source, e.g., a notebook computer's USB port.
- The Band includes two bone conduction transducers providing sound energy to the nasal passages.

- The Band is activated by a power button.
- The Band should be wrapped around the head and adjusted so that the transducers are placed on the forehead above the eyebrows and maintain contact between the device and the skin.
- The Sonu Application (App) is installed on a smartphone to capture your craniofacial landmarks, and to deliver and monitor the treatment.

3. Safety

3.1. Indications for Use

Sonu is indicated for the relief of moderate to severe nasal congestion due to allergic and non-allergic rhinitis. Sonu is a treatment to be used at home by individuals 22 and older.

3.2. Contraindications

You should not use this device if:

- You have a dental infection.
- You are receiving treatment for neurological conditions.
- You have electrostimulation devices implanted in your head, including a deep brain stimulation (DBS) devices or cochlear implants
- You had any type of surgery to the face, head, nose or sinuses within the past 3 months
- You had an intracranial or and intracerebral bleeding in the past 6 months.
- You have open wounds, rashes, over swollen, red, infected or inflamed areas, skin eruptions or fragile skin on the forehead (treatment location).
- You have a history of cranial surgery.
- You are sensitive to sound.

3.3. Precautions

- Congestion relief for greater than 2 weeks has not been studied.
- Do not attempt to perform any treatment before carefully reading this User Manual and Quick Start Manual provided with the package.
- Do not use the device on the heart, chest, neck, or any other body location other than the forehead as directed.
- Do not share the device with other people. The device is intended to be used by a single person to receive therapy based on their craniofacial anatomy.
- Refer to Sound Health Systems' website: https://soundhealth.life for detailed information.

3.4. Warnings

Sonu transmits acoustic vibrations from the bone conduction transducers in the Band to the sinus cavities. After you pair the Band with your smartphone and play the audio track, you will hear sound during treatment (essential performance).

- Do not use Sonu if you are unable to pair the Band with the Sonu App on your smartphone or do not hear sound when you play the audio track (i.e., essential performance is lost or degraded) due to electromagnetic disturbances
- Do not use Sonu if it shuts down or the performance has degraded in any way.
- Do not use Sonu near active high-frequency (HF) surgical equipment or in the radio-frequency (RF) shielded room of a magnetic resonance imaging (MRI) scanner or near RF emitting equipment where electromagnetic disturbances are high, because it could result in improper operation.
- Avoid using Sonu adjacent to or stacked with other equipment because it could result in improper operation. If such use is necessary, please verify that Sonu and the other equipment are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of Sonu could result in increased electromagnetic emissions or decreased electromagnetic immunity of Sonu and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Sonu, including cables specified by the manufacturer. Otherwise, degradation in performance of Sonu could result.

4. Package Contents

• 1 Sonu Band • 1 USB-C charging cable • 1 Storage Box • 1 Quick Start Manual	

5. Symbols

Symbol	Description
	Read and fully understand user manual before using this device
Qty	Quantity of devices in the package
	Manufacturer
	Model identifier
	Lot Number
	Use by date - indicates the date after which the device is not to be used
	Keep dry
	Non-Sterile
MAC ID	MAC address of the device
	Do not use if package is damaged

6. Setup and Use

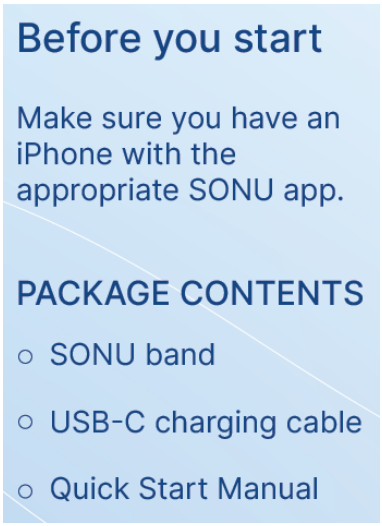
Before using the device for the first time, install the Sonu App, and connect the Band to the App. ***Make sure that Bluetooth connection on your Smartphone is enabled.***

6.1. Downloading and Installing the Application

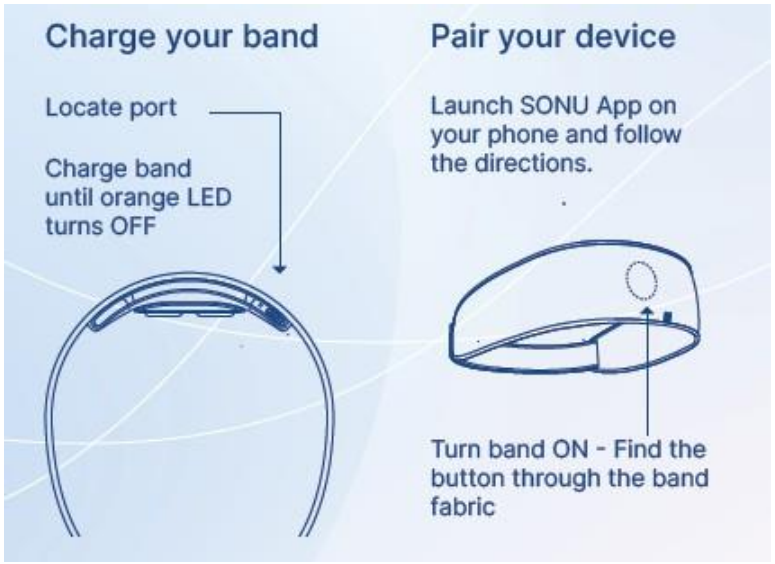
Step 1: Verify that your smartphone is compatible with the Sonu App. You will need an iPhone 10 (x) or later that has a FaceID front facing camera.

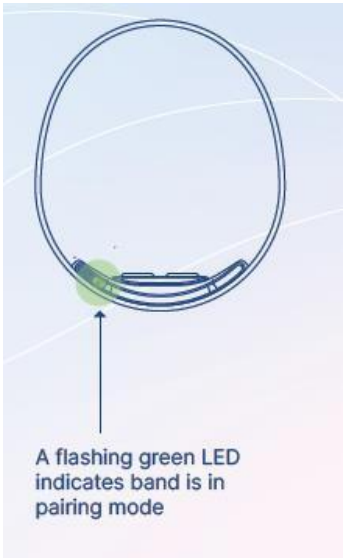
Step 2: Download and install the 'Sonu' App from the Apple App Store.

How to operate SONU BAND?



This device is only available in iOS system and iPhone needs to be 10 or above.



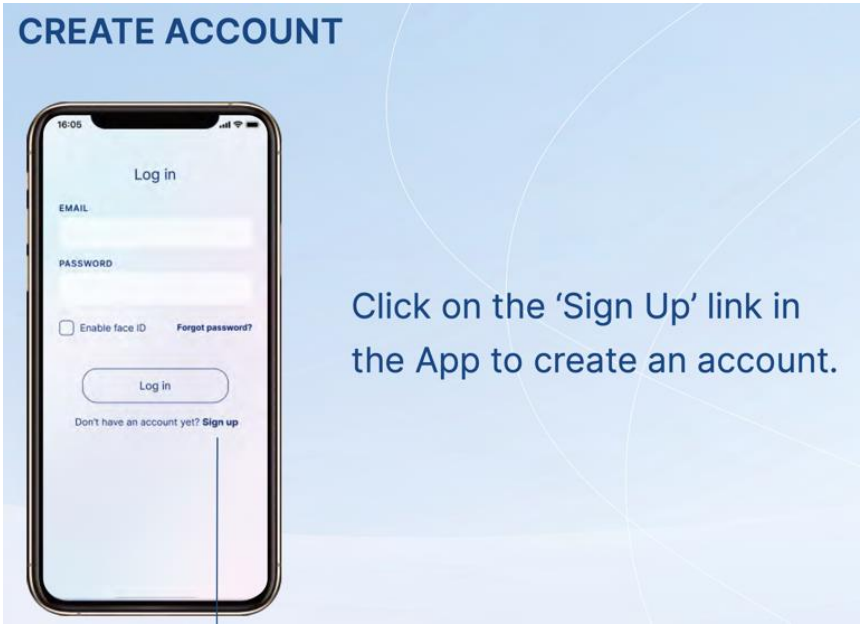


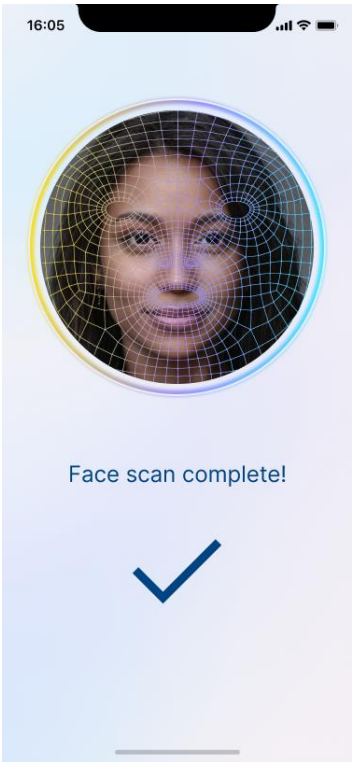
Step 3: Press and hold the power button until the Light Emitting Diode (LED) flashes green. This indicates band is in pairing mode and ready to connect to the iPhone via Bluetooth.

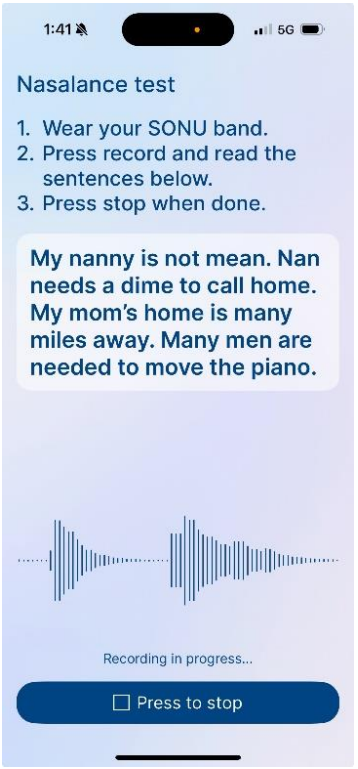
Step 4: Open the mobile phone Bluetooth connection and ensure Bluetooth is turned on. Pair the band with SONU_1.X.X

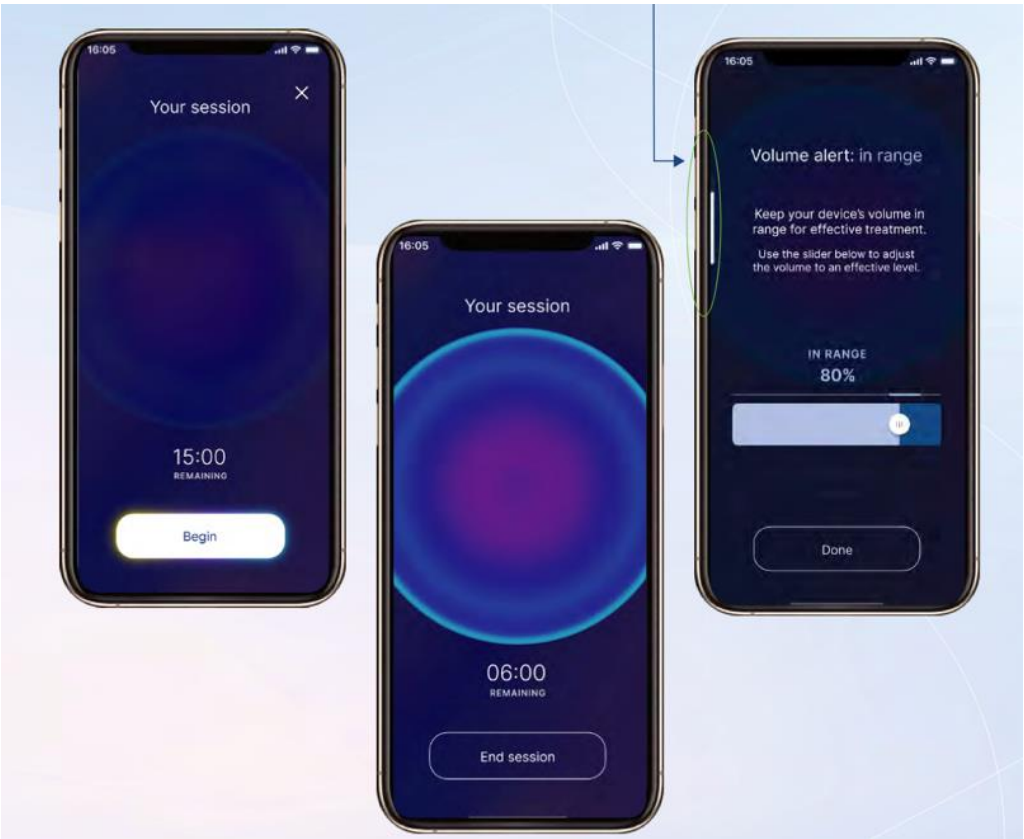
Step 5: Open the APP ‘SONU’

Step 6: Connect Sonu band and follow the instructions in the app screens









You may continue to use the Band away from the phone as long as the band is within normal Bluetooth accessory wireless range (10-15 feet). Should the App lose connection to the Band, the treatment will be paused. You can restart paused treatments when the Band and the smartphone are in range.

6.2. Band Placement and Adjustment

Positioning the Band on the forehead with a snug fit is important for treatment efficacy. You should adjust the Band to ensure that it does not slip side to side when you turn your head. Make sure that the bone conduction transducers in the center of the Band are in good contact with the skin on your forehead.

Also note that the silver markers on the band should be aligned with the middle of your forehead right above your brow line as shown in the Figure below:

7. Treatment Duration

Each treatment dose is 15 minutes. The recommended treatment is two doses per day for relief of nasal congestion.

CAUTION: Do not share the Sonu Band or App. Sonu is intended for a single user and the treatment is specific to you.

8. Treatment Completion

- When the treatment is complete, remove the Band. The Band will turn off automatically within 15 minutes of the end of a treatment session or inactivity.
- Close the App on the phone

9. Cleaning and Maintenance

- Clean the device with a dry cloth.
- Please contact customer support if the package and/or device labeling are damaged.
- The lifetime of the Band is approximately 1 year and varies depending on skin conditions, individual use, storage conditions, and climate.
- You can update the App using the standard update procedures on Apple's iOS operating system.

10. Storing the Device for next use

Once the treatment has been completed, please clean and store the device until the next treatment. Store the device in its original package in an indoor environment, away from direct sunlight and according to storage environment conditions specified in this user manual.

11. Technical Specifications

Parameter	Specification
Sonu Audio	
Power Source	3-10 V rechargeable battery supply
Weight	0.14 to 2.46 ounces
Dimensions	Width: 0.82 - 4.92 inches Height: 0.82 - 3.94 inches Depth: 0.32 - 1.89 inches
Maximum current consumption	200 mA
Rated input power	1 W Nominal / 1.5W Max
Impedance	8.5 Ohms ± 10%
Maximum Output Power (Corrected for Position)	88dB ± 3dB
Transducer Frequency Range	100Hz +- 20% to 15KHz
Bluetooth	
Frequency Range	The frequency range used is 2402MHz – 2480MHz (79 channels, at intervals of 1MHz); the frequency block is 2400MHz to 2483.5MHz.
Modulation Type	Bluetooth: FHSS (GFSK)
Bluetooth version	5.1
Antenna Type	PCB Antenna
Antenna Gain	5.46 dBi max
Number of Hopping Frequency	>15
Measured Output Peak Power	< 0.6 dBm; <1.20 mW
20 dB Bandwidth	0.9567MHz
Carried Frequency Separation	0.64MHz (2/3rd of the 20dB bandwidth of the hopping channel)
Time of Occupancy (Dwell Time)	<0.4 sec
Conducted Spurious Emission	At least 20dB below that in the 100kHz bandwidth within the band that contains the highest level of the desired power
Restricted Frequency Bands	
Conducted Emission	Radio frequency voltage that is conducted back onto the AC power line on any frequency within the band 150kHz to 30MHz shall not exceed the limits
Radiated Emission	Comply with the radiated emission limits specified in FCC section 15.209(a).

12. FCC Statements

15.19

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.

15.105(b)

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.

15.21

The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC RF Radiation Exposure Statement:

This device complies with FCC radiation exposure limits set forth for general population. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. Users should avoid using other body-worn accessories with metallic components in them to maintain compliance with FCC RF exposure guidelines.

FCC ID: 2A8X7SHS-HW-001X

Guidance and Manufacturer's declaration- Electromagnetic emissions		
Sonu is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of Sonu should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for home healthcare environment)**
RF emissions CISPR 11	Group 1	Sonu uses RF energy only for its internal function. Therefore, its RF emissions are very low compared to the FCC Group 1 limits and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	Sonu 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. RF emissions are low compared to FCC Class B limits.

Guidance and Manufacturer's declaration- Electromagnetic immunity			
Sonu is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of Sonu should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2 kV,±4 kV,±8 kV,±15 kV	Contact: ±8 kV Air: ±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	Sonu power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

Guidance and Manufacturer's declaration- Electromagnetic immunity			
Sonu is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of Sonu should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of Sonu** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d = 1,2 d = 1,2 $\sqrt{P}$ 80MHz to 800 MHz d = 2,3 $\sqrt{P}$ 800MHz to 2,7 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 metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between portable and mobile RF communications equipment and Sonu

Sonu is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of Sonu can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Sonu 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	**80 MHz to 800 MHz** d =1,2	**800 MHz to 2,7 GHz** d =2,3
0,01	$0,12\sqrt{P}$	$0,12\sqrt{P}$	$0,23\sqrt{P}$
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's declaration- Electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Sonu is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of Sonu should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Emission Test: IEC 61000-4-39

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Sonu is intended for use in the electromagnetic environment (for home healthcare) specified below.

The customer or the user of Sonu should ensure that it is used in such an environment.

Frequencies	Test Level [A/m]	Point / Window	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for home healthcare)
30 kHz (a)	8	All points on photo below	CW	3	8
134,2 kHz	65	All points on photo below	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	All points on photo below	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:
(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
(c) r.m.s., before modulation is applied.