

Sound Health Systems	SONU USER MANUAL - COMMERCIAL	CD-013.E
		Effective Date: 18 Nov 2022
		DCO: 027

**Sonu**

by Sound Health Systems

# Rapid Non-Pharmaceutical Relief from Nasal Congestion

USER MANUAL

Sound Health Systems	SONU USER MANUAL - COMMERCIAL	CD-013.E
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		DCO: 027

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**Model name:** SHS-HW-001

**Brand name:** SONU

**Manufacturer:**



**Sound Health Systems Inc.**

**650B Fremont Avenue, #65**

**Los Altos, CA 94024**

Web: [www.soundhealth.life](http://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](mailto:support@soundhealth.life)

## 1. Product Overview

- Sonu is a non-invasive, over-the-counter (OTC) device designed to provide temporary relief of nasal congestion through the delivery of sound, or acoustic vibrational energy, to the sinus cavities and nasal passages

## 2. Product Functions

- The Sonu headband is battery-powered. The battery is rechargeable and integrated with the bone conduction transducer assembly.
- The headband only includes a USB type C cable for charging.
- During charging, the headband does not function as a medical device (Bluetooth is disabled and band cannot be used as a medical device when it is charging)
- The headband can be charged via a DC power source e.g. a notebook computer's USB port
- The headband includes two bone conduction transducers providing acoustic vibrational energy to the nasal passages.
- The headband is activated by a power button.
- The headband 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 Chronic Application (App) is installed on a smartphone to capture your craniofacial landmarks, and to deliver and monitor the personalized treatment.

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### 3. SAFETY

#### 3.1. Conditions for Use

Sonu is intended to be used for the temporary relief of nasal congestion. Sonu treatment can be used in a home healthcare or professional healthcare facility environments by individuals 18 and older.

#### 3.2. Contraindications

You should not use this device if:

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

#### 3.3. Precautions

- I. Do not attempt to perform any treatment before carefully reading the user manual and instructions for use.
- II. Do not use the device on the heart, chest, neck, or any other body location other than the forehead as directed.
- III. Do not share the device with other people. The device is intended to be used by a single person to receive personalized therapy based on their individual craniofacial anatomy.
- IV. Refer to Sound Health Systems' website: <https://soundhealth.life> for detailed information.

#### 3.4. Warnings

1. Sonu transmits acoustic vibrations from the bone conduction transducers in the headband to the sinus cavities. After you pair the headband with your smartphone and play the audio

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track, you will hear sound during treatment (essential performance). Do not use Sonu if you are unable to pair the headband with the Sonu Chronic 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.






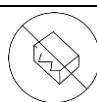
2. Do not use Sonu if it shuts down or the performance has degraded in any way.
3. Do not use Sonu near active high-frequency (HF) surgical equipment or in the radio-frequency (RF) shielded room of a magnetic resonance imaging (MRI) scanner or near RF emitting equipment where electromagnetic disturbances are high, because it could result in improper operation.
4. 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.
5. 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.
6. 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

<ul style="list-style-type: none"> <li>• 1 Sonu Headband</li> <li>• 1 Micro-USB charging cable</li> <li>• 1 Storage Box</li> <li>• 1 Quick-start Guide</li> </ul>	
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## 5. Symbols

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

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## 6. Setup and Use

Before using the device for the first time, install the Sonu Chronic App, and connect the headband 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 Chronic App.

You will need an iPhone 10 (x) or better that has a FaceID front facing camera.

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

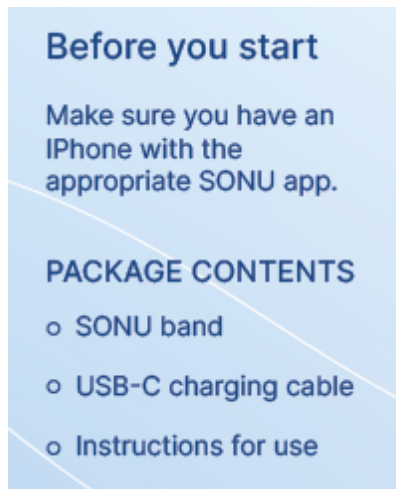
**Step 3:** Install the Sonu 'Chronic' App via the TestFlight App.



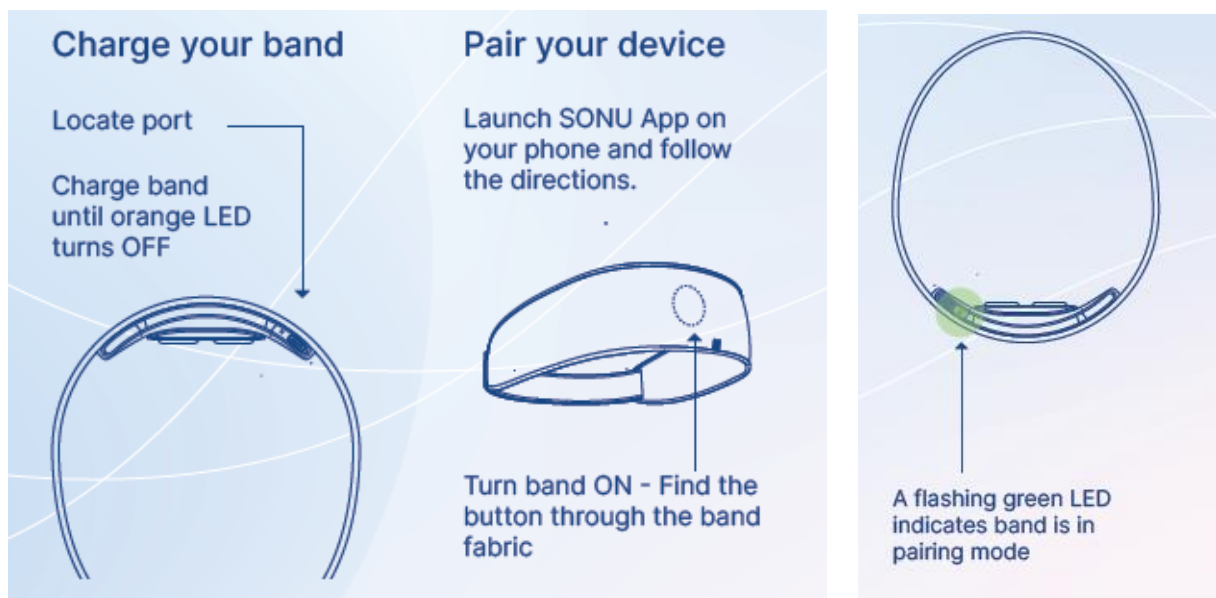


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How to operate SONU BAND?



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



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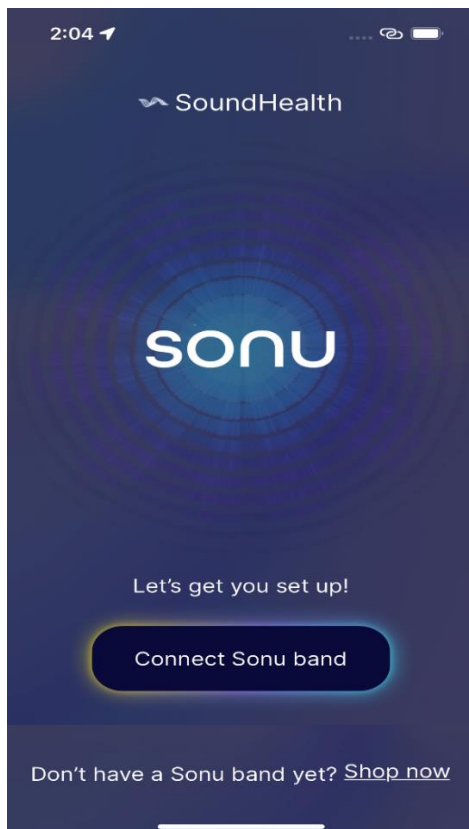
**Step 4:** Press and hold the power button until the prototype flashes green. This indicates band is in pairing mode and ready to connect to the iPhone via Bluetooth.



**Step 5:** Open the mobile phone Bluetooth connection and ensure Bluetooth is turned on. LINK SONU\_1.8.13

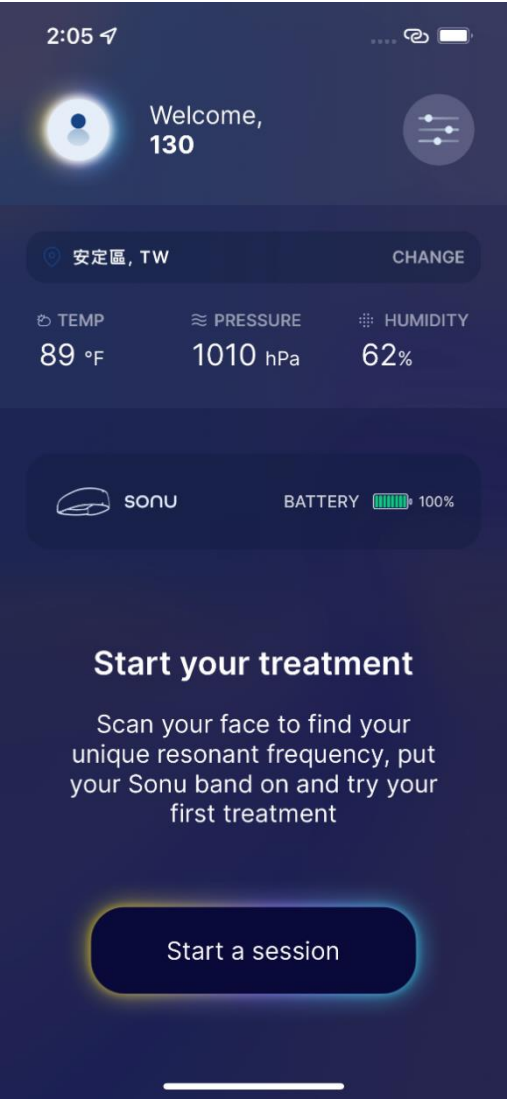
**Step 6:** Open the APP Chronic

**Step 7:** Connect Sonu band and follow the instructions in the app screens



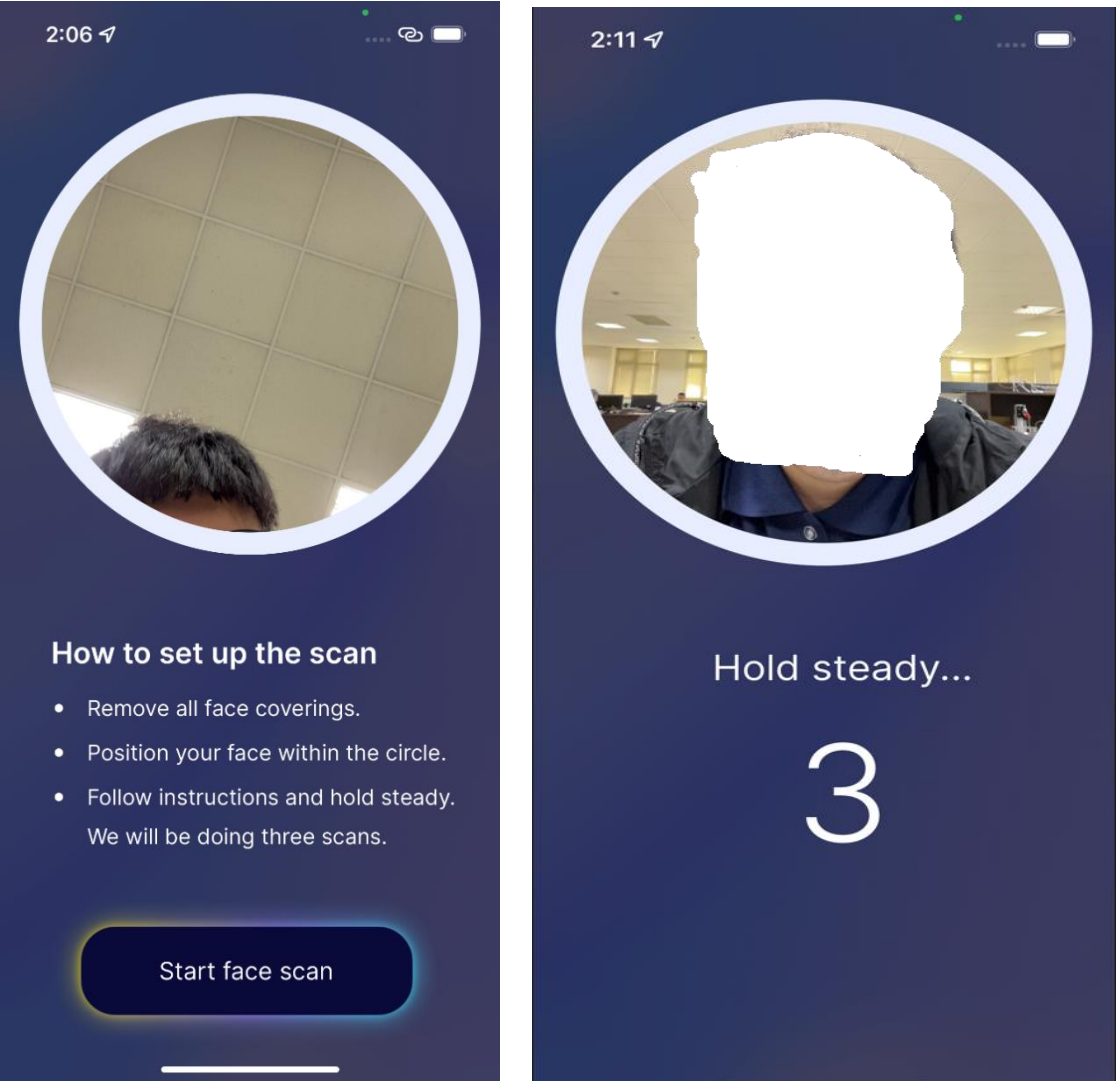
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Step 8: Start a session



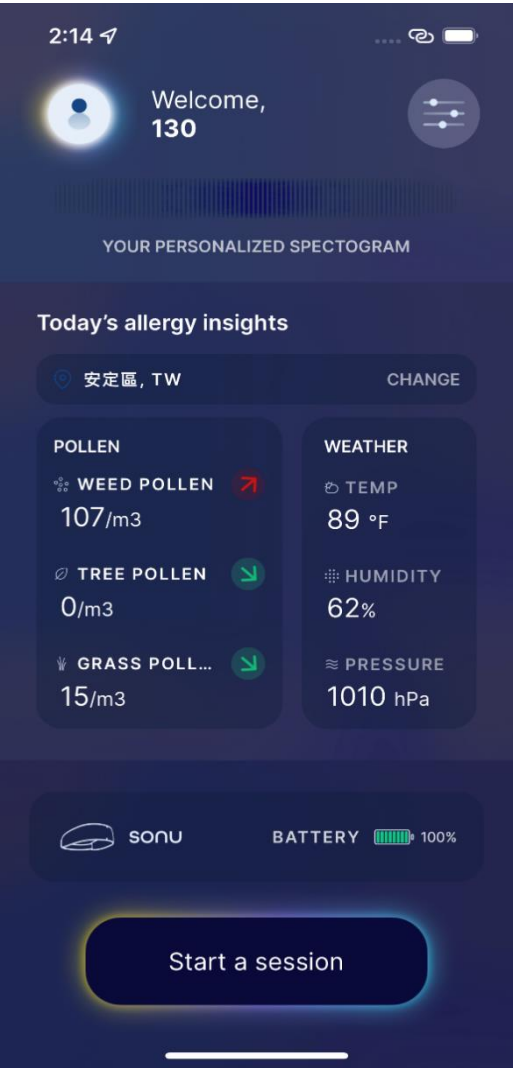
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**Step 9: Start face scan.**

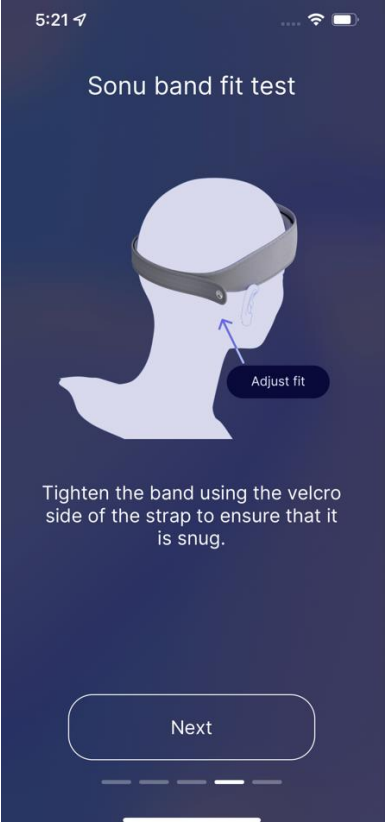
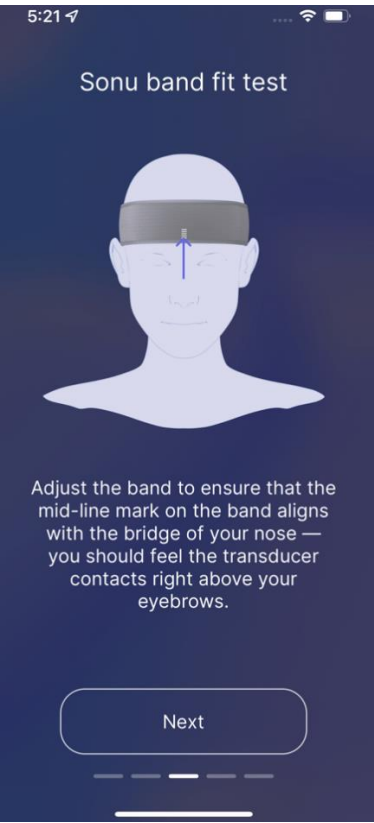
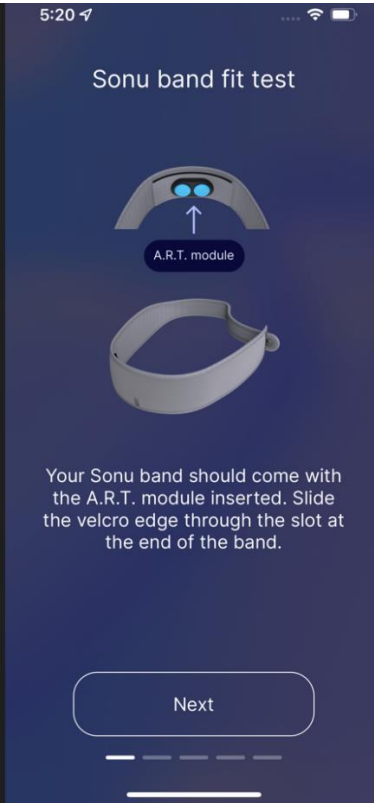


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Step 10: Start a session.

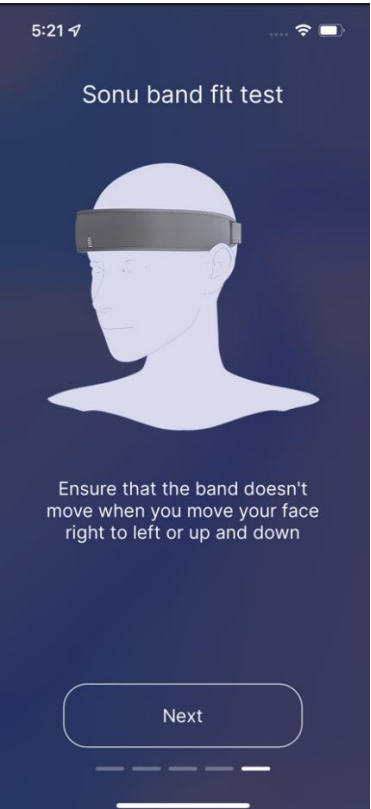


**Step 11:** Sonu band fit test. Follow the instructions on APP.

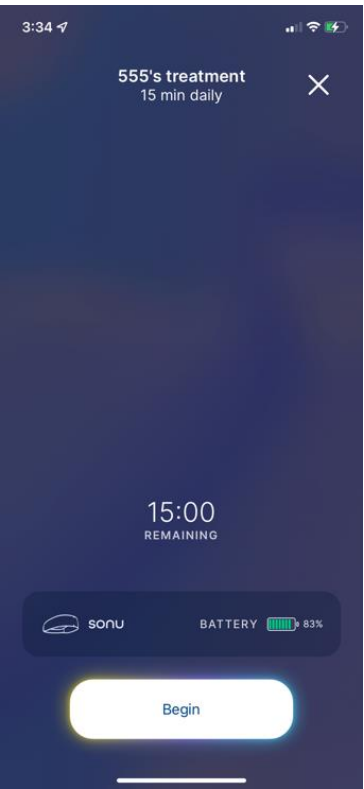


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**STEP 12: Start to Use**



**Step 13: Begin treatment.** You should hear audio from the band when you press 'Begin'





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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 Headband 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. A maximum of two 15-minute treatment sessions (30 minutes total) per day is recommended.

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



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## 8. Treatment Completed

**Step 1:** When the treatment is complete, remove the headband. The headband will turn off automatically within 15 minutes of the end of a treatment session or inactivity.

**Step 2:** 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.

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## 11. Technical Specifications

Parameter	Specification
<b>Transducer</b>	
Power Source	3.7 V rechargeable battery supply
Weight	1.20oz / 0.034kg
Dimensions	Width: 28mm Height: 36mm Depth: 105mm
Maximum current consumption	500 mA
Rated input power	1 W
Impedance	8 Ohms $\pm$ 10%
Maximum Output Power (Corrected for Position)	88dB SPL
Transducer Frequency Range	100Hz to 15KHz
<b>Bluetooth</b>	
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 (2/3 <sup>rd</sup> of the 20dB bandwidth of the hopping channel)
Time of Occupancy (Dwell Time)	<0.4 sec
Conducted Spurious Emission Restricted Frequency Bands	At least 20dB below that in the 100kHz bandwidth within the band that contains the highest level of the desired power
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).

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## 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

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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 <u>Sonu</u> 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: $\pm 8$ kV Air: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV	Contact: $\pm 8$ kV Air: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ 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.

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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	<p><b>Portable and mobile RF communications equipment should be used no closer to any part of Sonu</b> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b></p> $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80\text{MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800\text{MHz to } 2,7 \text{ GHz}$ <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

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**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 $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
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.

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### 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 <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	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.

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## Emission Test: IEC 61000-4-39

<p align="center"><b>Manufacturer's declaration-electromagnetic immunity</b></p> <p align="center"><b>Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields</b></p> <p>Sonu is intended for use in the electromagnetic environment (for home healthcare) specified below.</p> <p>The customer or the user of Sonu should ensure that it is used in such an environment.</p>					
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)
<p>Note:</p> <p>(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.</p> <p>(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.</p> <p>(c) r.m.s., before modulation is applied.</p>					



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### REVISION HISTORY

Revision	Description of Change	Effective Date	Originator
A	Initial Release	July 27, 2021	KT VRao
B	Updated warnings and EMC compatibility information from EMC testing	Dec 3, 2021	KT VRao
C	Updated instructions for use to be understandable to lay users. Included language on two 10-minute treatments per day.	May 6, 2022	KT VRao
D	Updated company name and product name to Sound Health Systems and Sonu respectively Updated instructions to turn on headband and pairing with the App; and treatment time Updated App screen images Updated with EMC tests to be conducted on Sonu	Aug 29, 2022	KT VRao
E	Updated with App Screen Images and EMC Testing results	Nov 18, 2022	Vivek Mohan