SomniResonance®

SLEEP NATURALLY

GET STARTED

OVERVIEW

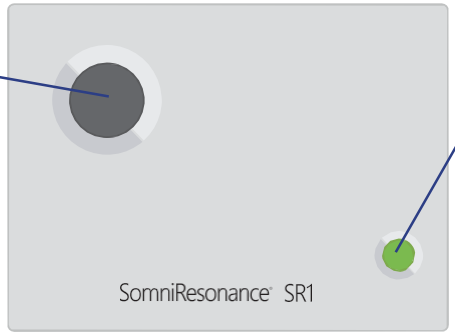
The **SomniResonance® SR1** is a precision medical instrument. It is a small, non-invasive, lightweight, battery-powered device that delivers a weak pulsing electromagnetic signal to induce sleep. The human brain naturally generates specific electromagnetic frequency patterns that reflect the patient's state of consciousness. The process of falling asleep, staying asleep, dreaming and awakening generate their own specific pattern.

When an individual experiences difficulty falling or staying asleep, usually that means the normal frequency patterns of the brain are altered. By mimicking the normal frequency patterns of the brain in the process of falling asleep, the SomniResonance® SR1 gently encourages the brain to fall asleep.

GET TO KNOW YOUR DEVICE

ON/OFF

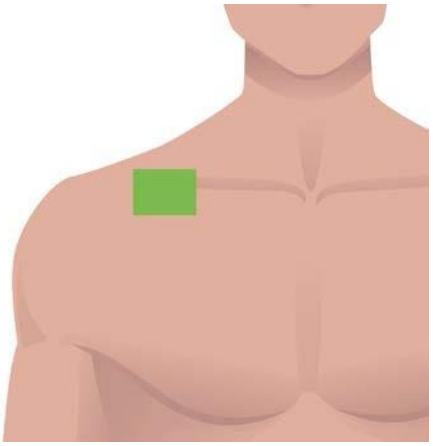
The device is designed to generate the program for 22 minutes then shut down automatically. The device can be reactivated or manually shut off by pressing the on/off button.



LED LIGHT

When the device is turned on, the indicator green light will flash slowly. If LED light does not flash, the battery needs to be replaced or the device is experiencing difficulties. *(See Troubleshooting, pg. 3)*

OPERATING INSTRUCTIONS: APPLICATION



You will find hypoallergenic, double-sided adhesive patches included in your package. Attach one side of the patch to the back side of the device opposite the LED light and the **On/Off** button. The side with the adhesive patch is pressed onto your chest over the brachial plexus, below the middle of the collar bone. Do not place the device on damaged skin. Incorrect application or operation of the SomniResonance® SR1 may fail to provide the desired effects. The green LED light should be on the side of the device away from the skin.

After you have attached the SomniResonance® SR1 and are ready for sleep, press the **On/Off** button. Check to see that the device is on and the light is flashing. The SomniResonance® SR1 will be on for 22 minutes and then automatically turn off. If you wake up during the night, you can turn it on by pressing the **On** button again. After 22 minutes it will automatically turn itself off again.

SOMNIRESONANCE® SR1 IMPORTANT INFORMATION

The SomniResonance®SR1 device should not be regarded as a substitute for the attention of your family doctor or medical specialist.

- If you discover or suspect that you are pregnant, discontinue using the SomniResonance® SR1 immediately.
- Do not wear the SomniResonance® SR1 if you are fitted with a pacemaker or other implanted device.
- If you have a partner fitted with a pacemaker, do not allow the SomniResonance® SR1 within six inches of the pacemaker.
- Do not wear the SomniResonance® SR1 near a MRI or other sensitive medical equipment such as EEG.
- The SomniResonance® SR1 may affect the normal function of sensitive medical electrical equipment.
- Do not wear the SomniResonance® SR1 while driving or operating machinery.
- Do not wear the SomniResonance® SR1 in any area where medical diagnostic or treatment devices are in use.
- Do not store the SomniResonance® SR1 on or near a microwave or any electrical/electromagnetic devices.
- Do not leave the SomniResonance® SR1 on or near any heat producing surfaces, or in a wet or moist area such as a bathroom.

ADVERSE EFFECTS

Users of the SomniResonance® SR1 may experience lucid dreams and/or an allergic reaction to the adhesive tape used to hold the device on the skin.

CLEANING

The SomniResonance® SR1 must NOT be immersed in water or other liquids. Do NOT use solvents or abrasive cleaners to clean the device; wipe using a damp cloth with mild detergent. Apply the liquid to the cloth and squeeze out surplus liquid. Do not apply liquid to the device directly. Alternatively, an alcohol wipe may be used for cleansing.

STORAGE

Store the SomniResonance® SR1 in a dry place out of direct sunlight.

MAINTENANCE

The SomniResonance® SR1 is not waterproof and should not be worn in the bath, shower or while swimming. Do not leave the SomniResonance® SR1 in the bathroom when showering or bathing. If your SomniResonance® SR1 is immersed in water remove the battery immediately. Allow the SomniResonance® SR1 to dry (do not use a hair dryer or any other hot object to dry it) and insert a new

battery. There is a great possibility that getting your SomniResonance® SR1 wet will ruin it. There is no warranty for devices that have been exposed to moisture.

DISPOSAL

If you ever need to dispose of the SomniResonance® SR1, please follow your local ordinance requirements. Dispose of button batteries at a hazardous waste collection site. These are considered hazardous material, and must be taken to a household hazardous waste collection site for proper disposal.

ADHESIVE DISCS

The SR1 is shipped with 30 adhesive discs. The adhesive discs are Nikstix brand Product No. 8810. Additional adhesive discs can be purchased from Nikstix directly: 1-877-NIKSTIX (1-877-645-7849) or www.nikstix.com.

TROUBLESHOOTING

If the green LED light fails to flash when your SomniResonance® SR1 is turned on, the battery needs to be replaced. The replacement battery should be a CR 2032. To change the battery, locate the two rectangular openings on the bottom of the device enclosure. Insert a flat screwdriver or similar tool into the rectangle and **gently** pry open. Repeat with other side. The top of the device will pop open. Remove the top to expose the battery. Slide the battery out of the holder, paying careful attention to the side of the battery with the plus sign (+). Slide in the new battery. Be sure the plus sign (+) is on the same side as the battery just removed. Turn device ON and ensure that the LED light is activated. If the LED light does not turn ON, reverse the plus sign (+) and try again. Turn OFF the device, place top back on enclosure and press until it snaps in place. Be careful to ensure that the switch opening on the top of the device is aligned with the switch on the circuit board. Battery changing is the only troubleshooting action the purchaser can perform. If this fails to activate the device, contact the health care professional from whom you obtained the device for further instructions.

ASSISTANCE

With the exception of changing the battery, nothing in the SomniResonance® SR1 can be serviced by the owner. For further assistance contact the health care professional from whom you obtained the device.

WARRANTY INFORMATION

The SomniResonance® SR1 is intended to induce sleep in people who have a problem falling asleep or staying asleep. However, each person is different and individual results may vary. SomniResonance® Biomedical Corp makes no warranties as to the effectiveness on an individual basis. SomniResonance® Biomedical Corp warrants (to the original purchaser only) that the SomniResonance® SR1 will be free

of defects in workmanship and materials, under normal use, for a period of one (1) year from the date of purchase. During the warranty period, SomniResonance® Biomedical Corp will repair or replace the unit at no charge to the patient at the discretion of the corporation. A copy of the original invoice will be required by SomniResonance® Biomedical Corp to ensure the device is within the warranty period. Claims under this warranty are initiated by contacting the health care professional from whom you obtained the device. This warranty is voided in case of abuse (including exposure to liquids or excessive moisture), damage to case or circuit board, disassembly, improper battery use, negligence and/or acts of nature.

Technical and Safety Information

Symbols

IEC 60417-5140
RF equipment marked with Symbol IEC 60417-5140 for non-ionizing radiation.

This symbol means this is a Type B Applied Part.

This symbol means Attention: Consult Accompanying Documents (User Instructions)

The SR1 is: Internally Powered Equipment.
A Type B Applied Part Rated for Short Time Operation.

Recommended Operating Conditions
(A) Ambient temperature range of +10 C to +40 C
(B) A relative humidity range of 30% to 75%
(C) An atmospheric pressure range of 700 hPa to 1,060 hPa

Compliance Summary

The SomniResonance Device is a stand-alone technology. It is not part of a medical system. There are no accessories or connector cables for this device.

The SomniResonance Device may affect the normal function of sensitive medical electrical equipment. Do not wear the Device in any area where medical diagnostic or treatment devices are in use.

Do not store the SomniResonance Device on or near a microwave or any electrical or electromagnetic devices. Do not leave the Device on or near any heat producing surfaces or in a wet or moist area such as a bathroom.

Table 1: Manufacturers Declaration: Electromagnetic Emissions

The SR 1 is intended for use in the electromagnetic environment specified below. The customer or the user of the SR 1 should assume that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment
RF emissions CISPR-11	Group 1 Class B	**T**he SR 1 uses RF emissions that are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	N/A	N/A
Voltage fluctuations/flicker emissions ICE 61000-3-3	N/A	N/A
RF emissions CISPR 14-1	N/A	N/A
RF emissions CISPR 15	N/A	N/A

Table 2: Manufacturers Declaration: Electromagnetic Immunity

The SR 1 is intended for use in the electromagnetic environment specified below. The customer or the user of the SR 1 should assume that it is used in such an environment.

Immunity Test	Compliance Level
Electrostatic Discharge (ESD) IEC 6100-4-2	+/- 6 kV contact +/- 8 kV air
Electrical fast transient/burst IEC 6100-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines
Surge IEC 6100-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines	< 5% U_r (>95% dip in U_r for 0.5 cycle) < 40% U_r (>60% dip in U_r for 5 cycle) < 70% U_r (>30% dip in U_r for 25 cycle) < 5% U_r (>95% dip in U_r for 5 s)
Power frequency (50/60 Hz) magnetic field IEC 61000-4-5	3 A/m

Table 3: Manufacturers Declaration: Electromagnetic Immunity

The SR 1 is intended for use in the electromagnetic environment specified below. The customer or the user of the SR 1 should assume that it is used in such an environment.

Immunity Test	IEC 60601 Test Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 Vrms 60 MHz to 2.5 GHz

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the SR 1.

The SR 1 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of SR 1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SR 1 as recommended below according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5GHz
0.01 W	N/A	0.116	0.233
0.1 W	N/A	0.368	0.737
1 W	N/A	1.166	2.333
10W	N/A	3.689	7.378
100 W	N/A	11.667	23.333

SomniResonance®

The SomniResonance® technology is based on decades of clinical and academic research.

To learn more about this research please visit the :DSleep website:

www.deltasleeper.com

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