

SleepImage SR1 Getting Started

Step 1

Download the Mobile App



Scan the QR code or visit the link below in your mobile device's browser.

sleepimage.com/app-download

Step 2

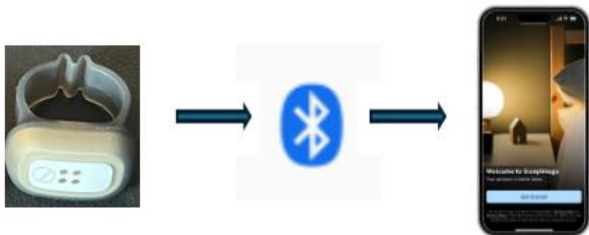
Connect the Charger



Connect the SR1 to the charger. You must supply a USB Type-C power adapter. An indicator light on the side of the SR1 device will pulse green when connected to power.

Step 3

Continue in the App



Open the app on your mobile device to pair the SR1 and complete setup.

SleepImage SR1

User Manual

1. Descriptive Information

1.1 Device Description

The SleepImage SR1 is a finger-worn wearable sensor which is designed for continuous data recording, typically during sleep, and spot checking of physiological signals in home and clinical environments excluding acute settings. It measures photoplethysmography (PPG) and accelerometer data and calculates physiological parameters such as functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (PR) and respiration rate (RR).

The SleepImage SR1 is used with a silicone-based ring accessory that holds the module in place on the finger. The silicone ring accessory is available in different sizes for appropriate fitting of adult and pediatric fingers, from the age of 3 years. It has an internal rechargeable battery and memory for overnight measurements. It turns on automatically as the device is placed on the finger and shuts down when device is removed from the finger.

When the SR1 is paired with a compatible mobile application, the data is automatically transferred to a compatible mobile application via Bluetooth. The SleepImage SR1 does not display or interpret the collected data. Instead, a compatible mobile application running on a mobile device (iOS or Android), which may independently perform further processing, visualization, or analysis. The mobile application operates also as a relay to transfer the data to the cloud service for potential further analysis.

1.2 Intended Use / Indications for Use

The SleepImage SR1 and Accessories are intended for noninvasive recording of photoplethysmography (PPG) and accelerometer data to report functional oxygen saturation of arterial hemoglobin (SpO₂), Pulse Rate (PR), and Respiration Rate (RR) displayed on a compatible mobile application.

The SleepImage SR1 and Accessories are indicated for spot-checking during no-motion conditions to report SpO₂ and PR, or for continuous recording during sleep to report SpO₂, PR, and RR of adult and pediatric patients who are well or poorly perfused in hospitals, hospital-type facilities, and home environments.

The device is not intended for real time monitoring and does not provide alarms.

1.3 Contraindications

No contraindications

1.4 Box Contents

- 1 SR1 Device
- 3 Rings (S, M, L)
- 1 Charging Cable
- 1 Instructions

1.5 Cautions

- Avoid contact with sharp objects while using this device.
- To prevent damage, keep the device inside the silicone ring while not in use.
- Using device during a normal sleep duration is generally safe but may cause skin irritation.
- SleepImage SR1 is not intended for diagnosis or screening of lung disease and treatment decisions using the device should only be under the advice of a healthcare provider.

1.6 Warnings

- CHOKING HAZARD - Small parts. Not for children under 3 years old.
- CHOKING HAZARD - Keep the device within the ring and out of the children and animals
- CHOKING HAZARD - Use tape to secure the ring in place on small children
- STRANGULATION HAZARD - Store the cable securely when not in use, out of reach of children and individuals who may not recognize the hazard.

- Users under the age of 12 years MAY ONLY use the SR1 under adult / guardian supervision
- Do not attempt to modify or disassemble the device. Unauthorized modifications may damage the device and violate regulations governing radio devices.
- MAGNETIC FIELD - ensure the device is kept at least 6 inches away from medical implants or medical devices that can be impacted by the magnetic fields to avoid possible effect from localized magnetic fields.
- Remove the device if you suspect overheating. The device should shut off if the temperature exceeds 41°C (105.8°F).
- Do not disassemble, crush, puncture or expose to excessive heat.
- Only use the charging cable specifically designed for this device.
- Do not wear the device while connected to the charger.
- Do not store or charge in a hot environment, such as direct sunlight or inside a parked car.
- Do not open or disassemble the device.
- Do not modify the device. Unauthorized modifications may damage the device and violate regulations governing radio devices.
- Disposal of the device into fire or a hot oven, or mechanically crushing or cutting the device can result in an explosion.
- Leaving the device in an extremely high temperature surrounding environment can result in an explosion or the leakage of flammable liquid or gas.
- The device subjected to extremely low air pressure may result in an explosion or the leakage of flammable liquid or gas.
- BATTERY- Keep small cells and batteries which are considered swallowable out of the reach of children.
- BATTERY- Swallowing may lead to burns, perforation of soft tissue, and death. Severe burns can occur within 2 hours of ingestion.
- BATTERY- In case of ingestion of a cell or battery, seek medical assistance promptly.

2 Operating Instructions

2.1 Download the Mobile App

- Scan the QR code or go to: sleepimage.com/app-download.

2.2 Charge the Device

- Connect charging cable to a power source.
- Magnets will ensure proper alignment as the SR1 is attached to the charging cable.
- The SR1 indicator light, located on one side of the sensor will pulse green while charging and turn to steady green when fully charged.

2.3 Pair device with mobile app

- Create a user account to store your data.
- Enter the patient ID that was provided by your physician. Your date of birth is used to verify that you entered the correct patient ID.
- Pair the SR1 with your mobile device by following instructions in the mobile app.

2.4 Find your ring size

- The Device is shipped in the Medium 'M' ring. Slide the ring onto your middle finger with the device facing the palm side of your hand.
- Ensure that you are wearing the SR1 in a ring that is not too tight around your finger.
- Ensure that the sensor touches the skin; if the fit is too loose, use a smaller ring, if it is too tight, use a larger ring. Proper fit and sensor location are critical for good signal.
- When changing ring sizes, take care to avoid dropping the device.

2.5 Alternative 1: Spot Checking

- Slide the device onto your finger facing the palm of your hand as shown.
- Follow instructions on the mobile app for your data.
- There may be a slight delay before data appears.
- Keep your hand still when checking your SpO2 and pulse rate.
- When you are finished, return the device to the charger.

2.6 Alternative 2: Overnight Recording during Sleep

- Fully charge the device before starting an overnight recording.
- Verify that your mobile device is paired with the SR1 before starting an overnight recording.
- Slide the device onto the base of your finger facing the palm of your hand as shown.
- On the mobile app, tap "Start" before going to sleep.
- On the mobile app, tap "Stop" to complete session and send your data to your provider.

- When you are finished sleeping, return the device to the charger.

2.7 View Reports

- On the mobile app, select History to view Spot Checking and Sleep reports.
- Follow the report guidance to determine if your SpO2 and Heart Rate values are within the expected ranges.

3 Maintenance

3.1 Cleaning and disinfection

- **General instruction**
 - Always clean and disinfect the SR1 and silicone ring between patients to prevent possible cross-contamination.
 - The components should also be cleaned whenever they become soiled, to ensure correct measurement result.
- **Precautions**
 - Remove the SR1 from the silicone ring before cleaning or disinfection.
 - Do not use harsh cleaning agents, abrasives, or sharp objects to clean the SR1 or the ring. This may damage them.
 - Allow components dry properly before assembling them together or placing the SR1 onto the charger.
 - Do not expose the device or its accessories to sterilizing agents or autoclaves.
- **Warnings**
 - IP22 warning - Do not submerge the SR1 into any liquid. Submerging will damage the device and prevent correct functioning.
- **Manual cleaning of SR1**
 - Remove the SR1 device from the silicone ring.
 - Use a soft brush (toothbrush or similar) to remove any loose particles from the surface or recesses.
 - Wipe SR1 with a soft, lint-free cloth, moistened with mild detergent and warm water solution.
 - Make sure that any visible soil is removed from the pin holes, interfaces, and recesses.
- **Manual cleaning of silicone ring**
 - Remove the SR1 device from the silicone ring.
 - Clean the silicone ring using running warm tap water and a dab of mild detergent. Make sure that both inner and external surfaces are cleaned.
 - Rinse thoroughly with warm tap water for 1 minute.
- **Manual disinfection of SR1**
 - Disinfect all surfaces of the SR1 with a 70% isopropyl alcohol wipe for at least 2 minutes.
 - Make sure that also any recesses are contacted with the disinfectant wipe.
- **Manual disinfection of silicone ring**
 - Disinfect all surfaces of the silicone ring with a 70% isopropyl alcohol wipe for at least 2 minutes. Alternatively, the ring can be submerged to 70% IPA bath for 2 minutes.

3.2 Battery Life

- To keep the battery in good condition, charge the device every 2 months when not in use.

3.3 Storage

- DO NOT store the Ring in the following locations: direct sunlight, lint, dust, high temperatures, high levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations subject to strong electromagnetic influences.

3.4 Disposal

- Disposal of the device and its accessories must be done in accordance with local regulations for recycling.

3.5 Accessories

- Replacement rings and charging cables are available for purchase. Contact your healthcare provider for details or visit www.sleepimage.com to order directly through SleepImage.

4 Troubleshooting

4.1 Indicator Lights

Occurs	Indicator Light	Meaning
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While charging	Green	Pulsing = SR1 is charging. Solid = SR1 is fully charged.
While wearing	Green	Pulses slowly to indicate recording, then dimming before going dark in 5 minutes.
While wearing	Red	Memory is full or insufficient charge. Connect to App to upload data & clear memory and return to charger to charge.

4.2 Troubleshooting

Symptoms	Possible causes	Actions
Pairing with mobile App fails / the SR1 is not discovered	SR1 is not on pairing mode, or the phone does not have Bluetooth turned on.	Connect the SR1 to the charger, which needs to be connected to power and check that indicator light turns on, then retry pairing with mobile app. If that does not work, check the phone settings to make sure Bluetooth is turned on.
SR1 sensor light does not turn on when placed on finger	Battery is empty	Connect the SR1 to the charger and wait and follow indicator lights for charging status (see above) before use.
SR1 indicator light does not turn on when placed on finger	Poor skin contact	Remove the SR1 from finger, wait for 30s before putting it back on. If indicator light or sensor light turns on, continue recording as instructed. Otherwise, contact your provider.
SR1 does not start charging while on the charger	SR1 incorrectly connected to charger, or the charger is not connected to power.	Check that the orientation of the SR1 is correct on the charger and check that the dock is connected to power.
SR1 comes out of sleeve during the recording period	SR1 is incorrectly placed in sleeve or sleeve is damaged.	Make sure the SR1 is placed in the sleeve as instructed, and check that it is not broken or torn.
SR1 feels uncomfortable on finger and/or finger is swollen	Sleeve is too small for the finger	Try using another finger or another sleeve size
SR1 does not stay in place during recording period	Sleeve is too large, or worn on finger that is too small	Consider using another finger or sleeve size with better fit.

5 Symbols

Symbol	Name of symbol/reference
	Catalogue Number
	Manufacturer
	Serial Number
	Date of Manufacture
	Unique device identifier
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Type BF applied part
	Non-ionizing electromagnetic radiation. Bluetooth with a maximum range of 33 feet.
IP22	Protected against solid objects larger than 12.5mm and against dripping water
	Follow Instructions for Use.
	Medical device
	Waste from Electrical and Electronic Equipment
	Recyclable cardboard package material
	Magnetic Resonance (MR) unsafe
	Conforms with Federal Communications Commission standards for electromagnetic safety.
Rx only	Prescription only. Rx Caution

6 Specifications

Dimensions	1.1" x 0.7" x 0.4" (27mm x 17mm x 11mm) w/o ring 1.2" x 0.8" x 1.2" (30mm x 20mm x 31mm) with ring
Weight	0.007 lbs (3g) without silicone ring 0.013 lbs (6g) with silicone ring
IP rating	IP22
Operating temperature and humidity	Temperature: 41°F - 104°F (+5°C to +40°C) Relative Humidity: 0% to 95% RH non-condensing
Storage temperature and humidity	Temperature: -4°F - 140°F (-20°C to +60°C) Relative Humidity: 0% to 95% RH non-condensing
Charging temperature and humidity	Temperature: -50°F - 113°F (+10°C to +45°C) Relative Humidity: 0% to 95% RH non-condensing
Operating time	16 hours when fully charged
Charging time	2-3 hours
Wireless	Bluetooth version BLE 5.1
Battery	3.8Vdc. Rechargeable Lithium-polymer
SpO₂ range	0-100%
SpO₂ accuracy	± 3.0% for 70% to 100%
HR (pulse) range	25-240 bpm
HR (pulse) accuracy	± 3 bpm or 3.0%, whichever is greater
RR range	4 – 70 rpm
RR accuracy	3 rpm ARMS, 1 rpm Mean Error
Recorded signals	SpO ₂ , Pulse Rate, Respiratory Rate
Expected life	1 year
Ring material	Medical-grade silicone (does not contain natural rubber latex or DEHP)

7 FCC Statement

FCC ID: 2BOTNUS101

FCC REQUIREMENTS FOR OPERATION IN THE UNITED STATES

FCC Information for the User

This product does not contain any user serviceable components and is to be used with approved, internal antennas only. Any product changes or modifications will invalidate all applicable regulatory certifications and approvals.

FCC Guidelines for human Exposure

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance of 5 mm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Federal Communications Commission Statement

This device complies with Part 15 Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

FCC Radio Frequency Interference Warnings & Instructions

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 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 methods:

- Increase the separation between the equipment and the receiver.
- Connect the equipment into an electrical outlet on a circuit different from that which the radio receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

FCC Caution

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

8 IC Caution

IC: 34393-US101

Innovation, Science and Economic Development Canada (ISED) regulatory information

This device complies with RSS-247 of the Innovation, Science and Economic Development Canada (ISED) 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.

Ce dispositif est conforme à la norme RSS-247 d'Innovation, Sciences et Développement Économique Canada applicable aux appareils radio exempts de licence. Son fonctionnement est sujet aux deux conditions suivantes: (1) le dispositif ne doit pas produire de brouillage préjudiciable, et (2) ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable

Radiation Exposure Statement

This device complies with ISED radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 5 mm between the radiator and your body.

NOTE IMPORTANTE: Déclaration d'exposition aux radiations:

Cet équipement est conforme aux limites d'exposition aux rayonnements ISED établies pour un environnement non contrôlé. Cet équipement doit être installé et utilisé avec une distance minimale de 5 mm entre le radiateur et votre corps.

9 Electromagnetic Compatibility

The device meets the requirements of IEC 60601-1-2:2014.

10 Return Procedure

Contact SleepImage for product support support@sleepimage.com.

Clean contaminated/dirty equipment before returning per Cleaning and disinfection instructions. Make sure the equipment is fully dry before packing. Package the device securely, in the original shipping box if possible, and enclose the following information and items:

- Include a letter describing in detail any difficulties experienced with SR1
- Warranty information, a copy of the invoice or other applicable documentation must be included
- Ship-to and bill-to information. Person (name, telephone/Telex) to contact for any questions about the repairs
- A certificate stating that the device has been decontaminated for bloodborne pathogens.

11 Warranty

The SR1 is sold with a One-Year Limited Warranty. SleepImage warrants the included hardware product and accessories against defects in materials and workmanship for one year from the date of original purchase. SleepImage does not warrant against normal wear and tear, nor damage caused by accident or abuse. Battery must be charged regularly to maintain warranty. To obtain service, contact SleepImage or a representative of SleepImage from whom you may have purchased the device by phone or by emailing support@sleepimage.com. Available service options are dependent on the country in which service is requested and may be restricted to the original country of sales. Call charges and international shipping charges may apply, depending on the location. Subject to the full terms and detailed information on obtaining service contact support@sleepimage.com. If you submit a valid claim under this warranty, SleepImage will either repair, replace, or refund your SR1 at its own discretion. Warranty benefits are in addition to rights provided under local consumer laws. You may be required to furnish proof of purchase details when making a claim under this warranty.



MyCardio LLC, 3200 E Cherry Creek South Dr, Suite 540, Denver, CO 80209, USA

Product Name: SleepImage SR1
Model: SR1
SleepImage Website: www.sleepimage.com
Contact SleepImage: support@sleepimage.com



ART-3
SleepImage SR1 Instructions for Use
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