

SleepImage Ring®

Model: PO2/PO4

User Manual

The SleepImage Ring® (Ring) uses Bluetooth to communicate with the SleepImage Mobile App® (App). The Ring must be paired with the SleepImage App to collect and transfer data to the SleepImage System, which is a Software as a Medical Device (SaMD) intended for establishing sleep quality and evaluating sleep disorders for clinical diagnosis and management of sleep disordered breathing.

The Ring, as a general wellness product, displays Pulse Rate and SpO₂ data while in use. It should not be used to directly diagnose or treat any medical condition, and it does not store any data.

1. Introduction

1.1. Intended Use

The Ring is intended to be used for measuring, displaying, storing and transmitting functional saturation of arterial hemoglobin (SpO₂) and pulse rate of adult patients in home or healthcare facilities environment. (USA, EU)

The Ring is a pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate for adult patients. It is intended for spot-check and/ or continuous data storage, and not continuous monitoring. It can be used in sleep labs, long-term care, hospitals (except the operating room, ICU) and home use. (AU, CA)

This Ring can display SpO₂ and pulse rate values on its display while in use. No data is stored on the Ring.

1.2. Included in Box

SleepImage Ring®, Quick Start Guide, Warranty Card, Charging Cable.

2. Using the Ring and App

2.1. Charging

Charge battery before using by connecting Ring to computer USB or USB charging adapter with the included USB cable. When fully charged, Ring will power off automatically.

2.2. Download the App

SleepImage Mobile App

App Name: SleepImage

iOS: App Store

Android: Google Play

NOTE:

- Ensure that the App is updated to the latest version prior to each use.

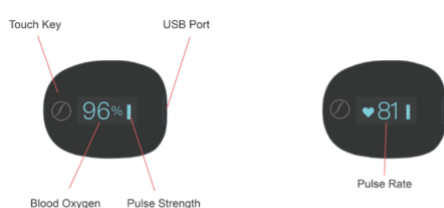
2.3. Pair the Ring with the App

The Ring uses Bluetooth to communicate with the SleepImage Mobile App. The Ring MUST be paired with the App to collect and transfer data to SleepImage.

NOTE:

- Only pair the Ring to your phone in the App. DO NOT pair in phone settings and follow the Mobile App Instructions for Use.

2.4. Ring Display



Touch the SleepImage logo on the display to switch between displaying (1) time & battery level and (2) Pulse/SpO₂ readings or unavailable symbol.

2.5. Charging

Charging time may take 120 – 180 minutes.

2.6. Unavailable Symbol



This symbol on the Ring display indicates that readings are temporarily unavailable, which may be caused by:

- Excessive movement;
- Poor signal;
- Finger being too cold;
- Ring initiating at the start of a recording.

2.7. Screen Wake up

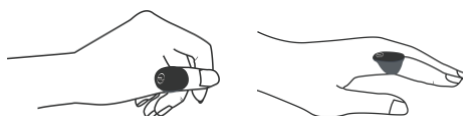
The screen turns off automatically during recordings. Touch SleepImage logo on the display to wake up screen.

2.8. POWER ON/OFF

The Ring will turn on automatically when worn and turn off when removed from finger.



2.9. Start recording



Wear Ring on thumb or index finger, preferably on the left hand. Ring will turn on automatically. Start recording in the App to begin data collection.

NOTE:

- Proper fit is essential. If the Ring is too tight for thumb or index finger, try an alternate finger, but avoid the middle finger.
- Loose fit may lead to poor data collection.
- Avoid excessive motion during recording.
- Avoid strong ambient light during recording.
- If the Ring is removed briefly during a recording session, simply put the Ring back on to resume the recording.
- DO NOT stop recording in the App during the night if you wake up and temporarily take the Ring off.

2.10. Stop Recording

At the end of your sleep test, stop the recording in the App and remove the Ring from your finger which will automatically turn itself off.

2.11. Data Upload

After the recording is stopped in the App, the recording will upload to SleepImage. If the study does not upload, check Troubleshooting in the SleepImage App instructions, or find further information on www.sleepimage.com.

3. Maintenance

3.1. Time & Date

The Ring's time will automatically sync with your phone time after connection with App.

3.2. Cleaning

Use a soft cloth, lightly moistened with water or isopropyl alcohol, to clean the device surface. Do not use acetone or other volatile solutions.

3.3. Warning and Cautions

- DO NOT squeeze the sensor, apply excessive force, drop the Ring, nor subject it to any strong impact.



- DO NOT use the Ring during an MRI examination.
- DO NOT use the Ring with a defibrillator.
- DO NOT store the Ring in the following locations: direct sunlight; high temperatures, high levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations subject to strong electromagnetic influences.

- DO NOT use the Ring in a combustible environment.
- NEVER submerge the Ring in water or other liquids.
- The Ring and its accessories are non-sterile.
- DO NOT clean the ring with acetone or other volatile solutions.
- DO NOT place the Ring in pressure vessels or gas sterilization devices.
- DO NOT dismantle the Ring or open the display cover without authorization. The cover should only be opened by a qualified service personnel.
- The Ring shall only be maintained by qualified professionals.
- The manufacturer shall provide the service personnel with circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair the device.
- Only use the charging cable specified in this manual.
- Consult your doctor immediately if you experience symptoms that could indicate acute disease.
- DO NOT self-diagnose or self-medicate solely based on data displayed by the Ring.
- Wearing the Ring during a normal sleep duration is generally safe but may cause skin irritation.
- DO NOT dismantle the Ring or open the display.
- DO NOT self-diagnose or self-medicate solely based on data displayed by the Ring.
- Wearing the Ring during a normal sleep duration is generally safe but may cause skin irritation.

4. Ring Disposal

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

5. Troubleshooting

Problem	Possible Cause	Possible Solution
Device does not turn on or no response	Battery may be low.	Charge battery and try again.
	Device may be damaged.	Please contact your local distributor.
The app cannot find or pair with the device	The device is off.	Turn on device.
	Bluetooth cannot work without location permission (Android)	Allow location access.
	The Bluetooth of your phone is off.	Turn on the Bluetooth in the phone.
Only one Light Emitter on the ring turns red.	This is normal, the Ring only has one light emitter.	No need to worry about it.
The device screen displays "Error 1".	Errors occur during data analysis.	Connect the power supply and plug in the charging cable, press and hold the touch key for 3s to reset the hardware.
	Your mobile device may not meet the minimum specifications required.	(See www.sleepimage.com for information).

6. Guide to Symbols

Symbol	Description
	Type BF-Applied Part
	Manufacturer
	Date of manufacture
	Follow Instructions for Use.
	No alarm system
	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
	Conforms with Federal Communications Commission standards for electromagnetic safety.
	Declaration of compliance with EU Medical Device Directive
	Authorized representative in the European community
	UKCA marking.
	Authorized Representative in the United Kingdom.
	Non-ionizing radiation.
	This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s).
IP22	Against ingress of solid foreign objects $\geq 12.5\text{mm}$ diameter, splashing.
	Medical device
SN	Serial number
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Indicate separate collection for electrical and electronic equipment (WEEE).
	This product complies with verpackG
	Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market).

7. Specifications

Environmental	Operating	Storage
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (noncondensing)	10% to 95%	10% to 95%
Barometric	700 to 1060hPa	700 to 1060hPa
Protection against electric shock	Internally powered equipment	
Degree protection against electrical shock	Type BF	
Electromagnetic compatibility	Group I, Class B	
Degree of dust & water resistance	IP22	
Weight	PO2: 15 g PO4: 12 g	
Size	PO2: 38mm×30mm×38 mm PO4: 38mm×30mm×27 mm	
Battery	3.7Vd.c., Rechargeable Lithium-polymer	
Charge time	2-3 hours	
Battery life	PO2: 12-14 hours for typical use PO4: 14 hours for typical use	
Wireless	Bluetooth 4.0 BLE	
Oxygen level range	70% to 100%	
SpO ₂ Accuracy (Arms)	80-100%: $\pm 2\%$, 70-79%: $\pm 3\%$	

Pulse Rate range	30 to 250 bpm
Pulse Rate accuracy	± 2 bpm or $\pm 2\%$, whichever is greater
Recorded parameters	Oxygen level Pulse Rate Plethysmograph Actigraphy
Data storage	No data is stored on the Ring
Frequency range	2.402-2.480GHz
Max RF power	-10 dBm
Expected service life	3 years
Wavelength/Max emission power	660nm/940nm, 0.8mW/1.2mW

8. FCC Statement

FCC Warning:

FCC ID: 2ADXX-8326

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

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.

NOTE:

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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

9. IC Caution

IC:29845-S001

This device contains license-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

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

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Contact SleepImage: support@sleepimage.com

SleepImage Website: <https://sleepimage.com>

Trade Name: SleepImage Ring (Large)

Product Name: Pulse Oximeter Model: PO2

Trade Name: SleepImage Ring (Small)

Product Name: Pulse Oximeter Model: PO4

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