

Masimo Sensor and Masimo Chip en

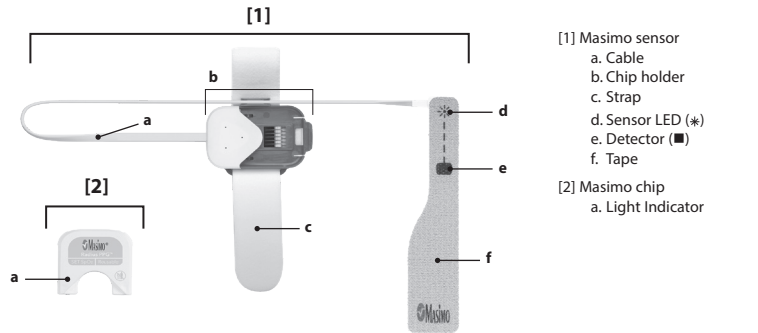
Masimo Sleep™ Wireless Wearable Sensor

USER'S GUIDE

Download the Masimo Sleep application before using this product.
For help, go to www.masimo.com/Sleep for additional tips and tutorials, a full list of supported devices, warranty, trouble shooting, and customer support.

INTRODUCTION

Masimo Sleep™ uses the Masimo Sensor and Masimo Chip to pair with the Masimo Sleep app to measure your oxygen level, pulse rate and respiration rate.



SAFETY PRECAUTIONS

- Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your doctor.
- The Masimo sensor is to only be used with the Masimo authorized devices. Connection to other devices may not allow the sensor to work properly.
- Do not use the sensor if it has visible defects, appears damaged, or seams discolored. Otherwise the sensor may not work properly.
- Check the sensor for proper securement and alignment periodically. Adjust the sensor as necessary. Misapplied sensors may cause incorrect readings.
- Do not leave the sensor components unattended around children. Small items may become choking hazards.
- Carefully select where the sensor strap is attached to avoid entanglement.
- Do not use additional tape to secure the sensor to the site. This can restrict blood flow and cause incorrect readings. Use of additional tape can also cause skin damage, and/or pressure injury or damage the sensor.
- Avoid placing the sensor directly under bright lights (e.g. fluorescent lights, infrared heating lamps, and direct sunlight) as they can interfere with the performance of the sensor. Cover the sensor site with opaque material, if required.
- Avoid applying the sensor on abnormal fingers or on nails with externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc. This may lead to no or incorrect readings.
- Check pairing before use to ensure proper wireless connection.
- To prevent damage, do not soak or immerse the sensor in any liquid solution.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance.

WEARING YOUR SENSOR

- a) Remove the sensor from its packaging. See Fig. 1.
- b) Attach the strap to the wrist of your non-dominant hand
- Peel off the yellow label to activate the battery. See Fig. 2.
 - Wrap the strap around your wrist and secure it to a comfortable fit. See Fig. 3.
- c) Pick a finger to apply the sensor
- The recommended site is the middle or ring finger.
- d) Attach the sensor LED to your finger and align with the detector
- Remove the backing from the sensor, if present. Set the backing aside and save for future storage. Position the LED (*) so that it is on the top of the finger over the nail. See Fig. 4a.
 - Wrap around your finger so the detector (■) is placed on the fleshy part of the finger and aligns directly opposite the LED (*). Complete coverage of the detector is needed to ensure accurate data. See Figs. 4b and 4c.
 - Check that LED (*) and detector (■) are aligned and reposition if necessary.
- e) Adjust the sensor cable and insert the Masimo chip
- Adjust the sensor cable to a comfortable length. See Fig. 5.
 - Click in the Masimo chip and check that the light indicator turns on. See Fig. 6.
- f) Pairing sensor to your phone
- Download and open the Masimo Sleep App.
 - Make sure your phone Bluetooth is turned on.
 - While wearing the sensor, follow the on-screen instructions to pair the sensor to the phone.
 - Verify the Masimo chip light turns blue. (See LIGHT INDICATOR GUIDE section.)

MAINTAINING YOUR SENSOR

- a) Disconnect chip, remove and store sensor
- After your sleep sessions, remove the sensor by first disconnecting the Masimo chip. Push down on the tab to release the Masimo chip from the sensor. See Fig. 7. Separate the two pieces.
 - Remove the strap from your wrist.
 - Carefully unwrap the tape from your finger.
 - Store the tape onto the non-stick backing that you had set aside prior to attaching the sensor to your finger.
 - Store the Masimo chip in its reusable plastic bag. Keep the sensor and Masimo chip in a dry location until it needs to be reused.
- b) Replacing the tape
- Remove the existing tape and discard. See Fig. 8.
 - Peel the replacement tape from backing to expose adhesive. See Fig. 9.
 - Stick the replacement tape onto the sensor, in the same position as the used tape. See Fig. 10.

CLEANING YOUR MASIMO CHIP

CAUTION: Before cleaning, the Masimo chip should be removed from the sensor.

Compatible Cleaning/Disinfection Agents:

- The following solutions can be used on the surfaces of the Masimo chip:
 - 70% Isopropyl alcohol
 - 10% (1:10) chlorine bleach to water solution
 - Quaternary ammonium chloride solution

Note: Check the contents of your household solutions for compatibility.

CAUTIONS:

- To avoid permanent damage to the Masimo chip, do not clean in dishwasher or boil product. This will cause it to no longer function and void the warranty.

LIGHT INDICATOR GUIDE

The Masimo chip includes a light to indicate sensor and pairing status. Refer to the table for a description of the colored lights.

Color	Description	Next Steps
Green	• Masimo chip ready to pair	• Follow app instructions for pairing
Blue	• Successful pairing of Masimo chip	• Verify data is displayed on app
Purple	• Sensor battery issue	• Remove yellow label and any obstruction to the white portion of the chip holder • Disconnect Masimo chip from sensor, wait 30 seconds, insert chip into sensor
Orange	• Low sensor battery	• Consider replacing sensor, do not discard Masimo chip
Red	• Battery depleted or sensor needs to be replaced	• Replace sensor, do not discard Masimo chip. If issue persists, replace Masimo chip • Contact Masimo Customer Support, or replace sensor and Masimo chip

TROUBLESHOOTING

Symptom	Potential Causes	Next Steps
Vitals data not displayed or measurement values don't look correct	<ul style="list-style-type: none">Obstructed or misaligned sensor LED (*) and detector (■).Masimo chip is not fully inserted or has not been properly paired.Sensor is damaged.	<ul style="list-style-type: none">Readjust alignment of the sensor LED (*) and detector (■). Re-install the Masimo chip and repeat the pairing process.Click in the Masimo chip and repeat pairing.Review Safety Precautions for possible reasons for no readings.Replace sensor.Contact Masimo Customer Support.

For additional help, contact Masimo Customer Support at (800) 916-1270. Local contact information can be found at <https://www.masimopersonalhealth.com>.

Masimo Sensor and Masimo Chip

Masimo Sleep™ Wireless Wearable Sensor

Manufacturer:




Masimo Corporation
52 Discovery
Irvine, CA 92618
USA

www.masimo.com

PERFORMANCE SPECIFICATIONS

When used with the Masimo chip, the Masimo sensor has the following specifications:

Masimo sensor		Adult	
 Body Weight		> 40 kg	
Application Site		Finger	
SpO2 Accuracy, No Motion, ARMS ¹ (70–100%)	2%	Pulse Rate Accuracy, No Motion, ARMS ¹ (25–240 bpm)	3 bpm
SpO2 Accuracy, Motion, ARMS ²	3%	Pulse Rate Accuracy, Motion, ARMS ²	5 bpm
SpO2 Accuracy, Low Perfusion, ARMS ³	2%	Pulse Rate Accuracy, Low Perfusion, ARMS ⁴	3 bpm

Note: ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within ± ARMS of the reference measurements in a controlled study.

Respiratory Rate (RRp)	Adult
Respiratory Rate, No Motion (4-70 rpm ⁵)	3 rpm ARMS ± 1 rpm mean error

¹ The Masimo SET Technology has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70–100% SpO2 against a laboratory co-oximeter.

² The Masimo SET Technology has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70–100% SpO2 against a laboratory co-oximeter.

³ The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%.

⁴ The Masimo SET Technology has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%.

⁵ RRp performance has been clinically validated on 28 healthy, adult volunteers, 59 hospitalized adult patients, and 28 hospitalized pediatric patients (> 2 years of age). The clinical testing included non-randomized studies comparing RRp measurements against manual, clinician-scored capnograms. The clinical testing on hospitalized adult and pediatric patients was conducted using convenience sampling and did not necessarily include all patient conditions found in hospitals and hospital-type settings. The clinical testing results may not be generalized to all patient conditions. RRp performance was validated across the entire range of 4 to 70 RPM through bench testing.

ENVIRONMENTAL

Storage/Transport Temperature	0–50°C @ ambient humidity
Operating Temperature	0–40°C @ ambient humidity
Storage/Transport Humidity	5–95% non-condensing
Operating Humidity	5–95% non-condensing

BATTERY LIFE

Battery Life	96 hours in typical continuous usage
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WIRELESS TECHNOLOGY INFORMATION

Bluetooth LE Wireless Technology Information		Radio Equipment
Modulation Type	GFSK	Chip:
Max. Output Power	+8 dBm	EN 301 489-17 V3.1.1 EN 300 328 V2.2.1
Frequency Range	2402–2480 MHz	
Antenna Peak Gain	1 dBi	FCC ID are as follows: Chip: VKF-AIRTB01
Recommended Range	100 ft (~30 meters) line-of-sight	
Quality of Service (QoS)	Delay < 30 seconds	IC IDs are as follows: Chip: 7362A-AIRTB01
Security	Proprietary binary protocol	

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

WARNING: The frequency bands of this device (2.4 GHz) are only for indoor use, in accordance with international telecommunication requirements.

CAUTION: Keep the sensor away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.

Note: This device complies with part 15 of FCC Rules and Industry Canada's license-exempt RSSs: 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: When using sensor consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

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.
- Consult the dealer or an experienced radio/TV technician for help.

RF Radiation Exposure Statement: This equipment has been exempted from FCC RF radiation exposure testing set forth for an uncontrolled environment.

Note: Users are advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5250–5350 MHz and 5650–5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices

The following symbols may appear on the product or product labeling:

SYMBOL	DEFINITION	SYMBOL	DEFINITION	SYMBOL	DEFINITION
 (blue background)	Follow instructions for use		Separate collection for electrical and electronic equipment (WEEE)		Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eFU is not available in all countries.
	Consult instructions for use		Lot code		
	Manufacturer		Catalogue number (model number)		Authorized representative in the European community
	Date of manufacture YYYY-MM-DD		Masimo reference number		Body weight
	Use-by YYYY-MM-DD		Light Emitting Diode (LED) LED emits light when current flows through		Storage temperature range
	Fragile, handle with care		Storage humidity limitation		Keep dry
	Non-Sterile		Bluetooth		Do not use if package is damaged
	Not made with natural rubber latex		Federal Communications Commission (FCC) Licensing		Atmospheric pressure limitation
	Do not re-use/Single patient use only		Identifies unit has been registered as a radio device		Protected against solid foreign objects of 12.5 mm diameter and greater and protection against vertically falling water drops when enclosure is tilted at 15 degrees

Patents: <http://www.masimo.com/patents.htm>

Masimo Sleep is a trademark of Masimo Corporation.

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