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 securing and alignment periodically. Adjust the sensor as necessary. Misaligned 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 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

1. Peel off the yellow label to activate the battery. See Fig. 2.
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

1. The recommended site is the middle or ring finger.

d) Attach the sensor LED to your finger and align with the detector

1. Remove the backing from the sensor, if present. Set the backing aside and save for future storage. Position the LED (a) so that it is on the top of the finger over the nail. See Fig. 4a.
2. Wrap around your finger so the detector (b) is placed on the fleshy part of the finger and aligns directly opposite the LED (a). Complete coverage of the detector is needed to ensure accurate data. See Figs. 4b and 4c.
3. Check that LED (a) and detector (b) are aligned and reposition if necessary.

e) Adjust the sensor cable and insert the Masimo chip

1. Adjust the sensor cable to a comfortable length. See Fig. 5.
2. Click in the Masimo chip and check that the light indicator turns on. See Fig. 6.

f) Pairing sensor to your phone

1. Download and open the Masimo Sleep App.
2. Make sure your phone Bluetooth is turned on.
3. While wearing the sensor, follow the on-screen instructions to pair the sensor to the phone.
4. Verify the Masimo chip light turns blue. (See LIGHT INDICATOR GUIDE section.)

MAINTAINING YOUR SENSOR

a) Disconnect chip, remove and store sensor

1. 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.
2. Remove the strap from your wrist.
3. Carefully unwrap the tape from your finger.
4. Store the tape onto the non-stick backing that you had set aside prior to attaching the sensor to your finger.
5. 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

1. Remove the existing tape and discard. See Fig. 8.
2. Peel the replacement tape from backing to expose adhesive. See Fig. 9.
3. 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:

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

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

MAINTENANCE INSTRUCTIONS

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.

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.

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.

LEGAL DISCLAIMER

Masimo Corporation does not assume responsibility for any errors that may appear in this guide and makes no commitment to update the information contained herein. Masimo Corporation reserves the right to make changes to this document at any time without notice.

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
© 2020 Masimo Corporation
301789/10872A-0820
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, Axs 1 | 2% Pulse Rate Accuracy, No Motion, Axs 1 | 3% Pulse Rate Accuracy, Motion, Axs 2
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<tbody>
<tr>
<td>70–100%</td>
<td>25–240 bpm</td>
<td>5–60 bpm</td>
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<tr>
<td>SpO2 Accuracy, Low Perfusion, Axs 1</td>
<td>2% Pulse Rate Accuracy, Low Perfusion, Axs 2</td>
<td>3% Pulse Rate Accuracy, Motion, Axs 2</td>
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<tr>
<td>70–100%</td>
<td>25–240 bpm</td>
<td>5–60 bpm</td>
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Note: Axs accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fall within ± 1 Axs of the reference measurements in a controlled study.

| Respiratory Rate (RRp) | Adult
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<tr>
<td>Respiratory Rate, No Motion (4-70 rpm)</td>
<td>3 rpm Axs ± 1 rpm mean error</td>
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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 hypoaemia 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 hypoaemia studies while performing rubbing and tapping motions, at 2 to 4 Hz, at 4 cm, and at a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoaemia 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 0.05% and transmission of greater than 3% 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 0.05% and transmission of greater than 3% for saturations ranging from 70% to 100%.

5 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 0.05% and transmission of greater than 3% for saturations ranging from 70% to 100%.

| ENVIRONMENTAL
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| BATTERY LIFE
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| WIRELESS TECHNOLOGY INFORMATION
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<td>Recommended Range</td>
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<td>Quality of Service (QoS)</td>
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WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the user’s warranty to operate the equipment.

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.

FCC Identification Numbers: Chip: VKF-AIRTB01

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