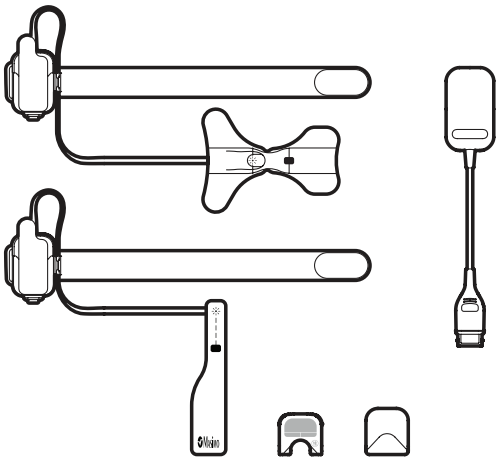
Radius PPG™

Wireless SpO2 Sensors

eIFU indicator



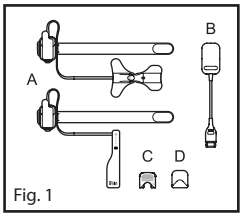
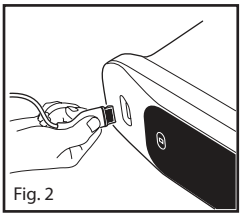


Fig. 1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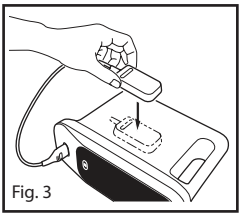
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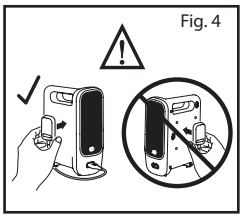
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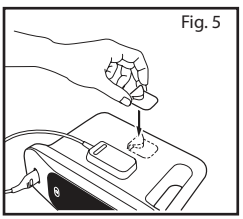
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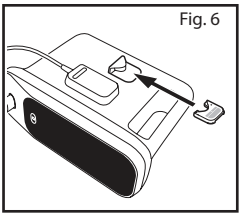
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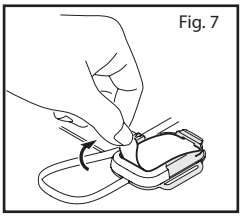
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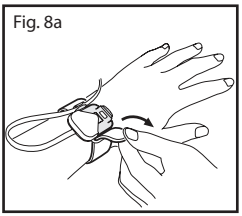
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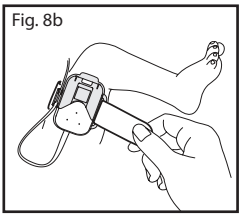
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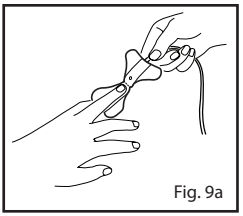
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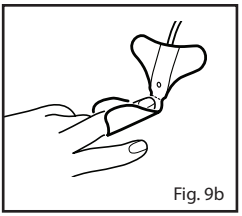
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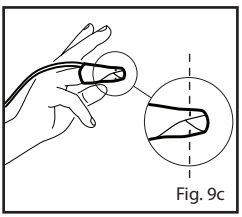
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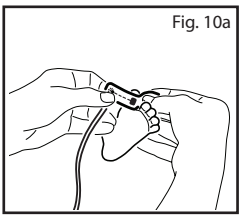
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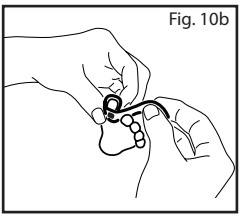
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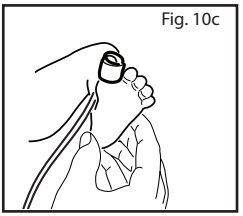
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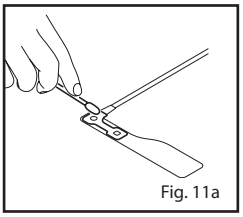
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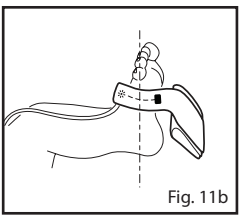
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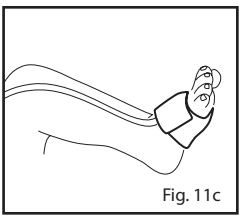
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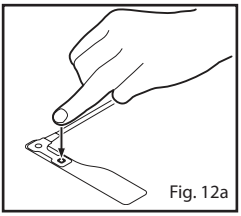
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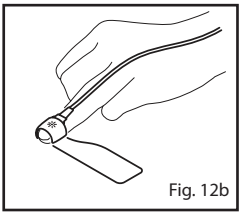
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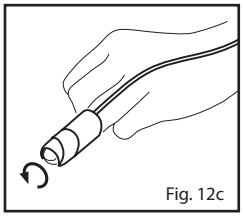
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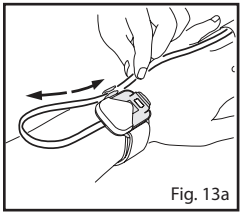
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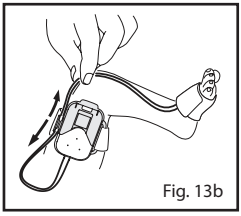
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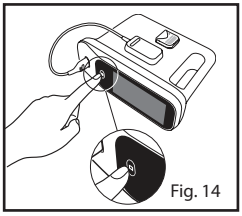
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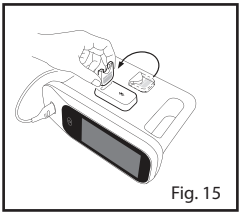
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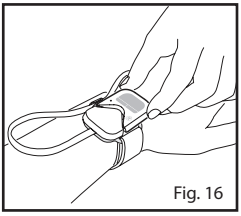
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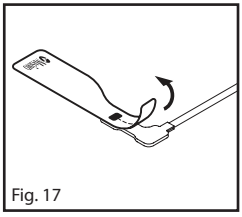
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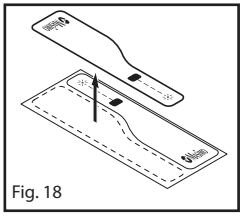
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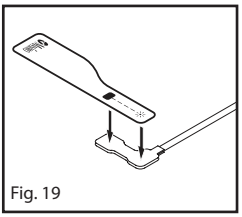
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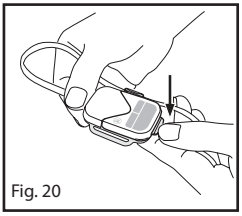
Fig. 20

Radius PPG™

Wireless SpO2 Sensors

DIRECTIONS FOR USE

Adhesive Sensor	Single patient use only	Not made with natural rubber latex	Non-sterile
Reusable Chip and Wireless Receiver	Reusable	Not made with natural rubber latex	Non-sterile

Prior to using this product the user should read and understand the Operator's Manual for the device/monitor and this Directions for Use.

INDICATIONS

Masimo Radius PPG™ is intended for the non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR).

Masimo Radius PPG is indicated for the continuous monitoring of functional arterial oxygen saturation of hemoglobin (SpO_2) and pulse rate (PR) for use with adult, pediatric and neonatal patients during both no motion and motion conditions and for patients who are well or poorly perfused in hospital, hospital-type facilities and home environments.

Devices with Masimo technology are only to be used with Masimo sensors and cables.

CONTRAINDICATIONS

The Radius PPG is contraindicated for patients who exhibit allergic reactions to foam rubber products and/or adhesive tape.

DESCRIPTION

Radius PPG consists of three parts:

- Radius PPG wireless receiver
- Radius PPG reusable chip
- Radius PPG adhesive sensor

Radius PPG is a wireless sensor for use with devices containing Masimo technology MX Version 7.14.8.x. or higher. Consult individual device manufacturers for compatibility of particular device and sensor models. Each device manufacturer is responsible for determining whether their device is compatible with each sensor model.

WARNINGS, CAUTIONS, AND NOTES

- All sensors and cables are designed for use with specific monitors. Verify the compatibility of the monitor, cable and sensor before use, otherwise degraded performance and/or patient injury can result.
- The sensor should be free of visible defects, discoloration and damage. If the sensor is discolored or damaged, discontinue use. Never use a damaged sensor or one with exposed electrical circuitry.
- Do not leave the sensor components unattended around children. Small items may become choking hazards.
- The site must be checked frequently or per clinical protocol to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.
- Exercise caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess site as frequently as every (1) hour with poorly perfused patients and move the sensor if there are signs of tissue ischemia.
- Circulation distal to the sensor site should be checked routinely.
- The sensor attachment strap site must be checked frequently or per clinical protocol to ensure adequate securement, circulation and skin integrity.
- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- With very low perfusion at the monitored site, the reading may read lower than core arterial oxygen saturation.
- Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage, and/or pressure necrosis or damage the sensor.
- Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis.
- Misapplied sensors or sensors that become partially dislodged may cause incorrect measurements.
- Misapplications due to wrong sensor types can cause inaccurate or no readings.
- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor).
- Venous pulsations may cause erroneous low SpO_2 readings (e.g. tricuspid value regurgitation).
- The pulsations from intra-aortic balloon support can affect the pulse rate displayed on the oximeter. Verify patient's pulse rate against the ECG heart rate.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If sensor is exposed to the

radiation, the reading might be inaccurate or not provided for the duration of the active radiation period.

- Do not use the sensor during MRI scanning or in a MRI environment.
- High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor.
- To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 measurements.
- Elevated Total Bilirubin levels may lead to inaccurate SpO_2 measurements.
- High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Abnormal fingers, Intravascular dyes such as indocyanine green or methylene blue or externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc. may lead to inaccurate SpO_2 measurements.
- Inaccurate SpO_2 readings may be caused by severe anemia, low arterial perfusion, motion artifact, hypocapnic or hypercapnic conditions, EMI radiation interference.
- To ensure continued monitoring, routinely verify the wireless connection.
- When using multiple Radius PPG sensors, repeat pairing before monitoring 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 and/or accuracy.
- Do not attempt to reuse on multiple patients, reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.
- When using Radius PPG, keep it within the recommended range from the connected host (see Wireless Technology Information for details); moving outside of this range may cause a loss in connection with the host device.
- When using Radius PPG, relocate the devices away from sources that may interfere with the Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service (see Specifications for details) of the Bluetooth connection. Devices that may cause RFI include but are not limited to the following: electrocautery equipment, diathermy equipment, other cellular telephones, wireless PC and tablets, pagers, RFID devices, MRI, and electromagnetic security systems.
- **Caution:** Replace the sensor when a replace sensor message is displayed, or when a low SIQ message is consistently displayed after completing the low SIQ troubleshooting steps identified in the monitoring device operator's manual.
- **Note:** The sensor is provided with X-Cal® technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. After single-patient use, discard sensor.

INSTRUCTIONS

a) Verification of components

1. Gather all components required for monitoring. Refer to **Fig. 1.**
   - **A. Radius PPG adhesive sensor**
   - **B. Radius PPG wireless bluetooth receiver**
   - **C. Radius PPG reusable chip**
   - **D. Radius PPG reusable chip holder for device**

b) Initial setup

1. Turn on the patient monitor.
2. Plug the cable into the patient monitor. Refer to **Fig. 2**. The light on wireless receiver will be white.
3. Attach the wireless receiver to the side of the patient monitor using the adhesive provided. Refer to **Fig. 3.**
4. Avoid covering speakers or holes used for mounting when attaching the module. Refer to **Fig. 4.**
5. Attach the chip holder near the receiver on the patient monitor. Refer to **Fig. 5.**
6. Verify that the wireless receiver is attached and plugged in to patient monitor. Verify that the chip holder is attached to patient monitor. Refer to **Fig. 6.**

c) Sensor site selection

- Radius PPG ADT: **Adult Sensor** > 30 kg: The preferred site is the middle or ring finger of the non-dominant hand.
- Radius PPG PDT: **Pediatric Sensor** 10–50 kg: The preferred site is middle or ring finger of the non-dominant hand.
- Radius PPG INF: **Infant Sensor** 3–10 kg: The preferred site is the great toe. Alternatively, the toe next to the great toe, or the thumb can be used. 10–20 kg: The preferred site is the middle or ring finger of the non-dominant hand.
- Radius PPG NEO: **Neonatal/Adult Sensor** < 3 kg: The preferred site is the foot. Alternatively, across the palm and back of the hand can be used. > 40 kg: The preferred site is the middle or ring finger of the non-dominant hand.

d) Attaching the strap to the patient

1. Open the pouch and remove the single-patient-use sensor.
2. Peel off the plastic tab to activate the battery, and discard the tab. Refer to **Fig. 7.**
3. Thread the attachment strap through the plastic loop hole. Wrap the attachment strap around the wrist or limb of the patient (based on selected sensor site) and attach using the hook and loop closure. Refer to **Figs. 8a and 8b.**
4. Remove the backing from the sensor, if present.

e) Attaching the sensor to the patient.

Adt sensor for ADULTS (> 30 kg) and Pdt sensor for PEDIATRICS (10–50 kg)

1. Orient the sensor so that the detector can be placed first. Place the tip of the finger on the dashed line with the fleshy part of the finger covering the finger outline and detector window. Refer to **Fig. 9a.**
2. Press the adhesive wings, one at a time, onto the finger. Fold the sensor over the finger with the emitter window (✳) positioned over the fingernail. Secure the wings down, one at a time, around the finger. Complete coverage of the detector window is needed to ensure accurate data. Refer to **Fig. 9b.**
3. When properly applied, the emitter and detector should be vertically aligned (the black lines should align). Reposition if necessary. Refer to **Fig. 9c.**

Inf sensor for INFANTS (3–10 kg)

1. Direct the sensor cable so that it runs along the top of the foot. Position the detector on the fleshy pad of the great toe. Alternatively, the toe next to the great toe, or the thumb can be used (not shown). Refer to **Fig. 10a.**
2. Wrap the adhesive wrap around the toe so the emitter is positioned on the nail bed of the great toe. Complete coverage of the detector window is needed to ensure accurate data. Refer to **Fig. 10b.**
3. Ensure that the emitter window (✳) aligns on the top of the toe directly opposite the detector. Verify correct positioning and reposition if necessary. Refer to **Fig. 10c.**

Neo sensor for NEONATES (< 3 kg)

1. For fragile skin, the stickiness of the medical grade adhesive can be diminished or eliminated by daubing the adhesive areas with a cotton ball or gauze. Refer to **Fig. 11a.**
2. Direct the sensor cable toward the ankle (or wrist). Apply the sensor around the lateral aspect of the foot (or hand), aligned with the fourth toe (or finger). Complete coverage of the detector window is needed to ensure accurate data. Refer to **Fig. 11b.**
3. Wrap the adhesive/foam wrap around the lateral aspect of the foot (or hand) and ensure that the emitter window(✳) aligns directly opposite of the detector. Be careful to maintain proper alignment of the detector and emitter windows while attaching adhesive/foam wrap to secure the sensor. Verify correct positioning and reposition if necessary. Refer to **Fig. 11c.**

Neo sensor for ADULTS (> 40 kg) Inf sensor for INFANTS (10–20 kg)

1. Direct the sensor cable so that it runs along the top of the hand. Position the detector on the fleshy part of the finger. Refer to **Fig. 12a.**
2. Alternatively, the sensor may also be applied to the toe (not shown).
3. Wrap the adhesive wrap around the finger so the emitter window (✳) aligns on the top of the finger directly opposite the detector. Complete coverage of the detector window is needed to ensure accurate data. Refer to **Fig. 12b.**
4. Check the sensor to verify correct positioning and reposition if necessary. Refer to **Fig. 12c.**

f) Adjusting the sensor cable

1. With the sensor attached on the selected application site, adjust the thin flexible sensor cable. Refer to **Figs. 13a and 13b.**

g) Pairing the reusable transmitter chip with the wireless receiver

1. Ensure the device is powered on. Refer to **Fig. 14.**
2. Hold the reusable chip to the indent on the wireless receiver until the Bluetooth symbol on the wireless receiver turns green. Refer to **Fig. 15.**
3. Insert the reusable chip into the sensor attachment strap until there is a tactile or audible click of connection. Refer to **Fig. 16.**
4. Verify the light on the wireless receiver turns blue. (See LIGHT INDICATOR GUIDE section.)

h) Reattachment

1. The sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

i) Applying replacement tape (for Neo sensor only)

1. Remove the existing tape and discard Refer to **Fig. 17**.
2. Remove the replacement tape from the release liner. Refer to **Fig. 18.**
3. Position the replacement tape over the sensor, aligning the emitter component with the sensor cable. Refer to **Fig. 19**.

j) Disconnecting

1. Push down on the tab to release the reusable chip from the sensor. Refer to **Fig. 20.**
2. After cleaning, store the reusable chip in the chip holder attached to the patient monitor. Refer back to **Fig. 6.**
3. Discard the adhesive sensor and strap.

CLEANING

WARNING: Before cleaning, make sure the chip is not applied to a patient.

To surface clean the reusable chip and wireless receiver:

1. Wipe all surfaces of the reusable chip and wireless receiver with one of the following:
   a. 70% Isopropyl alcohol
   b. 10% (1:10) chlorine bleach to water solution
   c. Quaternary ammonium chloride solution
2. Inspect for visible debris and repeat the above cleaning step as needed.
3. Dry cleaned parts before use.

CAUTIONS:

- To avoid permanent damage to the reusable chip and wireless receiver, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.
- Do not immerse the reusable chip and wireless receiver in any liquid solution.
- Do not sterilize by irradiation, steam, autoclave or ethylene oxide.

LIGHT INDICATOR GUIDE

Color	Wireless receiver	Transmitter chip	Description	Next steps
No light	--	--	• Wireless receiver cable is not connected to host device with power • Chip not connected to sensor with battery	• Turn on patient monitor and plug cable into patient monitor • See *Instructions,* section *b)* for set up
White	solid	--	• Wireless receiver is connected to host device with power ready to initiate pairing with transmitter chip • Paring search period has expired	• Hold reusable chip to the indent on the wireless receiver to initiate pairing • See *Instructions,* section *g)* for pairing
Green	solid (2 seconds)	--	• Chip and receiver are linked	• Insert reusable chip into sensor attachment strap to complete pairing • See *Instructions,* section *g)* for pairing
	flashing (30 seconds)	flashing (30 seconds)	• Pairing search period	
Blue	solid	flashing	• Successful pairing of receiver and chip	• Verify sensor attachment so host device can receive data
Purple	flashing	flashing	• Battery seal tab has not been removed to activate battery • Battery is obstructed	• Remove tab to activate battery (Refer to **Fig. 7.**) • Disconnect reusable chip from sensor, wait 30 seconds, insert chip into sensor (Refer to **Figs. 20** and **16.**)
Orange	flashing	flashing	• Low sensor battery	• Consider replacing sensor, do not discard reusable chip • See *Instructions,* section *j)* for disconnecting
Red	flashing	flashing	• Depleted sensor battery • Hardware or sensor failure, chip blinking board failure code	• Replace sensor, do not discard reusable chip. If issue persists, replace reusable chip • See *Instructions,* section *j)* for disconnecting • Contact Masimo Technical Support, or replace sensor and chip

SPECIFICATIONS

When used with Masimo SET pulse oximetry monitors, or with licensed Masimo SET pulse oximetry modules the Radius PPG sensors have the following specifications:

Radius PPG sensor used with Masimo device	Radius PPG Adt	Radius PPG Pdt	Radius PPG Inf		Radius PPG Neo	
Body Weight	> 30 kg	10–50 kg	3–10 kg	10–20 kg	< 3 kg	> 40 kg
Application Site	Finger or Toe	Finger or Toe	Thumb or Great Toe	Finger or Toe	Hand or Foot	Finger or Toe
SpO_2 Accuracy, No Motion (70–100%[1])	2%	2%	2%	2%	3%[5]	2%
SpO_2 Accuracy, Motion[2]	3%	3%	3%	3%	3%	3%
SpO_2 Accuracy, Low Perfusion[3]	2%	2%	2%	2%	3%[5]	2%
Pulse Rate[1] Accuracy, No Motion (25–240 bpm)	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm
Pulse Rate Accuracy, Motion[2]	5 bpm	5 bpm	5 bpm	5 bpm	5 bpm	5 bpm
Pulse Rate Accuracy, Low Perfusion[4]	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm

SpO2 Upper and Lower Limits of Agreement (LoA)*	
	No Motion
Upper 95% LoA	1.98%
Lower 95% LoA	-2.91%

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.

[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% SpO_2 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% SpO_2 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] The saturation accuracy of the Neonate and Preterm sensors were validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.

[*] See Bland and Altman. Agreement between methods of measurement with multiple observations per individual Journal of Biopharmaceutical Statistics (2007) vol. 17 pp. 571-582.

The emitted wavelengths range from 600 to 1000 nm and the peak optical power is less than 15 mW. Information about the wavelength range can be especially useful to clinicians.

ENVIRONMENTAL SPECIFICATIONS

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

BATTERY LIFE

Battery Life	Minimum 96 hours with continuous usage

WIRELESS TECHNOLOGY INFORMATION

Bluetooth LE Wireless Technology Information	
Modulation Type	GFSK
Max. Output Power	+8 dBm
Frequency Range	2402 MHz - 2480 MHz
Antenna Peak Gain	0 dBi
Recommended Range	100 ft (~30 meters) line-of-sight
Quality of Service (QoS)	Delay <30 seconds
Security	Proprietary binary protocol

FCC ID are as follows: Chip: AIRTB01 Receiver: AIRDG01

COMPATIBILITY

This sensor is intended for use only with devices containing Masimo SET oximetry or pulse oximetry monitors licensed to use Masimo sensors. Radius PPG sensors are compatible with the following Masimo technology boards and software versions and higher: MX version 7.14.8.x. Each sensor is designed to operate correctly only on the pulse oximetry systems from the original device manufacturer. Use of this sensor with other devices may result in no or improper performance. For Compatibility Information Reference: www.Masimo.com

WARRANTY

Masimo warrants to the initial buyer only that these products, when used in accordance with the directions provided with the Products by Masimo, will be free of defects in materials and workmanship for a period of six (6) months. Single use products are warranted for single patient use only.

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For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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).	Rx ONLY	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician
	Consult instructions for use	LOT	Lot code	CE 0123	Mark of conformity to European Medical Device Directive 93/42/EEC
	Manufacturer	REF	Catalogue number (model number)	EC REP	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
	Do not discard	>	Greater than		Keep dry
NON STERILE	Non-Sterile	<	Less than		Do not use if package is damaged
	Not made with natural rubber latex	%	Storage humidity limitation		Atmospheric pressure limitation
	Caution		Bluetooth	IP22	Protection from ingress of particulates > than 12.5 mm and protection against vertically falling water drops when enclosure is tilted at 15 degrees.
	Do not re-use/Single patient use only	FC	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device
	Fragile, handle with care	eIFU indicator	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs **Note: eIFU is not available in all countries.**		

Patents: http://www.masimo.com/patents.htm
Radius PPG is a trademark of Masimo Corporation.
Masimo, SET, X-Cal, and are federally registered trademarks of Masimo Corporation.

RECOMMENDED SEPARATION DISTANCES

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT AND THE ME EQUIPMENT

The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment 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 (m)		
	150 K Hz to 80 MHz $d = 1.17*\sqrt{P}$	80 MHz to 800 MHz $d = 1.17*\sqrt{P}$	800 MHz a 2.5 GHz $d = 2.33*\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

PERFORMANCE SPECIFICATIONS

The table below shows ARMS (Accuracy Root Mean Square) values measured using the Radius PPG sensors under no motion, with Masimo Technology in a clinical study.

Radius PPG Sensor

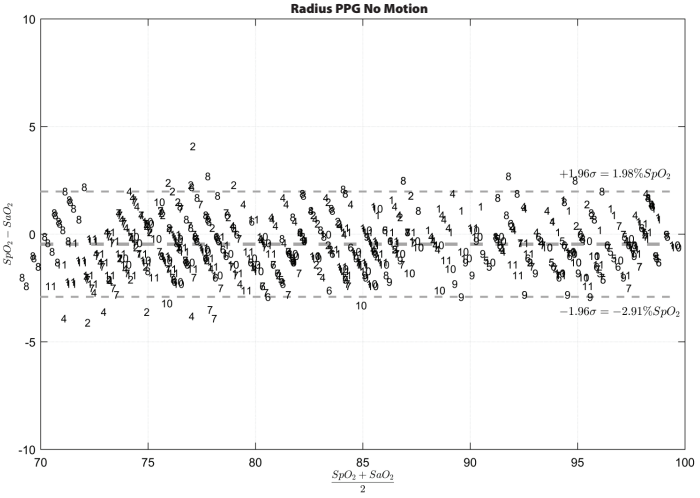
SpO_2	ARMS
90-100%	1.14 (1,14) %
80-90%	1.29 (1,29) %
70-80%	1.41 (1,41) %
70-100%	1.33 (1,33) %

SpO_2 Upper and Lower Limits of Agreement (LoA)*	
	Actual Value
Upper 95% LoA	1.98%
Lower 95% LoA	-2.91%

** See Bland and Altman. Agreement between methods of measurement with multiple observations per individual Journal of Biopharmaceutical Statistics (2007) vol. 17 pp. 571-582.*

70 -100%

(SpO_2-SaO_2) vs. (SpO_2+SaO_2)/2 Bland Altman fit and upper 95% and lower 95% limits of agreement.



Manufacturer:
Masimo Corporation
52 Discovery
Irvine, CA 92618
USA

www.masimo.com

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