MASiMO Rad-G YI SpO2 Multisite Reusable Sensor User Manual

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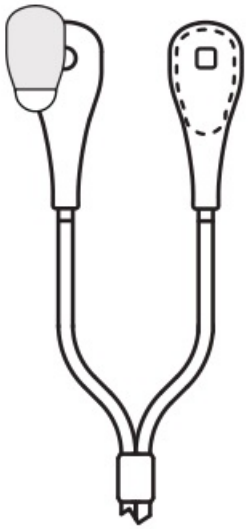
Rad-G® YI

SpO2 Multisite Reusable Sensor and Single Patient Use Attachment Wraps



Images	2-3
en English	4-7

Performance Specifications	96

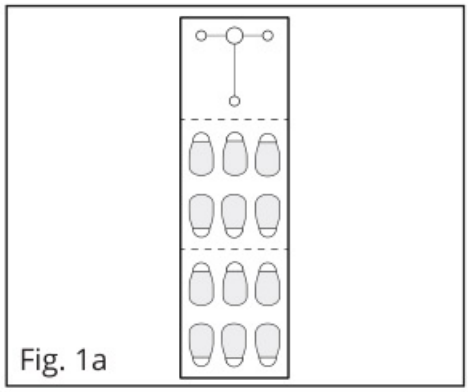


Fig. 1a

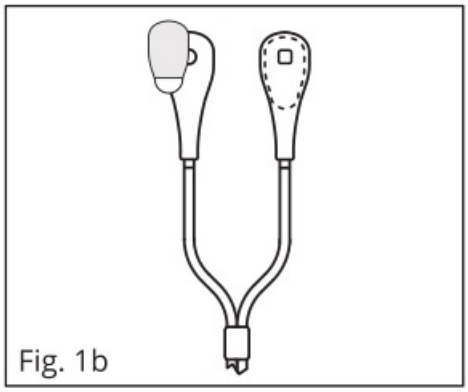


Fig. 1b

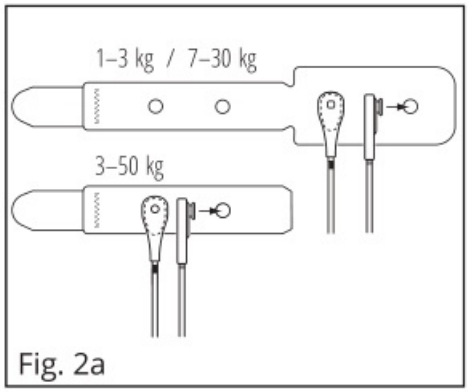


Fig. 2a

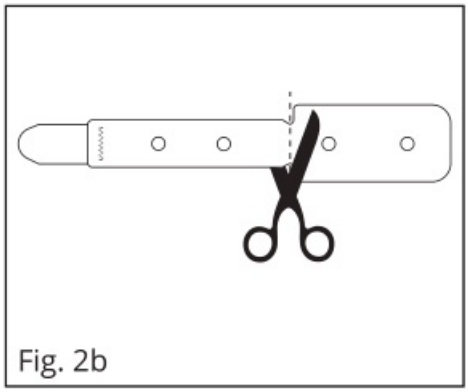


Fig. 2b

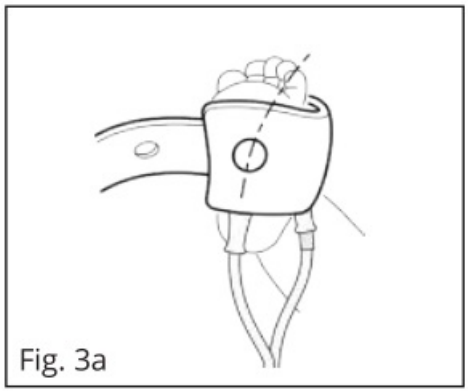


Fig. 3a

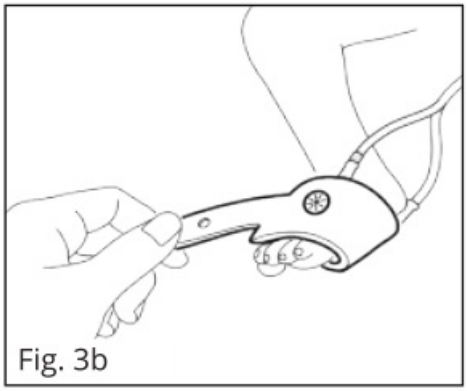


Fig. 3b

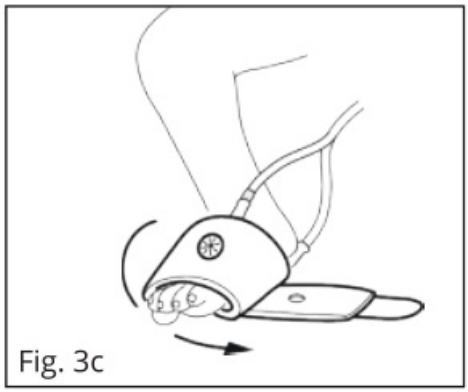


Fig. 3c

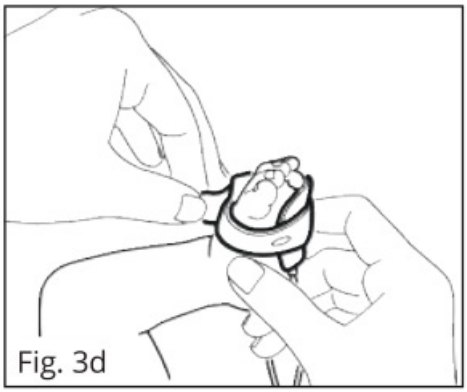
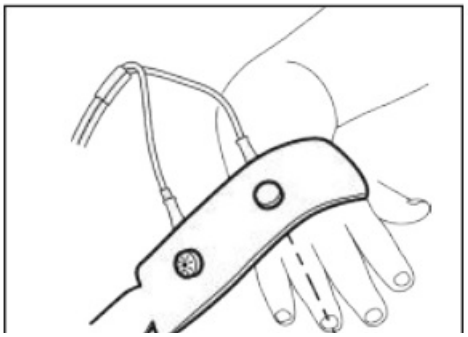


Fig. 3d



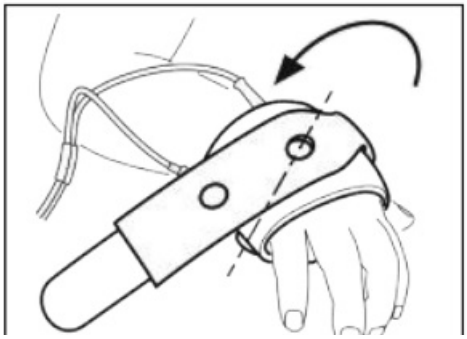



Fig. 4a


Fig. 4b

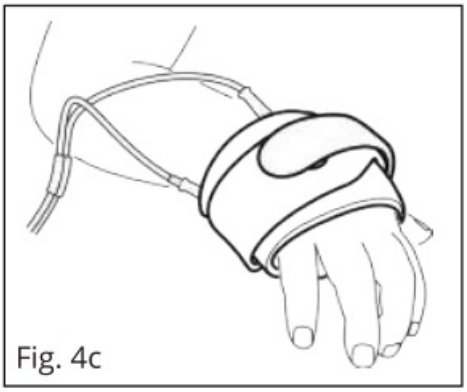


Fig. 4c

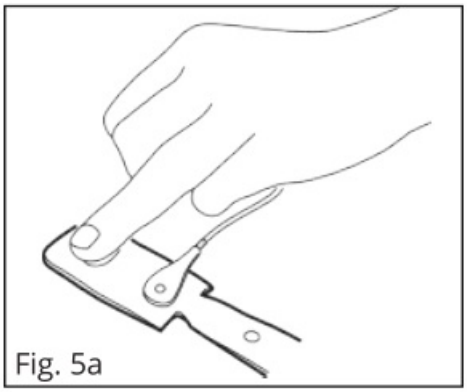
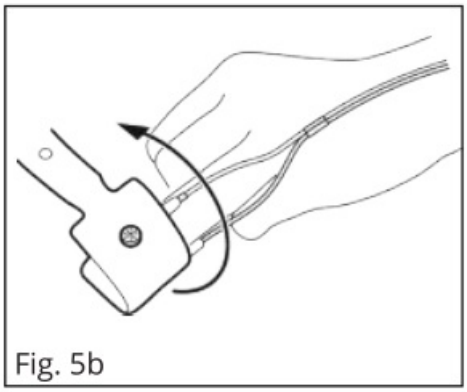


Fig. 5a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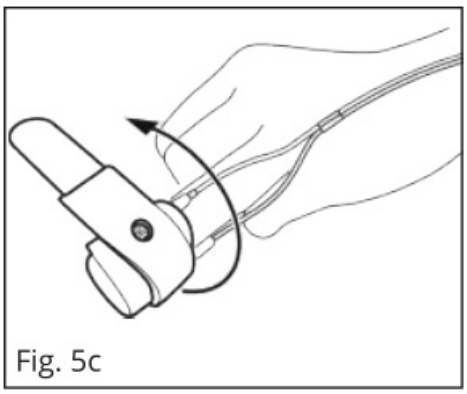


Fig. 5c

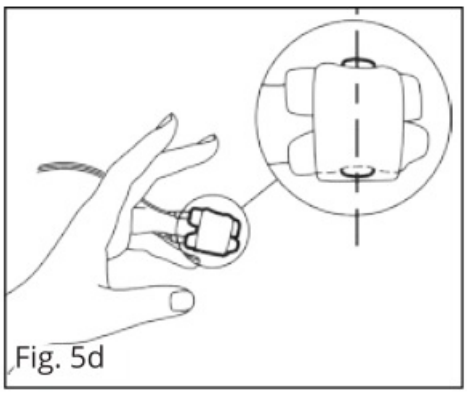


Fig. 5d

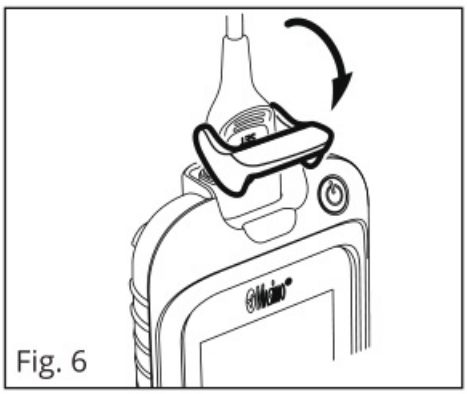


Fig. 6

DIRECTIONS FOR USE

Reusable (sensor)

Not made with natural rubber latex

Non-sterile

Prior to using this sensor, the user should read and understand the Operator's Manual for the Device and this Directions for Use.

Contents

1 INDICATIONS
2 CONTRAINDICATIONS
3 DESCRIPTION
4 WARNINGS, CAUTIONS AND NOTES
5 INSTRUCTIONS
6 CLEANING
7 SPECIFICATIONS
8 ENVIRONMENTAL
9 COMPATIBILITY
10 WARRANTY
11 WARRANTY EXCLUSIONS
12 PERFORMANCE SPECIFICATIONS
13 Documents / Resources
13.1 References

INDICATIONS

The Rad-G® YI Reusable Sensor is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for use with adult, pediatric, infant, and neonatal patients during both no motion and motion conditions and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

CONTRAINDICATIONS

The Rad-G YI Multisite Reusable Sensor is contraindicated for patients who exhibit allergic reactions to foam urethane products and/ or adhesive tape.

DESCRIPTION

The Rad-G YI sensor is applied to the sensor site using Masimo® attachment wraps. The attachment wraps are for single-patient use only. The Rad-G YI is for use only with devices containing Masimo SET® oximetry or licensed to use Rad-G YI sensors. The Masimo Attachment Wraps are for use only with the Rad-G YI Reusable Multisite Sensors. Consult individual instrument manufacturer for compatibility of particular instrument and sensor models. Each instrument manufacturer is responsible for determining whether its instruments are compatible with each sensor model. The YI series has been verified using Masimo SET Oximetry Technology.

The sensor must be removed and the site inspected at least every four (4) hours or sooner, and, if indicated by circulatory condition or skin integrity, reapplied to a different monitoring site.

WARNING: Masimo sensors and cables are designed for use with devices containing Masimo SET® oximetry or licensed to use Masimo sensors.

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. · The site must be checked frequently or per clinical protocol to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.
- Exercise extreme 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.
- 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.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- Misapplied sensors or sensors that become partially dislodged may cause incorrect measurements.
- Misapplications due to wrong sensor types can cause inaccurate or no readings.
- Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis.
- Inaccurate SpO2 readings may be caused by abnormal venous pulsation or venous congestion.
- 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, Trendelenburg position).
- Venous pulsations may cause erroneous low SpO2 readings (e.g. tricuspid valve regurgitation, Trendelenburg position).
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient’s pulse rate against the ECG heart rate. · 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 the unit might read zero 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.
- Inaccurate readings may be caused by EMI radiation interference.
- 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 SpO2 measurements.
- High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO2 measurements.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO2 measurements.
- Elevated Total Bilirubin levels may lead to inaccurate SpO2 measurements.

- Inaccurate SpO2 readings may be caused by severe anemia, low arterial perfusion or motion artifact.
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc. may cause inaccurate SpO2 readings.
- Inaccurate SpO2 readings may be caused by vasospastic disease such as Raynaud's, and peripheral vascular disease.
- Inaccurate SpO2 readings may be caused by elevated levels of dyshemoglobin, hypocapnic or hypercapnic conditions and severe vasoconstriction or hypothermia.
- SpO2 readings may be affected under very low perfusion conditions at the monitored site.
- Readings provided with a low signal confidence indicator may not be accurate.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance and/or accuracy.
- Clean the sensors prior to reuse on multiple patients.
- To prevent damage, do not soak or immerse the connector in any liquid solution.
- Do not attempt to sterilize by irradiation, steam, autoclave or ethylene oxide.
- Do not attempt to 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.
- **Caution**: Replace the sensor when a replace sensor message is displayed, or when a low SIQ message is consistently displayed while monitoring consecutive patients 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. Replace the sensor when the patient monitoring time is exhausted.

INSTRUCTIONS

A. Selecting the site

Select the appropriate application site based on patient weight:

Body Weight	Application Site
1–3 kg	Foot, hand
3–10 kg	Foot, hand, great toe, thumb
10–50 kg	Finger, great toe
> 30 kg	Finger, great toe

- Always choose a site that will completely cover the sensor's detector window.
- The site should be free of debris prior to sensor placement.
- Choose a site that is well perfused and least restricts a conscious patient's movements.
- The sensor is not intended for placement on the ear, if the ear is the desired monitoring site the Masimo RD SET TC-I reusable sensor is recommended.

B. Attaching the adhesive squares to the sensor

- For improved adherence of the adhesive squares to the sensor, wipe the sensor pads with 70% isopropyl

alcohol and allow to dry prior to attaching the adhesive squares.

1. Remove the adhesive squares from the backing. (see Fig. 1a)
2. Attach one square to each window of the sensor pads (emitter and detector). Avoid touching the sticky side prior to applying to the sensor pads. (see Fig. 1b)
3. Do not remove the release liner until ready to apply the sensor to the site.

CAUTION: Do not use adhesive squares on fragile skin.

C. Inserting the sensor into the foam attachment wrap

1. Locate the sensor attachment holes on the wrap. Orient the wrap so that the patient-contacting surface is on top. (see Fig. 2a)
2. Locate the emitter side of the sensor (indicated by the red mark on the cable) and push the button on the back of the sensor into left hole on the wrap
3. Push the button on the detector side of the sensor into the right hole on the wrap.
4. The foam wrap can shortened for smaller site applications (child's finger or toe, pre-term infant's foot or hand). (see Fig. 2b)

D. Applying sensor to patient (see Figs. 3a5d)

1. Route the sensor cable towards the patient.
2. Place the detector side of the sensor on the fleshy portion of the application site.
3. Place the emitter side of the sensor directly opposite to the detector (nail bed, top of foot, palm of hand).
4. Wrap the tab around the application site to secure the alignment of the emitter and detector windows.
   Note: Wrap should be loose enough to avoid restricting circulation around the site.

E. Connecting the sensor to the device

1. Insert the sensor connector into the top of the device.
2. Ensure the connector is fully engaged with the device.
3. Push the connector cover closed until a tactile or audible click of connection is heard. (see Fig. 6)

F. Disconnecting the sensor from the device

1. Lift up the protective cover.
2. Pull firmly on the sensor connector to remove it from the patient cable.
   Note: To avoid damage, pull on the sensor connector, not the cable.

CLEANING

To surface clean the sensor:

1. Remove the sensor from the patient and disconnect it from the attachment wrap and patient cable.
2. Remove the adhesive squares.

3. Clean the YI sensor by wiping it with: Glutaraldehyde, Ammonium Chlorides, 10% chlorine bleach to water solution, 70% isopropyl alcohol, Hydrogen Peroxide, or Chlorhexidine 4%.
4. Dry the sensor by wiping all surfaces with a clean cloth or dry gauze pad.
5. Allow the sensor to dry prior to placement on a patient.

or

1. If low-level disinfection is required, wipe all surfaces of the YI sensor and cable with a cloth or gauze pad saturated with a 1:10 bleach/water solution.
2. Saturate another cloth or gauze pad with sterile or distilled water and wipe all surfaces of the YI sensor and cable.
3. Dry the sensor and cable by wiping all surfaces with a clean cloth or dry gauze pad.

To clean or disinfect the sensor using a soaking method:

1. Place the sensor in the cleaning solution (1:10 bleach/water solution), so that the sensor and desired length of cable are completely immersed.
   WARNING: Do not immerse the connector end of the sensor cable as this may damage the sensor.
2. Dislodge air bubbles by gently shaking the sensor and cable.
3. Soak the sensor and the cable for at least 10 minutes and not greater than 2 hours. Do not immerse the connector.
4. Remove from cleaning solution.
5. Place the sensor and the cable in room temperature sterile or distilled water for 10 minutes. Do not immerse the connector.
6. Remove from the water.
7. Dry the sensor and cable with a clean cloth or dry gauze pad.

CAUTION:

- Do not use undiluted bleach (5%5.25% sodium hypochlorite) or any cleaning solution other than those recommended herein because permanent damage to the sensor could occur.
- Do not immerse the connector on the YI cable in any liquid solution.
- Do not sterilize by irradiation, steam, autoclave, or ethylene oxide.
- Using excessive force when removing the attachment wrap may damage the sensor.

SPECIFICATIONS

When used with Masimo SET® pulse oximetry monitors, or with licensed Masimo SET pulse oximetry modules and patient cables, the YI sensors have the following specifications:

Rad-G YI Sensor:	Adults / Pediatrics / Infants	Neonates
Body Weight	> 3 kg	1–3 kg
Application Site	Finger, Hand, Thumb, Toe, Foot	Foot, Hand
SpO_2 Accuracy, No Motion[1]	2%	3%
SpO_2 Accuracy, Motion[2]	3%	3%
SpO_2 Accuracy, Low Perfusion[3]	2%	3%
Pulse Rate Accuracy, No Motion[4]	3 bpm	3 bpm
Pulse Rate Accuracy, Motion[4]	5 bpm	5 bpm
Pulse Rate Accuracy, Low Perfusion[4]	3 bpm	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.

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 70100% 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 70100% 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 25240 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%.

ENVIRONMENTAL

Storage/Transport Temperature	-40°C to +70°C, ambient humidity
Storage Humidity	10% to 95% relative humidity (non-condensing)
Operating Temperature	+5°C to +40°C, ambient humidity
Operating Humidity	10% to 95% relative humidity (non-condensing)

COMPATIBILITY

This sensor is intended for use only with devices containing Masimo SET oximetry or pulse oximetry monitors licensed to use Rad-G YI sensors. 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.

THE FOREGOING IS THE SOLE AND EXCLUSIVE WARRANTY APPLICABLE TO THE PRODUCTS SOLD BY MASIMO TO BUYER. MASIMO EXPRESSLY DISCLAIMS ALL OTHER ORAL, EXPRESS OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. MASIMO'S SOLE OBLIGATION AND BUYER'S EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY SHALL BE, AT MASIMO'S OPTION, TO REPAIR OR REPLACE THE PRODUCT.

WARRANTY EXCLUSIONS

This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product, or has been subject to misuse, neglect, accident or externally created damage. This warranty does not extend to any product that has been connected to any unintended device or system, has been modified, or has been disassembled or reassembled. This warranty does not extend to sensors or patient cables that have been reprocessed, reconditioned or recycled.

IN NO EVENT SHALL MASIMO BE LIABLE TO BUYER OR ANY OTHER PERSON FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION LOST PROFITS), EVEN IF ADVISED OF THE POSSIBILITY THEREOF. IN NO EVENT SHALL MASIMO'S LIABILITY ARISING FROM ANY PRODUCTS SOLD TO BUYER (UNDER A CONTRACT, WARRANTY, TORT OR OTHER CLAIM) EXCEED THE AMOUNT PAID BY BUYER FOR THE LOT OF PRODUCT(S) INVOLVED IN SUCH CLAIM. IN NO EVENT SHALL MASIMO BE LIABLE FOR ANY DAMAGES ASSOCIATED WITH A PRODUCT THAT HAS BEEN REPROCESSED, RECONDITIONED OR RECYCLED. THE LIMITATIONS IN THIS SECTION SHALL NOT BE DEEMED TO PRECLUDE ANY LIABILITY THAT, UNDER APPLICABLE PRODUCTS LIABILITY LAW, CANNOT LEGALLY BE PRECLUDED BY CONTRACT.

NO IMPLIED LICENSE

PURCHASE OR POSSESSION OF THIS SENSOR CONFERS NO EXPRESS OR IMPLIED LICENSE TO USE THE SENSOR WITH ANY DEVICE
WHICH IS NOT SEPARATELY AUTHORIZED TO USE Rad-G YI SENSORS.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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

If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

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

SYMBOL	DEFINITION	SYMBOL	DEFINITION	SYMBOL	DEFINITION
	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		Caution		Storage temperature range
	Do not discard	>	Greater than		Keep dry
	Non-Sterile	<	Less than		Do not use if package is damaged and consult instructions for use
	Not made with natural rubber latex		Storage humidity limitation		Atmospheric pressure limitation
	Fragile, handle with care	MD	Medical device	UDI	Unique device identifier
	Light Emitting Diode (LED) LED emits light when current flows through		Importer		Distributor
UK CA	UKCA Mark		Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs **Note: eIFU is not available in all countries.**		

http://www.Masimo.com/TechDocs

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

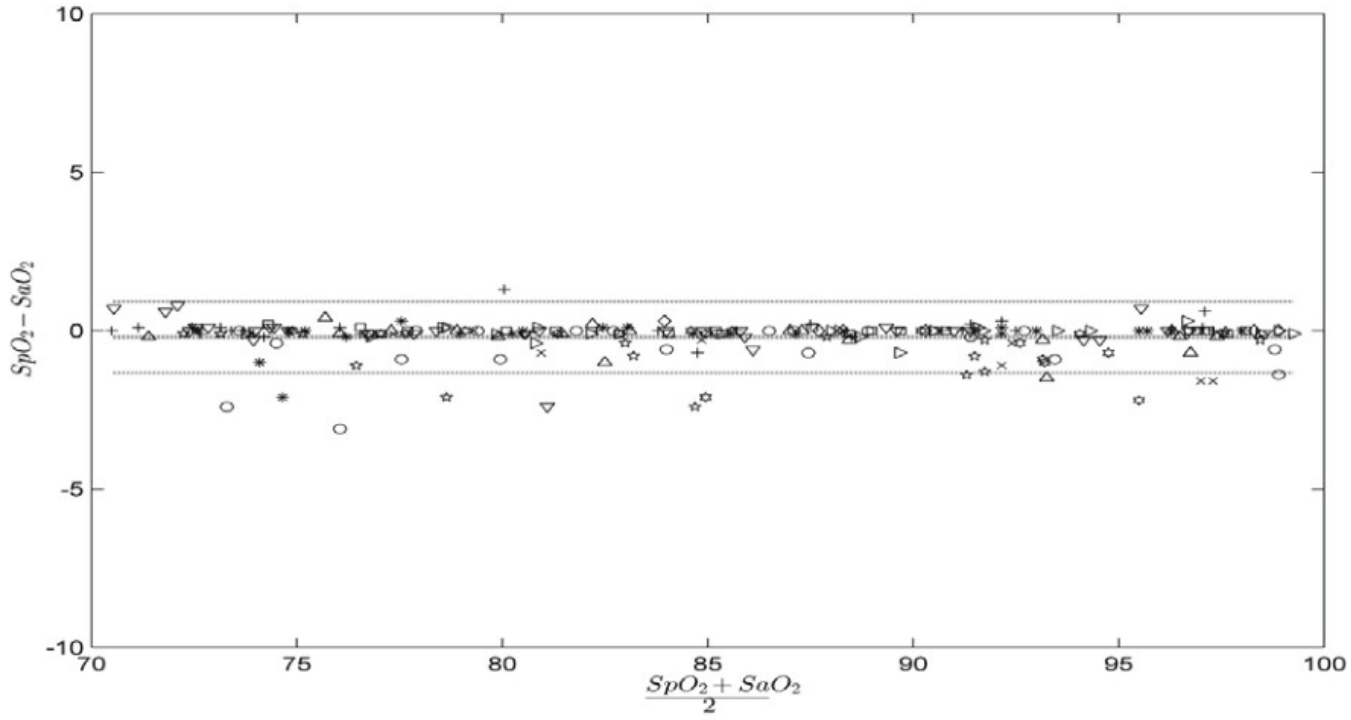
PERFORMANCE SPECIFICATIONS

Table information provides A rms values measured using reusable sensors with Masimo SET ® Oximetry Technology in a clinical study.

MEASURED ARMS VALUES	
RANGE	ARMS
90–100%	1.45%
80–90%	1.22%
70–80%	1.41%
OVERALL CLAIMED ACCURACY VALUE	
70–100%	1.36%

SaO 2 versus error (SpO 2 – SaO 2) with linear regression fit and upper 95% and lower 95% limits of agreement.

Reusable Sensor



Manufacturer:
Masimo Corporation
52 Discovery
Irvine, CA 92618
USA
www.masimo.com

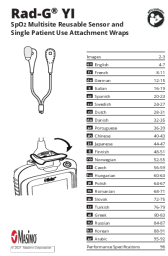
EU Authorized Representative for
Masimo Corporation:

EC REP

MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

CE

Documents / Resources



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4653, Rad-G YI, Rad-G YI SpO2 Multisite Reusable Sensor, SpO2 Multisite Reusable Sensor, Multisite Reusable Sensor, Reusable Sensor

References

- Masimo - Home
- Service masimo
- Masimo.com/TechDocs