RD rainbow SET®-2

SpO2, SpMet®, SpHb®, and ORi™ Disposable Sensors

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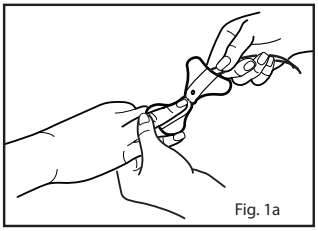


Fig. 1a

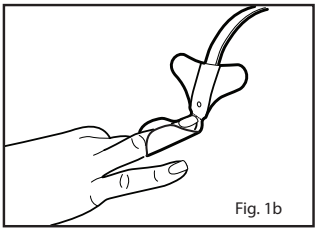


Fig. 1b

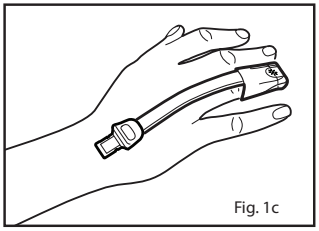


Fig. 1c

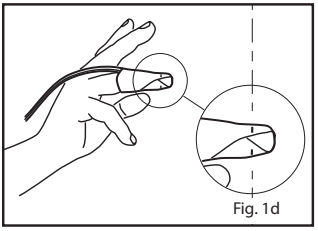
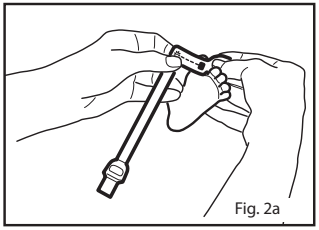


Fig. 1d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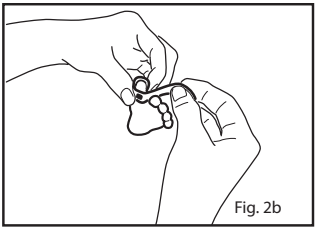


Fig. 2b

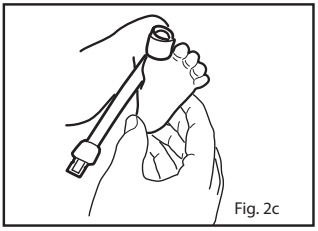


Fig. 2c

RD rainbow SET®-2

SpO2, SpMet®, SpHb®, and ORi™ Disposable Sensors

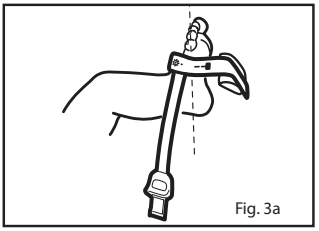


Fig. 3a

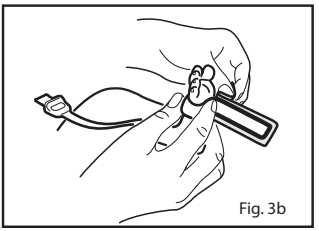


Fig. 3b

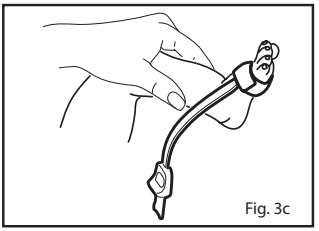


Fig. 3c

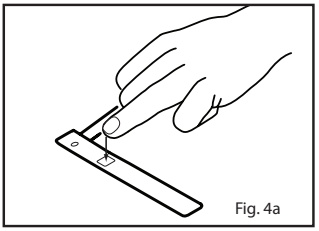


Fig. 4a

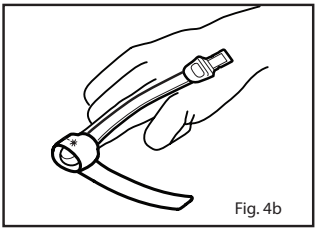


Fig. 4b

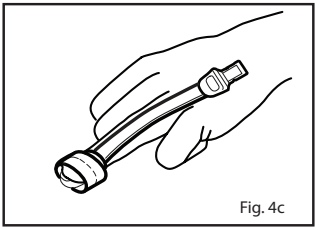


Fig. 4c

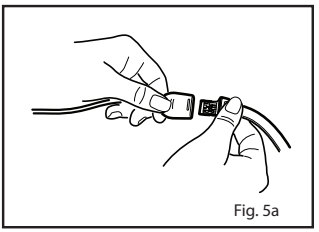


Fig. 5a

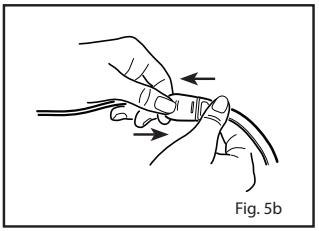


Fig. 5b

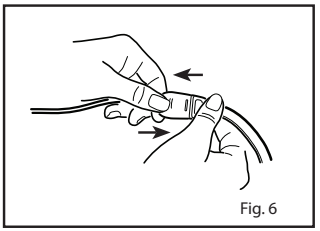


Fig. 6

RD rainbow SET®-2

en

SpO2, SpMet®, SpHb®, and ORi™ Disposable Sensors

DIRECTIONS FOR USE

Single patient - multiple use | 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.

INDICATIONS

RD rainbow SET®-2 disposable sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, methemoglobin saturation (SpMet®), and/or total hemoglobin (SpHb®). The rainbow® Series disposable sensors are indicated 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 hospitals, hospital-type facilities, mobile, and home environments.

The RD rainbow SET-2 adult adhesive sensors also support the ORi™ feature that is intended to be used in patients undergoing surgery as an adjunct to SpO_2 for increased monitoring resolution of elevated hemoglobin oxygen saturation levels (e.g., due to administration of supplemental oxygen).

The ORi feature is indicated for the monitoring of hemoglobin oxygen saturation levels in patients 18 years and older (adults and transitional adolescents), on supplemental oxygen during no-motion conditions perioperatively in hospital environments.

CONTRAINDICATIONS

RD rainbow SET disposable sensors are contraindicated for patients who exhibit allergic reactions to adhesive tape.

DESCRIPTION

RD rainbow SET-2 disposable sensors have been verified using Masimo® rainbow SET® technology. RD rainbow SET disposable sensors are for use with devices containing Masimo rainbow SET technology (Version 7.4 or higher) or licensed to use rainbow® compatible sensors. The ORi parameter requires Masimo rainbow SET technology board version 7.C [7.12] or higher. Consult individual oximetry system manufacturers for compatibility of particular devices and sensor models. Each device manufacturer is responsible for determining whether their devices are compatible with each sensor model.

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

NOTE: Though this sensor is capable of reading all parameters, it is limited by the parameters on the device.

WARNINGS

- Laboratory diagnostic tests using blood samples should be conducted prior to clinical decision making to completely understand the patient's condition.
- Comparisons between SpHb measurements and laboratory diagnostic hemoglobin measurements may be affected by sample type, collection technique, physiological, and other factors.
- 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 use the sensor during MRI scanning or in a MRI environment as it may result in physical harm.
- 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.
- Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis.
- 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.
- 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.
- 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.
- Misapplied sensors or sensors that become partially dislodged may cause incorrect readings.
- Misapplications due to wrong sensor types can cause inaccurate or no readings.
- Inaccurate readings may be caused when values are provided with a low signal confidence indicator.
- 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 or no readings.
- Inaccurate readings may be caused by birthmark(s), tattoos, or skin discolorations in sensor path, moisture on the skin, deformed fingers, misaligned sensor emitter and detector, EMC interference from other sensors attached to the patient, and objects blocking the light path.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- 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).
- Inaccurate SpO_2, SpHb, SpMet, and ORi readings may be caused by abnormal venous pulsation or venous congestion.
- 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.
- 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.
- High intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the Pulse CO-Oximeter® to obtain vital sign readings.
- 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 SpHb, SpMet, and ORi readings can be caused by extreme hemoglobin levels, low arterial perfusion, or motion artifact.
- Inaccurate SpHb and SpMet readings can be caused by extreme hemoglobin levels, low arterial perfusion, low arterial oxygen saturation levels including altitude induced hypoxemia, motion artifact.
- 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.
- Venous pulsations may cause erroneous low SpO_2 readings (e.g. tricuspid valve regurgitation, Trendelenburg position).
- Inaccurate SpO_2 readings may be caused by severe anemia, very low arterial perfusion, or extreme motion artifact.
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc. may cause inaccurate SpO_2, SpHb, and SpMet readings.
- Inaccurate SpO_2, SpHb, SpMet, and ORi readings may be caused by vasospastic disease such as Raynaud's, and peripheral vascular disease.
- Inaccurate readings may be caused by EMI radiation interference.
- Inaccurate SpO_2, SpHb, SpMet, and ORi readings may be caused by elevated levels of dyshemoglobin, hypocapnic or hypercapnic conditions and severe vasoconstriction, or hypothermia.
- With very low perfusion at the monitored site, the reading may read lower than core arterial oxygen saturation.
- SpHb, SpMet, and ORi readings may be affected under low perfusion conditions at the monitored site.
- Inaccurate SpHb and SpMet readings may be caused by elevated PaO_2 levels.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2, SpHb, SpMet, and ORi readings.
- 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.
- Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO_2, SpHb, and ORi readings.
- Elevated levels of total bilirubin or liver disease may lead to inaccurate SpO_2, SpHb, SpMet, and ORi readings.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance and/or accuracy.
- To prevent damage, do not soak or immerse the sensor in any liquid solution.
- Do not attempt to sterilize by irradiation, steam, autoclave or ethylene oxide as it will damage the sensor.
- 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.
- **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) Site Selection

- Always choose an application site which is well perfused and will completely cover the sensor's detector window.
- When aligning the emitter and detector, the emitter should not be placed behind the nail bed. If this occurs, it may be necessary to use a lower weight range sensor.
- Site should be cleaned of debris and dry prior to sensor placement.

RD rainbow SET Adt: Adult Sensor

> 30 kg The preferred site is the middle or ring finger of non-dominant hand.

RD rainbow SET Pdt: Pediatric Sensor

10 - 50 kg The preferred site is middle or ring finger of non-dominant hand.

RD rainbow SET 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 - 30 kg The preferred site is middle or ring finger of non-dominant hand.

RD rainbow SET Neo: Neonatal/Adult Sensor

< 3 kg The preferred site is the foot. Alternatively, across the palm and back of the hand can be used.

> 30 kg The preferred site is the middle or ring finger of non-dominant hand.

B) Attaching the sensor to the patient

- Open the pouch and remove the sensor. Remove the backing from the sensor, if present.

Adt Sensor for ADULTS (> 30 kg) and Pdt Sensor for PEDIATRICS (10 - 50 kg)

1. Refer to **Fig. 1a.** 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.
2. Refer to **Fig. 1b.** Press the adhesive wings, one at a time, onto the finger. Complete coverage of the detector window is needed to ensure accurate data.
3. Refer to **Fig. 1c.** 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.
4. Refer to **Fig. 1d.** When properly applied, the emitter and detector should be vertically aligned (the black lines should align). Reposition if necessary.

Inf Sensor for INFANTS (3 - 10 kg)

1. Refer to **Fig. 2a.** 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).
2. Refer to **Fig. 2b.** Wrap the adhesive wrap around the toe/thumb so the emitter is positioned on the back of the nail bed (not the tip of the nail). Complete coverage of the detector window is needed to ensure accurate data.
3. Refer to **Fig. 2c.** Ensure that the emitter window (✳) aligns on the top of the toe/thumb directly opposite the detector. Verify correct positioning and reposition if necessary.

Neo Sensor for NEONATES (< 3 kg)

1. Refer to **Fig. 3a.** 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.
2. Refer to **Fig. 3b.** Wrap the adhesive wrap around the lateral aspect of the foot/hand and ensure that the emitter (✳) aligns with the detector. Be careful to maintain proper alignment of the detector and emitter while attaching adhesive wrap to secure sensor.
3. Refer to **Fig. 3c.** Verify correct positioning and reposition if necessary. Continue to wrap the rest of the adhesive wrap around the foot/hand.

Neo Sensor for ADULTS (> 30 kg) and Inf Sensor for INFANTS (10 - 30 kg)

1. Refer to **Fig. 4a.** Direct the sensor cable so that it runs along the top of the hand. Position the detector on the fleshy part of the finger.
2. Refer to **Fig. 4b.** Wrap the adhesive wrap around the finger so the emitter is positioned on the back of the nail bed with the edge of the tape at the tip of the finger (not the tip of the nail). Complete coverage of the detector window is needed to ensure accurate data.
3. Refer to **Fig. 4c.** Ensure that the emitter window (✳) aligns on the top of the finger directly opposite the detector. Verify correct positioning and reposition if necessary.

C) Attaching the Sensor to the Patient Cable

1. Refer to **Fig. 5a.** Orient the sensor's connector tab so that the side with the "shiny" contacts is facing up. Orient the patient cable with the color bar and finger grips facing up.
2. Refer to **Fig. 5b.** Insert the sensor tab into the patient cable until there is a tactile or audible click of connection. Gently tug on the connectors to ensure a positive contact. Tape may be used to secure the cable to the patient for ease of movement.

D) Reattachment

- 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.
- If the adhesive no longer adheres to the skin, use a new sensor.

NOTE: When changing application sites, or reattaching sensor, first disconnect the sensor from the patient cable.

E) Disconnecting the Sensor from the Patient Cable

1. **Refer to Fig. 6.** 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.

SPECIFICATIONS

When used with Masimo rainbow SET technology monitors or with licensed Masimo rainbow SET technology modules using RD rainbow SET Series patient cables, the sensors are intended for the following performance specifications:

RD rainbow SET-2 Sensor:	Adt	Pdt	Inf		Neo	
Weight Range	> 30 kg	10 - 50 kg	3 - 10 kg	10 - 30 kg	< 3 kg[7]	> 30 kg
Application Site	Finger	Finger	Thumb or Great Toe	Finger or Toe	Hand or Foot	Finger
SpO_2 Accuracy, No Motion[1], (70 - 100%)	2%	2%	2%	2%	2%	2%
SpO_2 Accuracy, No Motion[1], (60 - 80%)	3%	3%	3%	3%	---	3%
SpO_2 Accuracy, Motion[2]	3%	3%	3%	3%	3%	3%
SpO_2 Accuracy, Low Perfusion[3]	2%	2%	2%	2%	2%	2%
Pulse Rate Accuracy, No Motion[4]	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm
Pulse Rate Accuracy, Motion[4]	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
SpMet Accuracy, No Motion[5]	1%	1%	1%	1%	1%	1%
SpHb Accuracy, No Motion[6]	1 g/dL	1 g/dL	1 g/dL	1 g/dL	---	1 g/dL
ORi No Motion	18 years and older	---	---	---	---	18 years and older

NOTE: *The table indicates Arms Accuracy which is calculated based upon measurement values that are statistically distributed; approximately 68% of the measured values fell within +/- the Arms value when compared to the reference device under 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 60%-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] SpMet accuracy was determined by testing on healthy adult volunteers with light to dark skin pigmentation in the range of 0% - 15% MetHb against a laboratory CO-Oximeter.

[6] SpHb accuracy, against that of a Coulter Counter, was determined by testing healthy adult volunteers with light to dark skin pigmentation in the range 8 to 17 g/dL.

[7] SpO_2 and SpMet accuracy for neonates was determined on 16 neonatal NICU patients ranging in age from 7 to 135 days old and weighing between 0.5 and 4.25 kgs. Seventy-nine (79) convenience data samples were collected over a range of 70-100% SaO_2 and 0.5 - 2.5% MetHb with a resultant neonatal accuracy of 2.9% SpO_2 (1 Std. Dev.) and 0.9% SpMet (1 Std. Dev.) against a laboratory CO-Oximeter.

COMPATIBILITY

Masimo SET® Masimo SET® rainbow

This sensor is intended for use only with instruments containing Masimo SET with rainbow technology or pulse oximetry monitors licensed to use RD rainbow SET compatible 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 instrument 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 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

This single-patient sensor is licensed to you under the patents owned by Masimo for single-patient use only. By acceptance or use of this product, you acknowledge and agree that no license is granted for use of this product with more than a single patient. After single-patient use, discard sensor.

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 rainbow 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.

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	European Union Conformity Mark
	Manufacturer	REF	Catalogue number (model number)	EC REP	Authorized representative in the European community
	Caution	####	Masimo reference number	CH REP	Indicates the authorized representative in Switzerland
	Use-by YYYY-MM-DD	>	Greater than		Body weight
	Do not re-use	<	Less than		Storage temperature range
NON STERILE	Non-Sterile	%	Storage humidity limitation		Keep dry
LATEX	Not made with natural rubber latex		Fragile, handle with care		Do not use if package is damaged and consult instructions for use
1	Single patient - multiple use	MD	Medical device		Atmospheric pressure limitation
	Importer		Distributor	UDI	Unique device identifier
	Light Emitting Diode (LED) LED emits light when current flows through	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

PERFORMANCE SPECIFICATIONS:

The table below shows Arms (Accuracy Root Mean Square) values measured using rainbow sensors with Masimo SET Oximetry Technology in a clinical study.

rainbow Series

70 - 100%

SpO2	Arms
90-100%	1.57 (1,57) %
80-90%	1.80 (1,80) %
70-80%	2.47 (2,47) %
70-100%	1.98 (1,98) %

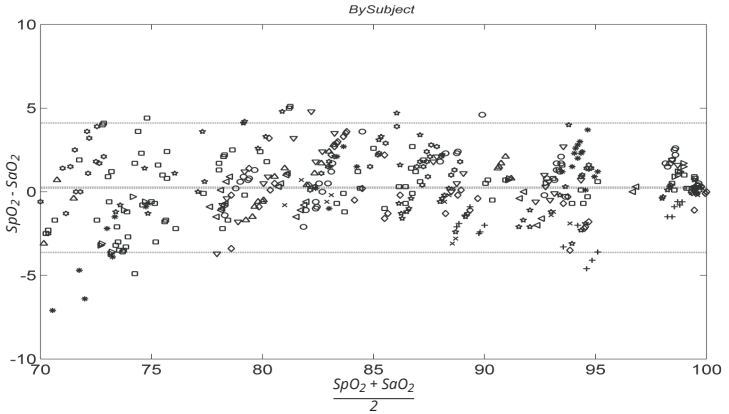
60 - 80%

SpO2	Arms
60-70%	3.42 (3,42) %
70-80%	2.49 (2,49) %
60-80%	2.99 (2,99) %

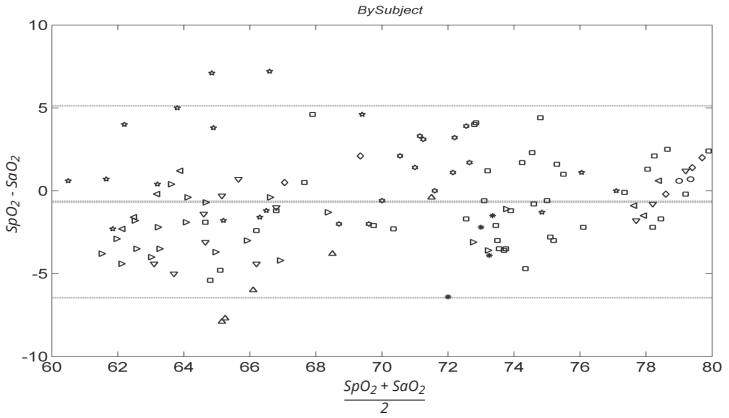
SaO2 versus error (SpO2 – SaO2) with linear regression fit and upper 95% and lower 95% limits of agreement.

rainbow Series

70 - 100%



60 - 80%



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