RD SET™ Series

Adt, Pdt, Inf, Neo, NeoPt, and NeoPt-500 SpO_2 Disposable Sensors, US

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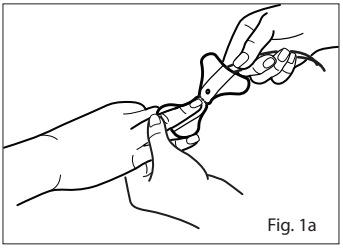


Fig. 1a

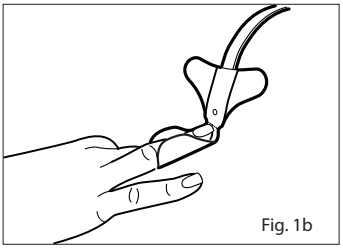


Fig. 1b

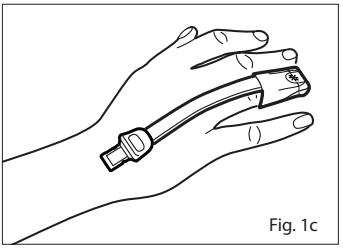


Fig. 1c

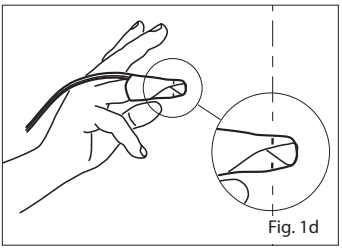


Fig. 1d

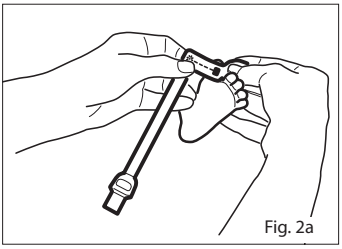


Fig. 2a

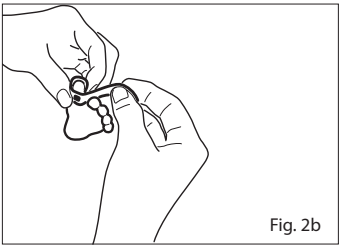


Fig. 2b

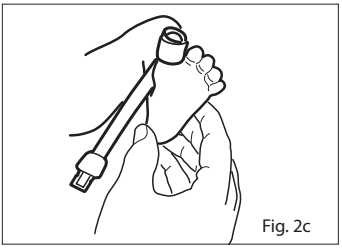
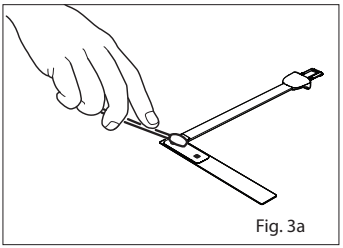


Fig. 2c



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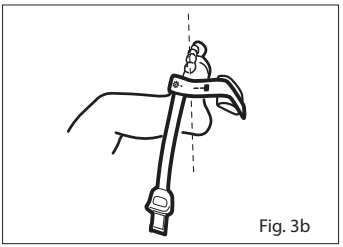

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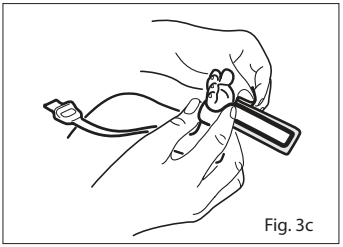


Fig. 3c

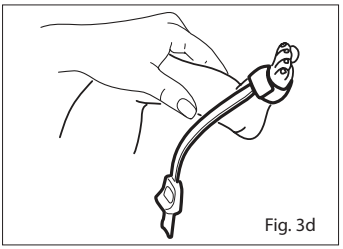


Fig. 3d

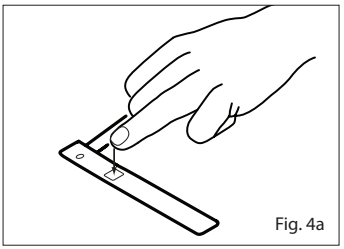
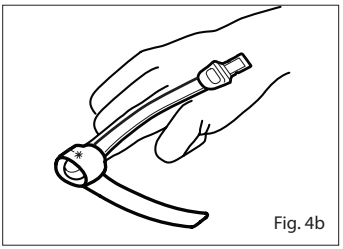


Fig. 4a



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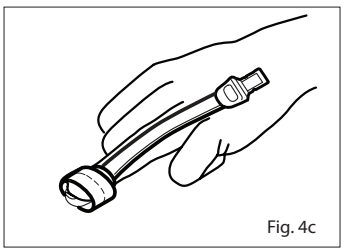

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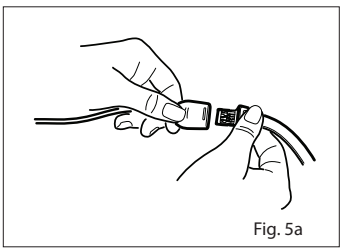

Fig. 5a

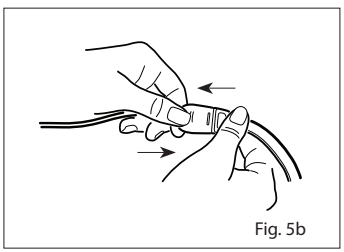

Fig. 5b

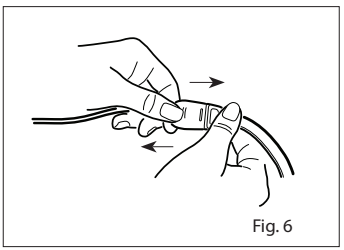

Fig. 6

RD SET™ Series

Adt, Pdt, Inf, Neo, NeoPt, and NeoPt-500 SpO_2 Disposable Sensors, US

DIRECTIONS FOR USE

Single patient use only | 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 - When Used With Masimo SET® and Masimo compatible Pulse Oximeters:
The RD SET™ Series disposable sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 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 RD SET sensors are contraindicated for patients who exhibit allergic reactions to foam rubber products and/or adhesive tape.

DESCRIPTION
The RD SET Series sensors are for use with devices containing Masimo SET oximetry or licensed to use RD SET Series sensors. Consult individual device manufacturer for compatibility of particular device and sensor models. Each device manufacturer is responsible for determining whether its devices are compatible with each sensor model.

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

WARNINGS

- 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 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.
- 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.
- 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 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.
- 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 or motion artifact.
- 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 performace 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.
- **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. The sensor will provide up to 168 hours of patient monitoring time or up to 336 hours for sensors with a replaceable tape. After single-patient use, discard sensor.

INSTRUCTIONS

A) Site Selection

- Always choose a site that is well perfused and will completely cover the sensor's detector window.
- Site should be cleaned of debris and dry prior to sensor placement.

RD SET Adt: Adult Sensor

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

RD SET Pdt: Pediatric Sensor

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

RD 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.

10–20 kg The preferred site is the middle or ring finger of the non-dominant hand.

RD 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.

> 40 kg The preferred site is the middle or ring finger of non-dominant hand.

RD SET NeoPt/NeoPt-500: Preterm Sensors

< 1 kg The preferred site is the foot. Alternatively, across the palm and back of the hand can be used.

B) Attaching the sensor to the patient

1. 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)

2. 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.
3. 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.
4. 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.
5. 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)

2. 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).
3. Refer to **Fig. 2b.** Wrap the adhesive wrap around the toe so the emiter is positioned on the nailbed of the great toe. Complete coverage of the detector window is needed to ensure accurate data.
4. Refer to **Fig. 2c.** Ensure that the emitter window (✳) aligns on the top of the toe directly opposite the detector. Verify correct positioning and reposition if necessary.

Neo sensor for NEONATES (< 3 kg) and NeoPt/NeoPt-500 sensor for PRETERMS (< 1 kg)

2. Refer to **Fig. 3a.** 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.
3. Refer to **Fig. 3b.** 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.
4. Refer to **Fig. 3c.** 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.
5. Refer to **Fig. 3d.** Verify correct positioning and reposition if necessary.

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

2. 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. Alternatively, the sensor may also be applied to the toe (not shown).
3. Refer to **Fig. 4b.** 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.
4. Refer to **Fig. 4c.** Check the sensor to 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 SET pulse oximetry monitors, or with licensed Masimo SET pulse oximetry modules the RD SET Sensors have the following specifications:

RD Sensor used with Masimo Device	RD SET Adt	RD SET Pdt	RD SET Inf		RD SET Neo		RD SET NeoPt/ NeoPt-500
Body Weight	> 30 kg	10–50 kg	3–10 kg	10–20 kg	< 3 kg	> 40 kg	< 1 kg
Application Site	Finger or Toe	Finger or Toe	Thumb or Great Toe	Finger or Toe	Hand or Foot	Finger or Toe	Hand or Foot
SpO_2 Accuracy, No Motion (70–100%[1, 5])	1.5%	1.5%	1.5%	1.5%	3%	1.5%	3%
SpO_2 Accuracy, Motion[2, 5]	1.5%	1.5%	1.5%	1.5%	3%	1.5%	3%
SpO_2 Accuracy, Low Perfusion[3]	2%	2%	2%	2%	3%	2%	3%
Pulse Rate Accuracy, No Motion (25–240 bpm[1])	3 bpm	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	5 bpm
Pulse Rate Accuracy, Low Perfusion[3]	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm

SpO_2 Upper and Lower Limits of Agreement (LoA)*		
	No Motion	Motion
Upper 95% LoA	2.3%	2.9%
Lower 95% LoA	-2.3%	-2.2%

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] Specification represents clinical study results using Masimo SET Technology under no motion conditions in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70%–100% SpO2 against a laboratory co-oximeter.

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

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

[4] The Masimo SET Technology has been validated for pulse rate accuracy for the range of 25–240 bpm in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%. Pulse rate accuracy under motion was verified by bench top testing in the range of 45-180 bpm against a Biotek simulator using the motion preset setting.

[5] Specification reflects use with the following Masimo technology boards and software versions and higher: MS-2000 SB version V5.1, MSX-1 version V5.3, MX-5 version V7.12

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

COMPATIBILITY

This sensor is intended for use only with devices containing Masimo SET oximetry or pulse oximetry monitors licensed to use RD SET 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

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 RD 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
 (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 re-use/Single patient use only	>	Greater than		Keep dry
	Non-Sterile	<	Less than		Do not use if package is damaged
	Not made with natural rubber latex		Storage humidity limitation		Atmospheric pressure limitation
	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

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RD SET is a trademark of Masimo Corporation.

STUDY RESULTS FOR SPECIFICATIONS

The table below shows ARMS (Accuracy Root Mean Square) values measured using the RD SET sensors under no motion, with Masimo MX Technology (V7.D.2.3) in a clinical study.

RD SET

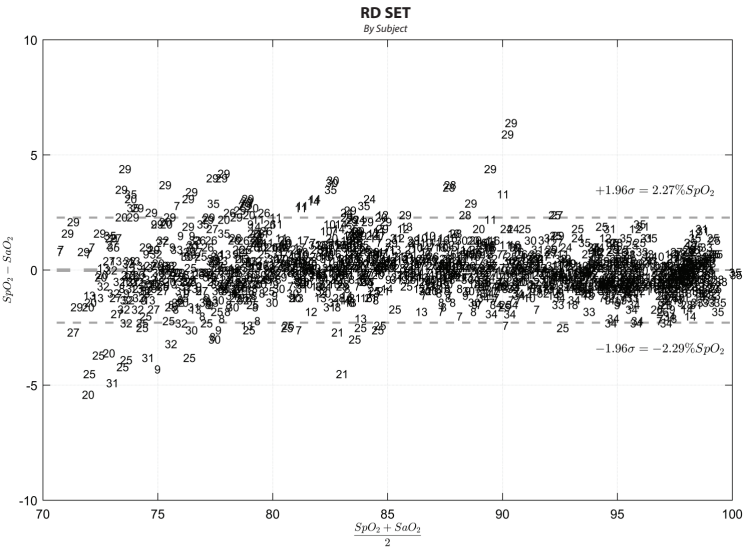
SpO_2	ARMS
90–100%	0.83 %
80–90%	1.11 %
70–80%	1.53 %
70–100%	1.15 %

Sp02 Upper and Lower Limits of Agreement (LoA)*	
	Actual Value
Upper 95% LoA	2.27%
Lower 95% LoA	-2.29%

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

70 -100%

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



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10131A-eIFU-1118