RD SET™ Blue®

SpO2 Disposable Sensor

MASIMO

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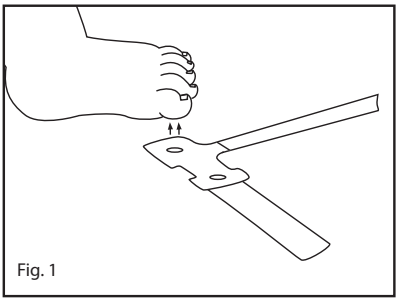

Fig. 1

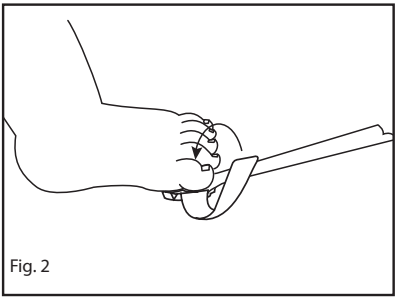

Fig. 2

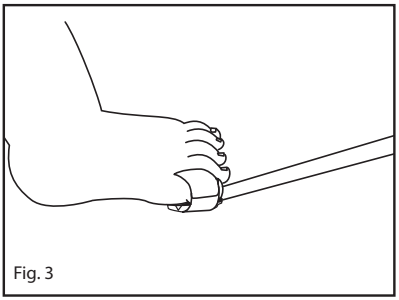

Fig. 3

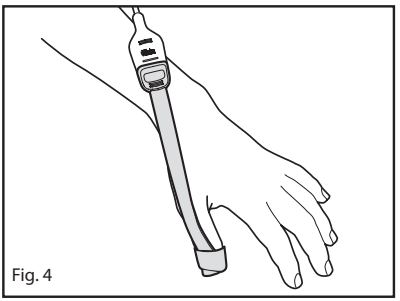

Fig. 4

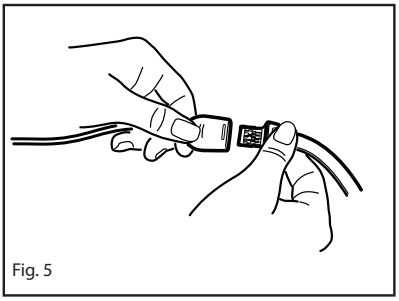

Fig. 5

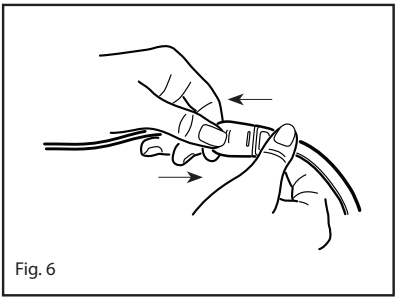

Fig. 6

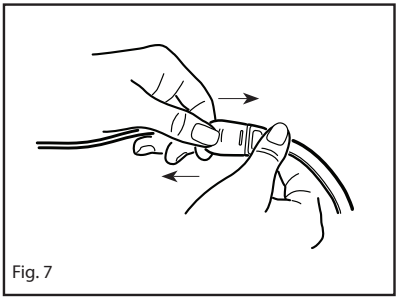

Fig. 7

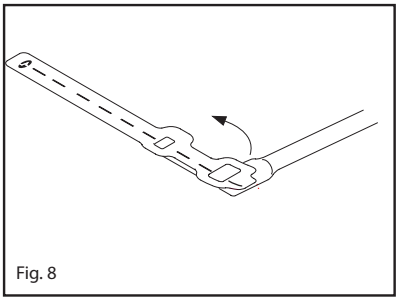

Fig. 8

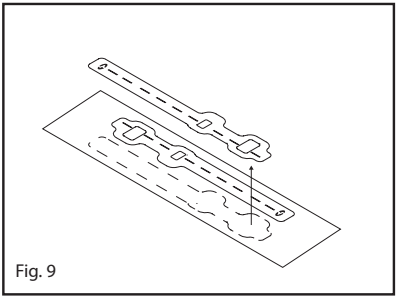

Fig. 9

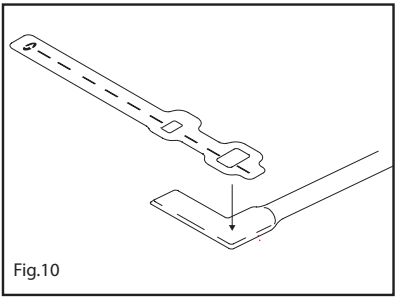

Fig.10

RD SET™ Blue®

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SpO2 Disposable Sensor

DIRECTIONS FOR USE

Single Patient Use Only | Not made with natural rubber latex | Non-sterile

INDICATIONS

The Masimo® RD SET™ Blue® sensor is indicated for single-patient use for the continuous noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulse rate for neonates, infants and pediatric patients with congenital cyanotic cardiac lesions in hospitals, hospital type facilities, mobile and home environments.

CONTRAINDICATIONS

The RD SET Blue Sensor is contraindicated for patients who exhibit allergic reactions to foam rubber products and/or adhesive tape.

DESCRIPTION

The RD SET Blue sensor is for use only with devices containing Masimo SET® oximetry or licensed to use RD SET sensors. Consult individual oximetry system 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.

The RD SET Blue Sensor was validated on Masimo SET Oximetery Technology on neonates, infants and pediatric patients with congenital cyanotic cardiac lesions.

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 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.
- 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.
- 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 SpO_2 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.
- 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.
- 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 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.
- 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.
- 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 attempt to sterilize the sensor.
- Do not attempt to sterilize by irradiation, steam, autoclave or ethylene oxide.
- 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.
- **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.

B. Attaching the sensor to the patient

1. Open the pouch and remove the sensor. Remove the backing from the sensor and attachment wrap.
2. Refer to **Fig 1**. Position the emitter window (✳) of the attachment wrap on the top of the great toe/thumb nail bed. The sensor can point toward or away from the patient.
3. Refer to **Fig 2**. Ensure that the emitter window is positioned correctly. Wrap the attachment wrap around the great toe or thumb so the detector is opposite the emitter.
4. Refer to **Fig 3**. (toe) or **Fig. 4**. (thumb) Check the sensor to verify correct positioning and reposition if necessary. Complete coverage of the detector window is needed to ensure accurate data.

WARNING: Do not apply the sensor too tightly as this may lead to pressure necrosis.
NOTE: For best accuracy the sensor must be applied to the great toe or thumb.

C. Attach the Sensor to the Patient Cable

1. Refer to **Fig. 5**. Orient the sensor's connector tab so that the side with the "shiny" contacts facing up. Orient the patient cable with the color bar and finger grips facing up.
2. Refer to **Fig. 6**. 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.

D. Reapplication

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.

NOTE: Prior to reattachment, disconnect the sensor from the sensor cable.

E. Cable Disconnection

1. Refer to **Fig. 7**. 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.

F. Replacement Tapes

1. Refer to **Fig. 8**. Remove the existing tape and discard.
2. Refer to **Fig. 9**. Remove the replacement tape from the release liner.
3. Refer to **Fig. 10**. Position the replacement tape over the sensor and press in place.

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

SPECIFICATIONS

When used with Masimo SET technology, the RD SET Blue Disposable sensors have the following specifications:

RD SET Blue	
Body Weight	2.5 - 30 kg
Application Site	Great Toe / Thumb
SpO_2 Accuracy, No Motion[1], (60-80%)	4%
SpO_2 Accuracy, No Motion[1], (70-100%)	3.3%
SpO_2 Accuracy, No Motion[1], (80-100%)	3%
SpO_2 Accuracy, Low Perfusion[2]	3%
Pulse Rate Accuracy, No Motion[3]	3 bpm
Pulse Rate Accuracy, Low Perfusion[2]	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 Blue sensor SpO_2 accuracy has been validated using convenience blood samples from neonatal, infant, and pediatric patients with light to dark pigmented skin diagnosed with congenital cyanotic cardiac lesions in the range of 60-100% SpO_2 using a laboratory blood gas analyzer.

[2] The Masimo SET Technology has been validated for low perfusion SpO_2 and pulse rate accuracy with a signal strength of 0.02% over a range of 70% to 100% SpO_2 in bench top testing against a Biotek Index 2 simulator.

[3] The Masimo SET Technology has been validated for pulse rate accuracy in bench top testing against a Biotek Index 2 simulator over a range of 25-240 bpm.

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 this product, 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 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

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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 TFA-1 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	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		Storage humidity limitation		Storage temperature range
	Do not re-use/Single patient use only		Do not use if package is damaged		Keep dry
	Pediatric patient	>	Greater than	<	Less than
	Non-Sterile		Not made with natural rubber latex		Atmospheric pressure limitation
	Light Emitting Diode (LED) LED emits light when current flows through		Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs **Note: eIFU is not available for CE mark countries.**		

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

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