rainbow® DCI®-mini Series

Reusable SpHb®& SpO2 Sensors

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Reusable SpHb®& SpO2 Sensors

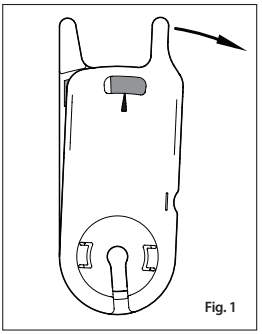
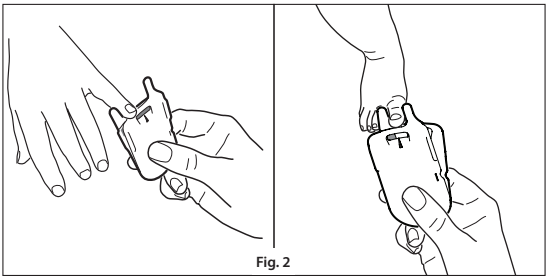


Fig. 1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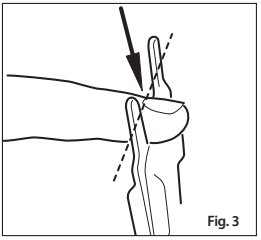
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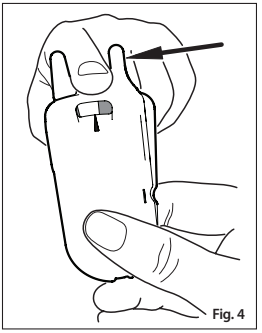
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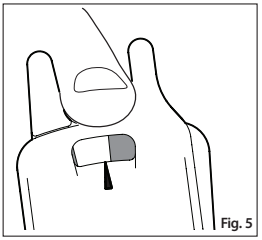
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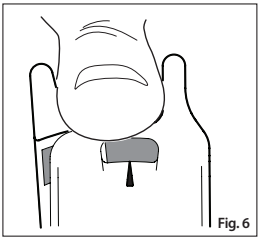
Fig. 6

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Reusable SpHb®& SpO2 Sensors

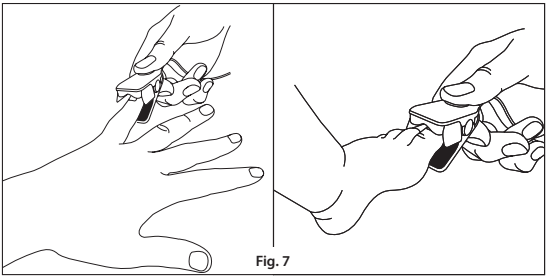


Fig. 7

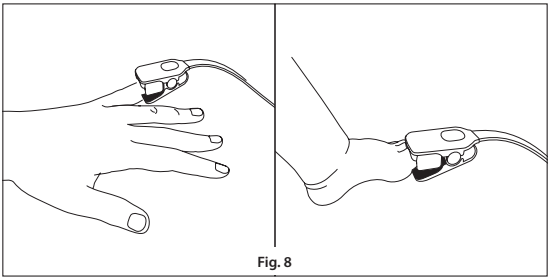


Fig. 8

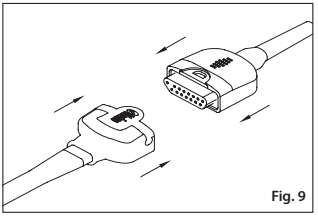


Fig. 9

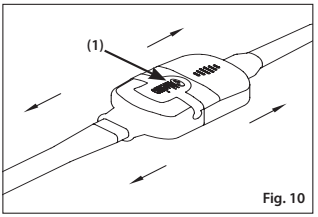


Fig. 10

rainbow® DCI®-mini Series

Reusable SpHb® & SpO2 Sensors

en

DIRECTIONS FOR USE

Reusable | 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 or Monitor and this Directions for Use.

INDICATIONS

The rainbow DCI-mini sensor is intended for use in clinical and non-clinical settings.

The rainbow DCI-mini sensor is indicated for non-invasive spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients who are well or poorly perfused during both motion and no motion conditions.

The rainbow DCI-mini sensor is indicated for non-invasive spot-checking of total hemoglobin concentration (SpHb®) for adult patients.

DESCRIPTION

The rainbow DCI-mini reusable sensors have been verified with Masimo® rainbow SET™ technology. Consult individual oximetry system manufacturers for compatibility of particular device and sensor models. Each device manufacturer is responsible for determining whether their devices are compatible with each sensor model.

NOTE: rainbow DCI-mini reusable sensors are for use with devices containing Masimo rainbow SET technology (Version 7.4 or higher) or licensed to use rainbow compatible sensors.

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

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

WARNINGS, CAUTIONS, AND NOTES

- 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 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 extreme caution; skin erosion, tissue ischemia, and/or pressure necrosis can be caused when the sensor is not frequently moved, applied too tightly, or becomes too tight due to edema. Assess site as frequently as every (1) hour and move the sensor if there are signs of loss of skin integrity and/or loss of circulation or perfusion.
- Do not use additional tape to secure the sensor to the site that may cause skin damage, pressure necrosis, damage to the sensor, and/or incorrect readings, and may restrict blood flow.
- Carefully route sensor and patient cables to reduce the possibility of patient entanglement or strangulation.
- 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 inaccurate readings.
- Inaccurate readings may be caused by the use of incorrect sensor type (size).
- Reading may be inaccurate 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.
- Venous congestion may cause inaccurate readings. 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 SpO2 or SpHb 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.
- Inaccurate readings may be caused by EMI radiation interference.
- 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.
- Venous pulsations may cause erroneous low SpO2 readings (e.g. tricuspid valve regurgitation, Trendelenburg position).
- Inaccurate SpO2 readings may be caused by severe anemia, very low arterial perfusion, or extreme motion artifact.
- Inaccurate SpHb readings can be caused by extreme hemoglobin levels, low arterial perfusion, or motion artifact.
- Inaccurate SpHb readings can be caused by extreme hemoglobin levels, low arterial perfusion, low arterial oxygen saturation levels including altitude induced hypoxemia, or motion artifact.
- Inaccurate SpO2 or SpHb readings may be caused by abnormal venous pulsation or venous congestion.

- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc. may cause inaccurate SpO2 and SpHb readings.
- Inaccurate SpO2 or SpHb readings may be caused by vasospastic disease such as Raynaud's, and peripheral vascular disease.
- Inaccurate SpO2 or SpHb 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.
- SpHb readings may be affected under low perfusion conditions at the monitored site.
- Inaccurate SpHb readings may be caused by elevated PaO2 levels.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO2, SpHb readings.
- Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO2, and SpHb readings.
- 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 total bilirubin or liver disease may lead to inaccurate SpO2, SpHb readings.
- 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 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 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 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. Reusable spot-check sensors are available with different quantities of spot-check measurements. The sensor will stop functioning after the specified number of spot-check measurements have been completed.

INSTRUCTIONS

A) Site Selection

- Choose a site that is well perfused and least restricts a conscious patient's movements.
- Always choose a site that will completely cover the sensor's detector window.
- Site should be free of debris and dry prior to sensor placement.
- Select a site that is free of externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Select a digit without long fingernails.

Preferred Site By Weight Range

- Use the digit gauge to select the appropriate digit. See **Digit Gauge Instructions.**
- **3 - 10 kg** - The preferred site is the Great toe. Alternatively, either thumb can be used.
- **>10 kg** - The preferred site is the 5th digit (**Fig. 2**) of the non-dominant hand; however, the other digits can be used. Alternatively, the dominant hand can be used if necessary.

Digit Gauge Instructions

1. Refer to **Fig. 1.** Open the measurement guides.
2. Refer to **Fig. 2.** Place the selected digit (see Site Selection) between the guides.
3. Refer to **Fig. 3.** Ensure the guides are aligned with the cuticle.
4. Refer to **Fig. 4.** Close guide to loosely contact the digit.
5. Refer to **Fig. 5.** Confirm gauge indicator arrow is in the green.
6. Refer to **Fig. 6.** If the arrow is in the red area, select a different digit and repeat Steps 1-5.

NOTE: If all digits are too small, use a disposable rainbow SpHb sensor.

NOTE: If all digits are too large, use a rainbow SpHb reusable DC-I or DCI-P sensor.

B) Attaching the sensor to the patient

1. Refer to **Fig. 7.** Orient the cable away from the sensor site. Open the sensor by pressing on the sensor indentations.
2. Refer to **Fig. 8.** Place the selected digit over the sensor window in the bottom half of the sensor with the black pad. The fleshiest part of the digit should be covering the detector window. The tip of the finger, not the fingernail, should touch the digit stop on the back of the black pad.
3. The sensor should be opened enough to evenly distribute the grip pressure of the sensor along the length of the finger. Check the arrangement of the sensor to verify correct positioning. Complete coverage of the detector window is needed to ensure accurate data.

NOTE: The sensor is not intended for use across a child's hand or foot.

C) Attaching the sensor to the patient cable

Refer to **Fig. 9.** Insert the sensor connector completely into the patient cable connector and lock in place.

D) Removing the sensor from the patient

1. Open the sensor by pressing on sensor indentations. Remove the sensor from the digit and follow the cleaning instructions.
2. Store the sensor for its next use.

E) Disconnecting the sensor from the patient cable

1. Refer to **Fig. 10**. While holding the sides of the cable connector, place thumb on the latch (1) and press.
2. Hold the latch down while pulling the connectors apart.

CLEANING

1. Remove the sensor from the patient and disconnect it from the patient cable.
2. Clean the sensor by wiping with a 70% isopropyl alcohol pad.
3. Allow the sensor to dry thoroughly prior to placement on a patient.

or

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

CAUTIONS:

- Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor may occur.
- To prevent damage, do not soak or immerse the sensor in any liquid solution.
- Do not sterilize by irradiation, steam, autoclave or ethylene oxide.

SPECIFICATIONS

When used with Masimo rainbow SET technology monitors or with licensed Masimo rainbow SET technology modules using rainbow Series patient cables, the DCI-mini sensors have the following performance specifications:

DCI-mini Sensor	Infant	Adult / Pediatric
Weight Range	3 - 10 kg	>10 kg
Application Site	Finger, Thumb or Great Toe	Finger
SpO2 Accuracy, No Motion, (70 - 100%)[1]	2%	2%
SpO2 Accuracy, Motion[2]	3%	3%
Pulse Rate Accuracy, No Motion[3]	3 bpm	3 bpm
Pulse Rate Accuracy, Motion[3]	5 bpm	5 bpm
SpO2 Accuracy, Low Perfusion[4]	2%	2%
Pulse Rate Accuracy, Low Perfusion[4]	3 bpm	3 bpm

SpHb Upper and Lower Limits of Agreement (LoA)[5]*	
Upper 95% LOA	2.07%
Lower 95% LOA	-1.82%

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 rainbow SET Technology has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70%-100% SpO2 against a laboratory co-oximeter.

[2]The Masimo rainbow 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 pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Fluke Index2 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 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%.

[5]SpHb accuracy has been validated on healthy and unhealthy adult male and female volunteers and on patients with light to dark skin pigmentation in the range of 8 g/dL to 17 g/dL SpHb against tHb reference blood measurements determined by HiCN methods. The SpHb accuracy has not been validated with motion or low perfusion.

**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

These sensors are intended for use only with devices containing Masimo rainbow SET technology or pulse oximetry monitors licensed to use rainbow 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 from defects in materials and workmanship for a period of one (1) year.

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

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
	Consult instructions for use		Do not discard
 (blue background)	Follow instructions for use	LOT	Lot code
	Manufacturer	REF	Catalogue number (model number)
	Date of Manufacture	####	Masimo reference number
	Non-sterile		Body weight
	Not made with natural rubber latex	>	Greater than
Rx ONLY	Federal law (U.S.A) restricts this device to sale by or on the order of a physician	<	Less than
CE 0123	Mark of Conformity to European Medical Device Directive 93/42/EEC		Storage humidity limitation
EC REP	Authorized representative in the European community		Storage temperature range
	Separate collection for electrical and electronic equipment (WEEE).		Do not use if package is damaged

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

Masimo, , rainbow, DCI, SpHb, Pulse CO-Oximeter, X-Cal and SET are federally registered trademarks of Masimo Corporation.

rainbow SET is a trademark of Masimo Corporation.

PERFORMANCE SPECIFICATIONS

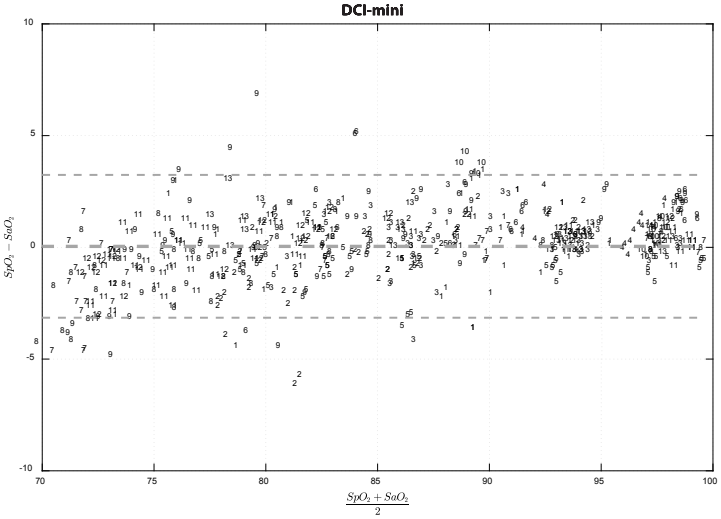
The table below shows ARMS (Accuracy Root Mean Square) values measured using the DCI-mini sensors with Masimo SET Oximetry Technology in a clinical study.

DCI-Mini

SpO2	ARMS
90-100%	1.2 %
80-90%	1.7 %
70-80%	1.9 %
Overall	1.6 %

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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