O3® Sensor Series

Adult and Pediatric rSO2 Adhesive Sensors

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Adult and Pediatric rSO2 Adhesive Sensors

DIRECTIONS FOR USE

Single Patient Use Only

Not made with natural rubber latex

Non-sterile

INDICATIONS

The noninvasive Masimo O3® Regional Oximeter System and accessories are intended for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥ 40 kg and on pediatrics ≥ 5 kg and < 40 kg, in healthcare environments.

CONTRAINDICATIONS

The O3 Sensors are contraindicated for patients who exhibit allergic reactions to adhesive tapes.

DESCRIPTION

The rSO2 sensor is a part of the Masimo O3 Regional Oximeter System. The sensor is intended for non-invasive rSO2 measurements and for single patient use.

WARNINGS

- Periodically check skin integrity according to your institutions patient care protocol or at least every 24 hours.
- The O3 Sensor is intended only as an adjunct in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.
- Always use the O3 Module and O3 Sensor in conjunction with Root. Do not use parts from other systems. Injury to personnel or equipment damage could occur.
- The O3 Sensor should be free of visible defects, discoloration and damage. If the Sensor appears or is suspected to be discolored or damaged, discontinue use. Never use a damaged sensor or one with exposed electrical circuitry.
- Do not modify or alter the O3 Sensor in any way. Alteration or modification may affect performance and/or electrical safety.
- Do not use sensors that are wet.
- Do not use the O3 Sensor during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the O3 Module and O3 Sensor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide to avoid risk of explosion. Refer to the O3 Module Operator's Manual for additional information.
- Do not place electrodes between the surgical site and the electro-surgical return electrode. Doing so increases the risk of burns in case of a defect in the electro-surgical return electrode.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- 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.
- The site must be checked frequently or per clinical protocol to minimize the risk of skin irritation and to ensure adequate 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 one (1) hour with poorly perfused patients and move the sensor if there are signs of tissue ischemia.
- For patients experiencing complete bilateral External Carotid Artery (ECA) occlusion, rSO2 measurements may be lower than expected.

WARNING: Optical measurements (rSO2) can be affected by the following:

- Improper sensor application or use of incorrect sensor.
- Intravascular dyes such as indocyanine green or methylene blue or externally applied coloring (such as indelible ink).
- Venous congestion and pooled blood under the skin.
- Moisture, birthmarks, skin discoloration or foreign objects (e.g. metal plate) in the light path.
- Elevated level of total bilirubin.
- A physiological condition that may affect vasomotor tone or changes in vasomotor tone.

- Excessive ambient light, high intensity light, or direct sunlight.
- Adjacent placement of optical sensors that are not connected to the same O3 Module.
- Abnormal venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg position).

WARNING: Inaccurate rSO2 readings or no rSO2 reading may be caused by:

- Anemia or low hemoglobin concentrations
- Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (Quantitative defects such as Thalassemias).
- Elevated levels of COHb and/or MetHb levels.
- Non-normocapnic conditions or other conditions that affect blood volume.
- Hypotension, severe vasoconstriction, or hypothermia.
- Induction of extracranial hypoxia-ischemia.
- Cardiac arrest.
- Electrosurgical interference.
- Excessive induced motion.

CAUTIONS

- Do not use the O3 Sensor past its expiry date.
- Avoid contact with the sensor during defibrillation.
- Avoid sensor contact with liquids as it may cause damage to the sensor.
- Do not submerge the O3 Sensor in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the O3 Sensor.
- This O3 Sensor is for single patient use only - do not clean.
- If using the O3 Sensor during full body irradiation, keep the sensor out of the radiation field.
- Disposal of product – Comply with local laws in the disposal of the instrument and/or its accessories.
- rSO2 readings represent a small volume of tissue beneath the O3 Sensor site and may not reflect oxygenation elsewhere.
- Do not attempt to reprocess, recondition or recycle any Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- Do not expose the Sensor to excessive humidity. It should be used and stored in a cool, dry place.

NOTES

- The value of data from the system has not been demonstrated in specific disease states, under conditions of hemoglobinopathies or clinical conditions that may affect blood volume, or under hypocapnic and hypercapnic conditions.
- If the desired tissues cannot be palpated or visualized, it is recommended to use a secondary method of confirmation, such as ultrasound or X-ray.
- The O3 Sensor duration of use is dependent on the condition of the sensor site and patient's skin integrity and sensor adhesion quality. The O3 Sensor has been biocompatibility tested for the intended continuous use up to 72 hours.

INSTRUCTIONS

Applying the Sensor on the Patient

- Ensure that the patient's skin is clean, dry, and free of debris and oil.
- The preferred measuring site is the forehead, above the eyebrows.
- Remove the sensor from the release liner.
- Apply the sensor to the forehead. Sensor should be just above each of the eyebrows.
- The cable portion should be routed such that it does not apply pressure to the skin and is not pulling on the sensor.

Connecting the Sensor to the O3 Module

- Up to two Sensors can be connected to the O3 Module simultaneously.
- Align the connector at the end of the Sensor's cable portion to the sensor connection on the Module.
- Insert the connector securely into the sensor connection.
- The Sensor Site screen will display on Root each time a new Sensor is connected to the Module.

Disconnecting the Sensor from the O3 Module

Gently pull the Sensor connector out of the sensor connection on the Module.

Sensor Removal

Gently peel off the Sensor from the application site. If the Sensor is difficult to remove, use alcohol to assist in removal.

Note: The Sensor is not reusable. Dispose of the sensor according to local laws.

ENVIRONMENTAL

Operating Temperature	41°F to 104°F (5°C to 40°C)
Storage Temperature	-40°F to 140°F (-40°C to 60°C)
Storage Humidity	15% to 90% humidity, 86˚F to 140˚F (30˚C to 60˚C)

SPECIFICATIONS

When used with Masimo O3 Regional Oximeter, the O3® Sensor's have the following performance specifications:

O3 Sensor		
rSO_2 Adhesive Sensor	**Adult[1]**	**Pediatric**
Body Weight	≥ 40 kg	≥ 5 kg and < 40 kg
Application Site	Forehead	Forehead
Trending Regional Oxygen Saturation (rSO_2) Accuracy (Arms)	3%	3%
Absolute Regional Oxygen Saturation (rSO_2) Accuracy (Arms)	4%	5%[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 between +/- Arms of the reference measurements in a controlled study.

[1] Absolute and trending rSO2 (Arms) accuracy were determined by testing on healthy adult volunteers with light to dark pigmentation in the range of 45% to 85% SavO2 against 30% arterial and 70% jugular venous blood oxygen saturations, measured with a laboratory CO-Oximeter.

[2] Absolute rSO2 accuracy (Arms) was determined by testing on pediatric patients ≥5 kg, <40 kg with varying skin pigmentation in the range of 45% to 85% SavO2 against 30% arterial and 70% jugular venous blood oxygen saturations, measured with a laboratory CO-Oximeter.

COMPATIBILITY

Masimo SET® Masimo SET® rainbow

This sensor is intended for use only with devices containing Masimo SET oximetry or pulse oximetry monitors licensed to use O3 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.

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 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 O3 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 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		Follow instructions for use
	Manufacturer		Date of manufacture YYYY-MM-DD
	Use-by YYYY-MM-DD		Do not re-use/Single patient use only
	Non-sterile		Not made with natural rubber latex
Rx ONLY	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician	EC REP	Authorized representative in the European community
CE 0123	Mark of conformity to European medical device directive 93/42/EEC		Separate collection for electrical and electronic equipment (WEEE)
LOT	Lot code	REF	Catalogue number (model number)
####	Masimo reference number		Body weight
>	Greater than	<	Less than
	Fragile, handle with care		Atmospheric pressure limitation
	Keep dry		Storage humidity limitation
	Do not use if package is damaged		Storage temperature range
	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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