LNCS® and M-LNCS™ TFA-1™

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SpO2 Disposable Transflectance Forehead Sensor

DIRECTIONS FOR USE

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

INDICATIONS

The Masimo Disposable Transflectance Forehead Sensors are indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The Masimo Disposable Transflectance Forehead Sensors are intended for use with adult and pediatric patients, weighing greater than 10 kg, who are well or poorly perfused in healthcare environments.

CONTRAINDICATIONS

The LNCS and M-LNCS TFA-1 is contraindicated for certain patient positions that affect the monitoring site - see the Warnings Section below.

DESCRIPTION

The LNCS and M-LNCS TFA-1 sensors are intended for use only with devices containing SET® technology, Masimo® SET® MS-2000 (Version 4.8.1.1 or higher) technology or Masimo rainbow SET™ MX (Version 7.1 or higher) technology.

The LNCS and M-LNCS TFA-1 sensors have been validated on the Masimo rainbow® SET MX technology which includes the Masimo SET Oximetry technology. The Masimo rainbow SET MX technology is included in the Radical-7®, Rad-87®, and Rad-57® devices.

The LNCS and M-LNCS TFA-1 sensors are applied to the sensor site using a headband. The sensor may be applied up to twelve (12) hours with periodic checking for circulatory condition changes and skin integrity. Remove and assess skin conditions every 2 hours, if needed.

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.
- 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. 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.
- 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 (such as indelible ink) 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 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.
- **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

- Ensure that the patient's skin is clean, dry and free of debris and oil.
- Do not place the LNCS or M-LNCS TFA-1 on sites with a palpable pulse.
- The preferred measuring site is the forehead, above the eyebrow.

B) Attaching the sensor to the patient

CAUTION: Headband must be used to avoid inaccurate readings.

Initial Application

1. Remove the sensor from the release liner.
2. Refer to **Fig. 1.** Apply the sensor to the forehead. Sensor should be just above the eyebrow with the center lines in line with the center of the eye (pupil).
3. Refer to **Fig. 2.** Apply the headband. Headband should be secure enough to apply slight pressure to the sensor and should completely cover the sensor.
4. The cable should be routed up and over the headband so the cable does not apply pressure to the skin and is not pulling on the sensor.

C) Attaching the Sensor to the Patient Cable

M-LNCS TFA-1

Refer to **Fig. 3.** Insert the sensor connector completely into the patient cable connector and lock into place.

LNCS TFA-1

Refer to **Fig. 4.** Insert the sensor connector completely into the patient cable connector (1). Completely close the protective cover (2) over the patient cable connector until it locks in place.

NOTE: When changing application sites, or reattaching sensor, first attach the sensor to the application site, then connect the patient cable to the sensor.

D) Disconnecting the Sensor from the Patient Cable

M-LNCS TFA-1

Refer to **Fig. 5**. Pull firmly on the sensor connector to remove from the patient cable.

LNCS TFA-1

Refer to **Fig. 6**. Lift the protective cover to gain access to the sensor connector (1). Pull firmly on the sensor connector to remove from the patient cable (2).

E) 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.

Using a New Adhesive Pad

- The adhesive pads included with the LNCS and M-LNCS TFA-1 sensors are double sided adhesive pads used when the stickiness of the adhesive covering the sensor is no longer effective.
- Up to 3 adhesive pads may be applied to each sensor placing one on top of the other.

1. Remove one of the adhesive pads from the strip.
2. Refer to **Fig. 7.** Place the adhesive pad over the sensor as shown. Do not cover the emitter or detector, located in the center of the sensor.
3. Refer to **Fig. 8.** Remove the protective paper that covers the pad.
4. Refer to Steps 2 through 4 under "Initial Application" for patient application.

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

SPECIFICATIONS

When used with Masimo SET technology, the LNCS and M-LNCS TFA-1 Disposable Transflectance forehead sensors have the following specifications:

TFA-1	
Body Weight	> 10 kg
Application Site	Forehead
SpO_2 Accuracy, No Motion (70 - 100%)[1]	2%
SpO_2 Accuracy, Low Perfusion[2]	2%
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 Masimo SET Technology has been validated for no motion SpO_2 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% SpO_2 against a laboratory co-oximeter.

[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

Devices and sensors containing Masimo rainbow SET technology are identified with the Masimo rainbow SET logo.

Devices and sensors using Masimo SET technology are identified with the Masimo SET logo. These sensors are for use only with devices containing Masimo SET technology, Masimo SET MS-2000 (Version 4.8.1.1 or higher) technology or Masimo rainbow SET MX (Version 7.1 or higher) technology.

Each sensor is designed to operate correctly only on the pulse oximetry system from the original equipment manufacturer (OEM).

Use of this sensor with other devices may result in no or improper performance. Look for the Masimo SET or Masimo rainbow SET designation on both the sensors and monitors to ensure accurate pulse oximetry when needed most.

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.

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NO IMPLIED LICENSE

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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 LNCS OR M-LNCS 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
(blue background)	Follow instructions for use		Separate collection for electrical and electronic equipment (WEEE).	Rx ONLY	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 EEC/42/93 Medical Device Directive
	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
2	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	Non-Sterile		Not made with natural rubber latex		Atmospheric pressure limitation
eIFU Indicator	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

M-LNCS, rainbow SET, X-Cal, and TFA-1 are trademarks of Masimo Corporation.

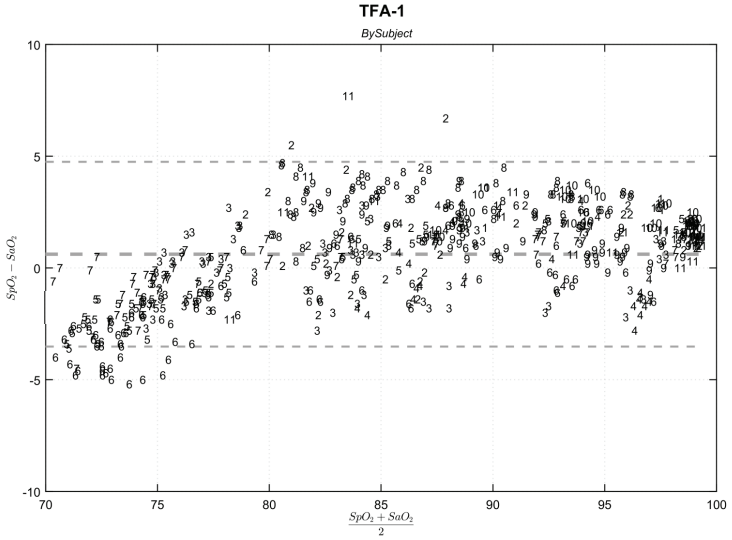
Masimo, SET, , rainbow, Radical-7, Rad-87, Rad-57 and LNCS are federally registered trademarks of Masimo Corporation.

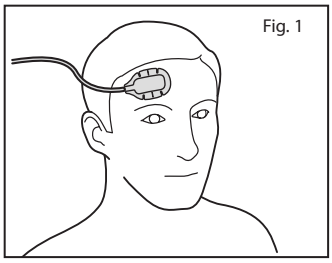
PERFORMANCE SPECIFICATIONS

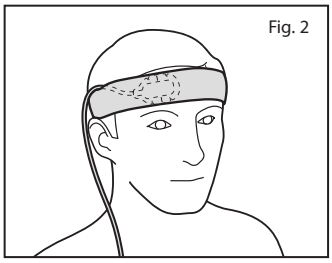
The table below shows Arms (Accuracy Root Mean Square) values measured using the TFA-1 Sensor with Masimo SET Oximetry Technology in a clinical study.

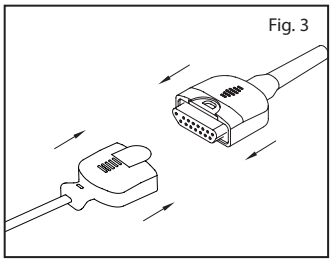
MEASURED Arms VALUES	
Range	**Arms**
90 - 100%	1.90%
80 - 90%	2.27%
70 - 80%	2.47%
70 - 100% (Overall)	2.19%

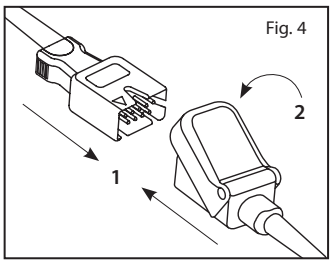
(SpO2 + SaO2)/2 versus error (SpO2 – SaO2) with linear regression fit and upper 95% and lower 95% limits of agreement.

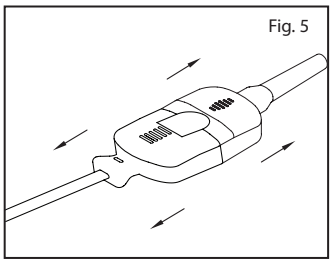


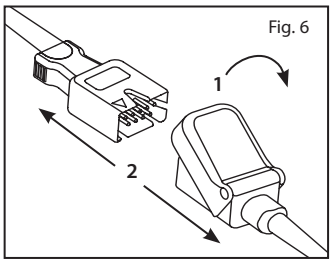


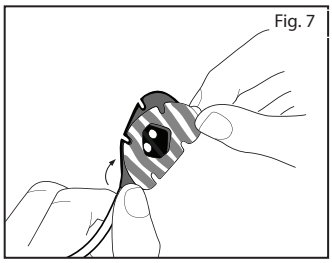


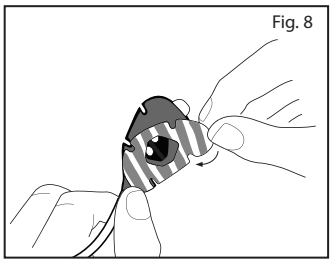












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