

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed Masimo LNCS[®] Pulse Oximeter Sensor

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- LATEX-FREE
- NON-STERILE

Explanation of Icons



Date of Reprocessing



Use by Date



Product Code



Do Not Reuse



See Instructions For Use

Reprocessed Masimo Pulse Oximeter Sensor

Device Description

Reprocessed Low Noise Cabled Sensors (LNCS)® Series - Adult, Pediatric, and Infant SpO₂ adhesive sensors.

When used with Masimo SET® Radical™:

	1859 and 2317 Adult	1860 Pediatric	1861 Infant	1862 Adult	2319 and 2328 Infant	2320 and 2329 Adult
	> 30 kg	10 - 50 kg	3 - 20 kg	> 40 kg	3 - 20 kg	> 40 kg
Application Site	Finger	Finger or toe	Thumb or great toe	Adult finger or toe	Thumb or great toe	Adult finger or toe
Saturation Accuracy, No Motion	± 2.3%	± 2.3%	± 2.3%	± 2.3%	± 2%	± 2%
Pulse Rate Accuracy, No Motion	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm

Indications for Use

This sensor is indicated for use in continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Contraindications for Use

This device should not be used in patients who exhibit allergic reactions to foam rubber products and/or adhesive tape.

Warnings

- Prior to use, read and follow these instructions as well as those of the Operator's Manual for your pulse oximetry system.
- Do not use if there is any evidence of damage to the package.
- Inspect the sensor site periodically to ensure correct sensor alignment and adhesion. Skin integrity and circulation distal to the site should be checked routinely and the sensor relocated to another site if found to be compromised.
- Incorrect application or duration of use of a sensor can cause tissue damage.
- During low perfusion, the sensor site needs to be reviewed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- The readings may read lower than core arterial oxygen saturation with very low perfusion at the monitored site.
- Erroneously low readings may occur if the sensor is applied too tightly.
- Do not use tape to secure the sensor. This can restrict blood flow and cause inaccurate readings. Additional tape can cause skin damage or damage the sensor.
- Inspect the sensor for visible defects. Never use a sensor with exposed electrical circuitry or one that appears to be damaged.
- High levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO₂ measurements.
- "Elevated levels of Total Bilirubin may lead to inaccurate SpO₂ measurements."
- High levels of Methemoglobin (MetHb) will lead to inaccurate SpO₂ measurements.
- Under reading of actual arterial oxygen saturation may be caused by venous congestion. Assure proper venous outflow from monitored site. The sensor should not be below heart level.
- Elevated oxygen concentrations may predispose a premature infant to retinopathy. The upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.
- Do not use oximetry sensors during magnetic resonance imaging (MRI), as the conducted current may cause burns. Cross-interference between the two devices can also cause inaccuracies in the measurements of either system.
- Do not attempt to repair, modify or clean the sensor. Immersion in water will compromise the device performance.
- Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation
- 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 irradiation field. If sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.

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- When uncertain about any measurement accuracy, check the patient's vital signs by alternate means; then make sure the pulse oximeter is working properly.
- In conjunction with clinical signs and symptoms, pulse oximeter sensors are exclusively designed to be used as an adjunct in patient assessment.
- Do not use a sensor or pulse oximeter cable if it is damaged and/or if optical components are exposed.
- Do not attach any cable intended for computer use into the sensor's port connector.
- Sensor application errors, certain patient and ambient environmental conditions, can affect pulse oximeter's readings and signal.
- Do not lift the sensor by the power cord or cable; this may cause the sensor to disconnect and drop on the patient.

Any of the following conditions can cause inaccurate oxygen measurements

- Failure to properly apply the sensor to the patient or to align the optical transducers.
- Application of sensor to an extremity with an arterial catheter, blood pressure cuff or intravascular infusion line in place.
- Application of sensor to a site that is too thick, thin or deeply pigmented.
- Venous pulsations if the sensor or supplemental tape is wrapped too tightly.
- Transducer exposure to excessive light. Cover the sensor with opaque material if it is suspected that the transducer is exposed to excessive ambient light.
- Intravascular dyes or applied coloring (nail polish).
- Excessive motion. Locate sensor at a stationary site and try to keep patient still.

Sensor Specifications for LNCS® Series:

When used with Masimo SET® Radical™ pulse oximetry monitors using LNC series patient cables, during no motion, the accuracy of the LNCS® sensors from 70% to 100% S_pO₂ is ± 2.3 digits (± 1 Standard Deviation) for adults/pediatrics/infants. The pulse rate accuracy from 30-180 bpm is ± 3 bpm (± 1 Standard Deviation). LNCS® series have been validated on the Masimo SET® Radical™ Pulse Oximeter.

Directions for Use

The package label is detachable and may be affixed to the medical record of the patient. When selecting a sensor, consider patient's weight and activity level, need for sterility, perfusion adequacy, sensor site availability, and expected monitoring duration

LNCS® Series:

1. Site Selection

- **1861, 2319 and 2328 Infant Sensor**
 - 3-20 kg The big toe is the preferred site, the toe next to the big toe, or the thumb can be used.
- **1860 Pediatric Sensor**
 - 10-50 kg The middle or ring finger of the non-dominant hand is the preferred site.
- **1859 and 2317 Adult Sensor**
 - > 30 kg The middle or ring finger of the non-dominant hand is the preferred site.
 - Always choose a site that will completely cover the sensor's detector window.
 - Site should be cleaned and dry prior to sensor placement.
- **1862, 2320 and 2329 Adult Sensor**
 - > 40 kg The middle or ring finger of the non-dominant hand is the preferred site.

2. Attaching the sensor to the patient

- Open pouch and remove the sensor. Remove backing from the sensor.

INFANTS (3-20kg)

- Adjust the sensor tail so that it either points away from the patient or runs along the bottom of the foot. Place the detector onto the fleshy part of the toe.
- Wrap the adhesive wrap around the toe. Ensure that the emitter window aligns on the top of the toe directly opposite of the detector.
- Check sensor to confirm correct positioning and reposition if necessary. Entire coverage of the detector window is needed to ensure accurate data.

PEDIATRIC (10-50kg) and ADULT 1859 and 2317 (>30kg) and ADULT 1862, 2320 and 2329 (>40kg)

- Adjust the sensor tail so that the detector can be placed first. Press the detector onto the part of the finger near the tip of the finger. Press the "T" shaped adhesive ends of the sensor onto the finger.

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- Wrap the sensor with the emitter over the fingernail and secure the wings down around finger. The emitter and the detector should be vertically aligned when properly applied.
- Check sensor to confirm correct positioning and reposition if necessary. Entire coverage of the detector window is needed to ensure accurate data.

3. Attaching the sensor to the Patient Cable

- Place the entire sensor connector into the patient cable connector.
- Close the protective cover.

4. Reattachment

ADULT, PEDIATRIC, INFANT

- If the emitter and detector windows are clear and the adhesive still adheres to the skin then the sensor may be reapplied to the same patient.
- Use a new sensor if the adhesive no longer adheres to the skin.
- NOTE: First disconnect sensor from the patient cable when changing application sites, or reattaching sensor.

5. Disconnecting the Sensor from the Patient Cable

- To gain access to the sensor connector, lift the protective cover.
- To remove from the patient cable, pull firmly on the sensor connector.

Returning the Sensor to Stryker Sustainability Solutions for Reprocessing

- Only sensors that functioned properly during clinical use should be placed in the collections container for reprocessing.
- Gently coil the sensor and place in the Stryker Sustainability Solutions provided collection container.
- Once the container is full, place it in the pre-addressed carton provided by Stryker Sustainability Solutions seal the carton and deliver it to the hospital shipping department.

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Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

This product and its packaging have been exposed to ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been exposed to ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Low Noise Cabled Sensors (LNCS)[®] and SET[®] are registered trademarks of Masimo Corporation.
Masimo SET[®] Radical[™] is a registered trademark of Masimo Corporation.

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