Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed Masimo LNCS® Pulse Oximeter Sensor Exposed to Vaporized Hydrogen Peroxide (VHP)

Reprocessed Device for Single Use

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

- NOT MADE WITH NATURAL RUBBER LATEX
- NON-STERILE

Explanation of Symbols

Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
Rx Only	21CFR801	N/A	Prescription only	Indicates Federal (USA) law restricting device to sale by or on order of a physician
	ISO 15223-1 Clause 5.1.1	3082	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1 Clause 5.2.7	2609	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1 Clause 5.1.3	2497	Manufacturing Date (Reprocessing Date)	Indicates the date which the medical device is manufactured
	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Clause 5.1.5	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Clause 5.4.3	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.2	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1 Clause 5.2.8	2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	N/A	N/A	Does not contain natural rubber latex	Notification that natural rubber latex was not used as a material in the finished product or packaging.
	F2503-20	N/A	MR Unsafe	Indicates a medical device poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

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Reprocessed Masimo Pulse Oximeter Sensor Description

Reprocessed Low Noise Cabled Sensors (LNCS)® Series - Adult, Pediatric, and Infant S_pO_2 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%	± 2%	± 2%	± 2%	± 2%	± 2%
Pulse Rate Accuracy, No Motion	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm

Indications for Use

Reprocessed Masimo LNCS Adhesive Pulse Oximeter Sensors are indicated for single patient use for continuous noninvasive arterial oxygen saturation and pulse rate monitoring during no motion conditions, and for patients who are well perfused in hospitals and hospital-type facilities.

Contraindications for Use

Reprocessed Masimo Pulse Oximeter sensor 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 SpO_2 measurements.
- "Elevated levels of Total Bilirubin may lead to inaccurate SpO_2 measurements."
- High levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 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.
- 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:

Accuracy

SpO2: ±2% over the range of 70% to 100%

Pulse Rate: ±3 beats/min over the range of 30-180 BPM

Operating Environment

Temperature: 5° to 40° C.

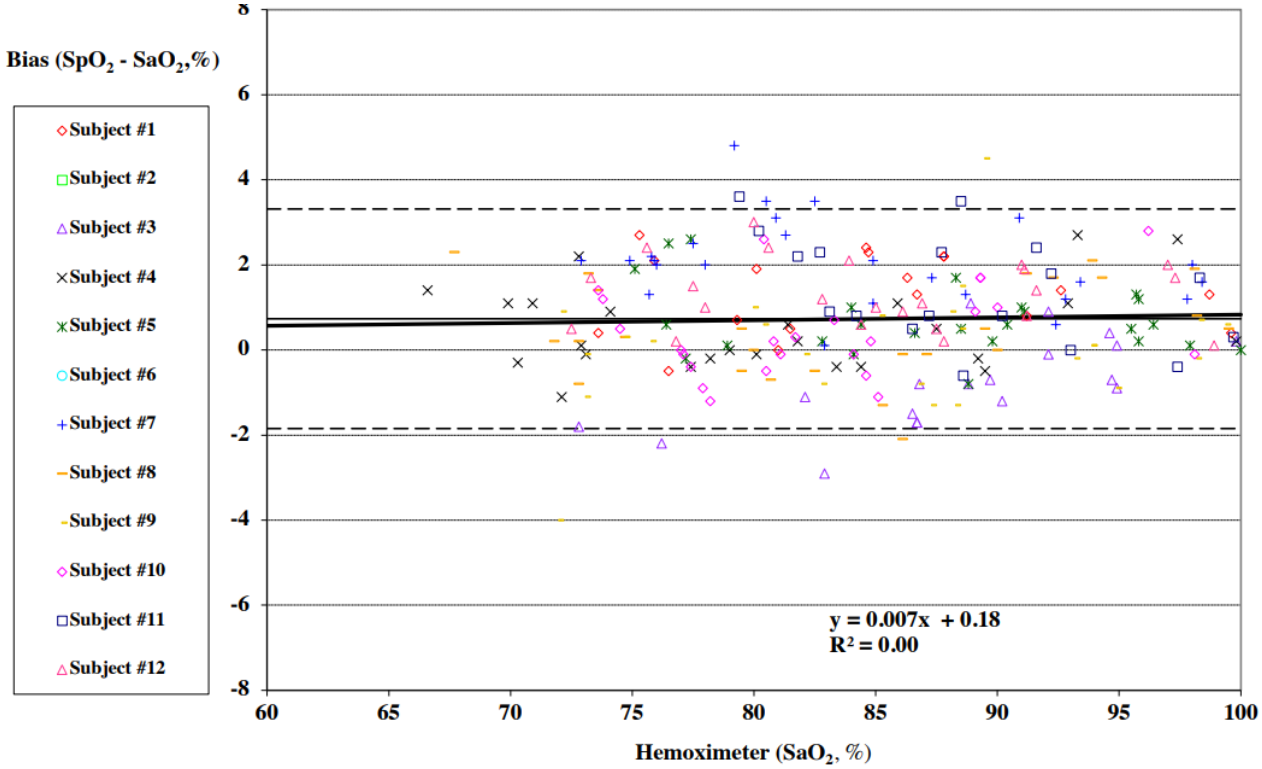
Relative Humidity: 5% to 95%

Performance Specifications:

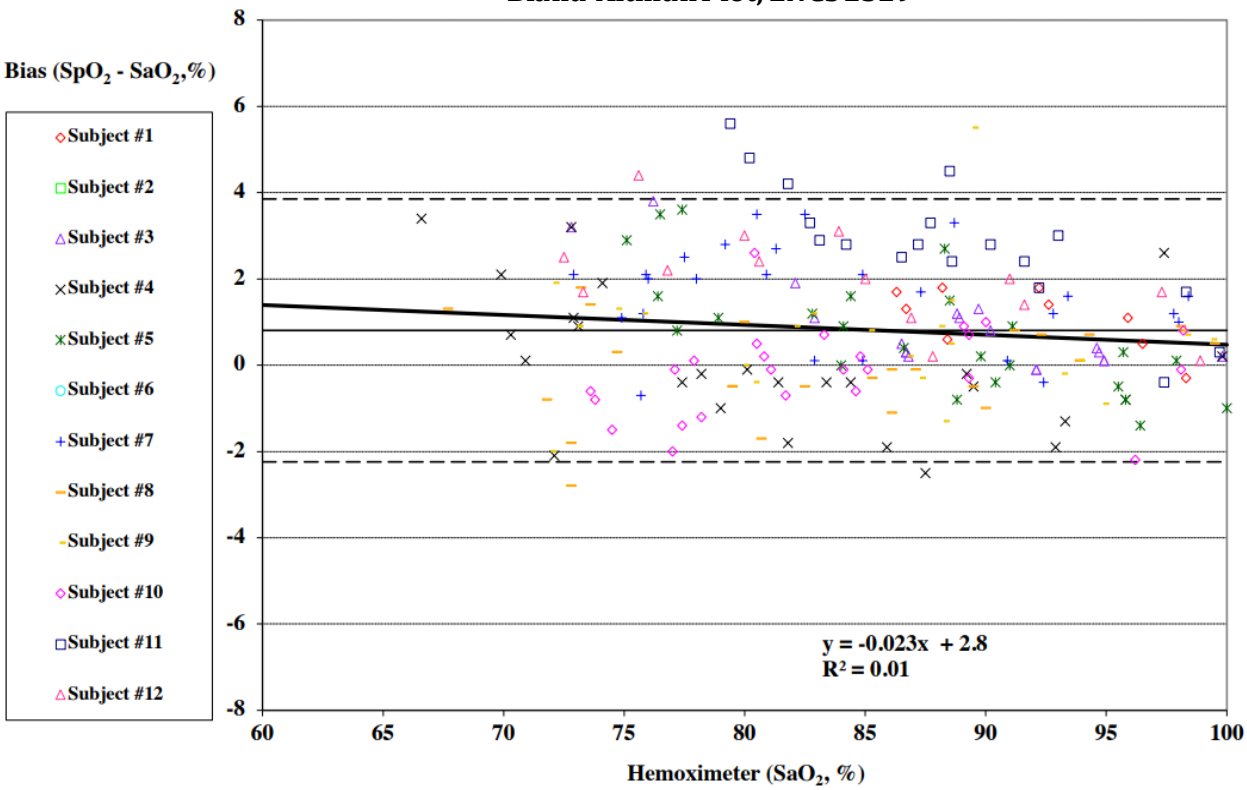
The table below shows Arms (Accuracy Root Mean Square) values measured using the LNCS Adhesive Sensor with Masimo SET Oximetry Technology in a clinical study.

SpO_2 Decile	Masimo 1859	Masimo 2329
	Arms	Arms
70-80	1.61%	2.04%
80-90	1.52%	1.85%
90-100	1.30%	1.16%

Bland-Altman Plot, LNCS 1859



Bland-Altman Plot, LNCS 2329



Directions for Use

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 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.
- 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.

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.

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.

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