

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed Pulse Oximeter Sensor Sterilized Using Vaporized Hydrogen Peroxide

Reprocessed Device for Single Use

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

- STERILE
- NOT MADE WITH NATURAL RUBBER LATEX

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 5.2.1	2499	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	ISO 15223-1 Clause 5.1.4	2607	Use-by date	Indicates the date after which the medical device is not to be used.
	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	Not made with 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.

Reprocessed Pulse Oximeter Sensor Description

This Reprocessed Oxygen Transducer is a previously used Nellcor™ Oxisensor II® or OxiMax™ transducer which has been reworked, inspected, tested, packaged and sterilized by Stryker Sustainability Solutions.

This insert is intended for the following oxygen transducers:

Model	Description
D-25	Adult Sensor for use on finger of patients > 30 kg, 18" cable
D-25L	Same as D-25, with 36" instrument cable
D-20	Pediatric Sensor for use on finger of patients 10-50 kg, 18" cable
N-25	Adult Sensor for use on patient finger if > 40 kg, 36" cable Adult use only
I-20	Infant O2 Transducer for use on toe of patient 3-20 kg, 36" cable
Max-A	Adult Sensor for use on finger of patients > 30 kg, 18" cable
Max-AL	Same as Max-A, with 36" instrument cable
Max-P	Pediatric Sensor for use on finger of patients 10-50 kg, 18" cable
Max-N	Adult Sensor for use on patient finger if > 40 kg, 36" cable Adult use only
Max-I	Infant O2 Transducer for use on toe of patient 3-20 kg, 36" cable

Indications for Use

This sensor is indicated for single patient 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 the 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.
- This oxygen transducer package is provided sterile by method of vaporized hydrogen peroxide. Do not use if there is any evidence of damage to the sterile 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.
- 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.
- Reprocessed OxiMax™ sensors have the event history recording feature disabled.
- 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.
- Excessive motion. Locate sensor at a stationary site and try to keep patient still.

Sensor Specifications

Accuracy

SpO₂: ± 3% over the range of 70% to 100%

Pulse Rate (Oxisensor): ± 3 beats/min over the range of 30-240 BPM

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

Operating Environment

Temperature: 5° to 50° C.

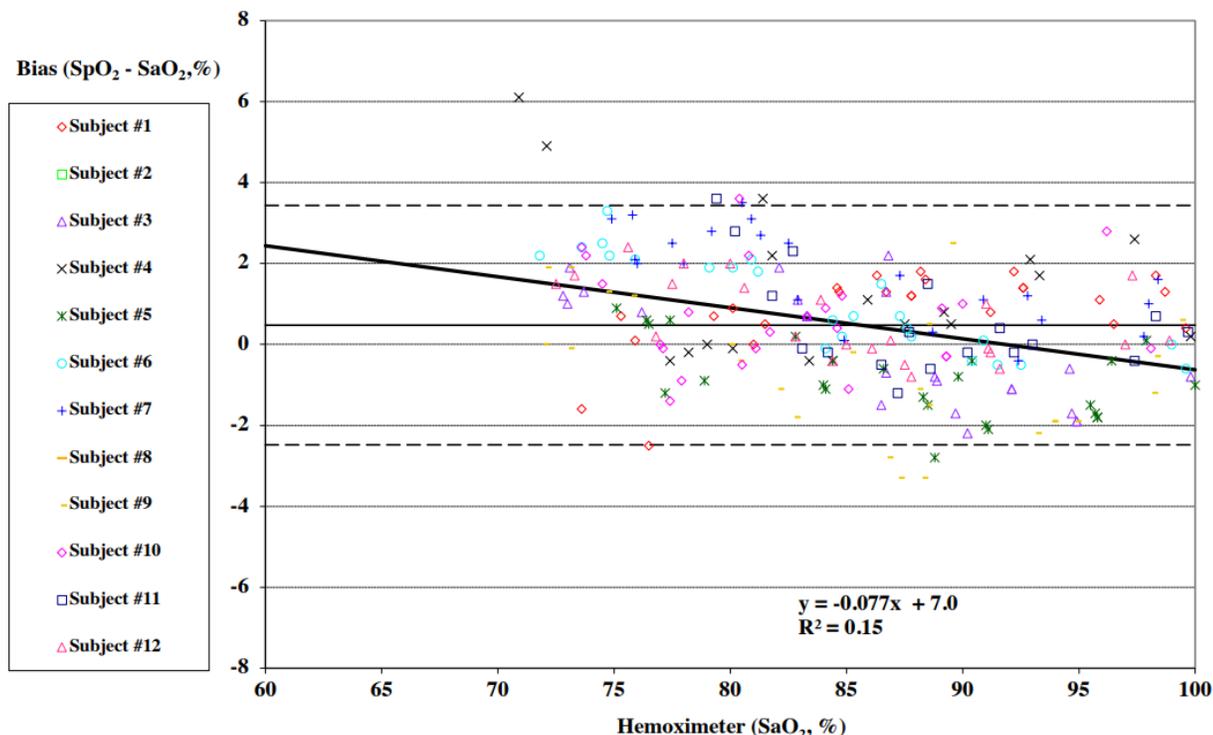
Relative Humidity: 10% to 75%

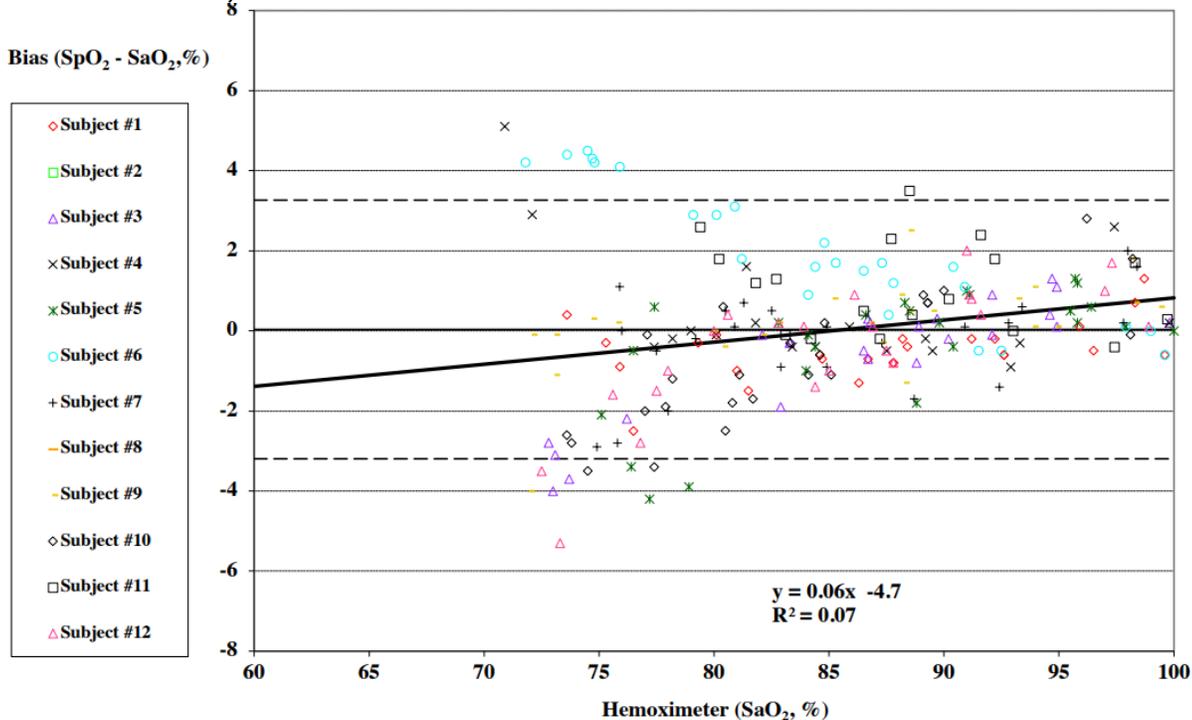
The table below shows Arms (Accuracy Root Mean Square) values measured using the Nellcor™ sensors and N-595 oximeter.

SpO ₂ Decile	Arms	
	MAX-A	MAX-N
70-80	2.01%	2.70%
80-90	1.46%	1.09%
90-100	1.26%	1.03%

Nellcor™ sensors were validated with a Nellcor™ N-595 oximeter against co-oximetry measurements of arterial saturation during a controlled hypoxia “breathe-down” study.

Bland-Altman Plot, MAX-A



Bland-Altman Plot, MAX-N**Directions for Use**

1. When selecting a sensor, consider patient's weight and activity level, need for sterility, perfusion adequacy, sensor site availability, and expected monitoring duration.
2. Locate a suitable site for monitoring oxygen saturation and pulse rate.
For pediatric and adult patients, an index finger is the preferred sensor site, or alternatively another finger or a great toe. For newborns and infants, the preferred site is the great toe or sole of the foot (alternatively the hand).
3. Peel the pouch open and remove the transducer from its package. Remove the paper liner from sensor. On the non-adhesive side of the device are two solid lines with a dashed line at their midpoint. The solid lines are aligned with the transparent windows on the reverse (adhesive) side of the sensor that cover the optical transducers.
4. Orient the sensor so that the dashed line is at the tip of the finger/toe or on the lateral side of the foot/hand. The solid line closest to the cable should be positioned on the nail side of the finger/toe, the sole of the foot or palm of the hand. Wrap the sensor firmly (but not too tightly) around the finger, toe, foot or hand so that the solid lines oppose each other.
5. Plug the sensor into the pulse oximeter module and verify proper operations as described in the system operator's manual. If the sensor does not indicate reliable tracking of the pulse rate, relocate sensor to an alternative site or choose an alternative sensor. The oxygen transducer can be reused on the same patient for as long as the adhesive provides an adequate attachment.

Returning the sensor to Stryker 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 provided collection container.
- Once the container is full, place it in the pre-addressed carton provided by Stryker, 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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