stryker D-25 Pulse Oximeter Sensor Instruction Manual

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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.
STERILE	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.
REF	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	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.
2	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.
MR	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 NellcorTM Oxisensor II® or OxiMaxTM transducer which has been reworked, inspected, tested, packaged and sterilized by Stryker Sustainability Solutions.
This insert is intended for the following oxygen transducers:

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
- This oxygen transducer package is provided sterile by method of vaporized hydrogen 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 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
- Do not use oximetry sensors during magnetic resonance imaging (MRI), as the conducted current may cause 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 Immersion in water will compromise the device performance.
- Reprocessed OxiMaxTM sensors have the event history recording feature
- 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
- Do not attach any cable intended for computer use into the sensor’s port

- Sensor application errors, certain patient and ambient environmental conditions, can affect pulse oximeter's readings and
- Do not lift the sensor by the power cord or cable; this may cause the sensor to disconnect and drop on the

Any of the following conditions can cause inaccurate oxygen measurements

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

Sensor Specifications

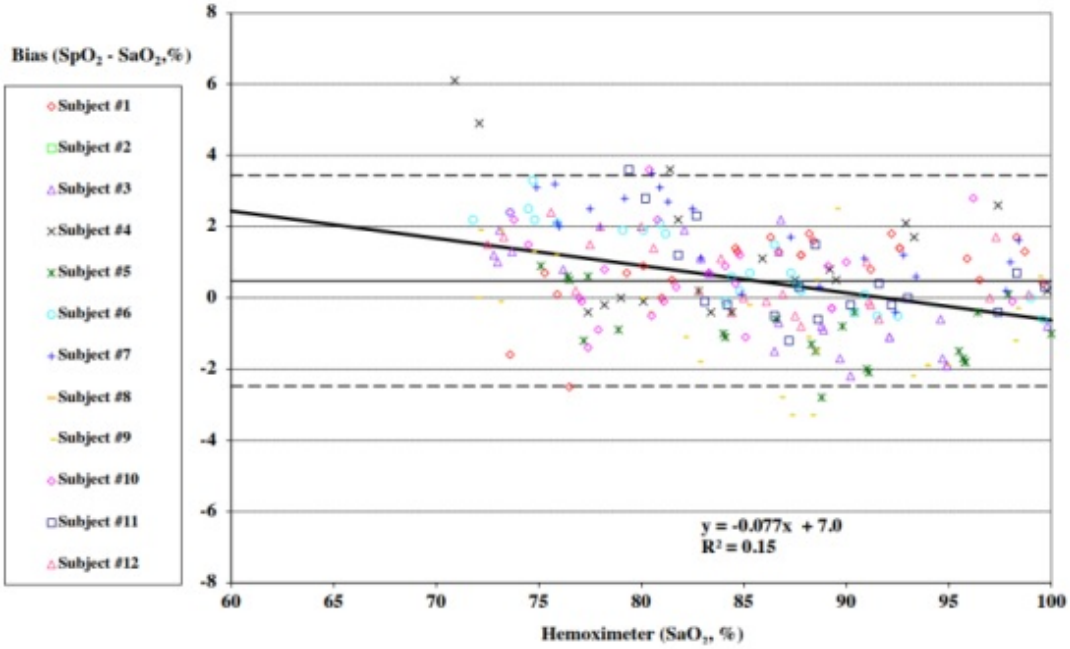
Accuracy

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: 5o to 50o C. Relative Humidity: 10% to 75%
The table below shows Arms (Accuracy Root Mean Square) values measured using the NellcorTM sensors and N-595 oximeter.

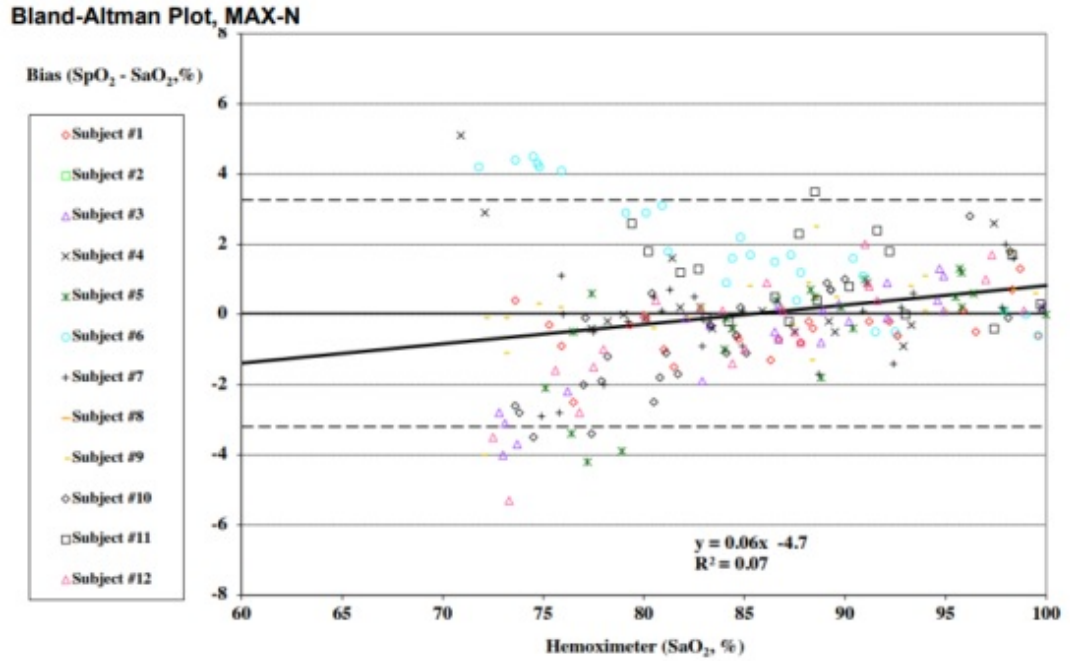
SpO2 Decile	**Arms**	
	MAX-A	**MAX-N**
70-80	2.01%	2.70%
80-90	1.46%	1.09%
90-100	1.26%	1.03%

NellcorTM sensors were validated with a NellcorTM 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

3. When selecting a sensor, consider patient's weight and activity level, need for sterility, perfusion adequacy, sensor site availability, and expected monitoring duration.
4. Locate a suitable site for monitoring oxygen saturation and pulse
   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).
5. Peel the pouch open and remove the transducer from its 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.

6. 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.
7. 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
- Gently coil the sensor and place in the Stryker provided collection
- 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 withoutthe 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 refundis 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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Mode d'emploi

Capteur d'oxymètre de pouls retraité stérilisé au peroxyde d'hydrogène vaporisé

Dispositif retraité à usage unique

Mise en garde : selon la loi fédérale américaine (É.-U.), ce dispositif ne peut être vendu que par un médecin ou sur ordonnance médicale.

- STÉRILE
- NON FABRIQUÉ À PARTIR DE LATEX DE CAOUTCHOUC NATUREL

Explication des symboles

Symbole	Référence aux règles/normes	Numéro d'enregistrement ISO 7000	Titre du symbole	Description
Rx Only	21CFR801	S.O.	Sur ordonnance uniquement	Indique que selon la loi fédérale américaine, le dispositif ne peut être vendu que par un médecin ou sur ordonnance médicale
	ISO 15223-1, clause 5.1.1	3082	Fabricant	Indique le fabricant du dispositif médical
	ISO 15223-1, clause 5.2.1	2499	Stérile	Indique qu'un dispositif médical a été soumis à un processus de stérilisation
	ISO 15223-1, clause 5.1.4	2607	Date de péremption	Indique la date à partir de laquelle le dispositif médical ne doit plus être utilisé
	ISO 15223-1, clause 5.1.6	2493	Numéro de catalogue	Indique le numéro de catalogue du fabricant afin que le dispositif médical puisse être identifié
	ISO 15223-1, clause 5.1.5	2492	Code de lot	Indique le code de lot du fabricant afin que le lot puisse être identifié
	ISO 15223-1, clause 5.4.3	1641	Consulter le mode d'emploi	Indique la nécessité pour l'utilisateur de consulter le mode d'emploi
	ISO 15223-1, clause 5.4.2	1051	Ne pas réutiliser	Indique un dispositif médical destiné à un usage unique ou à être utilisé sur un seul patient au cours d'une seule procédure
	ISO 15223-1, clause 5.2.8	2606	Ne pas utiliser si l'emballage est endommagé	Indique que le dispositif médical ne doit pas être utilisé si son emballage a été endommagé ou ouvert
	S.O.	S.O.	Non fabriqué à partir de latex de caoutchouc naturel	Avis indiquant que le latex de caoutchouc naturel n'a pas été utilisé comme matériau dans le produit fini ou l'emballage
	F2503-20	S.O.	Non compatible avec l'IRM	Indique qu'un dispositif médical présente des risques inacceptables pour le patient, le personnel médical ou d'autres personnes dans un environnement à résonance magnétique

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References

- Sustainability Solutions | Stryker
- User Manual