

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Pulse Oximeter Sensors
Manufactured by SterilMed, Inc.
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Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

These devices are reprocessed "Pulse Oxisensors" from various original equipment manufacturers (OEM.). The reprocessed pulse oxisensors are intended for use when continuous external monitoring of arterial oxygen saturation and pulse rate are required for neonates weighing less than 3 kg, adults weighing more than 40 kg, infants between 3 and 20 kg, and pediatric patients between 10 and 50 kg. The reprocessed N-25/N-25LF and D-25/D-25L oxisensors are indicated to be used in conjunction with the Nellcor N-395 Pulse Oximeter System or equivalent Nellcor compliant oximeters. The reprocessed Max-N, Max-A/Max-AL, Max-I, and Max-P oxisensors are indicated to be used in conjunction with the Nellcor N-595 Pulse Oximeter System or earlier Nellcor and Nellcor compliant oximeters.

DEVICE DESCRIPTION

The reprocessed oximetry sensor device is an electro-optical sensor that uses an optical means to determine the light absorption of functional arterial hemoglobin. The sensor contains three optical components: two light emitting diodes (LEDs) that serve as light sources, and one photodiode, that acts as a light receiver. The sensor is positioned so that the LED's and photodiode oppose one another across the tissue. The sensor is connected via cable to a pulse oximeter, which provides continuous non-invasive, self-calibrated measurements of pulse rate and oxygen saturation of functional hemoglobin.

Reprocessed oxisensors have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from an owner (health institution), reprocessed, and returned for single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor and ensure the number of times reprocessed.

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CONTRAINDICATIONS

1. This device should not be used on patients who exhibit allergic reactions to the adhesive.
2. Do not position the oxisensor on an edematous site as the fluid in the edematous tissue may affect the readings.

This device has been reprocessed for single use only and must be returned for reprocessing prior to another use.

WARNINGS AND PRECAUTIONS

1. Do not use the oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.
2. As with the use of any medical device, it is necessary to have adequate training and a thorough understanding of the use and applications of the device.
3. Inspected the device and packaging prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
4. SterilMed's reprocessed oxisensors should be used only with Nellcor Puritan Bennett (NPB) sensor cable model FGA-2B.
5. SterilMed's reprocessed oxisensors are for use only with the Nellcor compatible Pulse Oximeter Systems.
6. Examine the device after removal from package. Do not use an oximetry sensor with exposed optical components.
7. Remove nail polish or apply sensor to unpolished site.
8. When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff or intravascular infusion line.
9. Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
10. Adhesive sensor sites must be checked at least every 8 hours for adhesion, skin integrity and sensor alignment. If any of these are compromised, move the sensor to a new site.
11. A more complete assessment of oxygenation beyond pulse oximetry is recommended whenever dysfunctional hemoglobins are suspected.
12. Tissue damage can be caused by incorrect application or use of an oximeter sensor, such as wrapping the sensor too tightly or applying supplemental tape.
13. For additional warnings, cautions or contraindications when using this sensor with Nellcor compatible instruments refer to the instrument's operator's manual or contact the manufacturer of the instrument

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INNACURATE MEASUREMENTS

Inaccurate measurements may be caused by:

1. Incorrect sensor application or use
2. Excessive patient movement
3. Significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin or methemoglobin)
4. Exposure to excessive light such as xenon light sources, bilirubin lamps or direct sunlight (should this occur, cover the sensor and application site with opaque material)
5. Intravascular dyes such as indocyanine green or methylene blue

LOSS OF PULSE SIGNAL

Loss of pulse signal may be caused by:

1. Patient is in cardiac arrest or shock
2. Applying the sensor too tightly
3. Inflating a blood pressure cuff on the extremity where the sensor is attached
4. Patient has hypotension, severe vasoconstriction, severe anemia or hypothermia
5. An arterial occlusion proximal to the sensor
6. Excessive illumination

POTENTIAL ADVERSE EVENTS

The following potential risks may be associated with the use of pulse oximetry sensors. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Swelling or reddening of skin
2. Burns
3. Blisters
4. Burns
5. Pressure sores
6. Skin removal

INSTRUCTIONS FOR USE

1. The patient's extremity or other sensor site should be at the level of the heart for best sensor performance, and no arterial catheter or blood pressure cuff should be in place in that extremity.
2. The patient should avoid movement whenever possible for best sensor performance.
3. Remove the backing from the oximetry sensor transducer.
4. Orient the oximetry sensor such that the alignment mark is centered on the extremity directly opposite the alignment mark on the other side of the extremity.
5. Press the oximetry sensor onto the skin and wrap the adhesive flaps around the extremity.

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6. To optimize the oximetry sensor performance in bright light environments such as sunlight or bright operating lights, cover the sensor completely with an opaque material such as a blanket or towel.
7. Plug the oximetry sensor into the instrument cable receptacle.

ACCURACY SPECIFICATIONS

SterilMed Sensor Model Numbers	Saturation (%SaO ₂ , +/-1SD)	Heart Rate
N-25/N-25LF, D-25/D-25L, Max-A/Max-AL, Max-N	<i>Adults:</i> 70-100% +/-3 Digits 1-69% Unspecified <i>Neonates:</i> 70-100% +/- 4 Digits* 1-69% Unspecified	+/- 2 beats per minute (bpm)
Max-I	<i>Infants:</i> 70-100% +/- 4 Digits* 1-69% Unspecified	
Max-P	<i>Pediatrics:</i> 70-100% +/- 4 Digits* 1-69% Unspecified	

***Note:** The N-25, Max-N, Max-I, and Max-P sensors were tested on adults only. Due to the risk involved in testing neonates, infants and children it is reasonable and is common practice to add one digit to the adult accuracy specifications to account for differences in the hemoglobin spectrum, and possibly other differences.

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Remove the device from the sterile packaging using proper sterile technique.

Use of this reprocessed device should be limited to clinicians trained in the use of this oximetry sensors as well as appropriate associated equipment. For specific details in the use of pulse oximetry and the techniques employed in measurement of arterial hemoglobin the physician should be referred to the medical literature and rely on training and practical experience.

METHODS TO TEST REPROCESSED DEVICES

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, routine sterilization, and functional testing. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

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**Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product 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 sterilized with 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.*

Instructions for Use can be found at www.SterilMed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.

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