

Reprocessed by



Instructions for Use Reprocessed 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.

- **STERILE**
- **LATEX-FREE**

Explanation of Icons

 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

REF Ascent Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed Pulse Oximeter Sensor

Device Description

This Reprocessed Oxygen Transducer is a previously used Nellcor Puritan Bennett™ (NPB) Oxisensor II® or OxiMax™ transducer which has been reworked, inspected, tested, packaged and sterilized by Ascent Healthcare 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	Neonatal Sensor for use on patient foot if < 3 kg or finger if > 40 kg, 36" cable
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	Neonatal/Adult Sensor for use on patient foot if < 3 kg or finger if > 40 kg, 36" cable
Max-I	Infant O2 Transducer for use on toe of patient 3-20 kg., 36" cable

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 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 ethylene oxide gas. 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.

Reprocessed Pulse Oximeter Sensor

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

Oxisensor®

Accuracy S_pO_2 : $\pm 3\%$ ($\pm 4\%$ in Neonates) over the range of 70% to 100%*
Pulse Rate: ± 3 beats/min over the range of 30-240 BPM
Operating Environment: Temperature 5° to 50° C. 10% to 75% Relative Humidity

OxiMax™

Accuracy S_pO_2 : $\pm 3\%$ ($\pm 4\%$ in Neonates) over the range of 70% to 100%*
Pulse Rate: ± 3 beats/min over the range of 30-180 BPM
Operating Environment: Temperature 5° to 50° C. 10% to 75% Relative Humidity

*Oxisensors were validated with a Nellcor™ N-395 oximeter against co-oximetry measurements of arterial saturation during a controlled hypoxia “breathe-down” study. OxiMax™ sensors were validated with Nellcor™ N-595 oximeters against co-oximetry measurements of arterial saturation during a controlled hypoxia “breathe-down” study. Specified accuracy range is increased by $\pm 1\%$ for neonates in order to account for potential influences of fetal hemoglobin upon oximetry measurements.

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. When selecting a sensor, consider patient’s weight and activity level, need for sterility, perfusion adequacy, sensor site availability, and expected monitoring duration.
3. 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).
4. Peel the pouch open and remove the transducer from its package. Remove the plastic backing 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.
5. 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.
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 Ascent 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 Ascent provided collection container.
- Once the container is full, place it in the pre-addressed carton provided by Ascent, seal the carton and deliver it to the hospital shipping department.

Reprocessed Pulse Oximeter Sensor

Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. 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.

Sterilization: This product and its packaging have been sterilized with 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 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.

Nellcor™ and OxiMax™ are trademarks of Nellcor Puritan Bennett LLC.
Oxisensor II® is a registered trademark of Nellcor Puritan Bennett LLC.