Reprocessed by

ReNu Medical, Inc.

Instructions for Use

Reprocessed Masimo Pulse Oximeter Sensor LNCS® Series

Reprocessed Device for Single Use

Symbol Legend:

	Date of Reprocessing		Reprocessor/Manufacturer
	Do Not Reuse		Not made with natural rubber Latex
	Consult instructions for use		Fragile, handle with care
	Do not use if package is damaged		Keep dry
	Non-Sterile – High Level Disinfection	Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution See Instructions for use	OEM	Original Equipment Manufacturer Catalog#
REF	ReNu Medical Catalog#	LOT	ReNu Medical Sales Order
CID	Customer ID#, if none specified; ReNu Medical Catalog#	QTY	Qty of Devices included in Pkg/Cs

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Reprocessed Masimo Pulse Oximeter Sensor LNCS® Series

Indications for Use

Masimo Pulse Oximeter Sensors LNCS® Series are indicated for single patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Sensor	ADTX, ADTX-3	PDTX, PDTX-3	INF, INF-L, INF-3	NEO, NEO-L, NEO-3
Model	1859, 2317	1860, 2318	2328, 1861, 2319	2329, 1862, 2320
Patient Weight	>30kg	10-50kg	3-20 kg	<3kg; >40kg
Application Site	Finger or Toe	Finger or Toe	Thumb or great toe	Neo: hand or foot Adult: finger or toe
SpO2 Saturation Accuracy Range	70-100% ± 3.5%	70-100% ± 3.5%	70-100% ± 3.5%	70-100% ± 3.5%
Pulse Rate Range: 25-240 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm

Contraindications

Patients who exhibit allergic reaction to foam rubber products and/or adhesive tape.

Warnings

- Prior to use, read and follow these instructions as well as Original Equipment Manufacturer's Operator's Manual.
- All sensors and cables are designed for use with specific monitors. Verify the compatibility of the monitor, cable and sensor before use, otherwise degraded performance and/or patient injury can result.
- The site must be checked frequently or per clinical protocol to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.
- Exercise caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess site as frequently as every (1) hour with poorly perfused patients and move the sensor if there are signs of tissue ischemia.
- Circulation distal to the sensor site should be checked routinely.
- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- With very low perfusion at the monitored site, the reading may read lower than core arterial oxygen saturation.
- Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage, and/or pressure necrosis or damage the sensor. Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis.
- Misapplied sensors or sensors that become partially dislodged may cause incorrect measurements.
- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor).
- Venous pulsations may cause erroneous low SpO2 readings (e.g. tricuspid value regurgitation).
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.

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- The sensor should be free of visible defects, discoloration and damage. If the sensor is discolored or damaged, discontinue use. Never use a damaged sensor or one with exposed electrical circuitry.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If sensor is exposed to the radiation, the reading might be inaccurate, or the unit might read zero for the duration of the active radiation period.
- Do not use the sensor during MRI scanning or in an MRI environment.
- High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor.
- To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.
- High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO2 measurements.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO2 measurements.
- Elevated Total Bilirubin levels may lead to inaccurate SpO2 measurements.
- Intravascular dyes such as indocyanine green or methylene blue or externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc. may lead to inaccurate SpO2 measurements.
- Inaccurate SpO2 readings may be caused by severe anemia, low arterial perfusion or motion artifact.
- To prevent damage, do not soak or immerse the sensor in any liquid solution.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance and/or accuracy.
- Do not attempt to reuse on multiple patients, reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.
- Caution: Replace the sensor when a replace sensor message is displayed, or when a low SIQ message is consistently displayed after completing the low SIQ troubleshooting steps identified in the monitoring device operator's manual.
- Note: The sensor is provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. The sensor will provide up to 168 hours of patient monitoring time or up to 336 hours for sensors with a replaceable tape. After single-patient use, discard sensor.

Precautions

- Proper sizing and application is essential.

Directions for Use

1. Choose the appropriate site selection

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2. Attach the sensor to the patient. Open the pouch and remove the sensor. Remove the backing from the sensor and locate transparent/detector windows on the adhesive side. Windows cover optical components. Note corresponding alignment marks on non-adhesive side and dashed line midway between the marks.
   ADULT (> 30 kg) and PEDIATRIC (10 - 50 kg)
- Orient the sensor cable so that the detector can be placed first. Place the tip of the finger on the dashed line with the fleshy part of the finger covering the detector window.
- Press the adhesive wings one at a time onto the finger. Complete coverage of the detector window is needed to ensure accurate data.
- Fold the sensor over the finger with the emitter window positioned over the fingernail. Secure the wings down one at a time around the finger. When properly applied, the emitter and detector should be vertically aligned.
- Verify correct positioning and reposition if necessary (all lines should align).

INFANTS (3 - 20 kg)

- Direct the sensor cable so that it either points away from the patient or runs along the bottom of the foot. Position the detector onto the fleshy part of the great toe. Complete coverage of the detector window is needed to ensure accurate data.
- Wrap the adhesive wrap around the toe and ensure that the emitter window aligns on the top of the toe directly opposite the detector.
- Verify correct positioning and reposition if necessary.

NEONATES (< 3 kg) and PRETERM (< 1kg)

- For fragile skin, the stickiness of the medical grade adhesive can be diminished or eliminated by daubing the adhesive areas with a cotton ball or with gauze.
- Direct the sensor cable so that it either points away from the patient or runs along the bottom of the foot. Apply the detector onto the fleshy part of the lateral aspect of the sole of the foot aligned with the fourth toe. Alternatively, the detector may be applied to the top of the foot. Complete coverage of the detector window is needed to ensure accurate data.
- Wrap the adhesive wrap around the foot and ensure that the emitter window aligns directly opposite of the detector. Be careful to maintain proper alignment of the detector and emitter windows while attaching adhesive wrap to secure the sensor.
- Verify correct positioning and reposition if necessary.

3. Attaching the Sensor to the Patient Cable
- Insert the sensor connector completely into the patient cable connector.
- Completely close the protective cover.

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4. Reattachment
   - The sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.
   - If the adhesive no longer adheres to the skin, use a new sensor.
   - Note: When changing application sites, or reattaching sensor, first disconnect sensor from the patient cable.

5. Disconnecting the Sensor from the Patient Cable
   - Pull firmly on the sensor connector to remove it from the patient cable.
   - Lift the protective cover to gain access to the sensor connector.
   - Pull firmly on the sensor connector to remove from the patient cable.

Return for reprocessing to ReNu Medical

1. Only sensors that function properly during clinical use should be returned for reprocessing.
2. Gently coil and place used sensors in the reprocessing collection container to be returned to ReNu Medical.

The names of the actual Original Equipment Manufacturer and products mentioned within this document and any information listed on the label is provided as identification prior to High-Level Disinfection reprocessing and may contain trademarks of unrelated third parties who may not represent the device after reprocessing.

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