

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Masimo® 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 sensors are indicated for use in continuous noninvasive arterial oxygen saturation and pulse rate monitoring. These devices have been validated using the Masimo SET® Radical® Pulse Oximeter System and exhibit the following properties:

Model Number/ Description	Sensor Type	Application Site	Saturation Accuracy, No Motion	Pulse Rate Accuracy, No Motion	Patient Weight (kg)
1859 – Adult	LNCS®	Finger or Toe	± 3%	± 2%	> 30
1861 – Infant (Long Cable)		Thumb or great toe	± 4%*	± 2%	3 – 20
2328 – Infant (Short Cable)		Thumb or great toe	± 4%*	± 2%	3 – 20
1025 – Pediatric	LNOP®	Finger or Toe	± 4%*	± 2%	10 – 50

**\*Note: These sensors were tested on adults only. Due to the risk involved in testing 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.**

The OEM provided an “Instructions for Use” (IFU) document with the original device. The health institution that wishes for the device to be reprocessed should retain this original document.

## 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 (LED’s) 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 noninvasive, self-calibrated measurements of pulse rate and oxygen saturation of functional hemoglobin.

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The Reprocessed Masimo Pulse Oximeter Sensors have been cleaned, evaluated for continued integrity, packaged, and sterilized for a single subsequent use. Devices are tracked throughout the reprocessing steps to monitor and ensure that they do not exceed the specified number of reprocessing cycles.

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

## CONTRAINDICATIONS

1. This device should not be used on patients who exhibit allergic reactions to foam/rubber products or adhesive tape.
2. Do not position the sensor on an edematous site as the fluid in the edematous tissue may affect the readings.

## WARNINGS AND PRECAUTIONS

1. 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.
2. Adhesive sensor sites must be checked at least every eight (8) hours for adhesion, skin integrity and sensor alignment. If any of these are compromised, the sensor should be moved to a new site. Circulation distal to the sensor site should be checked routinely.
3. Inspect the device and packaging prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
4. Exercise caution with poorly perfused patients; skin erosion and/or pressure necrosis may occur.
5. During low perfusion, the sensor site needs to be reviewed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
6. The readings may read lower than core arterial oxygen saturation with very low perfusion at the monitored site.
7. Exercise caution when applying a sensor to a site with compromised skin integrity; applying tape or pressure to such a site can further reduce circulation.
8. Do not use tape to secure the sensor. This can restrict blood flow and cause inaccurate readings. Additional tape can cause skin damage or damage the sensor.
9. Misapplied sensors or sensors that become partially dislodged may cause inaccurate readings of actual oxygen saturation.
10. Inaccurate low readings may be generated if the sensor is applied too tightly.
11. The sensor should be free of visible defects. Never use a damaged sensor or one with exposed electrical circuitry.
12. Do not attempt to repair, modify or clean the sensor. Immersion in water will compromise the device performance.
13. Carefully route the cable and patient cable to reduce the possibility of patient entanglement or strangulation.
14. Elevated levels of Total Bilirubin may lead to inaccurate  $S_pO_2$  measurements.

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15. Do not use the oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.
16. If using pulse oximetry during full body irradiation, keep the sensor out of the irradiation field. If sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.
17. Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
18. 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.
19. Under reading of actual arterial oxygen saturation may be caused by venous congestion. Assure proper venous outflow from monitored site. The sensor should not be below heart level.
20. Venous pulsations may cause erroneous low readings (e.g. tricuspid valve regurgitation).
21. High oxygen concentrations may predispose a premature infant to retinopathy. The upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.
22. For additional warnings, cautions or contraindications when using these sensors with Masimo SET Radical Pulse Oximeter Systems, refer to the instrument's operator's manual or contact the manufacturer of the instrument.

## **INNACURATE MEASUREMENTS**

Inaccurate measurements may be caused by:

1. Failure to apply the sensor correctly may cause incorrect measurements.
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) or externally applied coloring (such as nail polish) may lead to inaccurate  $S_pO_2$  measurements.

## **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

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## 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

### LNCS Series:

#### 1. Site Selection

- **Adult Sensor (> 30 kg)**
  - The preferred site is the middle or ring finger of non-dominant hand.
  - Always choose a site that is well perfused and will completely cover the sensor's detector window.
  - Site should be cleaned of debris and dry prior to sensor placement.
- **Pediatric Sensor (10 – 50 kg)**
  - The preferred site is middle or ring finger of non-dominant hand.
- **Infant Sensor (3 – 20 kg)**
  - The big toe is the preferred site. The toe next to the big toe or the thumb can be used.

#### 2. Attaching the sensor to the patient

- Open pouch and remove the sensor. Remove the backing from the sensor.  
**Infants (3 – 20 kg)**
  - Adjust the sensor tail 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.
  - Wrap the adhesive wrap around the toe and ensure that the emitter window aligns on the top of the toe directly opposite the detector.
  - Confirm that the sensor is positioned correctly and reposition if necessary.**Pediatric (10 – 50 kg) & Adult (> 30 kg)**
  - Adjust 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 on one at a time onto the finger.
  - Wrap the sensor with the emitter over the fingernail and secure the wings down and around finger. Ensure proper alignment by verifying that the emitter and detector are vertically aligned.

#### 3. Attaching the sensor to the patient cable

- Place the entire sensor connector into the patient cable connector.

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- Close the protective cover.

#### 4. Reattachment

##### Adult, Pediatric, and Infant

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

#### 5. Disconnecting the sensor 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.

### LNOP Series:

#### 1. Site Selection

- **Adult and Pediatric (> 30 kg & 10 – 50 kg)**
  - The preferred site is the middle or ring finger of non-dominant hand.
  - Always choose a site that is well perfused and will completely cover the sensor's detector window.
  - Site should be cleaned of debris and dry prior to sensor placement.
- **Infant (3 – 20 kg)**
  - The preferred site is the big toe is the preferred site. The toe next to the big toe or the thumb can be used.

#### 2. Attaching the sensor to the patient

- Open pouch and remove the sensor. Remove the backing from the sensor.

##### Infants (3 – 20 kg)

- Adjust the sensor tail 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.
- Wrap the adhesive wrap around the toe and ensure that the emitter window aligns on the top of the toe directly opposite the detector.
- Confirm that the sensor is positioned correctly and reposition if necessary.

##### Pediatric (Pdt, Pdtx 10 – 50 kg)

- Adjust the sensor cable so that the detector can be placed first. Place the detector on the fleshy part of the finger, near the tip of the finger, covering the detector window. Press the "T" shaped adhesive ends on one at a time onto the finger.
- Wrap the sensor with the emitter over the fingernail and secure the wings down and around finger. Ensure proper alignment by verifying that the emitter and detector are vertically aligned.

##### Adult (Adt, Adtx > 30 kg)

- Adjust the sensor cable so that the detector can be placed first. Place the detector on the fleshy part of the finger, near the tip of the finger, covering the detector window. Press the "T" shaped adhesive ends on one at a time onto the finger.

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- Wrap the sensor with the emitter over the fingernail and secure the wings down and around finger. Ensure proper alignment by verifying that the emitter and detector are vertically aligned.

### 3. Attaching the sensor to the patient cable

- Place the sensor's connector tab so that the side with the reflective contacts is facing up. Insert the patient cable until there is an audible "click", verifying proper connection.

### 4. Reattachment

#### Adult, Pediatric, and Infant

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

### 5. Disconnecting the sensor from the patient cable

- Depress the gray tabs on either side of the patient cable connector and pull the sensor to remove.

## ACCURACY SPECIFICATIONS

When used with Masimo SET Radical Pulse Oximeter systems using LNC or PC patient cables during no motion, the accuracy of the LNCS and LNOP sensors from 70% to 100%  $S_pO_2$  is  $\pm 3\%$  for the adult models and  $\pm 4\%$  for the pediatric and infant models ( $\pm 1$  standard deviation). The pulse rate accuracy is  $\pm 2$  beats per minute (bpm). Both the LNCS and LNOP sensors have been validated on the Masimo SET Radical Pulse Oximeter.

## GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and 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 these 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.

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## METHODS TO TEST REPROCESSED DEVICES

Devices have been determined to be biocompatible following reprocessing and have been verified to be sterile. Validated methods are used for 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.

*\*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.*

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*Instructions for Use can be found at [www.sterilmed.com](http://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.*

