

Reprocessed by



434 Industrial Lane Birmingham, AL 35211
1-866-943-6670

Instructions for Use Hygia LNCS Pediatric Pulse Oximetry Probe IFU

Reprocessed Device for Single Use.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

NON-STERILE NOT MADE WITH NATURAL RUBBER LATEX

Indications for Use/Description

The Hygia Health Services Reprocessed Masimo LNCS pediatric sensor (1860) is used as a non-invasive method to provide continuous SpO₂ monitoring and pulse rate monitoring. The HHS –Masimo LNCS pediatric sensor is indicated for patient weighing between 10 and 50 kg. The Hygia reprocessed LNCS pediatric sensor has been validated with the Masimo Radical SET pulse Oximeter and is intended to be used with the Radical SET oximeter and LNCS cable. The reference has been validated in induced hypoxia studies in humans against a laboratory hemoximeter.

Warnings

1. Failure to apply the LNCS pediatric sensor properly may cause incorrect measurements.
2. While the LNCS pediatric sensor is designed to reduce the effects of ambient light, excessive light may cause inaccurate measurements, in such cases, cover the sensor with opaque material.
3. Circulation distal to the sensor site should be checked routinely. The site must be inspected every 8 hours to ensure adhesion, skin integrity, and correct optical alignment. If skin integrity changes, move the sensor to another site.
4. Intravascular dyes may lead to inaccurate measurements.
5. Excessive motion may compromise performance. In such cases, try to keep the patient still, or change the sensor site to one with less motion.
6. Do not immerse in water or cleaning solutions
7. If the sensor is wrapped too tightly or supplemental tape is applied, venous pulsations may lead to inaccurate saturation measurements.
8. Do not use the LNCS pediatric sensor or other oximetry sensors during MRI scanning. Conducted current may cause burns. Also, the LNCS pediatric sensor may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.
9. Do not alter or modify the LNCS pediatric sensor. Alterations or modifications may affect performance or accuracy.
10. For additional warnings, cautions or contraindications when using this sensor with Masimo Radical SET™ compatible instruments, refer to the instrument operator's manual or contact the manufacturer of the instrument.
11. If the pulse Oximeter cable is being used without the security clamp, the loose connection may lead to inaccurate saturation measurements.

CAUTION:

Pulse oximeter probes and cables are designed for use with specific monitors. The user and/or operator needs to verify compatibility of the monitor, probe and cable before use, otherwise degraded performance and patient injury can result. Product should not be used with X-Cal Technology.

Instructions for Use

1. Remove plastic backing from the LNCS pediatric sensor and locate transparent windows on the adhesive side. Windows cover optical components.

Reprocessed LNCS Pediatric Pulse Oximetry Sensor

An index finger is the preferred LNCS pediatric sensor location. Alternatively, apply the sensor to a small thumb, smaller finger, or great toe.

Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.

2. Orient the LNCS pediatric sensor so the dashed line in the middle of the sensor is centered on the tip of the digit. Wrap adhesive flaps on non-cable end around the digit. Note that the cable must be positioned on the top of the hand or foot.
3. Fold cable end over top of digit so that windows are directly opposite each other. Wrap adhesive securely around sides of digit.
4. Plug the LNCS pediatric sensor into the oximeter and verify proper operation as describe in the oximeter operator's manual.

Note: If the sensor does not track the pulse reliably, it may be incorrectly positioned—or the sensor site may be too thick, thin, or deeply pigmented to permit appropriate light transmission. If any of these situations occurs, reposition the sensor or choose an alternate Masimo LNCS™ sensor. Also, using a pulse Oximeter cable without the security clamp may cause a loose connection and may lead to inaccurate saturation measurements. Cables with security clamps should always be used with all pulse Oximeter sensors.

Specifications:

Range:	Saturation: 0-100%	Temperature: Operational: 1°C-42°C (34°F-107°F)
	Pulse Rate: 30-240 bpm (beats per minute)	Storage: -20°C-50°C (-4°F-122°F)
Accuracy:	Saturation: 70 to 100% +/- 3 digits	Humidity: 15% - 95% non-condensing
	Pulse Rate: 30 to 240 bpm +/- 3 digits	

Accuracy Notes: Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurement can be expected to fall within +/- 3 Arms of the value measured by a CO-oximeter.

Patient contact materials have been demonstrated to be biocompatible for patient use.

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.

This product and its packaging have been exposed to 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 exposed to 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.