Reprocessed by

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

Instructions for Use
Hygia Infant 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 Nellcor MAX (MAX I) infant sensor indicated for use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing between 3 and 20 kg. The Hygia reprocessed MAX infant sensor has been validated with the Nellcor N-595 pulse oximeter and is intended to be used with the N-595 pulse oximeter. The reference has been validated in induced hypoxia studies in humans against a laboratory hemoximeter.

Warnings
1. Failure to apply the MAX infant sensor properly may cause incorrect measurements.
2. High oxygen levels may predispose a premature infant to develop retinopathy. Therefore, the upper alarm limit for oxygen saturation must be carefully selected in accord with accepted clinical standards and considering the accuracy range of the oximeter being used.
3. While the MAX infant 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.
4. 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.
5. Intravascular dyes may lead to inaccurate measurements.
6. Excessive motion may compromise performance. In such cases, try to keep the patient still, or change the sensor site to one with less motion.
7. Do not immerse in water or cleaning solutions.
8. If the sensor is wrapped too tightly or supplemental tape is applied, venous pulsations may lead to inaccurate saturation measurements.
9. Do not use the MAX infant sensor or other oximetry sensors during MRI scanning. Conducted current may cause burns. Also, the MAX infant sensor may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.
10. Do not alter or modify the MAX infant sensor. Alterations or modifications may affect performance or accuracy.
11. For additional warnings, cautions or contraindications when using this sensor with compatible NPB™ instruments, refer to the instrument operator's manual or contact the manufacturer of the instrument.
12. If the pulse Oximeter cable is being used without the security clamp, the loose connection may lead to inaccurate saturation measurements.

Instructions for Use
1. Remove plastic backing from the MAX infant sensor and locate transparent windows on the adhesive side. Windows cover optical components. Note corresponding alignment marks on non-adhesive side and dashed line midway between the marks.

2. Orient the MAX infant sensor so the dashed line is on the lateral edge of the site: A great toe is the preferred MAX infant sensor location. Alternatively, apply the sensor to another digit of similar size, for example, a thumb.

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.

3. Wrap the MAX infant sensor firmly, but not too tightly around the foot or finger. Windows must *oppose* each other.

4. Plug the MAX infant sensor into the oximeter and verify proper operation as described 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 Nellcor Puritan Bennett™ 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: -2°C-42°C (28°F-107°F)
	Pulse Rate: 30-240 bpm (beats per minute)		Storage: -38°C-49°C (37°F-120°F)
Accuracy:	Saturation: 70 to 100% +/- 3 digits in adults	Humidity:	15% - 95% non-condensing
	Saturation: 70 to 100% +/-4 digits in neonates		
	Pulse Rate: 30 to 240 bpm +/- 3 digits		

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.