Reprocessed by

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Instructions for Use
Hygia Nellcor Neonatal N-25 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 N-25 is indicated for use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for neonates weighing less than 3 kg or adults weighing more than 40 kg. The Hygia reprocessed N-25 sensor has been validated with the Nellcor N-200 pulse oximeter and is intended to be used with the N-200 pulse oximeter. The reference has been validated in induced hypoxia studies in humans against a laboratory hemoximeter

Warnings/Precautions
1. Failure to apply the N-25 properly may cause incorrect measurements. One must ensure that the sensor is applied properly and ensure that the sensor is correctly connected to the oximeter and that the connection is secure.
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 N-25 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. If the patient experiences numbness, tingling, or pain the sensor should be removed. Check attachment sight every 8 hours.
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 N-25 or other oximetry sensors during MRI scanning. Conducted current may cause burns. Also, the N-25 may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.
10. Do not alter or modify the N-25. Alterations or modifications may affect performance or accuracy.
11. For additional warnings, cautions or contraindications when using this sensor with NPB™-compatible instruments, refer to the instrument operator's manual or contact the manufacturer of the instrument.

Contraindications
1. The sensor may not be recommended for patients with the following:
    - Patients who exhibit allergic reactions to adhesive tape
    - Patients with fragile or damaged skin where discomfort might occur, such as gangrene, recent skin graft, untreated infected wounds, or burns

Instructions for Use
1. Remove plastic backing from the N-25 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 N-25 so the dashed line is on the lateral edge of the site: **Neonates:** The preferred site is a foot. Alternatively, use a hand. The window next to the cable goes on the sole of the foot. **Adults:** The preferred site is an index finger. Alternatively, other fingers may be used. The window next to the cable goes on the nail side, distal to the first joint. Do not place on a joint. Note that the cable must be positioned on the *top* of the hand.

   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 N-25 firmly, but not too tightly around the foot or finger. Windows must *oppose* each other.

4. Plug the N-25 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.

Specifications:

Range:	Saturation:	0-100%	Temperature:	Operational: -2°C-42°C (28°F-107°F)
	Pulse Rate:	20-250 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:	20 to 250 bpm +/- 3 digits		

**Neonatal Accuracy: When sensors are used on neonatal subjects as recommended, the specified accuracy range is increased by +/- 1 digit, to account for the theoretical effect on Oximeter measurements of fetal hemoglobin in neonatal blood.

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.