Reprocessed by

ReNu Medical, Inc.

Instructions for Use

Reprocessed Nellcor™ Pulse Oximeter Sensor

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 Nellcor™ Pulse Oximeter Sensor

Indications for Use

The Nellcor™ Pulse Oximeter Sensors are indicated for single patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Sensor	Adult	Pediatric	Infant	Neonatal
Model	D-25, D-25L, Max-A, Max-AL	D-20, Max-P	I-20, Max-I	N-25, Max-N
Application Site	index finger, small thumb, smaller finger, or great toe	small thumb, smaller finger or great toe	great toe or another digit of similar size: thumb	Neo: foot or hand Adult: index finger or other finger
Patient Weight	>30kg	10-50kg	3-20 kg	<3kg >40kg
Saturation Accuracy Range: 70%-100%	± 3%	± 3%	± 3%	Neo: ± 4% Adult: ± 3%
Pulse Rate Range: 30-180 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm
Low Perfusion Accuracy	SpO2 ± 2%	SpO2 ± 2%	SpO2 ± 2%	Neo: SpO2 ± 3% Adult: SpO2 ± 2%
	Pulse ± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm

Contraindications

Patients who exhibit allergic reaction to adhesive tape.

Warnings

Do not use the Nellcor™ Pulse Oximeter Sensors during MRI scanning. Conducted current may cause burns. Also, the Nellcor™ Pulse Oximeter Sensors may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.

Precautions

- Prior to use, read and follow these instructions as well as Original Equipment Manufacturer's Operator's Manual.
- Failure to apply sensors properly may cause incorrect measurements.
- While the 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.
- Circulation distal to the sensor site should be checked routinely. The site must be inspected every 8 hours to ensure adhesion, application pressure, skin integrity, and correct optical alignment. If skin integrity changes, move the sensor to another site. If the sensor is misapplied with excessive pressure, a pressure injury can occur.
- Intravascular dyes or externally applied coloring such as nail polish, dye, or pigmented cream may lead to inaccurate measurements.
- Excessive motion may compromise performance. In such cases, try to keep the patient still, or change the sensor site to one with less motion.
- Do not immerse in water or cleaning solutions
- If the sensor is wrapped too tightly or supplemental tape is applied, venous pulsations may lead to inaccurate saturation measurements.

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- Do not alter or modify the sensors. Alterations or modifications may affect performance or accuracy.
- For additional warnings, cautions or contraindications when using this sensor with Nellcor™-compatible instruments, refer to the instrument operator's manual or contact the manufacturer of the instrument. Note: High oxygen levels may predispose a premature infant to develop retinopathy. Therefore, the upper alarm limit for oxygen saturation must be carefully selected in accordance with accepted clinical standards and considering the accuracy range of the oximeter being used.

Directions for Use

1. Choose the appropriate site selection

Sensor	Adult	Pediatric	Infant	Neonatal
Model	D-25, D-25L, Max-A, Max-AL	D-20, Max-P	I-20, Max-I	N-25, Max-N
Application Site	index finger, small thumb, smaller finger, or great toe	small thumb, smaller finger or great toe	great toe or another digit of similar size: thumb	Neo: foot or hand Adult: index finger or other finger

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

- Orient the 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.
- Fold cable end over top of digit so that windows are directly opposite each other. Wrap adhesive securely around sides of digit.
- Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.

PEDIATRIC

- Orient the 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.
- Fold cable end over top of digit so that windows are directly opposite each other. Wrap adhesive securely around sides of digit.
- Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.

INFANT

- Orient the sensor so the window next to the cable is aligned on the bottom of the great toe. The cable should extend towards the heel.
- Wrap the sensor firmly, but not too tightly around the toe. Windows must oppose each other.

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- Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.

  NEONATAL
- Orient the sensor so the dashed line is on the lateral edge of the site.
  - Neonates: The window next to the cable goes on the sole of the foot.
  - Adults: 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.
- Wrap the sensor firmly, but not too tightly around the foot or finger. Windows must oppose each other.
- Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.

- 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.
- 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, or otherwise deeply colored (for example, as a result of externally applied coloring such as nail polish, dye, or pigmented cream) to permit appropriate light transmission. If any of these situations occurs, reposition the sensor or choose an alternate sensor for use on a different site.

3. 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.

4. 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.

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