Reprocessed by

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# Instructions for Use
# Hygia Nellcor Adult D-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 HHS-D-25 is used as a non-invasive method to provide continuous SpO2 monitoring and pulse rate monitoring. The HHS –D-25 is indicated for patient size > 30 kg. The Hygia reprocessed D-25 sensor has been validated with the Nellcor N-200 pulse Oximeter and is intended to be used with the N-200. The reference has been validated in induced hypoxia studies in humans against a laboratory hemoximeter.

**Warnings/Precautions**
1. Failure to apply the D-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. While the D-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.
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. If the patient experiences numbness, tingling, or pain the sensor should be removed. Check attachment sight every 8 hours.
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 D-25 or other oximetry sensors during MRI scanning. Conducted current may cause burns. Also, the D-25 may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.
9. Do not alter or modify the D-25 Alterations or modifications may affect performance or accuracy.
10. 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 D-25 and locate transparent windows on the adhesive side. Windows cover optical components.

   An index finger is the preferred D-25 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 D-25 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 D-25 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 Nellcor Puritan Bennett™ sensor.

**Specifications:**

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| 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 | Humidity: | 15% - 95% non-condensing |
| | Pulse Rate: 20 to 250 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.