



Handheld Pulse Oximeter

Instruction Manual for Sensor

INTENDED USE

The reusable pulse oximetry sensor is not recommended for prolonged use unless skin integrity is checked frequently and the measurement site is changed accordingly.

For long-term patient monitoring, use either single-patient disposable sensors or wrap sensors.

CLASSIFICATION

FDA Class II medical device.

CLEANING OR DISINFECTING

1. Unplug the sensor from the monitor before cleaning or disinfecting.
2. Clean or disinfect the sensor before attaching to a new patient to avoid infection.
3. Clean the sensor and patient contact surfaces with a soft cloth moistened in water or a mild soap solution.

4. To disinfect the sensor, wipe the sensor and patient contact surface with disinfecting solution. We recommend isopropyl alcohol as disinfecting solution.

CAUTION: Don't sterilize by irradiation, steam or ethylene oxide.

CONTRAINDICATIONS

The sensor is contraindicated for use on active patients.

WARNINGS

- This sensor is for use only with compatible units, instruments or oximeter modules. Using this sensor with other than the compatibles may result in improper performance.
- Intravascular dyes may affect the accuracy of measurements of the sensor and the unit.
- Excessive motions during measurement will cause inaccurate results.
- Fingernail polish, an artificial fingernail, poorly perfused finger, extreme finger size or improper placement of the sensor can cause inaccurate result of the measurement.
- Operation may be affected in the presence of bright lights. If necessary, please shield the sensor area with an opaque material.
- Operation may be affected in the presence of strong electromagnetic sources.
- The sensor is not recommended for use with imaging equipment such as Magnetic Resonance Imaging (MRI), etc.
- Do not immerse the sensor in any kind of liquid.
- Stop using the sensor immediately if it is damaged in any way.
- Stop using the sensor immediately if it is wet, and then wipe it dry with a dry cloth.
- Do not clip or wrap the measuring position too tightly.
- Check and reposition the sensor to an alternate location every one hour.
- Carefully route the cables to reduce the possibility of patient entanglement or strangulation.
- Refer to the unit's operation manual when connecting the sensor with unit.

NOTES

Refer to the Handheld Pulse Oximeter instruction manual for additional warnings, cautions, and notes.

APPEARANCE & MEASUREMENT PRINCIPLE

Appearance:

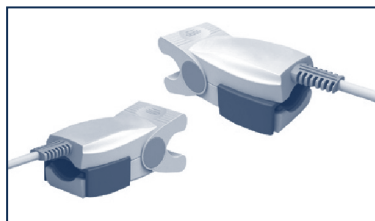


Figure 1. Adult Sensor (standard size)

Simple introduction: The adult sensor (standard size) is for individuals over the age of 12.

Principle:

The oximeter sensor's measuring principle is based on the spectroscopic characteristics of hemoglobin and oxyhemoglobin in red light and infrared spectrum, as well as the empirical data formula established through Lambert-Beer's law. Its operational principle is a combination of blood oxygen photoelectrical detecting technology and volume pulsation recording technology. The detailed procedures are as follows: Radiate finger tip with 660 nm red light and 940 nm near infrared light that generated by luminotron. Acquire the signal through light sensitive cell. The signal acquired will be displayed on the LED screen after being treated through electric circuit and microprocessor.

Diagram of Operation Principle:

1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube

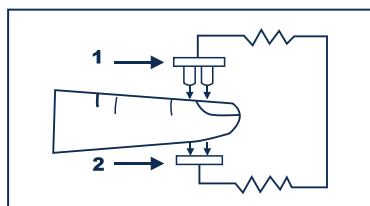


Figure 2. Principle Diagram

INSTRUCTION FOR USE

Adult and Optional Pediatric Sensor

1. Select a suitable site for the sensor. The first finger is the preferred location. Alternative sites recommended are the thumb, little finger or the large toe.
2. Fit the finger as illustrated in figure 4, the patient's finger must be inserted right to the end of the sensor. When using the adult sensor, make sure that the bottom of fingernail is right at the position of the mark in the side of the sensor to get accurate measurement.
3. The sensor should be oriented in such a way that the cable is positioned along the top of the hand.



Figure 3. Recommended position



Figure 4. Correct positioning



Figure 5. Cable position



Figure 6. Connect to monitor

4. Plug the sensor into the unit and verify proper operation as described in the instruction manual.
5. Hold the connector rather than the cable when connecting or disconnecting the finger sensor to the oximeter.

NOTE: Do not twist unnecessarily or use excessive force when using, connecting, or storing the finger sensor.

SPECIFICATIONS

1. **Measuring range:** 70%-100%
2. **Accuracy:** 70%-100% SpO₂:±3 Digits
<70% Unspecified

Probe LED Specifications:

	Wavelength	Radiant Power
RED	660+2nm	1.8mW
IR	940+10nm	2.0mW

3. **Storage temperature:** -4°F~+122°F (-20°C~+50°C)
Relative humidity: 10%~95%, no condensation
4. **Operation temperature:** +41°F~+104°F (+5°C~+40°C)
Relative humidity: ≤93%, no condensation
5. Not made with natural rubber latex. No toxicity, which meets biology compatibility requirement.

CALIBRATING THE 36403 SERIES PULSE OXIMETER SENSOR

1. The functional tester cannot be used to assess the accuracy of the oximeter.
2. The Dynarex Resp-O₂ Handheld Pulse Oximeter is a functional tester. The user can use this function tester to measure the oximeter.
3. The test method used to establish the SpO₂ accuracy is clinical testing. The oximeter used to measure the arterial hemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-Oximeter.

SYMBOL EXPLANATION

Symbol	Explanation	Symbol	Explanation	Symbol	Explanation
	Temperature limit		Humidity limitation		Fragile
	Not made with natural rubber latex		Serial number		Keep dry
	Consult accompanying documents		Federal law (USA) restricts this device to sale by or on the order of a physician		Protected against dripping water
	Type BF applied part		Manufacturer's information		Date of Manufacture

 Manufactured for:
Dynarex Corporation
 10 Glenshaw Street
 Orangeburg, NY 10962
 USA • www.dynarex.com
 Made in China R210119