

PRINCIPLES OF OPERATION

PULSE OXIMETRY SUBSYSTEM

The monitor is based on the principles of spectrophotometry and plethysmography. It includes an electro-optical sensor and a microprocessor-based monitor. The sensor has two low-voltage light-emitting diodes (LEDs) as light sources and one photodiode as a photodetector. One LED emits red light (nominal 660nm) and the other emits infrared (nominal 920nm). When the light from the LEDs passes through the sensor site, part of it is absorbed. The photodetector measures the light that passes through, which indicates red and infrared absorption.

With each heartbeat, a pulse of oxygenated arterial blood flows to the sensor site. Oxygenated hemoglobin differs from deoxygenated hemoglobin in its relative red and infrared absorption, and the monitor measures red and infrared absorption to determine the percentage of functional hemoglobin that is saturated with oxygen.

Light absorption that is measured when pulsatile blood is not present reflects absorption by tissue and nonpulsatile blood—absorption that does not change substantially during the pulse. This is analogous to the reference measurement of a spectrophotometer. Absorption is also measured when pulsatile, arterial blood is in the tissue. The monitor then corrects this measurement for absorption when the pulsatile blood is not present. The ratio of the corrected absorption at each wavelength determines arterial oxygen saturation (SpO_2).

Automatic Calibration

The oximetry subsystem incorporates automatic calibration mechanisms. It is automatically calibrated each time it is turned on, at periodic intervals thereafter, and whenever a new sensor is connected. Also, the intensity of the sensor's LEDs is adjusted automatically to compensate for differences in tissue thickness.

Each sensor is calibrated when manufactured: the effective mean wavelength of the red LED is determined and encoded into a calibration resistor in the sensor plug. The instrument's software reads this calibration resistor to determine the appropriate calibration coefficients for the measurements obtained by that sensor.

Functional versus Fractional Saturation :

Because the monitor measures functional SpO_2 , it may produce measurements that differ from those of instruments that measure fractional SpO_2 . Functional SpO_2 is oxygenated hemoglobin expressed as a percentage of the hemoglobin that is capable of transporting oxygen. Because the monitor uses two wavelengths, it measures oxygenated and deoxygenated hemoglobin, yielding functional SpO_2 . It does not detect dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin.

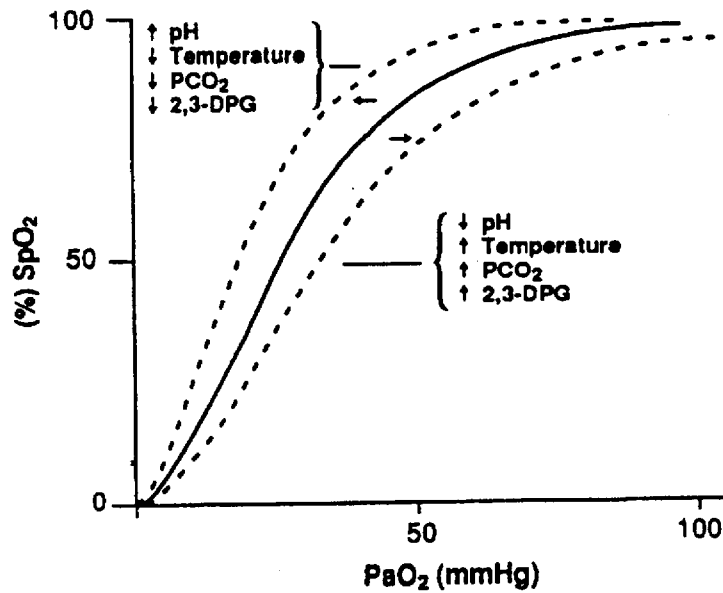
In contrast, some laboratory instruments such as the Instrumentation Laboratory 282 CO-Oximeter report fractional SpO_2 —oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, whether or not that hemoglobin is available for oxygen transport. Measured dysfunctional hemoglobins are included.

Consequently to compare this monitor's measurements directly with those of another instrument, that other instrument must measure functional SpO_2 . If it measures fractional SpO_2 , those measurements can be converted using the following equation:

$$\frac{\text{functional saturation}}{\text{fractional saturation}} \times \frac{100}{100 - (\% \text{ carboxyhaemoglobin} + \% \text{ methaemoglobin})}$$

Measured versus Calculated Saturation

When SpO_2 is calculated from a blood gas measurement of the partial pressure of arterial oxygen (PaO_2), the calculated value may differ from the monitor's SpO_2 measurement. This is because the calculated SpO_2 may not have been corrected for the effects of variables that shift the relationship between PaO_2 and SpO_2 (see Figure below): temperature, pH, the partial pressure of carbon dioxide ($PaCO_2$), and the concentrations of 2,3-DPG and fetal hemoglobin.



Oxyhemoglobin Dissociation Curve

SAFETY INFORMATION

WARNINGS

DANGER! Explosion hazard. Do not use in the presence of flammable anesthetics.

Carefully read this operators manual, accessory directions for use, all precautionary information (which is set in boldface type), and specifications before application and use of the equipment.

The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Do not silence the audible alarm if patient safety could be compromised.

Tissue damage can be caused by incorrect application or use of a sensor (e.g., wrapping the sensor too tightly, applying supplemental tape, or failing to inspect the sensor site periodically).

Loss of pulse signal can occur if:

- the sensor is too tight;
 - there is excessive illumination: e.g., a surgical or bilirubin lamp or sunlight;
- the sensor is placed on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
- the patient is in shock, has hypotension, severe vasoconstriction or anemia, hypothermia, arterial occlusion proximal to the sensor, or cardiac arrest.

Inaccurate measurements may be caused by:

- Incorrect application or use of a sensor;
- significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin;
- significant levels of indocyanine green, methylene blue or other intravascular dyes;
- exposure to excessive illumination, such as surgical lamps, especially ones with a xenon light source; bilirubin lamps; fluorescent lights; infrared heating lamps; or direct sunlight;
- excessive patient movement;
- venous pulsations;
- electrosurgical interference;
- placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line.

Do not use the pulse oximeter or *NELLCOR_(R)* oximetry sensors during magnetic resonance imaging (MRI) scanning. Conducted current could potentially cause burns. Also, the *NELLCOR_(R)* pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.

Do not use a damaged sensor or one with exposed electrical contacts. Do not immerse in liquids. Do not sterilize by irradiation, steam or ethylene oxide.