

SmartPulse

Fingertip Pulse Oximeter

MADE IN THE USA

INTENDED USE

The SmartPulse fingertip pulse oximeter is a small portable device that measures oxygen saturation (% SpO₂) and pulse rate on the finger. The device may be used as a spot-check device in the home or clinical environment, and will provide measurements on both pediatric and adult patients.

THEORY OF OPERATION

The pulse oximeter determines % SpO₂ and pulse rate by passing red and infrared light beams through finger tissue. The signal measured by a photo detector is mainly defined by the pulsation of arterial blood. The pulse oximeter processes the signal picked up by the photo detector, which calculates oxygen concentration and determines heart rate. Oximetry is measured by oxygenated arterial blood absorbing less red light than oxygen depleted blood.

WARRANTY

SeQual guarantees that the oximeter will be free from defects in material and/or workmanship for 4 years from the date of delivery.

In the event of a defect under this warranty, SeQual will at our option, repair or replace the product, provided that the customer returns the product, postage prepaid to:

SmartPulse
4757 E. Greenway Rd. #107B303
Phoenix, AZ 85032

Please also include your name, address and an explanation of the defect. This warranty does not cover defects caused by misuse or improper handling, installation, or water damage. SeQual reserves the right to replace the defective unit with a comparable one. Shipping costs are the responsibility of the purchaser.

The purchaser must notify SeQual of any defect within the warranty period and return the unit in question. Proof of purchase may be required before any warranty consideration may occur.

Any signs of tampering with this product voids the warranty in its entirety.

CONTRAINDICATIONS

- Do not use this device on infants or neo-natal patients.
- This device is not intended for continuous patient monitoring.

PRECAUTIONS

- Federal law restricts this device to sale by or on the order of a physician.
- Do not use this device when dyes are introduced into the bloodstream.
- Do not use this device in the presence of flammable anesthetics.
- Do not use this device in the presence of magnetic resonance imaging equipment.
- Do not autoclave, ethylene oxide sterilize or immerse in liquid.
- Operation of this device may be adversely affected in the presence of a strong electromagnetic source, such as electro surgery equipment.
- Operation of this device may be affected in the presence of computer tomography equipment.
- This device is intended for use by persons trained in professional healthcare who have a complete understanding of pulse oximetry.
- This device is only intended to be an adjunct in patient assessment.
- % SpO₂ measurements may be adversely affected in the presence of high ambient light. Avoid exposure to high ambient light.
- Optical cross-talk can occur when two or more sensors are placed in close proximity. This may be eliminated by covering the sensors with an opaque material.
- Improper handling of the device could result in damage to the device and may cause inaccurate readings.
- Any condition that restricts bloodflow, such as use of a blood pressure cuff, extremes in systemic vascular resistance or reduction of peripheral circulation caused by hypothermia, may cause an inability to determine accurate pulse rate and % SpO₂ readings.
- Check the application site of the unit frequently to determine the positioning of the sensor and the circulation and the skin sensitivity of the patient.
- Fingernail polish or false fingernails may cause inaccurate % SpO₂ readings.
- Significant levels of dysfunctional hemoglobins (methemoglobin or carboxyhemoglobin) will affect the accuracy of the % SpO₂ readings.
- Although this device has been tested for electromagnetic immunity per EN6061-1-2:2002, excessive amount of electromagnetic radiation caused by radio-frequency transmitting devices (for example, cellular phones, mobile two-way electrical appliances) may cause interference due to close proximity or strength of a source, and may result in disruption of performance of this device.
- Obstruction or dirt on the device red light or detector may cause the device sensor to fail. This device must be used in conjunction with clinical signs and symptoms.
- Prolonged use or the patient's condition may require changing the application site periodically. Change site and check skin integrity, circulatory status, and correct alignment every 30 minutes.

TROUBLESHOOTING

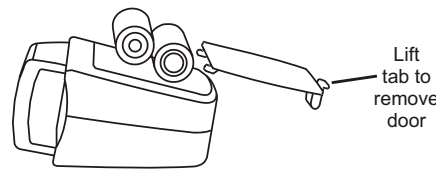
Problem	Possible Cause	Corrective Action
No pulse shown LED heart indicator	Device incorrectly positioned on patient	Reposition device
	Poor patient perfusion	Contact supplier
	Defective device	
Incorrect pulse rate	Device incorrectly positioned on patient	Reposition device Patient must remain still
% SpO ₂ Incorrect	Poor patient perfusion	Reposition device Patient must remain still
	Patient motion	
Device does not turn on	Batteries weak	Replace batteries
	Batteries incorrectly installed	
Device turns off unexpectedly	Automatically turns off after device is removed from patient	None
	Batteries are weak or dead	Replace batteries

SYMBOL DEFINITIONS

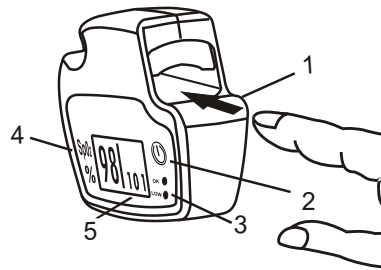
Symbol	Definition
Ω	Type BF equipment
△	Attention, see user manual
% SpO ₂	Percent oxygen saturation
BPM	Pulse rate (beats per minute)
△ SpO ₂	Not for continuous monitoring No alarms for SpO ₂
Rx Only	Sold by prescription only
⏻	On / Battery Test
☀	Do not use this device in the presents of flammable anesthetics
IPX1	Drip proof
●	Low battery indicator
SN	Serial number

OPERATING INSTRUCTIONS

Lift tab to open battery door, install batteries in accordance with + and – signs on the inside of the battery compartment. Unit automatically shuts off after eight seconds of non use.



1. Place index finger in finger holder.
2. Use thumb to depress (ON) button.
3. Battery Indicator: **Green LED** good
Red LED replace battery
4. **% SpO₂** shows patient's blood oxygen percentage.
5. **Pulse Rate** display indicates pulse rate in beats per minute.



POWER REQUIREMENTS

Two (2) standard "AAA" alkaline cells (IEC Type LR03)
Battery life: 50 hours continuous use

DIMENSIONS

Width 56 mm Height 60 mm
Depth 30 mm Weight 50 grams with batteries

MAINTENANCE

To disinfect the device, wipe with isopropyl alcohol. Replace batteries when low battery indicator is flashing.

ENVIRONMENTAL SPECIFICATIONS

Operating Temp: 0-55° C (32-131° F)
Storage Temp: -22°-55° C (-30°-131° F)
Relative Humidity: 95% storage or operating

EQUIPMENT CLASSIFICATION

Type of protection against electrical shock: Internally powered
Mode of operation: Continuous
Degree of protection against liquids: IPX1, Drip Proof
Degree of mobility: Portable
Degree of protection against electrical shock: Type 8F
Safety requirements: EN60601-1: 1990

DISPLAY INDICATOR KEYS

% SpO₂: LED numeric displays (10 mm)
Pulse: LED numeric display (6 mm)
Heart Indicator: LED 0.1 inches (3.0 mm)
Keys: Power ON button

% SPO₂

Range: 9-99% functional SpO₂ (1 % Increments)
Accuracy: ± 2 at 70-99% less than 70% in unspecified
Alarms: None
Averaging: 8 pulse beat average
Calibrations: Factory calibrated over the range of 70% to 99% SpO₂

PULSE RATE

Range: 30-254 BMP (1 bmp increments)
Accuracy: ± 2% or 2 BMP, whichever is greater
Alarms: None
Averaging: 8 pulse beat average

PULSE STRENGTH

Range: Heart LED indicates logarithmic strength of patient's pulse



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