# Information Manual

Version: 1.0C2

Fingertip Pulse Oximeter

inogen®

**OX-100**

CE 0123

**Caution: SpO2 and pulse rate data is displayed for informational purposes only. This info does not constitute a diagnoses or medical advice of any kind. Consult your doctor for all medical information and guidance.**

## 1. Measurement principle

The oximeter is calibrated to display functional oxygen saturation. The principle of the Oximeter is as follows: A data process formula is established using the Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(R Hb) and Oxyhemoglobin (O2 Hb) in glow and near-infrared zones. The operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology, which is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto human nail tip through a perspective clamp finger-type sensor. A measured signal is obtained by a photosensitive element. This information is shown on two groups of LEDs after being processed through electronic circuits and microprocessor.

## 2. Precautions for use

- Before use, carefully read the manual
- The operation of Pulse Oximeter may be affected by the use of an electrosurgical unit (ESU).
- To ensure the Pulse Oximeter is able to obtain an accurate SpO2 measurement, verify nothing is interfering with the pulse measurement before recording the SpO2 result.
- Do not use the Pulse Oximeter in an MRI or CT environment
- Do not use the Pulse Oximeter in situations where alarms are required. The device has no alarms.
- Explosion hazard: Do not use the Pulse Oximeter in an explosive atmosphere.
- The Pulse Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Check the Pulse Oximeter Sensor application site *frequently* to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
- Do not stretch the adhesive tape while applying the Pulse Oximeter Sensor. This may cause inaccurate readings or skin blisters.
- The Pulse Oximeter has no SpO2 alarms, it is *not for continuous monitoring*, as indicated by the symbol.
- Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

## 3. Inaccurate measurements may be caused by

- *Sterilization efforts. The device is not intended for sterilization . Use of an autoclave, ethylene oxide immersion or immersion in any liquid may cause inaccurate readings..*
- Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin)
- Intravascular dyes such as indocyanine green or methylene blue
- Use in high ambient light. SpO2 measurements may be adversely affected in the presence of high ambient light. When in use, the sensor should be shielded if exposed to direct sunlight or intense lighting .
- Excessive patient movement
- High-frequency electrosurgical interference and defibrillators
- Venous pulsations
- The placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Patient conditions of hypotension, severe vasoconstriction, severe anemia, or hypothermia
- Cardiac arrest or shock
- Fingernail polish or false fingernails.

## 4. Technical Specifications

4.1 Display type: OLED display
SpO2 display range: 0-100%
PR display range: 30-235 BPM
PR display mode: bargraph
Data update time: < 15 s

4.2 LED Wavelengths
Red: 660nm
Infrared: 940nm

4.3 Battery life
Two AAA 1.5V alkaline batteries could be continuously operated as long as 30 hours.

4.4 Resolution: ±1% for SpO2 and ±1 BPM for Pulse Rate

4.5 Measurement Accuracy:
SpO2: 70%-100%, ±3%; ≤70% no definition.
PR: ± 2 BPM during the pulse rate range of 30-99 BPM and 2% during the pulse rate range of 100-235 BPM

4.6 It is equipped with a function switch, through which the Oximeter can be powered off automatically in case no signal is detected for more than 8 seconds.

4.7 Outline dimension:
Length: 58mm
Width: 32mm
Height: 34mm
Weight: 50g (including two AAA batteries)

4.8 Environment requirements:
Operation Temperature: 5-40℃
Storage Temperature: -20-70℃
Humidity : 15%-80% in operation
<93% in storage
Declaration: EMC of this product comply with IEC60601-1-2 standard.

## 5. Product Features

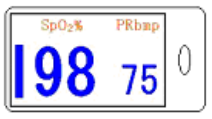
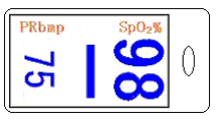
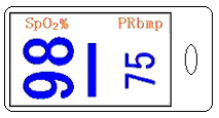
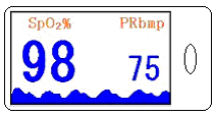
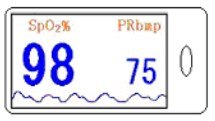
5.1 Operation of the product is simple and convenient.
5.2 The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying.
5.3 Power consumption of the product is low and the two originally-equipped two AAA batteries can be operated continuously for 30 hours.
5.4 Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the Oximeter might be influenced.
5.5 The product will automatically be powered off when no signal is detected for more than 8 seconds.

## 6. Product Intended Use

**Intended Use:**
Fingertip Pulse Oximeter is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult or pediatric patient at home, or hospital (including clinical use in internist/surgery, anesthesia, intensive care). This oximeter is not intended for continuous monitoring.
The Pulse Oximeter requires no routine calibration or maintenance other than replacement of batteries.

## 7. Operation Instructions

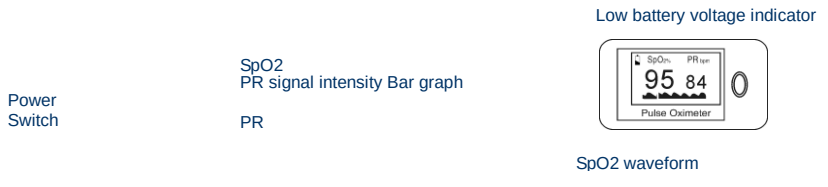
7.1 Install two AAA batteries into battery cassette before covering its cover.
7.2 Open the clamp as illustrated in the picture below.
7.3 Insert one finger into the rubber hole of the Oximeter (it is best to insert the finger thoroughly) before releasing the clamp.
7.4 Press the switch button once on the front panel.
7.5 Do not move fingers while using the Oximeter.
7.6 Read the data from the display screen.
7.7 Display modes
***After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode. There are 6 display modes shown as follows:***

| Display Mode | Description |
|---|---|
|  | Display mode when opening the device, horizontal and normal facing |
|  | After 1 click, the display is horizontal but handstand facing |
|  | After 1 click again, the display is vertical and handstand facing |
|  | After another click, the display is vertical and normal facing |
|  | After another click again, the display is horizontal and normal facing with wave-shape filled form display |
|  | After 1 click once more, the display is horizontal and normal facing with wave-shape wire form display |

When the power switch is depressed for more than one second, the brightness of the Oximeter will change. There are 10 levels on brightness; the default level is level four.

*When your finger is inserted into the Oximeter, your nail surface must be upward.*

## 8. Brief Description of Front Panel




Patient pulse rhythm is indicated as such by bar graph.

## 9. Product Accessories

9.1 One hanging lace
9.2 Two batteries
9.3 One instruction manual

## 10. Battery Installations

10.1 Put the two AAA batteries into battery cassette in correct polarities.
10.2 Push the battery cover horizontally along the arrow shown as below:

Notes: Battery polarities must be correctly installed. Otherwise, damage might be caused to device.
Please install or remove batteries in the correct order. .
Please remove the batteries if the Oximeter will not be operated for a long period of time.

## 11. Hanging Lace Installations

11.1 Thread thinner end of the hanging lace through the hanging hole.
11.2 Thread thicker end of the lace through the threaded end before pulling it tightly.

## 12. Maintenance and Storage

12.1 Replace the batteries when the low battery voltage indicator is lighted.
12.2 Clean surface of the fingertip on the Oximeter before each use.
12.3 Remove the batteries if the Oximeter will not be operated for a long period of time.
12.4 It is best to preserve the product in a place where ambient temperatures are between –10-40℃ or 14-104℉ and humidity is between10%-80%.
It is recommended that the product should be kept in a dry environment at all times. Moisture could affect the product life and might damage the product.
12.5 Follow local ordinances and recycling instructions regarding disposal or recycling of the

device and device components, including batteries.

**Cleaning the Pulse Oximeter**
Please clean the rubber touching the finger inside of the Oximeter with a soft dampened cloth with 70% isopropyl alcohol, and clean the test finger using alcohol before and after each test. Do not pour or spray any liquids onto the Oximeter, and do not allow any liquids to enter any openings in the device. Allow the Oximeter to dry thoroughly before reusing.

## 13. Possible Problems and Resolutions

| Problem | Possible reason | Solution |
|---|---|---|
| SpO2% or pulse rate is not displayed normally | 1. Finger is not inserted in correctly<br>2. Patient's SpO2 value is too low to be measured<br>3. Excessive ambient light | 1. Retry by reinserting your finger<br>2. Repeat measurements if SpO2 value is suspected to be low. Seek medical attention for professional medical diagnoses.<br>3. Shield from excessive ambient light |
| SpO2% or pulse rate is unstable | 1. Finger might not be inserted deep enough<br>2. Excessive patient movement | 1. Reinsert your finger<br>2. Be still for several minutes and retry. . |
| The Monitor can not be powered on | 1.No battery or battery voltage is too low<br>2.Battery is installed incorrectly<br>3. The monitor is damaged | 1. Replace battery<br>2. Reinstall the battery<br>3. Contact Inogen Technical Service |
| Display powers off | 1. The oximeter is automatically powered off when no signal is detected for more than 8 seconds<br>2. The battery power is too low | 1. The oximeter is performing to specifications<br>2. Replace the battery |
| "Error3" or "Error4" Displayed on screen | 1. Error 3 means the red emission LED is damaged.<br>2. Error 4 means the infra-red emission LED is damaged. | Contact Inogen Technical Service |
| Error 6 | Error 6 means the crystal is failure | Contact Inogen Technical Service |
| "Error7" displayed on screen | Error 7 means the emission LED or reception dioxide is damaged. | Check the emission LED and reception dioxide. |

## 14. Declaration

**Guidance and Manufacture's declaration – electromagnetic emissions-**
**For all EQUIPMENT and SYSTEMS**

| **Guidance and Manufacture's declaration - electromagnetic emission** | | |
|---|---|---|
| Guidance and Manufacture's declaration – electromagnetic environment specified below. The user of the *Pulse Oximeter* should ensure that it is used in a proper environment according to the following guidelines. | | |
| **Emission test** | **Compliance** | **Electromagnetic Environment – guidance** |
| RF emissions CISPR 11 | Group 1 | The Pulse Oximeter uses very low RF energy and is not likely to cause interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The Pulse Oximeter is suitable for use in all establishments, including homes directly connected to a public low-voltage power supply network. |
| Harmonic emissions IEC 61000-3-2 | Not Applicable | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-2 | Not Applicable | |

**Guidance and Manufacture's declaration – electromagnetic immunity-**
**For all EQUIPMENT and SYSTEMS**

| **Guidance and Manufacture's declaration - electromagnetic immunity** | | | |
|---|---|---|---|
| Guidance and Manufacture's declaration – electromagnetic environment specified below. The user of the *Pulse Oximeter* should ensure that it is used in a proper environment according to the following guidelines. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance Level** | **Electromagnetic Environment – guidance** |
| Electrostatic Discharge (ESD) IEC 61000-4-2 | +/- kV contact<br>+/- 8kV air | +/- kV contact<br>+/- 8kV air | Floors should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30%. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment. |

**Guidance and Manufacture's declaration – electromagnetic immunity-**
**For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

| **Guidance and Manufacture's declaration - electromagnetic immunity** | | | |
|---|---|---|---|
| Guidance and Manufacture's declaration – electromagnetic environment specified below. The user of the *Pulse Oximeter* should ensure that it is used in a proper environment according to the following guidelines. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance Level** | **Electromagnetic Environment – guidance** |
| Radiated RF IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | Portable and mobile RF communications equipment, including cables, should not be used in proximity of the Pulse Oximeter. The recommended separation distance is calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz<br>$d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz<br>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with following symbol: |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection structures, objects and people. | | | |
| A Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting or relocating of the Pulse Oximeter.<br>B Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m | | | |

**Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS -**
**For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

| **Recommended separation distances between portable and mobile RF communications equipment and *Pulse Oximeter*** | | |
|---|---|---|
| The *Pulse Oximeter* is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The user of the *Pulse Oximeter* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Pulse Oximeter* as recommended below, according to the maximum output power of the communications equipment. | | |
| **Rated maximum output power of transmitter (W)** | **Separation distance according to frequency of transmitter (m)** | |
| | 80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ | 800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ |
| 0.01 | 0.1167 | 0.2334 |
| 0.1 | 0.3689 | 0.7378 |
| 1 | 1.1667 | 2.3334 |
| 10 | 3.6893 | 7.3786 |
| 100 | 11.6667 | 23.3334 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.<br>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | |

## 15. Symbol Definitions

| Symbol | Definition | Symbol | Definition |
|---|---|---|---|
| | The equipment type is BF | | Low battery voltage indicator |
| | Refer to user manual before application | SN | Serial No. |
| $\%SpO_2$ | Hemoglobin saturation | SpO2 | Not for continuous monitoring |
| BPM | Heart rate (BPM) | | Address |

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