Department Manager
Paediatrics Department
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May 2021

Dear «UPOSITION»,

**Low Cost Finger Pulse Oximeters for Paediatric Patients
introducing the Panda design**

- Clear, bright colour
- OLED display
- Display can be viewed in 4 rotations
- Adjustable brightness: 10 levels
- Pleth waveform, displayed in 2 formats
- Signal strength indicator
- Automatic power-off when finger removed
- Includes free silicone cover and soft carrying case

Viamed offer a range of ultra-compact, lightweight, low cost finger pulse oximeters to suit a variety of applications, for use in GP surgeries, clinics and dental surgeries, through to spot-checking before, during and after exercise.

For paediatric applications, we offer the OLED display MD300-C5 range which includes a variety of novel, child-friendly designs including frog, bear and now introducing the panda, which are ideal for use with patients aged 2 and over.

Please find copy of user manual overleaf. Should you have any further questions regarding this or any of our oximeter range, please do not hesitate in contacting our sales team on 01535 634542 between 8:30am and 5:00pm Monday – Friday or email panda@viamed.co.uk.

Yours faithfully

Catrin Hollings
Marketing

**FREE DELIVERY •
NO MINIMUM ORDER
CHARGE**

Fingertip Pulse Oximeter MD300C5

USER MANUAL
Ver5.0C5

ChoiceMMed

General Description

Oxygen Saturation is a percentage of Oxyhemoglobin (HbO$_2$) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood. In other words, it is consistency of Oxyhemoglobin in blood. It is a very important parameter for the Respiratory Circulation System. Many respiratory diseases can result in oxygen saturation being lowered in human blood. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injuries caused by some medical examinations. That situation might result in light-headedness, asthenia, and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can find problems in a timely manner.

The fingertip pulse oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photoelectric sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display. It has been proven in clinical experiments that it also features high precision and repeatability.

Measurement Principle

Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO$_2$) in red and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 940nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

Diagram of Operation Principle
1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube

Precautions For Use

1. Before use, carefully read the manual.
2. Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO$_2$ measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO$_2$ measurement.
4. Do not use the fingertip pulse oximeter in an MRI or CT environment.
5. Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the fingertip pulse oximeter in an explosive atmosphere.
7. The fingertip 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.
8. In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
9. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
10. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
11. This equipment complies with IEC 60601-1-2:2007 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
12. Portable and mobile RF communications equipment can affect medical electrical equipment.
13. This equipment is not intended for use during patient transport outside the healthcare facility.
14. This equipment should not be used adjacent to or stacked with other equipment.
15. Do not disassemble, repair or modify the equipment without authority.
16. It may be unsafe to:
    —use accessories, detachable parts and materials not described in the instructions for use
    —interconnect this equipment with other equipment not described in the instructions for use
    —disassemble, repair or modify the equipment
17. These materials that contact with the patient's skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.

Rx only: "Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner."

Contraindication

It is not for continuous monitoring.

Inaccurate measurements may be caused by

1. Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive patient movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Low hemoglobin.

Product Properties

1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. OLED display SpO$_2$, PR, and Pulse bar.
4. Level 1-10 adjustable brightness.
5. 6 display modes.
6. 2pcs AAA-size alkaline batteries; battery-low indicator.
7. When no or low signal is detected, the pulse oximeter will power off automatically in 8 seconds.

Intended Use

Fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of pediatric patients in hospitals and hospital-type facilities.

Operation Instructions

1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Press the switch button one time on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
5. Read the data from the display screen.

6. Press the button again to toggle between six 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:

Holding the power switch for longer than one second, will adjust the brightness of the oximeter. There are 10 levels of brightness. The default is level four.

Front Panel
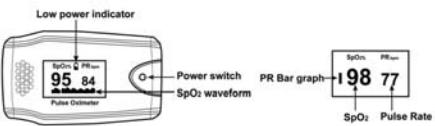
The height of the bar graph indicates the pulse and signal strength. The bar should be greater than 30% for a proper reading.

Product Accessories

1. One lanyard
2. Two AAA batteries
3. One user manual
4. One silicone case
5. One carrying bag

Battery Installation

1. Open the battery door cover shown as the picture.
2. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
3. Close the battery door cover.
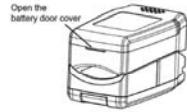
Note:
- Please remove the batteries if the pulse oximeter will not be used for long periods of time.
- Please replace the battery when the power indicator starting flickering.

Using the Lanyard

1. Thread thinner end of the lanyard through the hanging hole.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.

Warnings!
1. Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
2. Do not hang the lanyard from the device's electrical wire.
3. Please notice that the lanyard which is tied to the oximeter may cause strangulation due to excessive length.

Maintenance and Storage

1. Replace the batteries in a timely manner when low voltage lamp is lighted.
2. Clean surface of the fingertip oximeter before it is used in diagnosis for patients.
3. Remove the batteries if the oximeter is not operated for a long time.
4. It is best to store the product in -20℃～+55℃ and ≤93% humidity.
5. Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
6. Dispose of battery properly; follow any applicable local battery disposal laws.

Cleaning the fingertip pulse oximeter
Please use medical alcohol to clean the silicone touching the finger inside of Oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the being tested finger using alcohol before and after each test.
Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.

The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:
- An error in the *Possible Problems and solutions* is displayed on screen.
- The oximeter cannot be powered on in any case and not the reasons of battery.
- There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.

A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO$_2$ accuracy. The measured arterial hemoglobin saturation value (SpO$_2$) of the sensors is compared to arterial hemoglobin oxygen (SaO$_2$) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO$_2$ range of 70%-100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
A functional tester is used to measure how accurately Fingertip Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.
The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.

Specifications

1. Display Type
OLED display

2. SpO$_2$
Measurement range: 70%~99%
Accuracy: 70%~99%: ±3%; 0%~69% no definition
Resolution: 1%

3. Pulse Rate
Measure range: 30bpm~235bpm
Accuracy: 30bpm~99bpm, ±2bpm; 100bpm~235bpm, ±2%
Resolution: 1bpm

4. Probe LED Specifications

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

NOTE: The information about wavelength range can be especially useful to clinicians.