



Instruction Manual

Pulse Oximeter

OPO102



Please read instruction manual before use

General Description

Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage(%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO₂. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO₂ level.

PRINCIPLE of the oximeter is as follows:

The pulse oximeter works by applying a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light the other is 905nm, which is infrared-red light skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light

intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO₂.

Diagram of Operation Principle

1. Red and infrared-ray emission tube
2. Red and infrared-ray receipt tube



Safety Notice

1. Before use, carefully read the manual.
2. Do not use the pulse oximeter:
 - if you are allergic to rubber products.
 - if the device or finger is damp.
 - during MRI or CT scan.
 - while taking a blood pressure measurement on the arm.
 - nail polish, dirty, coating fingers and false nails applied fingers.
 - fingers with anatomical changes, edemas, scars or burns.
- Too big finger: the width of finger is over than 20mm and the thickness is over than 15mm.
- Too small finger: the width of finger is less than 10mm and the thickness is less than 5mm.
- Minors under 18 years old.
- The environmental light changes strongly.
- near flammable or explosive gas mixtures.
3. Extended use may cause pain for people with circulatory disorders. Do not use the pulse oximeter for longer than two hours on one finger.
4. Measurements are for your information only they are no substitute for a medical examination. If an unexpected reading occurs, the operator can take several more measurements and consult a doctor.
5. Check the pulse oximeter regularly before use to ensure that there is no visible damage and the batteries are still

- sufficiently charged. In case of doubt, do not use the device and contact customer services or authorized retailer.
6. Do not use any additional parts that are not recommended by the manufacturer.
 7. Any circumstances do not open or repair the device by yourself. Failure to comply will result in voiding of the warranty. For repairs, please contact customer services or authorized retailer.
 8. Do not look directly inside the housing during the measurement. The red light and the invisible infrared light in the pulse oximeter are harmful to your eyes.
 9. This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.
 10. If the unit has been stored at temperatures below 0°C, leave it in a warm place for about two hours before using it.
 11. If the unit has been stored at temperatures above 40°C, leave it in a cool place for about two hours before using it.
 12. Neither of the displays for the pulse wave and pulse bar allows the strength of the pulse or circulation to be evaluated at the measurement site. Rather, they are exclusively used to display the current visual signal variation at the measurement site and do not enable diagnostics for the pulse.
 13. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
 14. This equipment is not intended for use during patient transport outside the healthcare facility.
 15. When the signal is not stable, the reading may inaccurate. Please do not reference.

16. Portable and mobile RF communications equipment can affect medical electrical equipment.
17. WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
18. WARNING: PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm(12 inches) to any part of Fingertip Pulse Oximeter, including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.
19. Any serious incident that has occurred in relation to the device should be reported to the manufacture and the competent authority of the Member State in which the user and/or patient is established.

Important Testing Guidelines

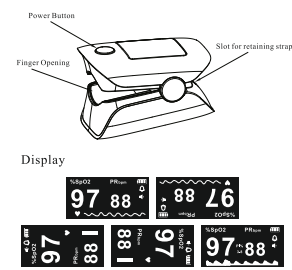
1. Non-observance of the following instructions can lead to incorrect or failed measurements
 - There must not be any nail polish, artificial nails or other cosmetics on the finger to be measured.
 - Ensure that the finger nail on the finger to be measured is short enough that the fingertip covers the sensor element in the housing.
 - Keep your hand, finger and body steady during the measurement.
 - In cases of carbon monoxide poisoning, the pulse oximeter will display a measurement value that is too high.
 - To avoid incorrect results, there should not be any strong light sources(e.g. fluorescent lamps or direct sunlight) in the immediate vicinity of the pulse oximeter.
 - Protect the pulse oximeter from dust, shocks, moisture, explosive materials.
 - Excessive patient movement.

2. The following situations may cause inaccurate measurements
 - Significant levels of dysfunctional hemoglobin (such as carboxyl hemoglobin or methemoglobin).
 - Venous pulsations.
 - Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
 - The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
 - The patient is in cardiac arrest or is in shock.
 - Weak pulse quality (low perfusion).
 - Low hemoglobin.

Unit Illustration

- Package contents
- 1 x OPO102 pulse oximeter
 - 1 x Owner's Manual
 - 1 x Retaining strap
 - 1 x Storage Bag
- Optional accessories
- 2 x 1.5V AAA batteries

Monitor Unit



Features

1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. Displays SpO₂, PR, Pulse bar, and waveform.
4. Level 1-5 adjustable brightness.
5. 5 display modes.
6. A low voltage warning will be indicated in visual window when battery voltage is

- so low that normal operation of the oximeter might be influenced.
7. When it shows "Finger out", the pulse oximeter will power off automatically in 10 seconds.
 8. Beep.
 9. When the buzzer and reminder function are turned on, the numbers on the screen will flash when the reminder occurs, and the buzzer will beep.
 10. Perfusion index (value in percent).

Unit Operation

Battery Installation

Follow the arrow to unlock the battery cover. Install 2 new AAA alkaline batteries according to polarity, install the battery cover and lock it in the opposite direction of the arrow.



Note:

- 1) Be sure to follow the correct polarity when installing the batteries. Reversed batteries may cause damage to the device.
- 2) Use only the size and type of batteries specified.
- 3) Do not mix different types of batteries together or old batteries with fresh ones. Always replace batteries as a simultaneous set.
- 4) Replace the batteries in a timely manner when low voltage lamp is lighted.
- 5) If the batteries in the device are depleted or the device will not be used for a long period of time, remove the batteries to damage or injury from possible battery leakage.
- 6) Do not try to recharge batteries not intended to be recharged; they can overheat and rupture.
- 7) Do not dispose of batteries in fire, batteries may explode or leak.
- 8) Keep batteries away from children and pets, Batteries may be harmful of swallowed. Should a child or pet swallow a battery, seek medical assistance

immediately.

9) Please follow the law of the local government to deal with used batteries.

System Settings

With power off, Press the power button about 2 seconds to actuate system setting.

Setting available for Tips, Beep, Language Default, SpO₂ Tips Lo, PR Tips Hi, PR Tips Lo and EXIT. Long press to enter the specific value setting, short press to switch among the setting items.

Settings	Settings
Tips * On	SpO ₂ Tips Lo * 90
BEEP On	PR Tips Hi 100
Language EN	PR Tips Lo 50
Default	Exit

To Use

CAUTION: Please make sure your finger size is appropriate (fingertip width is about 10-20 mm, thickness is about 5~15 mm)

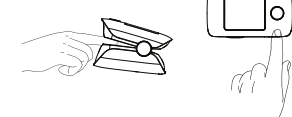
CAUTION: This device cannot be used in strong radiation environment.

CAUTION: This device cannot be used with other medical devices or non-medical devices.

CAUTION: When placing your fingers, ensure your fingers can completely cover the LED transparent window in the finger clamp compartment.

1. As shown in the figure, squeeze the clip of the pulse oximeter, fully insert your finger into the finger clip compartment, and then loosen the clip
2. Press the power button one time on front panel to turn the pulse oximeter on.
3. 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.
4. Read the data from the display screen.
5. To select your desired display brightness, press and hold the power button during operation until the brightness level changes..
6. To choose among the various display formats, press the power button briefly during operation.

7. If you remove the oximeter from your finger, it will shut off after about 10 seconds.



Cleaning and Maintenance

1. 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.
 2. 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.
 3. The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.
 4. The expected lifetime of the device is 3 years when it is used for 10 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.
 5. Cleaning
- Cleaning procedures:
- a) Put the oximeter on a clean table..
 - b) Use a clean lint-free soft cloth dipped in water to wring it out and clean the surface of the oximeter and the upper and lower finger pads.
 - c) If there are obvious stains, use commercially available neutral detergent to wipe and clean. After the stains are cleaned up, use a clean lint-free soft cloth dipped in water to wring out and clean the surface of the blood oxygen

meter and the upper and lower finger pads.

d) Fully dry the oximeter in a ventilated place.

Troubleshooting Guide

Problem	cause	Solution
Monitor do not display	Batteries are depleted	Replace the batteries
	Batteries not inserted correctly	Reinsert the batteries. If after reinserting the batteries correctly There are still no measurement values displayed, contact customer service
Measure -ments are erratic	Insufficient circulation. in the measur -ent finger	Observe the Important Guidelines
	Finger, hand or body is moving	Keep your finger, hand and body still during the measurement
	Cardiac arrhythmia	Seek medical attention
Measur -ements can not be shown normally	Finger is not inserted correctly	Retry by inserting the finger
	Patient's SpO ₂ value is too low to be measured	There is excessive illumination; Or, Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis.

Warranty

Passim Lifesciences Ltd. warrants this unit against defects in materials and workmanship for one year from the date of purchase. During the warranty period, any defective parts will be repaired or replaced free of charge, excluding consumable components such as the nasal steamer & facial steamer, which are not covered once used.

Warranty is void if:

- The device is misused or not

maintained per this manual.

- Unauthorized repairs or modifications are made.
- Operated in corrosive or harmful environments.
- The warranty card is not fully completed and presented upon claim.

Specifications

Model	OP0102	
Display	0.96" display	
SpO2	Display Range	0%~100%
	Measurement Range	70%~100%
	Accuracy	70%~100%±2% 0%~69% no definition
	Resolution	1%
Pulse Rate	Display Range	0~240bpm
	Measurement Range	30~240bpm
	Accuracy	30~100bpm, ±2bpm; 101~240bpm, ±2%
	Resolution	1bpm
Power supply : 2x1.5VAAA batteries		
Weight : Approx. 54g		
Dimensions : Approx. 60.2mm*35mm*35.5mm		
Operating Environment	Temperature : 5~40	
	Humidity : 15%~93%RH	
Storage Environment	Pressure : 700hPa~1060hPa	
	Temperature : -20~55	
	Humidity : 15%~93%RH	
	Pressure : 700hPa~1060hPa	
Ingress Protection Rating : IP22		
Classification : Internal Powered		
Equipment Type BF		
Applied parts : Finger pad		
The Data UPDATE period : Less than 12s		

Note: The functional tester cannot be used to assess the accuracy of the oximeter. The test methods used to establish the SpO₂ accuracy is clinical testing. The oximeter used to measure the arterial haemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-oximeter.

1. EN ISO 80601-2-61, medical electrical equipment part 2-61: particular

requirements for the basic safety and essential performance of pulse oximeter equipment.

2. EN 60601-1: medical electrical equipment part 1: general requirements for basic safety and essential performance.
3. EN 60601-1-2, medical electrical equipment part 1-2: general requirements for basic safety and essential performance collateral standard: electromagnetic disturbances - requirements and tests (General II (ES/EMC)).
4. EN 60601-1-11, medical electrical equipment part 1-11: general requirements for basic safety and essential performance collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Correct disposal of this product. (Waste electrical & electronic equipment)

This icon shown on the product indicates that it should not be disposed with other household waste at the end of its life. To prevent potential harm to the environment or to human health, please separate this product from other types of wastes and recycle it responsibly. When disposing this type of product, contact the retailer where product was purchased or contact your local government office for details regarding how this item can be disposed in an environmentally safe recycling centre. Business users should contact their supplier and check the terms and conditions of the purchasing agreement. This product should not be mixed with other commercial wastes for disposal. This product is free of hazardous materials.

* Terms & Conditions apply

WARRANTY CARD	Model No.:	Lot No.:
	Invoice No.:	Date of Purchase
	Purchased By:	Contact No.:
	Address:	
	Dealer's Name:	
Dealer's Sign & Stamp		

Register your product

Symbols

- Medical Device
- Lot No.
- Warning/Caution
- Serial No.
- Manufactured By
- No Trash
- Refer Instructions Manual
- Keep Away From Sunlight
- Do not use If Package damaged
- Must not be exposed in rain or excessive moisture
- Manufacturing Date

Manufactured by:
Passim Lifesciences Ltd.
Plot No. 45, Ind. Area, Phase-II, Panchkula - 134113, Haryana-INDIA
Mfg. Lic. No.: MFG/MD/2022/000633
For any Complaint / Suggestion please contact:
Customer care Number:
1800 309 3009
Timing: 9am-7pm, Mon.-Sat.
Email ID: customercare@frodin.in,
Website: www.drodrin.in