Dr. Odin®

Instruction Manual
Pulse Oximeter
OPO103
with bluetooth

Please read instruction manual before use

This Fingertip Pulse Oximeter is a kind of innovated medical device with non-invasive features for artery SPO_2 and PR detection. Being portable, it is able to measure SPO_2 and PR values quickly and precisely.

General Description

Haemoglobin Saturation is the percentage between the capacity of Oxyhemoglobin (HbO2) that compounded with oxygen and that of all combinativable haemoglobin (Hb) in blood. In other words, it is the saturation of Oxyhemoglobin in blood. It is a very important physiological parameter for Respiratory and Circulation Systems. Many respiratory diseases could reduce haemoglobin saturation in human blood. Moreover, factors such as Automatic Organic Regulation Malfunction caused by anaesthesia, trauma resulted from major operation and some medical examination can also cause problems in oxygen supply, which might reduce human haemoglobin saturation. As a result, such symptoms as megrim, vomiting and asthenia might appear to patients. Hence, it is very important to know hemoglobin saturation of patient timely in clinical medical aspects.

The fingertip pulse oximeter features in small volume, low power consumption, convenient operation and portability. It is only necessary for patient to put one finger into fingertip photoelectric sensor for diagnosis, and the display screen will directly show measured value of hemoglobin saturation. It has been proved in clinical experiments that it possesses rather high precision and repeatability.

Intended use

The fingertip pulse oximeter can be used to measure human haemoglobin saturation and pulse rate through finger , it can be used in hospitals, families, schools and medical centers.

User Group

-People who need blood oxygen measurement .

Contraindication : not found

⚠ Note :

1.The image in the instruction may have slight differences with the actual instruments.

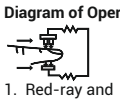
2.Technical parameters and appearance change, without prior notice.

Product include : main machine and SPO2 sensor.

Measurement principle

The principle of the oximeter is as follows: An experience formula of data process is established by exerting Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin and oxyhemoglobin （HbO2) in red light and infrared light zones. Operation principle of the instrument is to combine Photoelectric Oxyhemoglobin Inspection Technology with Capacity Pulse Scanning and Recording Technology, so that two lights with different wavelength (660nm red light and 940nm infrared light) can be focused onto human nail through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of diodes through process in electronic circuits and microprocessor.

Diagram of Operation Principle



1. Red-ray and Infrared-ray receiving diode
2. Red-ray and Infrared-ray transmitting diode

Precautions for use

1.Do not use the oximeter together with MRI or CT equipment.

2.Do not use the oximeter in the presence of flammable anesthetics or other flammable substances, oxygen-enriched environments, or nitrous oxide to avoid the risk of explosion.

3.The oximeter is intended only as an adjunct in patient assessment. Doctors should make diagnosis in conjunction with clinical manifestation and symptoms.

4.Check the oximeter sensor application site frequently to make sure that the circulation and skin integrality of patient are under good condition.

5.The sensor of the oximeter is not suitable for contacting the adhesive tape, which may lead to the error of measurement data or mistaking that there are blisters on the tested skin.

6.Please read the manual carefully before your operation.

7.The oximeter has no SpO_2 alarm, it is not for continuous monitoring, using during motion or using with low perfusion.

8.Check the sensor site every at least every 2 hours to ensure adequate blood circulation, intact skin, and appropriate sensor location. Otherwise, it may cause skin damage, compressive necrosis, or inaccurate measurement readings.

9.Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.

10.Significant levels of dysfunctional hemoglobins (such as carboxyl-hemoglobin or methe moglobin) may cause inaccurate reading.

11.Intravascular dyes such as indo cyanine green or methylene blue may cause inaccurate reading.

12.SpO_2 measurements may be adversely affected in the presence of high ambient light. Please shield the sensor area (with a surgical towel or direct sunlight, for example) if it is necessary.

13.Unexpected action may cause inaccurate reading.

14.Medical signal with high frequency or interference caused by defibrillator may lead to inaccurate reading.

15.Venous pulsations may cause inaccurate reading.

16.It may cause inaccurate reading when the positions of sensor and blood pressure cuff are on the same arterial catheter or intravascular line.

17.Hypotension, severe vasoc onstriction, severe anemia, or hypothermia may cause inaccurate reading.

18.It may cause inaccurate reading by giving use of cardiotonic to patient after his cardiac arrest or when he is in quiver.

19.Bright nail or painted nail may cause inaccurate SpO_2 reading.

20.Do not use this oximeter if you are allergic to ABS, black silicone pad and other materials.

21.If the performance is inconsistent with the description or changes, stop using immediately and contact the manufacturer.

22.Measuring function should not be used to evaluate oximeter accuracy.

23.The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems.

24.Please place the oximeter in a place where children, pets, etc. can not be touched, so as to prevent falling, biting and affecting the product performance.

25.Do not use beyond the service life of the device, otherwise the accuracy of the device will be affected.

26.No modification of this equipment is allowed.

27.Oximeter should be avoided in places with poor ventilation and high dust and lint content.

28.The products should be avoided direct sunlight and strong light sources.

29.The oximeter cannot be serviced and maintained during use.

30.The oximeter can be maintained and calibrated once every two years, and the basic safety and basic performance of the oximeter have been guaranteed.

31.The maximum temperature of the contact surface between the product and human body does not exceed 41 ℃.

32.The device is not intended for use in intensive care unit environments and emergency healthcare environments.

Features

Display

1.Product adopts color display can show the 4 different display mode.

2.Low-power consumption, continuously work for more than six hours with two AAA batteries

3.Low voltage indicator

4.In the absence of signals, the product will be in after 8 seconds to enter standby state.

5.Small in volume, light in weight, and convenient to carry.

Operation Instructions

1.Install two AAA batteries into battery cassette before covering its cover.

2.Plug one finger into rubber hole of the Oximeter (it is best to plug the finger thoroughly) .

3.Press button on the front panel;

4.Don't tremble your finger when the Oximeter is working. Your body is not recommended on moving status.

5.Press the button on the front panel, if we want change display direction;

6.Read relevant datum from display screen.

7.The instrument has the function of sleep, no signal 8seconds will enter standby state of sleep;

8.Please replace new batteries when display screen indicates the batteries are in low power.

Note: When plugging your finger into the Oximeter, your nail surface must be upward.

Declaration: Please use the medical alcohol to clean the rubber before each test and clean the tested finger with alcohol before and after the test. (The rubber inside of the Oximeter adopts medical rubber, which has no toxin, no harm, and brings no side effect such as allergy to the our skin).

Battery installation

1.According to the positive and negative identity right will be two AAA batteries into the battery compartments.

2.Push the battery cover horizontally in the direction of the arrow at the bottom.

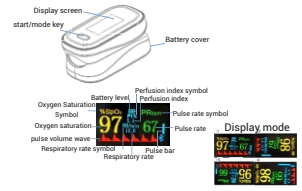
Please note: pay attention to the battery positive and negative polarity, must be installed correctly, otherwise it may cause damage to instrument.

Lanyard installation

1.Put the lanyard thin end through the hole.

2.Put the lanyard coarser end through the thin end and tighten it.

Brief Description of Front Panel



Keys function description: in standby mode, start the key instrument into the working state, push down this button under working state, can change the display mode.

⚠ Note

The machine profile picture only for your reference use, specific in kind prevail. The blood perfusion index (PI%), respiratory rate (RR),only show status values and are not used for clinical reference.

Parameter setup：

In the power on state, press start button（＞3s）into para meter setup .As men：

1.In menu ， the "⋆" signal is shown on the "Alm ",Press the button（<1s）can select item one by one. Press button（＞3s）to set the on/off for prompt ,beep, choose "+"or"-" to increase or decrease SpO2 or PR values , exit setup .When the "⋆" signal is shown on the "Restore",press the button（＞3s）and all the settings are back to the factory settings.

AIM		*off
Beep		on
SpO2	LO	94
PR	Hi	130
PR	LO	50
Restore		off
+/-		–
Menu	Exit	

Detailed descriptions of product functions:

1.SpO2: Measurement range: 70% ~ 100%
Accuracy: 80% ~ 100%:±2% (Including 80%); 70% ~ 79%: ±3%;Below 70% no requirement; Resolution：1%

2.PR: Measurement range:
30BPM ~ 254BPM
Accuracy：≤100BPM ,±1BPM
＞100BPM ,±2BPM

3.Parameters of LED probe

	Wavelength	radiation power
RED	Approx.660nm	1.8mW
IR	Approx.940nm	2.0mW

4.PI index: measurement scope:0%~20% (optimal)

5.Respiration rate: The value of respiration rate should be displayed (optional).

6.Data trans mission:The measurement data can be transmitted to the terminal device via Bluetooth in real time （ optional ）

7.Power: two AAA 1.5V batteries

8.Automatic stand by: the product shuts off by itself when no finger is in the product about 8 seconds .

9.Automatic start up: The device has the function of 5S automatic signal detection. When the finger is inserted, it will start up automatically;(optional)

10.Gravity sensing function: finger movement, the screen display will change with the gravity sensing changes (optional)

11.Dimension：about 59*32.5*29.3mm

12.Operation environment:
Temperature: 5 ℃ ~ 40 ℃
Humidity: 15%RH ~ 80%RH,no condensing
Atmospheric pressure: 70kPa ~ 106kPa
Transport, storage environment:
Temperature: -10 ℃ ~ 40 ℃
Humidity: 10%RH~ 95%RH,no condensing
Atmospheric pressure: 70kPa ~ 106kPa, non-corrosive gas and well ventilated environment.

13.Declaration：EMC of this product comply with IEC60601-1-2 standard.

14.This equipment has no alarm function.

15.Data averaging and signal processing delay the display and transmission of SpO2 data.

16.The date update period : < 12S

17.About 30min required for oximeter to warm from the minimum storage temperature between uses until it is ready for intended use.

18.About 30min required for oximeter to cool from the maximum storage temperature between uses until it is ready for intended use.

19.Applied parts specified: Probe and its circuit.

20.Service life:5 years

21.Use specification

Expected medical instructions	The fingertip pulse oximeter can be used to measure human haemoglobin saturation and pulse rate through finger
Expected patient population	-People who need blood oxygen measurement .
Expected use or interaction with body parts tissue type	Finger
Expected user profile	People who need blood oxygen measurement , doctors, etc
Application environment	Avoid electromagnetic interference Extreme temperature Avoid pollution and dust Avoid direct sunlight, etc
Operating principle	Operation principle of the instrument is to combine Photoelectric Oxyhemoglobin Inspection Technology with Capacity Pulse Scanning and Recording Technology, so that two lights with different wavelength (660nm glow and 940nm near infrared light) can be focused onto human nail through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of diodes through process in electronic circuits and microprocessor.

Bluetooth Download Method (optional)
Open the "scan" function of your browser, we chat or other software, directly scan the QR code provided below to obtain the Bluetooth download method file, and download the corresponding APP according to the file requirements.

Classification

1.Management Class for Medical Devices: Class Iia

2.Anti-electric Shock Type: Internally powered equipment

3.Anti-electric Shock Degree: Type BF equipment

4.Overvoltage category classification:Class I

5.Pollution degree: Pollution degree2:Micro-environment with non-conductive pollution,expect occasional conductivity caused by condensation.

Maintenance and Preservation

1.Replace the batteries timely when the low battery indicator flashes

2.Clean the surface of fingertip pulse oximeter before use.

3.Remove the batteries when the oximeter is not likely to be used for some time when leakage from batteries would result in an unacceptable risk.

4.It would be better to preserve the product in -10~40℃ (14-104℉) and humidity is 10%-95%.

5It is recommended that the product should be kept dry anytime. A wet ambience might affect its lifetime and even damage the product.

6.Cleaning frequency If the oximeter is dirty when used at home, it is recommended to clean the enclosure and silicone pad after each use. If the oximeter is not dirty, simply clean the black silicone pad before and after each use. When used in a medical institutions, clean it after each use.

7.Cleaning method When the oximeter is used at home, wipe and disinfect with 75% alcohol, then dry naturally or clean the product with dry cloth. Clean at least twice a week. When using in medical institutions, clean the tested finger with 75% alcohol before use. After each measurement, wipe and disinfect the contact part between black silicone and enclosure with 75% alcohol.

8.The oximeter can display functional arterial oxygen saturation and pulse rate after calibration.

9.The Blood oxygen simulator is calibrated to display functional oxygen saturation.

10.The maximum temperature of the contact surface between the product and human body does not exceed 41 ℃.

Waste disposal

1.Please follow local laws to dispose of waste scrap.

2.Follow local ordinances and recycling instructions regarding to disposal or recycling of the device and device components, including used batteries and packaging box.

Components

Components	Quantity
The host	1set
Lanyard	1pcs
User manual	1pcs
AAA battery (optimal)	2pcs

Manufacturer's Declaration of the EUT Statement:

1.The Fingertip Pulse Oximeter or user should use the product in the electromagnetic environment specified in the following table, otherwise it may cause abnormal operation of the product.

2.Fingertip Pulse Oximeter is a table-top equipment, it suitable for medical unit and home use.

3.Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas should be used no closer than 30cm(12 inches)to any part of the oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this Fingertip Pulse Oximeter could result.

4.Warning: Use of this Fingertip Pulse Oximeter adjacent to or stacked with other equipment should be avoided because it could result in improper observed to verify that they are operating normally.

5.Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in im propre operation.

Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer´s declaration – electromagnetic emission	
2	The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Fingertip Pulse Oximeter should assure that it is used in such an environment.	
3	Emissions test	Compliance
4	RF emissions CISPR 11	Group 1
5	RF emissions CISPR 11	Class B
6	Harmonic emissions IEC 61000-3-2	N/A
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A

Guidance and manufacturer's declaration electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration electromagnetic immunity for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer´s declaration – electromagnetic immunity		
The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Pulse Oximeter should assure that it is used in such an environment.		
Immunity test	**EN 60601 test**	**levelCompliance level**
Conducted RF IEC 61000-4-6	3 Vr 150 kHz to 80 MHZ	N/A

Table 9 – Test specifications for enclosure port immunity to RF wireless communications equipment

Possible Problems and Resolutions

Problem	Possible reason	Solution
SpO2 or PR can not be shown normally	1. Finger is not plugged correctly 2.Patient's Oxy-hemoglobin value is too low to be measured	1.Retry by plugging the finger 2.Try more times. If you can make sure there is no problem in the product, please go to hospital timely for exact diagnosis
SpO2 or PR is shown unsteady	1.The finger might not be plugged deep enough 2.Finger is trembling or the patient is on movement status	1. Retry by plugging the finger 2. Please remain at rest
The Oximeter can not be turned on	1.Inadequate power or power off 2.Batteries might be installed in correctly 3.The Oximeter might be damaged	1.Please replace the batteries 2.Please reinstall the batteries 3.Please contact with local customer service centre
Indication lamps are suddenly off	1.The product automatically shuts off when no signal is detected in 8 seconds 2. Inadequate power	1.Normal 2. Replace the batteries

Reserves the right to technical change appearance, our products are subject to change without prior notice, please forgive me!

Statement:

1, If you need maintenance, please contact the manufacturer

2, The company can be in the form of email or other electronic files provide users with random files.

3, The instrument is not used for evaluation of blood oxygen probe pulse and pulse blood oxygen monitor accuracy.

Unit Operation

How to Connect Your Dr. Odin Pulse oximeter via Bluetooth

Step 1: Download the App

First, you'll need to download the official Dr. Odin app. You can find it by searching for **"Dr. Odin"** on the Google Play Store for Android devices or the Apple App Store for IOS devices.

Step 2: Enable Bluetooth

Once the app is installed, open it on your device. The app requires Bluetooth to function, so make sure it's enabled in your smartphone's Settings menu. This allows the app and the pulse oximeter to communicate with each other.

Step 3: Log In or Create an Account

You'll be prompted to either create a new user account or log in with an existing one. Follow the on-screen instructions to proceed.

Step 4: Pair Your Device

On the app's home screen, navigate to the **"Connect Your Devices"** section and select pulse oximeter Next, start your Dr. Odin Pulse oximeter to begin a reading.

The app will automatically detect the device. Then tap on device to connect it with you app.

Step 5: Sync Your Data

After the pulse oximeter completes the measurement, the results will be automatically reflected on the app via Bluetooth. The app will then save this data to your memory for future reference and tracking.

Important Note: To ensure a successful data transfer, keep the app open and active on your phone until the measurement is complete and the results have appeared.

Troubleshooting

If you encounter any issues with the Bluetooth connection, try the following steps:

1. Restart the app.

2. Re-connect the device by repeating the pairing process.

Remember, even if Bluetooth communication fails, you can always view your measurement data directly on the pulse oximeter display.

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.

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.

* Terms & Conditions apply

WARRANTY CARD

Lot No.:..... Date of Purchase:..... Contact No.:.....

Model No.:..... Invoice No.:..... Purchased By:..... Address:..... Dealer's Name:..... Dealer's Sign & Stamp

Register your product to claim warranty

SYMBOL

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

Manufactured by:
Passim Lifesciences Ltd.
Plot No. 45, Ind. Area, Phase-II,
Panchkula - 134113, Haryana-INDIA
Mfg. Lic. No.: MFG/MD/2022/000633
WPC ETA Reg. No.: ETA-SD-20250807434
For any Complaint / Suggestion please contact:
Customer care Number:
1800 309 3009
Timing: 9am-7pm, Mon.-Sat.
Email ID: customercare@drodin.in
Website: www.drodin.in

IM/OPO/91-00