Pulse Oximeter

Instruction for Use

1. Introduction

1.1 Intended use

This Pulse Oximeter is intended to be used for measuring, displaying and storing of pulse oxygen saturation (SpO$_2$), pulse rate of adults in home or healthcare facilities environment.

1.2 Contraindications

No contraindications.

1.3 Warnings and Cautions

- DO NOT squeeze the sensor part or apply excessive force on it.

- Do not use this device during MRI examination.
- Do not use this device with a defibrillator.
- Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations that are subject to strong electromagnetic influences.
- Do not use the device in a combustible environment (i.e., oxygen-enriched environment).
- Never submerge the device in water or other liquids.
- Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impact.
- The device and accessories are provided non-sterile.
- Do not place this device in pressure vessels or gas sterilization device.
- Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.
- Consult your doctor immediately if you experience symptoms that could indicate acute disease.
- Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- Use only cables, sensors and other accessories specified in this manual.
- Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.
- Do not open the device cover without authorization. The cover should only be opened by a qualified service personnel.
- The biocompatibility testing has been performed on the materials in contact with the person in accordance with ISO10993.
- Do not place the SpO$_2$ probe on a finger with edema or fragile tissue.
- Check the SpO$_2$ sensor and cable before use. Do not use a damaged SpO$_2$ sensor.
- Check the SpO$_2$ sensor application site every 6-8 hours to determine the positioning of the sensor and the circulation and skin sensitivity of the patient. Patient sensitivity varies depending on medical status or skin condition. For patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
- The functional tester cannot be used to assess the accuracy of the SpO$_2$ sensor or a device.
- The device has no alarm system.
- Continuous use for a long time may cause allergies, redness, blistering or burns. Check the wearing position every 6-8 hours.
- The local laws and regulations should be followed when disposing of the device and accessories.
- The battery inside this product cannot be replaced.

1.4 Guide to Symbols

Symbol	Description
⟨人⟩	Type BF-Applied Part
⟨▲▲⟩	Manufacturer
⟨⋀⟩	Date of manufacture
EC REP	Authorized Representative in the European Community
⟨👆⟩	Follow Instructions for Use.
⟨MR⟩	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
IP22	Protected against spraying water and against access to hazardous parts with a tool, per IEC60529.
SN	Serial number
⟨⊠⟩	No alarm system
⟨J⟩	Temperature limitation
⟨%⟩	Humidity limitation
⟨⊕⟩	Atmospheric pressure limitation
⟨☒⟩	Indicate separate collection for electrical and electronic equipment (WEEE).

1.5 Unpacking

- Device
- User Manual
- Data/ Charging Cable

2 Overview

Name: Pulse Oximeter
Model: PO2

1. Touch Switch:
   Wake up the screen and switch the interface.
2. Backlit Screen:
   Show SpO$_2$ value and pulse rate value .
3. USB Charging Port:
   Can be charged and data transmission.
4. Sensor:
   The device turns on/off automatically in a moment after you take on/off the sensor.
   The blood SpO$_2$ and pulse rate can be measured.

3 Using the Device

3.1 Charging

Use the USB cable to charge the product. Connect the USB cable to a USB charger or to the PC. There will be a battery logo flash on the device when charging.

A fully charge will need 2-3 hours. After fully charged, the device will power off automatically.

Note: The device cannot be used during charging, and if choosing a third party charging adaptor (Class II), select one that complies with IEC60950 or IEC60601-1.

3.2 POWER ON/OFF

POWER ON:
Wear the device, it will turn on automatically.

POWER OFF:
The device turns off automatically in a moment after you take off the sensor.

3.3 Typical steps

1) **START.** After charge the battery ,wear the device to power on.

2) **STOP.** Take off the device, the recording will be over after the countdown.

3) **DATA Uploading.** Run your phone to download data.

3.4 Start working

1) Wear the device on index finger. Try to move the device along the forefinger to find out a best fit. Avoid being loose. Loose wearing causes inaccurate measure.
2) Device will turn on automatically. After a few seconds, the device will begin to work.

Notice:
- *If the working time is less than 2 minute, the data will not be saved.*
- *Please avoid excessive motion.*
- *Please avoid strong ambient light condition.*

SpO$_2$ measurement principle:

The Pulse Oxiemter is a lightweight, portable health oximeter for use in the home or in

healthcare facilities. SpO2 measurement technology is based on developed photoelectron method, the circuit design and calculation software was developed by Shenzhen Viatom Technology Co., Ltd. The SpO2 sensor receives the optical signal from the red light and infra-red light through the finger. Insert the finger into the oximeter, there are two emitting tube (red light diodes and infrared diodes) located on the inner upside of the sensor and they can emit red light and infrared; There is the receiving end located on the inner downside of the sensor, and it can transmit the red light and infrared into the pulse signal through finger. The MCU receives the pulse signal, gets the frequency signal by counting, processes its digital signal, and finally gets the measured SpO2 value. The PR is averagely calculated by above peak intervals of PR waveform.

3.5 Stop working & Upload data

Take off the device, the countdown will begin.

| Stop? 10 |

(If the working time is less than 2 minute, there will be no countdown)

During the countdown, if you wear the device again, the record will be resumed.
After the countdown, the **data will be ready for uploading**.

Notice: The built-in memory can store 4 records. The oldest will be overwritten by the 5th. Please upload data to your phone in time.

3.6 Screen Wake up

The screen will go off automatically for saving power in Standard Mode; you can touch the key on top to wake up the screen.

3.7 How to Check Battery

Touch the key on top, you can switch display between readings and battery.

3.8 Unavailable Symbol

| —— —— |

When this symbol displays on device screen, it indicates the readings is unavailable right now.
It may caused by:
- Excessive movement;
- Poor signal, finger is too cold;

Usually, the readings will recover in a few seconds when at rest.

3.9 Bluetooth Connection

Problem	Possible Cause	Possible Solution
Device does not turn on or no response	Battery may be low.	Charge battery and try again.
	Device might be damaged.	Please contact your local distributor.
	Software exception	Keep device in charging, touch the key for 8 seconds.

The device Bluetooth will be enabled automatically after it's turned on.
To establish a Bluetooth connection,
1) **keep the device Bluetooth enabled.**
2) **Make sure the phone Bluetooth is enabled**.

Notice:
- *DO NOT PAIR in the settings of your phone.*

3.10 Add a New Device

For the initial use, you need to add a new device.
1) Turn on device, run phone, select <O2Ring>;
2) Touch the key on top of device.

3.11 Smart Vibration by SpO2

The vibrator in the sensor will be activated when the SpO2 fall below the pre-set value (Threshold). The vibration will stop when the SpO2 recover.

3.12 Smart Vibration by Pulse Rate

When your pulse rate is above the Upper Threshold or below the Lower Threshold, vibration will be activated.

4 Maintenance

4.1 Time & Date

After connection with phone, device time will upload from your phone time automatically.

4.2 Cleaning

The device can be repeatedly used. Please clean

before reuse as follow:
- Clean the device with a soft, dry cloth with 70% alcohol.
- Do not use petrol, thinners or similar solvent.
- Clean the cuff carefully with cloth soaked 70% alcohol.
- The cuff must not be washed!
- Clean on the monitor and the arm cuff, and then let it air dry.

Note: The device is a non-sterile medical device and does not contain any sterile or degradable component thus the device is not subject to the shelf life requirements.

5 Troubleshooting

6 Specifications

Environmental	Operating	Storage
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (noncondensing)	10% to 95%	10% to 95%
Barometric	700 to 1060hPa	700 to 1060hPa
Protection against electric shock	Internally powered equipment	
Degree protection against electrical shock	Type BF	
Electro-magnetic compatibility	Group I, Class B	
Degree of dust & water resistance	IP22	
Weight	15 g	
Size	38×30×38 mm	
Battery	3.7Vdc, Rechargeable Lithium-polymer	
Charge requirement	5VDC, Max. 40mA	
Charge time	2-3 hours	
Battery life	12-16 hours for typical use	
Wireless	Bluetooth 4.2 BLE	
Oxygen level range	70% to 100%	
SpO2 Accuracy (Arms)	80-100%:±2%, 70-79%:±3%	
A functional tester or SpO2 simulator can be used to determine the pulse rate accuracy.		
Pulse Rate range	30 to 250 bpm	
Pulse Rate accuracy	±2 bpm or ±2%, whichever is greater	

Wavelength / Max emission power	660nm/940nm, 0.8mW/1.2mW
SpO2 data averaging time	8s
SpO2 data update period	1s
Vibration source	low oxygen level; high/low pulse rate
Recorded parameters	Oxygen level, Pulse Rate
Record interval	4s
Data storage	4 records, up to 10 hours for each
Frequency range	2.402 – 2.480 GHz
Max RF power	-10 dBm
Expected service life	3 years

7 FCC Warnning:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

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Model: PO2
Version: A

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