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, lint,dust,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.
- Do not maintain the device while it is charging.
- Please keep the cable away from children. It can cause strangulation.
- Keep the device out of reach of pets, pests and children.
- The PULSE OXIMETER EQUIPMENT is calibrated to display FUNCTIONAL OXYGEN SATURATION.

1.4 Guide to Symbols

Symbol	Description
	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
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Indicate separate collection for electrical and electronic equipment (WEEE).

1.5 Unpacking

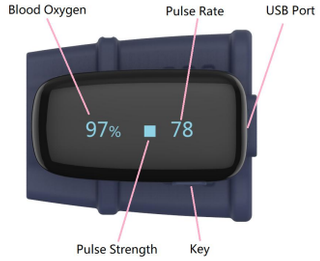
- Device
- User Manual
- Charging Cable

2 Overview

Name:Pulse Oximeter
Model: PO6，PO6A

Model and Configuration see the table below.

No.	Model	Appearance color
1	PO6	Blue
2	PO6A	Gray



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.When the battery is low,the display screen will display a low power prompt.

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.

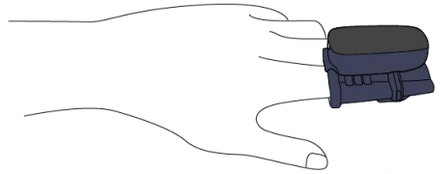
3.3 Typical steps

1) **START.** 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.
(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 1 records. The oldest will be overwritten by the 2th. Please upload data to your phone in time.*

3.6 How to Check Battery

Press the side button, you can switch display between readings and battery.

3.7 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.

3.8 Bluetooth Connection

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.*

3.9 Add a New Device

For the initial use, you need to add a new device.

1) Turn on device, run phone, select <Oxyfit>;
2) Press the button on the side of the device

3.10 Smart Vibration by SpO_2

When SpO2 drops below the preset value (threshold), the buzzer in the sensor will be activated. When SpO2 is restored, the sound will stop.

3.11 Smart Vibration by Pulse Rate

When your pulse frequency is higher than the upper limit or lower than the lower limit, the buzzer 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 and then let it air dry.
- Do not use petrol, thinners or similar solvent.
- Clean the SpO2 sensor carefully with cloth soaked 70% alcohol 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

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	Press the side button for 8 seconds
Inaccurate measured value	The device has not been placed for more than 30 minutes from the colder environment to the measuring environment.	Measurements should be taken before they are left in the measuring environment for more than 30 minutes
	The device has not been placed for more than 30 minutes from the warmer environment to the measuring environment.	Measurements should be taken before they are left in the measuring environment for more than 30 minutes

6 Specifications

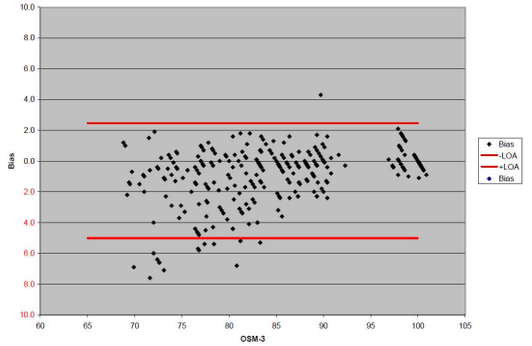
Environmental	Operating	Storage
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (noncondensing)	10% to 95%	10% to 95%
Barometric	700 to 1060hPa	700 to 1060hPa
Protection against electric shock	Internally powered equipment	
Degree protection against electrical shock	Type BF	
Electro-magnetic compatibility	Group I, Class B	
Degree of dust & water resistance	IP22	
Weight	28 g	
Size	38×30×38 mm	
Battery	3.7Vdc, Rechargeable Lithium-polymer	
Charge requirement	5VDC, Max. 80mA	
Charge time	2-3 hours	
Battery life	12-14hours for typical use	
Wireless	Bluetooth 4.2 BLE	
Oxygen level range	70% to 100%	
SpO2 Accuracy (Arms)	80-100%:±2%, 70-80%:±3%	
Pulse Rate range	30 to 250 bpm	
Pulse Rate accuracy	±2 bpm or ±2%, whichever is greater	
A functional tester or SpO_2 simulator can be used to determine the pulse rate accuracy.		
Wavelength / Max emission power	660nm/940nm, 0.8mW/1.2mW	
SpO_2 data averaging time	8s	
SpO_2 data update period	1s	
Vibration source	low oxygen level; high/low pulse rate	
Recorded parameters	Oxygen level, Pulse Rate	
Record interval	4s	
Data storage	1 records, up to 4hours for each	
Frequency range	2.402 – 2.480 GHz	
Max RF power	-10 dBm	
Expected service life	3 years	

7 Declared Accuracy

The table below shows Arms values measured using the Pulse Oximeter in a clinical study in non-motion conditions.

Accuracy Summary by Decade

Decade	Oxygen Saturation (Arms)
70-80%	**±3%**
80-90%	**±2%**
90-100%	**±2%**



This graph shows plots of the error (SpO2 − SaO2) by SaO2 using the Pulse Oximeter with a linear regression fit and upper 95% and lower 95% limits of agreement. Each sample data point is identified by subject from a clinical study in non-motion conditions.

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CE 0197

Model: PO6、PO6A
Version: A

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.