Pulse Oximeter

Instruction for Use

1. Introduction

1.1 Intended use

This Pulse Oximeter is intended to be used for measuring, displaying and storing adult ' s pulse oxygen saturation (SpO2), 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.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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.
- The product is for prescription use.
- This device is designed to determine the arterial oxygen saturation percentage of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
  - Excess ambient light
  - Excessive motion
  - Electrosurgical interference
  - Blood flow restrictors
    (Arterial catheters, blood pressure cuffs, infusion lines, etc.)
- Moisture in the sensor
  - Improperly applied sensor
  - Incorrect sensor type
  - Poor pulse quality
  - Venous pulsations
  - Anemia or low hemoglobin –concentrations
  - Cardiogreen and other -intravascular dyes
  - Carboxyhemoglobin
  - Methemoglobin
  - Dysfunctional hemoglobin

1.4 Guide to Symbols

Symbol	Description
	Type BF-Applied Part
	Manufacturer
	Date of manufacture
	Authorized Representative in the European Community
	Follow Instructions for Use.
	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).
RX only	Prescription Use

1.5 Unpacking

- Device
- User Manual
- Batteries
- Pouch
- Lanyard

2 Overview

Name:Pulse Oximeter
Model: PO6B，PO6C

Model and Configuration see the table below.

Model	PO6B	PO6C
Bluetooth	●	×
Note: '●' means standard configuration, '×' means no such configuration.		

2.1 Appearance

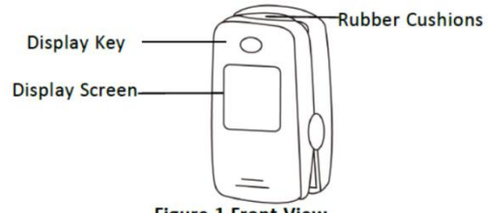


Figure 1 Front View

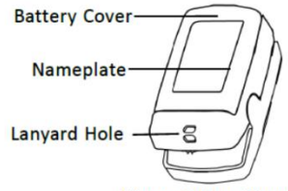


Figure 2 Rear View

3 Using the Device

3.1 Battery Installation

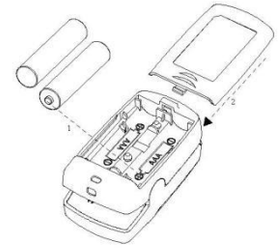


Figure 3 Battery Installation

1) Refer to Figure 3, insert two AAA size batteries into the battery compartment properly, and note the polarity markings.
2) Replace the cover.

- Please make sure that the batteries are correctly installed. Incorrect installation may cause the device not to work.
- Please remove batteries if the device is not being used for more than 7 days to prevent and avoid potential damage from the battery leaking.

Any such damage is not covered under the product warranty.

3.2 Operation

1) Start

Open the clip and put finger inside the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger, as shown in figure 4.

Figure 4 Put finger into the Oximeter

Wait 2 seconds, the Oximeter will power on automatically and start to measure;

2) END.

When finger is out, the Oximeter shuts down automatically.

3) Readings display screen:

Figure 5

The display direction is remembered at each startup, that is, the screen layout (display direction) of the last time will be used as the initial screen layout when powering on the Oximeter next time.

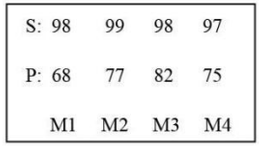


Figure 6

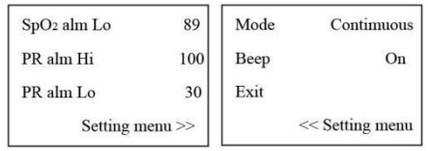
Recording & recall functions are available. At power off status, pressing Display key can bring up record list display screen, as shown in figure 6. In record list screen, press Display key to shift the records page.

If the time from displaying valid readings to the end of measurement is less than 5 seconds, then no recording will be done.

Up to 12 groups of records can be stored in the record list, the newest record is marked as M1, and the oldest record is marked as M12. The new record will override the previous record.

Menu

When finger is in oximeter, long time pressing display key can enter the setup menu screen.



Menu setup: Short time press Display Key to choose the setting item; Longtime press Display Key to active the setting item, then short time press it to modify the setting parameter; Next, longtime press Display Key to confirm the modification and exit from this setting item. At last, move the setting item to "Save, exit menu", and long time pressing Display Key to store the modification and exit from the setup menu.

"Pulse beep" / "Beep"： Pulse beep option. If it is set to on, every pulse beat makes a beep.

When beep is on and over-limits indication sound is activated, then Display key will work as the Mute key, and short time pressing it can mute the over-limits indication sound and pulse beep for 90 seconds.

Note: *Not all the product models have the features described in this chapter, please be subject to the actual products.*

Attention to the operation

- The finger should be put into the sensor correctly.
- Do not shake the finger and relax during measurement.
- Do not put wet finger directly into sensor.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
- Do not let anything block the emitting light from device, i.e. do not use finger nail polish/paints.
- Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
- Nail polish may affect the measuring accuracy, and too long fingernail may cause failure of measurement or inaccurate result.
- Existence of high intensive light sources, such as fluorescence light, ruby lamp, infrared heater or strong sunshine, etc. May cause inaccuracy of measurement result.
- Please put an opaque cover on the sensor or change the measuring site if necessary.
- If the first reading appears with poor waveform (irregular or not smooth), then the reading is unlikely true, the more stable value is expected by waiting for a while, or a restart is needed when necessary.

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.

3.2 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.*

4 Maintenance

4.1 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.*

4.2 Battery

To keep the device in good condition,when the battery is dead, it should be replaced immediately.

5 Troubleshooting

Problem	Possible Solution
Can not turn on the device	Charge battery and try again.
	Please contact your local distributor.
The SpO2 and Pulse Rate display unsteadily	Place the finger correctly inside and try again.
No display	Let the patient keep calm down

Note: If the above problem still exists please contact the local service center.

6 Specifications

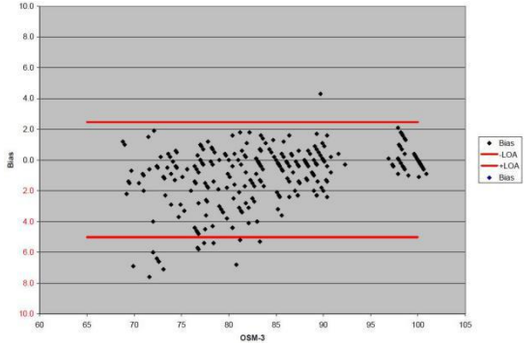
Environmental	Operating	Storage
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (noncondensing)	10% to 95%	10% to 95%
Barometric	700 to 1060hPa	700 to 1060hPa
Protection against electric shock	Internally powered equipment	
Degree protection against electrical shock	Type BF	
Electro-magnetic compatibility	Group I, Class B	
Degree of dust & water resistance	IP22	
Weight	60g	
Size	56 mm (L) × 34 mm (W) × 30 mm (H)	
Battery	DC 3.0V 2 x LR03 (AAA) alkaline batteries	
SpO2 display range	35% to 100%	
SpO2 Accuracy (Arms)	70%-100%: ±2% (Arms:1.88) 70%-80%: ±3% 80%-90%: ±2% 90%-100%: ±2% 0%-69%: not defined	
Pulse Rate range	30 to 240 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	663nm/890nm, ≤2mW	
Vibration source	Low SpO_2	
Recorded parameters	SpO_2 ,Pulse rate	
Record interval	5s	
Data storage	12 groups of records	
Wireless	Bluetooth 4.2 BLE	
Bluetooth RF Frequency range	2.402 – 2.480 GHz GFSK Modulation Adaptive Frequency Hopping (AFH)	
Wireless Quality of Service (QoS)	Transmission Distance: 1.5m Transmission Time: ≤10s Data integrity: 100%	

7 SpO_2 test summary

This graph shows plots of the error (SpO_2-SaO_2) by SaO_2 using the Checkme Pro health monitor with a linear regression fit and upper 95% and lower 95% limits of agreement. Subject from a clinical study in non-motion conditions identifies each sample data point. Clinical study was performed using healthy adult subjects.

The device is not intended to be used during motion and therefore testing in accordance with Clause 201.12.1.102 of ISO 80601-2-61:2011 was not conducted. Viatom does not make any claims about the accuracy of SpO_2 measurements under conditions of low perfusion, and therefore testing in accordance with Clause 201.12.1.103 of ISO 80601-2-61:2011 was not conducted.

The device uses the same SpO_2 measurement technology provided in the Checkme Pro health monitor. So the graph can also reflect the clinical study condition of the Oxiband pulse oximeter.



8 Electromagnetic Compatibility

The device meets the requirements of IEC 60601-1-2.

⚠ Warnings and Cautions

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of this device.
- Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).

Guidance and manufacturer's declaration– electromagnetic emissions		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	The quality of the power supply should meet the requirements of a typical commercial (initial power supply) or medical environment.
Surge IEC 61000-4-5	± 1 kV line to line ±2 kV line to earth	± 1 kV line to line ±2 kV line to earth	The quality of the power supply should meet the requirements of a typical commercial or medical environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 250/300 cycles	0% UT (100% dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 250/300 cycles	The quality of the power supply should meet the requirements of a typical commercial or medical environment.If the user of this product needs to continue poerating during power interruption,it is recommended to use uninterruptible power supply or battery power.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE : U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC61000-4-6	$3V_{rms}$ 150kHz to 80MHz (6V in ISM and amateur radio bands between 0.15MHz and 80MHz)	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d = 1.2 $\sqrt{P}$ d= 1.2 $\sqrt{P}$ 80MHz to 800MHz d= 2.3 $\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.7GHz	10V/m	

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter			
The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150kHz to 80MHz d = 1.16 $\sqrt{P}$	80MHz to 800MHz d = 1.16 $\sqrt{P}$	800MHz to 2.5GHz d = 2.33 $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Manufacturer: Shenzhen Viatom Technology Co., Ltd
ddress: 4E, 3#, Tingwei Industrial Park, Honglang
North 2nd Road, Baoan
District, Shenzhen, China

Weibsite: www.welluehealth.com

EC REP MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

CE 0197

Model: PO6B、PO6C
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.