Operation Manual of Pulse Oximeter

Note

Read this manual carefully for correct operation before using the Pulse Oximeter.

Keep the manual properly for reference at any time when necessary.

Product Name: Pulse Oximeter

Specification and model: OX201

Product structure and component: the equipment is composed of host, battery and display screen.

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Table of Content

1 Safety Information

1.1 Safety Information

1.1.1 Warning

(1) Only qualified personnel designated by the manufacturer is allowed to maintain the equipment. Users themselves are not allowed to repair the equipment.

(2) Explosion hazard: not use the equipment in environment with inflammable substances such as anesthetics.

(3) Not use the equipment in MRI and CT examination.

(4) When used with electrosurgical equipment together, the user shall ensure the safety of the monitored patient.

(5) Users who are allergic to silicone rubber is forbidden to use this equipment.

(6) The equipment, accessories and packaging (batteries, plastic bags, foam and cartons, etc.) shall be scrapped in compliance with local laws and regulations.

(7) Forbid to use the equipment once the equipment is found damaged, or have material deterioration.

(8) Do not use the equipment under the application conditions beyond its declared specification scope.

(9) When using the equipment for long-term continuous monitoring, check and replace measured parts at least every 2 hours. It is necessary for more frequent examinations in some scenarios, such as perfusion disorders and skin sensitivity. Prolonged monitoring may increase unpredictable skin changes, such as allergies, reddening, blistering, or compressive necrosis.

(10) For the special patients, there should be a more prudent inspecting in the placing process.The device cannot be clipped on the edema and tender tissue.

(11) The light (the infrared is invisible) emitted from the device is harmful to the eyes, so theuser and the maintenance man should not stare at the light.

(12) Testee cannot use enamel or other makeup.

(13) Testee's fingernail cannot be too long.

(14) Ensure that the environment in which the device is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away High level electromagnetic radiation emitted from such devices may greatly affect the monitor performance.

(15) Be careful with the use of the lanyard cord. Improper use of the lanyard cord will cause device damage not covered under the manufacturer's warranty. Swinging the device by the lanyard cord will void the warranty. Please do not use lanyard cord if allergic to lanyard cord.

(16) Please choose the accessories and probe which are approved or manufactured by the manufacturer, or else it may damage the device.

(17) Please don't measure this device with functional tester for the device's related information.

(18) When uploading, do keep the patient form touching the USB port. The computer used when uploading must be in accordance with EN60950.We recommended to use Lenovo Qitian M320,etc,in addition, when the data line connected to a computer, the medical electrical systems should be in accordance with IEC60601-1-1.

(19) It is not recommended to use the equipment in electric knife and other high frequency interference environment.

(20) Children are not recommended to operate the equipment directly and they must operate the equipment under adult supervision.

(21) Keep the application environment free of dust, vibration, corrosion or combustible substances, and avoid temperature and humidity too high or too low.

(22) Turn off the equipment immediately if water splash the equipment or there is condensate in the equipment.

(23) Do not use the equipment immediately when it is transferred from cold environment to warm and humid place.

(24) There is a visual indicator of low battery capacity in the equipment. Replace batteries in time when the low battery indicator appears.

(25) High temperature or high pressure steam disinfection of the Pulse Oximeter is not permitted.

(26) Do not have the Pulse Oximeter immerged in liquid. When it needs cleaning, please wipe itssurface with medical alcohol by soft material. Do not spray any liquid on the device directly.

(27) When cleaning the device with water, the temperature should be lower than 60℃ (140℉).

(28) As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients' SpO_2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.

(29) The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.

(30) Please read the measured value when the waveform on screen is equably and steady-going, This measured value is optimal value.

(31) If some abnormal conditions appear on the screen during test process, pull out the fingerand reinsert to restore normal use.

(32) The device has normal useful life for three years since the first electrified use.

(33) The device has the function of limits alarming, when the measured data is beyond thehighest or lowest limit, the device would start alarming automatically on the premise of the alarming function is on.

(34) The device may not work for all patients. If you are unable to achieve stable readings,discontinue use.

(35) A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

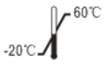
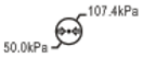
(36) Take out batteries if the equipment is not used for a long time.

(37) Properly carry the equipment and prevent it from falling, collision, strong vibration or other mechanical external force damage.

1.2 Symbol of Equipment

There are all or partial symbols in the equipment provided to you.

Symbol	***Implication***	***Symbol***	***Implication***
	BF application part		No alarm indication (The equipment has no alarm function)
IP22	IP code of the device: this device's grade of against ingress of solid foreign objects -- ≧ 12.5mm diameter (and the against access to hazardous parts with finger); the grade of waterproof is dripping (150 tilted).		Date of production
	Fragile, handle with care		Manufacturer information

	Keep dry		This side up
	Range of storage temperature		Stacking level
	Range of storage humidity		Range of atmospheric pressure
CE 1639	Complies with the European Medical Device Directive (93/42/EEC and amended Directive 2007/47/EC. Notified Body is SGS Belgium NV		Disposal in accordance with Directive 2002/96/EC (WEEE)
EC REP	Authorized representative in the European Community. The European representative is: Shanghai International Holding Corp. GmbH (Europe)	SN	Batch and serial number
	Follow operating instructions		

2 Overview

2.1 Product Introduction

2.1.1 Measurement Principle

Blood oxygen saturation, a key parameter of physiological circulatory system, means the percentage of oxyhemoglobin in total hemoglobin. Many heart diseases or respiratory system diseases may cause the decrease of blood oxygen saturation in human body. Besides, the automatic adjustment function of the body caused by anesthesia, major surgical trauma, and some injuries resulting from medical examination may cause the abnormal oxygen supply of the patient, which may lead to the decrease of blood oxygen saturation, resulting in dizziness, weakness, vomiting and other symptoms, and even giving rise to life-threatening symptoms in serious case. Therefore, knowing the patient's oxygen saturation in time is very important for doctors to detect problems in a timely manner and it is of great significant in the field of clinical medicine. The equipment applies the continuous and noninvasive quantitative method of pulsating blood oxygen. It measures the flux arriving at the photodetector of the sensor after the specific wavelength of light emitted from the sensor's light source is absorbed by the hemoglobin oxyhemoglobin in the patient's tissue, and then obtains the blood oxygen saturation and pulse rate.

The Pulse Oximeter has been calibrated to show functional blood oxygen saturation. The plethysmography waveform and parameter value will be displayed on the screen.

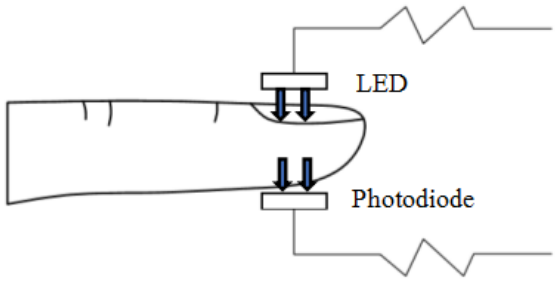


Figure 1 Schematic Diagram of Working Principle

2.1.2 Scope of Application

This equipment is used to measure blood oxygen saturation and pulse rate of patients.

It is expected to used by medical institutions, health care institutions or individuals.

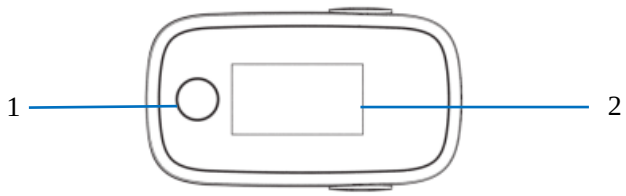
And it is suitable for adults and children

2.1.3 Contraindications

No contraindications

2.2 Product Structure and Appearance

2.2.1 Front View



1. ON / OFF Button

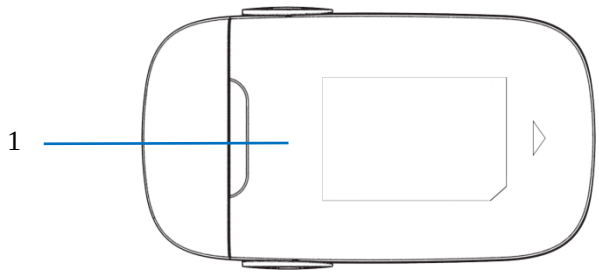
Turn on: after batteries are installed in the Pulse Oximeter, press **ON/OFF Button** to turn on the equipment.

Turn off: If the Pulse Oximeter does not detect the finger within 8 seconds, it will automatically shut down.

2. Display screen

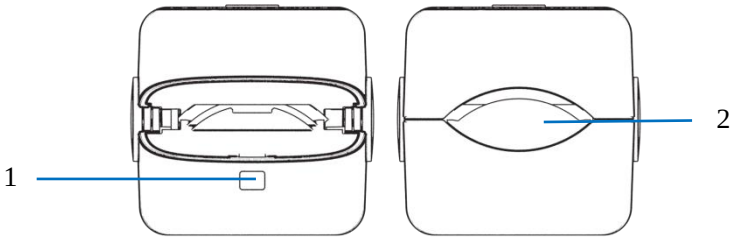
OX201: adopt OLED display screen.

2.2.1 Rear View



1．Battery compartment: two AAA batteries.

2.2.2 Side View

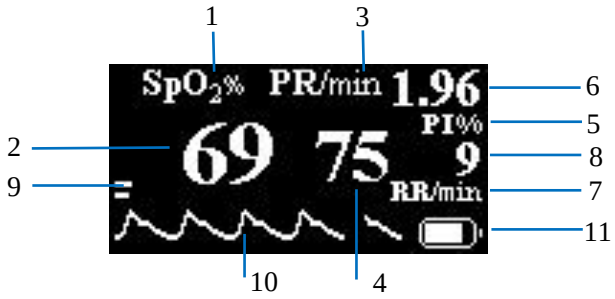


1．Hole of rope: to tie role.

2．Cavity of finger clip: place finger in this cavity to measure blood oxygen saturation.

2.3 Product Display

2.3.1 OX201 Display Screen



1．Unit of blood oxygen saturation: SpO_2%

2．Measured value of blood oxygen saturation: the display range is [1 ~ 100] and the sign “---” means invalid value.

3．Unit of pulse rate: PR/min

4．Measured value of pulse rate: the display range is [25 ~ 250] and the sign “---” means invalid value.

5．Unit of perfusion index: PI%

6．Measured value of perfusion index: the display range is [0.02 ~ 20.0]and the sign “---” means invalid value.

7．Unit of respiratory rate: RR / min

8．Measured value of respiratory rate: the display range is [4 ~ 70]and the sign “---” means invalid value.

9．Bar chart: showing the instantaneous state of blood pulse which is proportional to pulse intensity.

10．Tracing wave: display physiological pulse waveform, and non normalized processing.

11．Battery capacity: the indicator’s lighting length varies with remaining battery capacity.

3 Basic Operation

3.1 Installment

3.1.1 Battery Installment

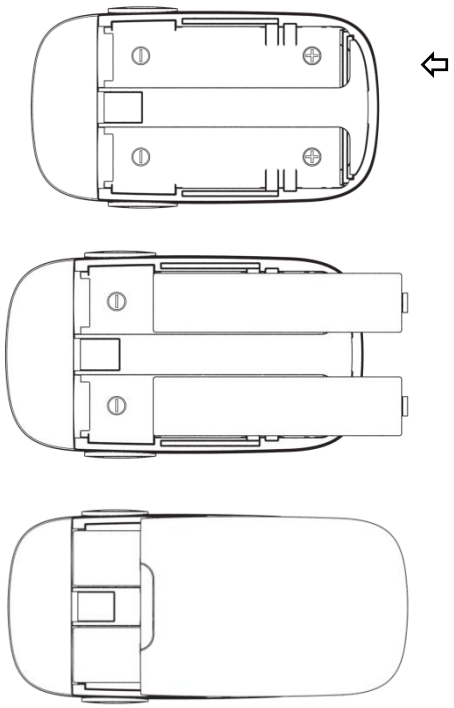


Fig. 2 Schematic Diagram of Battery Installment

1. Ensure the polarity of two AAA batteries in consistent with the polarity mark in the battery compartment;
2. Place two AAA batteries into the battery compartment gently.
3. Make the battery compartment covered rightly.

Note:

- ✧ Ensure correct polarity when install batteries.
- ✧ Please take out the battery if you do not use the thermometer for a long time.
- ✧ Please refer to the relevant laws and regulations for the disposal of waste batteries.
- ✧ Only use the recommended batteries, do not recharge non-rechargeable batteries and do not burn them.

3.1.2 Tie rope

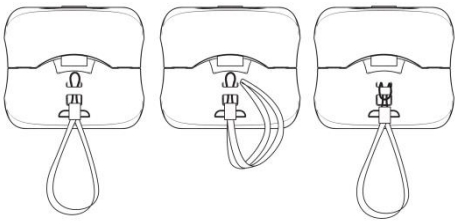


Fig. 2 Schematic Diagram of Rope

1. Put the thin end of the rope through the hanging hole.
2. Put the thicker end of the role through the thin end.
3. Tighten the rope.

3.2 ON/OFF

Turn On: after installing batteries, press **ON/OFF Button** to turn on the equipment. Enter into the measurement interface after the system starts.

If the Pulse Oximeter does not detect the finger within 8 seconds, it will automatically shut down.

4 Measurement

4.1 Alarm

1. Carefully check the measurement part before wearing the Pulse Oximeter. Do not wear the Pulse Oximeter to the damaged skins or tissues.

2. Do not place the Pulse Oximeter on the side of body with artery catheter or intravenous injection tube.

3. Do not put the Pulse Oximeter and blood pressure cuff on the same side of body as the blood flow occlusion during the course of blood pressure measurement may affect the reading of blood oxygen saturation.

4.2 Measurement Procedures

1. Press **ON/OFF Button** to turn on the Pulse Oximeter;

2. Open the finger clip, put the finger into cavity, and then release the finger clip. Make the display screen above the finger clip when putting the finger.

As shown in the figure below:

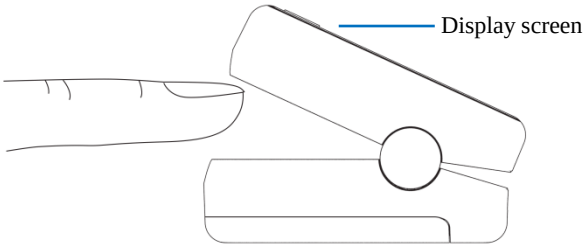


Fig. 4 Diagram to Wear Equipment

4.3 Measurement Precautions

(1) Please check the device before using, and confirm that it can work normally.

(2) The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject' sarteriole in a position there between.

(3) The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.

(4) Do not fix the SpO_2 sensor with adhesive or else it may result in venous pulsation and inaccurate.

(5) Put the proper finger into the Pulse Oximeter. The measured value may be affected if the finger is too cold or thin.

(6) The finger shall be inserted to the finger clip cavity deeply enough, and otherwise, the measured value may be inaccurate. Ensure the light between the photoelectric receiving tube and the luminescent tube of the Pulse Oximeter shall passes through the small artery bed of the finger of the subject.

(7) Keep the place where the light path passes free from light barriers such as adhesive tape to ensure the accuracy of parameter measurement.

(8) The product is suitable for children and adults with finger thickness of 7mm ~ 25.4mm.

(9) The measurement will be affected by excessively strong ambient light, including but not limited to fluorescent lamp, double Ruby lamp, infrared heater, direct sunlight, etc.

(10) The measurement accuracy will be affected if the subject performs strenuous activities.

(11) The interference of electrical surgical equipment may affect the measurement accuracy.

(12) The nail on the test site shall be free from nail polish and other cosmetics. To ensure measurement accuracy, remove nail polish or other cosmetics if any.

(13) The measured value of blood oxygen saturation may be inaccurate in case there is high content of the dye dilution drugs (such as methylene blue, indigo cyanide green, acid indigo carmine), carbon monoxide hemoglobin, methemoglobin or Thiohemoglobin and others in the body of the subject.

(14) Dopamine, Procaine, Procaine, Lidocaine, Buzocaine and other drugs will cause serious deviation in the measurement of blood oxygen saturation.

(15) The measured value of blood oxygen saturation is for reference only to anaemic hypoxia and toxic hypoxia. Some patients with severe anemia may still have higher measured value of blood oxygen saturation due to physiological reasons.

As the measure is taken on the basis of arteriole pulse,substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

4.4 Bluetooth and APP

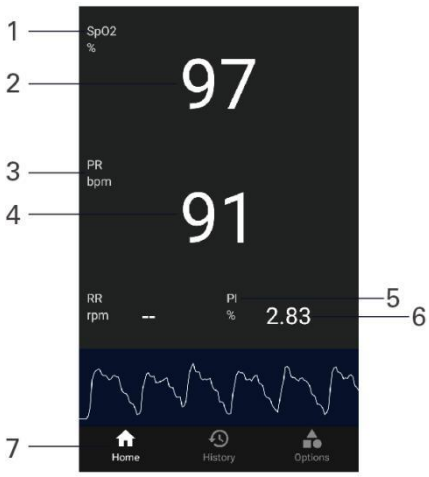
4.4.1 Download instructions

1.Scan the code and install the app, as shown in the figure below.

2.Open the download link at https://www.pgyer.com/spo2? Sign=& auSign=& Code = Download mobile APP-NargMed.

4.4.2 Operation interface description

1.Click the“connect to device” button. Then switch to the measurement interface.



1. Unit of blood oxygen saturation: SpO2%。

2. Measured value of blood oxygen saturation: the display range is [1 ~ 100] and the sign “---” means invalid value。

3. Unit of pulse rate: PR/min。

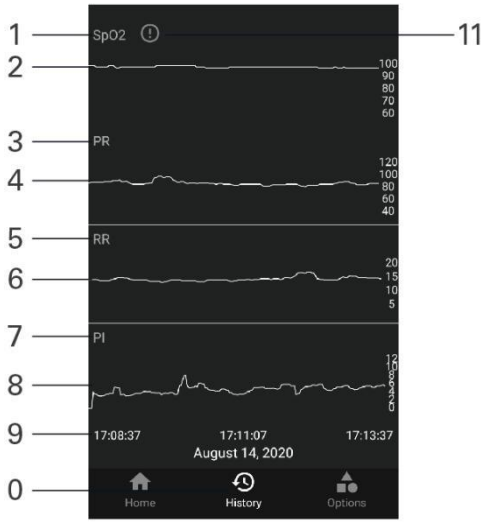
4. When the unit of pulse rate (3) lights up, display the measured value of pulse rate. The display range of pulse rate is [25 ~ 250] and the sign “---” means invalid value.

5. Unit of perfusion index: PI%

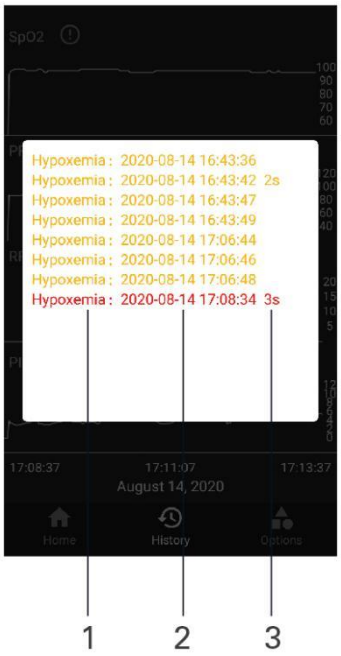
6. Measured value of perfusion index: the display range is [0.02 ~ 20.0]and the sign “---” means invalid value.。

7. Home。

2. Click the“History” button. Then switch to the historical data view interface.

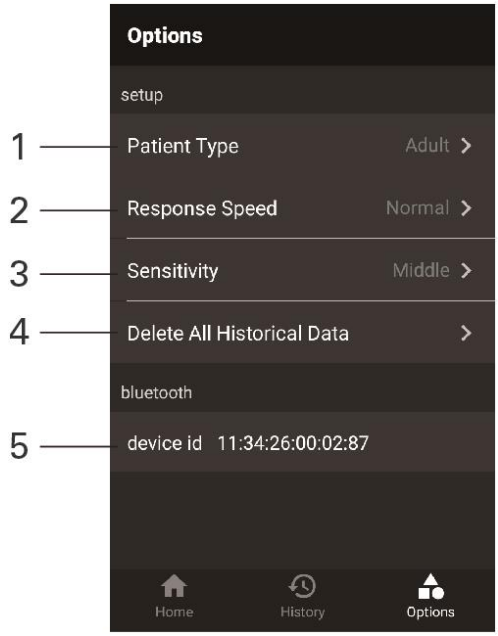


1. Unit of blood oxygen saturation: SpO2%
2. SpO2 historical data. Swipe left and right to view historical data.
3. Unit of pulse rate: PR/min
4. PR historical data. Swipe left and right to view historical data.
5. Unit of respiratory rate: RR / min
6. RR historical data. Swipe left and right to view historical data.
7. Unit of perfusion index: PI%
8. PI historical data. Swipe left and right to view historical data.
9. Historical data timeline
10. Historical Data menu
11. Click the “  ” button to see historical hypoxemia occurrence time



1. Historical oxygen drop events：Hypoxemia and Insufficient blood perfusion
2. Time of event
3. Duration

3. The parameters of the oximeter can be set through the following menu.



1. Patient type setting. Including: adult children
2. Response speed setting. Including: Rapid，Normal，slow
3. Sensitivity setting. Including: low，Middle，High.
4. Delete all Historical Data
5. Device search list

5 Product Specification

5.1 Specification of host

1．The product uses internal power supply.

2．Power requirements: 2 AAA batteries

3．Liquid inlet protection degree: IP22

4．Operation mode: run continuously

5． Electrical safety classification: BF type application part

6．Not suitable to use in places with flammable anesthetic gas.

7．Normal working conditions: ambient temperature range: 10 ~ 40 ℃ (50 ~ 104℉); ambient humidity range: 15% ~ 95% non condensing; atmospheric pressure range: 70kPa ~ 106kpa

8．Storage environment: environment temperature range: - 20 ~ 60 ℃ (-4 ~ 140℉); environment humidity range: 15% ~ 95%, non condensing; atmospheric pressure range: 50kPa ~ 107.4kpa

9．Physical dimension: 61.8×34.2×33.9mm

10．Product weight: About 50g (including battery)

11．Parameters of LED light source

12．Data shall be refreshed within two seconds. The average time of data is set in accordance with 3.5.7 and data in set average time will be selected and averaged.

Light Source	*Central Wavelength*	*Radiant Power*
Red light	660nm	<15mW
Infrared light	905nm	<15mW

5.2 List of Functions

List of Functions	*OX201*
Measurement of blood oxygen saturation	√
Measurement of pulse rate	√
Low battery indication	√
Display of pulse histogram	√
Display of perfusion intensity	√
Turn off automatically in eight(8) seconds if there is no finger	√
Bluetooth connectivity	√
Waveform display	√

5.3 Performance Index

1. Measurement scope and accuracy of blood oxygen saturation Measurement range: 1%～100%. Within measurement range of 70%～100%, the measurement accuracy is ±2%

2. Measurement range: 25 bpm～100bpm. The measurement accuracy is ±2bpm. Measurement range: 101 bpm～250bpm. The measurement accuracy is ±2%bpm.

3. Measurement scope and accuracy of respiratory measurement The measurement scope of respiratory rate is between 4rpm~70rpm with measurement accuracy not specified.

6 Maintenance

Regular maintenance is of great importance to ensure the normal operation of equipment.

⚠Caution：

- All safety inspection or maintenance work of equipment to be disassembled shall be carried out by professional maintenance personnel, and the non-professional personnel may cause equipment failure.
- If there is any problem with the equipment, please contact the maintenance personnel or our company.

6.1 Cleaning and Disinfection

1. Clean surface of the Pulse Oximeter before it is used for patients.

2. Shut down the equipment and take out batteries.

3. Clean the silica gel (inside face of the Pulse Oximeter, that can be contacted by finger when normal use) by wetting a small piece of cloth with isopropyl alcohol---75% medical alcohol.

4. Then to dry the Pulse Oximeter with a dry, soft cloth.

6.2 Maintenance

The design life of the product is 3 years. Please maintain the equipment as follows:

1. Clean and disinfect the equipment according to this instruction before using.

2. Replace batteries in time when the low battery indicator appears.

3. Take out batteries if the equipment will not be used for a long time.

4. The equipment shall be stored indoor, with temperature at - 20 ~ + 60 ℃ (-4 ~ 140℉), relative humidity no higher than 95%, free of corrosive gas and good ventilation. Moisture and light may affect the service life of the equipment, and even cause equipment damaged.

6.3 Troubleshooting

Only professional maintenance personnel is allowed to disassembled the Pulse Oximeter. There are no parts inside the equipment to be adjusted.

Malfunction	***Possible Cause***	***Solution***
Unable to turn on the equipment	Low or dead battery	Replace batteries
	No install batteries correctly	Install batteries correctly and ensure correct polarity
	Equipment is damaged	Contact the local customer service center
Blood oxygen saturation or pulse rate fail to display	Not insert fingers correctly	Put fingers correctly
	The patient's finger are too thin, resulting in light leakage.	Put a thicker finger
	The patient's finger is cold so that the blood perfusion is too low.	Keep the finger warm and put another finger for measurement.
	nail polish or manicure	Remove nail polish or manicure
Unstable display of blood oxygen saturation or pulse rate	No insert finger deep enough	Put the finger correctly
	Movement interfaces signal	Stay still
LED goes out suddenly	The product is designed to shut down automatically when no signs is detected.	Normal
	Low battery	Replace battery

7 Accessories

1. One pulse Pulse Oximeter
2. Two batteries（optional）
3. One manual

8 EMC Specification

The instructions for use shall include the following:

1： (a statement of the environments for which the Pulse oximeter is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed, e.g. hospitals except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.)

2： (the performance of the Pulse oximeter that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term “ESSENTIAL PERFORMANCE” need not be used).

3: (a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and MODEL OR TYPE REFERENCE).)

WARNING:

1. a warning statement to the effect that “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.

2. a warning statement to the effect that “WARNING:

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this the Pulse oximeter could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

3. a warning statement to the effect that: “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 the Pulse oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

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

Guidance and manufacturer ´s declaration – electromagnetic emission

The **Pulse oximeter** is intended for use in the electromagnetic environment specified below. The customer or the user of **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 Pulse oximeter uses RF energy only for its internal function. There for, 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 Pulse oximeter 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	Not applicable	
Voltage fluctuations flicker emissions IEC 61000-3-3	Not applicable	

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

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 ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0 ° 0 % UT; 250/300 cycle	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Pulse oximeter** requires continued operation during power mains interruptions, it is recommended that the **Pulse oximeter** be powered from an uninterruptible power supply or a battery.
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 a. c. mains voltage prior to application of the test level.

Guidance and manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM

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 IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	N/A 10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the **Pulse oximeter**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d=[\frac{3.5}{V_1}]\sqrt{P}$ $d=[\frac{12}{V_2}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz 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).[b] 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: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the**Pulse oximeter** is used exceeds the applicable RF compliance level above, the **Pulse oximeter** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the**Pulse oximeter**.

[c] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS

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 of transmitter W	**Separation distance according to frequency of transmitterm**			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70

10	3.8	6.32	1.10	2.21
100	12	20.00	35	70

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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.

FCC Statement

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.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This equipment should be installed and operated with a minimum distance of 0mm between the radiator and your body.

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.