yuwell 鱼跃

Model: YX500S/YX500M/YX500L/YX501S/YX501M/YX501L

Pulse Oximeter

Use Manual

Please read the Use Manual carefully before use! (Pictures are for reference only. Please subject to the actual product)

Scan the QR Code for
Immediate Online Services

Table contents

I. Warnings and Safety Notices

Warnings:

1. Do not forcefully squeeze the ring.
2. Do not modify the pulse oximeter without authorization from the manufacturer.
3. Do not use a functional tester to evaluate the accuracy of a pulse oximeter. The functional tester can only be used to check whether the device is operating properly. The pulse oximeter can be tested with the KWD OFFOLLOW simulator, select a specific curve (Yuwell 500), and verify whether the SpO_2 or pulse rate can be displayed normally by setting a fixed SpO_2 or pulse rate.
4. Do not use oximeter if it appears or is suspected to be damaged. Damage to internal parts can result in no or inaccurate reading.
5. Do not place the pulse oximeter within reach of children or infants to avoid choking caused by the charging cable wrapping around the neck.
6. Do not use the information displayed on the pulse oximeter as the sole basis for clinical diagnosis. The pulse oximeter is only used as an auxiliary diagnostic tool and must be used in conjunction with clinical manifestations and symptoms and the doctor's diagnosis.
7. Do not stare at the light (the infrared is invisible) emitted from the oximeter, which is harmful to the eyes.
8. Do not use the pulse oximeter for other purposes. Do not place the pulse oximeter on edematous or fragile tissues.

Safety notices:

1. SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
2. Target users of the pulse oximeter: adults and children; Applicable area: Fingers.
3. The pulse oximeter is easy to operate. Operators only need to have a certain level of reading ability (e.g. People who have received 8 years of education) and can operate without additional training.
4. The pulse oximeter is not recommended for use during motion or under low perfusion conditions.
5. The pulse oximeter is calibrated to display functional oxygen saturation. The device has been calibrated before leaving the factory. Users can send the pulse oximeter to a professional inspection institution and use a blood oxygen simulator to conduct periodic tests on its basic safety and fundamental performance once every year.
6. Check the SpO_2 sensor site every 6-8 hours to ensure adequate circulation, skin integrity, and sensor alignment. Skin damage, pressure necrosis, or inaccurate readings may result.
7. The pulse oximeter is not equipped with functions for SpO_2 and pulse rate alarms, and cannot be used as an alarm device and in places where the measurement value exceeds the limit alarm function. If the product is used in an environment that requires an alarm, there is a risk of not being able to obtain abnormal patient conditions in a timely manner.
8. Materials that come into contact with the human body (such as plastic casings

and silicone) have passed the biocompatibility testing.

9. The pulse oximeter conforms to the requirement of RoHS directive.
10. The maximum skin surface temperature is below 41℃(106℉) when measured in a 35℃(95℉) environment, which has been verified by measuring the skin surface temperature via a Pulse Oximeter under the reasonable worst conditions.
11. Please avoid the following situations to minimize the risk of inaccurate measurements:
    - Improper placement of the finger or incorrect contact with the sensor;
    - Presence of dysfunctional hemoglobin (e.g. carboxyhemoglobin or methemoglobin) in significant amounts;
    - Blood vessels contain dyes (such as indigo green or methylene blue);
    - Presence of external pigments and substances on the test site (e.g., glitter);
    - Users placing the pulse oximeter on an arm with an arterial catheterization or blood pressure cuff during measurement;
    - Elevated bilirubin levels and severe anemia;
    - Venous congestion and venous pulsations;
    - Extremely low arterial perfusion levels;
    - Excessive motion;
    - During cardiac arrhythmia.
12. The technology used in Pulse Oximeter has been verified with accuracy when there is no motion via human blood studies on healthy adult volunteers of both male and female with light to dark pigmented skin in induced hypoxia studies in

the range of 70%-100% SpO_2 against a laboratory co-oximeter. When required, the manufacturer can provide Graphical Plot of SaO_2 versus error (SpO_2 – SaO_2).

13. The accuracy of the pulse oximeter within the declared range of 25 bpm to 300 bpm has been verified through simulator and bench testing.
14. This product contains batteries and recyclable electronic waste. Waste batteries and scrapped products should be disposed of in accordance with local regulations to avoid pollution.
15. This product can be operated by patients to measure SpO_2 and pulse rate, or by others. The operation and maintenance methods are the same.
16. If necessary, for assistance in installing, using, or maintaining the pulse oximeter, or reports of abnormal operations or events, you can directly contact the manufacturer.
17. When the ambient temperature is 20℃, the time required for the pulse oximeter to warm/cool from the minimum/maximum storage temperature to the normal operating temperature is about 60 minutes.
18. The aging of sensors may reduce measurement performance or cause other issues.
19. When multiple devices are used simultaneously on the same patient, it may pose additional risks. It is recommended to consult the manufacturer for the correct usage method to ensure that the leakage current is within the safe allowable range, that is, it will not cause harm to patients, operators, and the surrounding

environment.

20. In case of any accident during the use of the product, please call the emergency hotline immediately and seek the help of a medical professional.
21. Under the combined effect of environment and frequency of use, the temperature of the inner wall of the product ring may reach 43℃. Before use, be sure to ensure that the finger skin is intact. If you feel burning during use, immediately remove the pulse oximeter and stop using it.

II. Product Introduction

1. Product name: Pulse oximeter
2. Product models: YX500S, YX500M, YX500L, YX501S, YX501M, YX501L;
3. Structure and composition: Composed of a main unit and a charging cable.
4. Measurement principle

   An experience formula of data process is established taking use of Lambert Beer law according to Spectrum Absorption Characteristics of deoxyhaemoglobin (HHb) and Oxyhemoglobin (O_2Hb) in glow and near-infrared zones.
5. Operating principle

   Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of light (red light and infrared light) can be focused onto human finger through perspective clamp finger-type

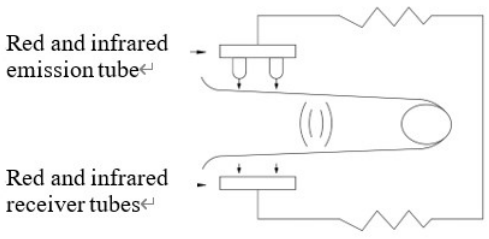


Diagram of operating principle

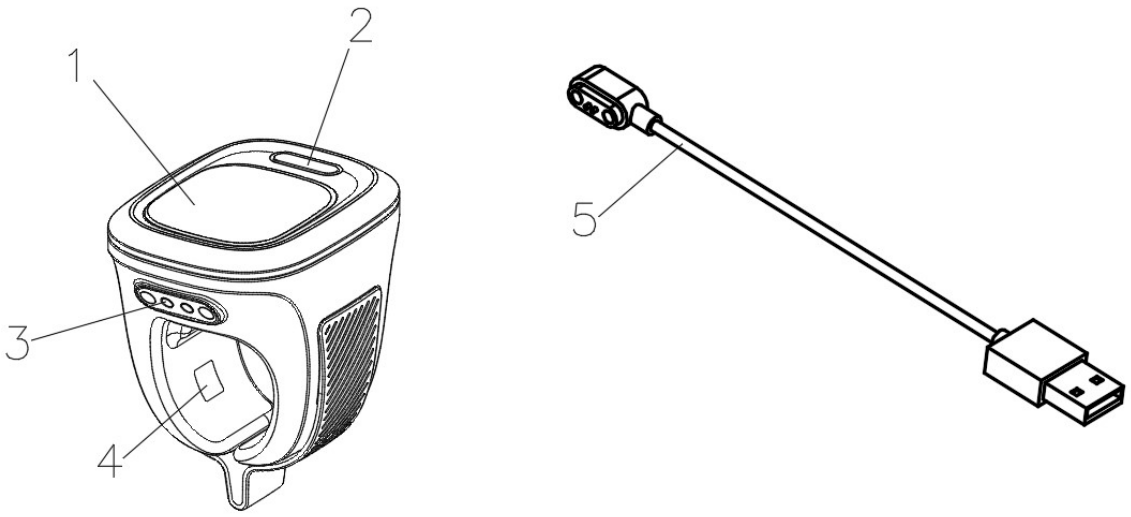
sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown display through process in electronic circuits and microprocessor.

6. Intended purpose

   The Pulse Oximeter is a kind of non-invasive device which can measure and display SpO_2 and pulse rate. It is intended for adults and children and is expected for home and hospital inspection.

7. Contraindication: none.

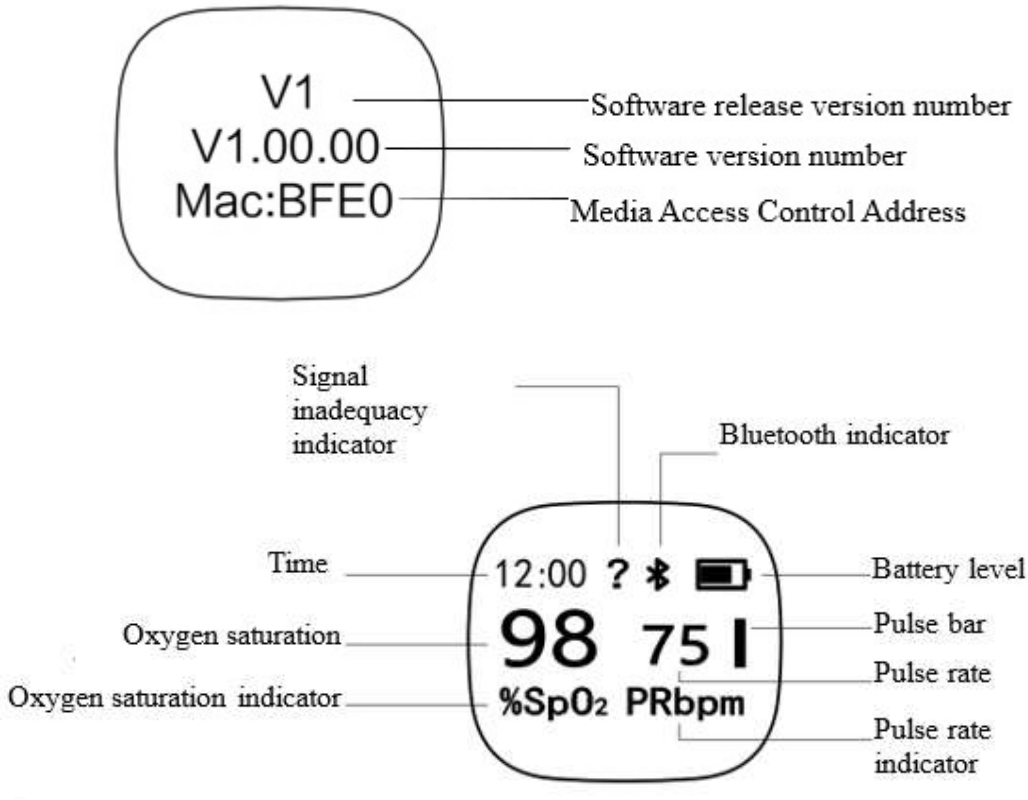
8. Diagram of outline structure



Items	Description	Function
1	Display screen	Display device status and measurement results.
2	Touch button	When the display screen goes off during measurement, lightly touch the button to turn on the screen； During measurement, lightly touch the button to achieve the function of turning the display content on

		the display screen. After the device is powered on, use this button to enable or disable the vibration function.
3	Charging interface	Connect the charging cable to charge the pulse oximeter.
4	Blood oxygen sensor	Detect oxygen saturation and pulse rate.
5	Charging cable	Connect the charging interface to charge the pulse oximeter.

9. Diagram of the display screen



III. Symbols and Meanings Related to Safety Requirements in the Device:

Symbol	Meaning	Symbol	Meaning
	Refer to instruction manual	CE 0123	This device is compliant with

	(Background: Blue; Symbol: White)		Medical Device Regulations 2017/745
	TYPE BF APPLIED PARTS		Serial number
	Caution		Manufacturer
	Medical devices		Batch code
	Signal inadequacy indicator		Date of manufacture
IP22	Protected against solid foreign objects of 12.5 Φ mm and greater. Protection against vertically falling water drops when ENCLOSURE tilted up to 15°		MR Unsafe. Not appropriate for use in MR environment (i.e.: inside the MR magnet room)
%SpO_2	Oxygen Saturation (%)	PR	Pulse rate (bpm:1/min)
	Alarm inhibit		Waste from electrical and electronic equipment (WEEE)
	Standby/operation key		Use-by data
	Safety and environmental protection use period for 10 years		Authorized representative in the European Community
	This way up		Humidity limitation
	Fragile, handle with care		Atmospheric pressure limitation
	Keep dry		Temperature limit
	General symbol for recovery /recyclable		Non-ionizing radiation
	Bluetooth indicator		

IV. Technical Parameters

1. SpO_2:

   Display range: 0%～100%;

   Declared range: 70%～100%

   Accuracy: a) ±2% in the range of 70%～100%;

   b) No definition under 70%.

   Resolution: 1%.

2. Pulse rate:

   Display range/ Declared range: 25 bpm～300 bpm;

   Accuracy: ±2% or ±2 bpm, whichever is greater;

   Resolution: 1 bpm.

   Note: The accuracy (A_{rms}) is calculated by the measurement values after a statistical distribution; compared to the reference device in a control study, approximately 2-thirds of the values were at (over or below) the accuracy (A_{rms}) value.

3. Internally Powered ME Equipment. Rated voltage: DC 3.8 V.
4. TYPE BF APPLIED PARTS.
5. Degrees of protection provided by enclosures (IP code): IP22
6. Operation mode: Continuous operation.
7. When there is no operation and no signal detected, the pulse oximeter will automatically shut down within 8 seconds (±3 seconds).
8. LED light source parameters

Light Source	Wavelength (nm)	Radiation Intensity (I_F=20 mA)
Red light	660±15	<5 mW/sr
Infrared light	905±20	<5 mW/sr

Light source parameters are particularly useful for clinicians and may have an impact on other medical devices using this wavelength range. For example, clinicians performing photodynamic therapy.

9. Data averaging and signal processing cause delays in displaying and transmitting data values for SpO_2 and pulse rate. The measurement data update cycle is less than 30 seconds (in case of signal attenuation, weak perfusion, or other interferences, it will cause an increase in the time to take the dynamic mean).
10. When the reliability of the measured values is low, the product indicates a signal inadequacy.
11. The pulse column is normalized and the fluctuations tend to be regular and stable, the measured value read is optimal.
12. Dimension

Models	Size Approximately (L*W*H)	Weight Approximately
YX500S，YX501S	36mm*28mm*33mm	15 g
YX500M，YX501M	36mm*28mm*40mm	15 g
YX500L，YX501L	36mm*28mm*43mm	15 g

13. Product service life: 5 years.

14. Working Environments:

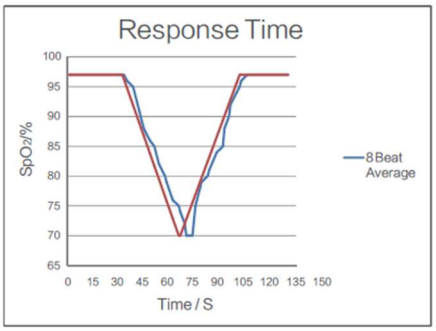
Ambient temperature: 5°C～40°C;

Relative humidity: 15%～90%, no condensation;

Atmospheric pressure: 700 hPa～1060 hPa;

Note: Please use the pulse oximeter in an environment that meets the performance requirements.

15. Device response time (see figure below)



16. Bluetooth information

Bluetooth specifications are as follows:

Transmitting and receiving frequency range	2402MHz-2480MHz
Receive bandwidth	1MHz, 2MHz
Frequency characteristics	UHF
Modulation	GFSK
Max Conducted TX Power	<8dBm

V. Preparation Before Use

Unpacking inspection

- Before unpacking, please carefully inspect the packaging box. If any damage is found, please contact the carrier immediately.

- After unpacking, carefully take out the pulse oximeter and other components from the packaging box, and check each item according to the packing list in the Manual. Check if the product and components are complete and if there is any mechanical damage. If you have any questions, please contact the Company immediately.
- Packaging waste should be treated as general garbage.

Environmental requirements

- Before using the pulse oximeter, ensure that the pulse oximeter is in normal operating condition and environment.
- To measure SpO_2 and pulse rate more accurately, use the pulse oximeters in a quiet and comfortable environment.
- Avoid using the pulse oximeter under high light sources, fluorescent lamps, infrared heating lamps, and direct sunlight to minimize interference that may result in inaccurate or no readings.
- Do not use the oximeter in the environment of magnetic field, electromagnetic field, external film noise, electrostatic discharge, pressure or pressure change, acceleration, hot ignition source, etc. Otherwise, it may result in the inability to read or inaccurate readings.

VI. Product Operation Steps

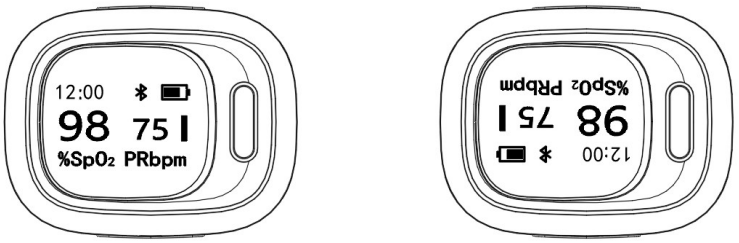
Startup

YX500S, YX500M, YX500L pulse oximeters are turned on by touching the button;

YX501S, YX501M, YX501L pulse oximeters will automatically turn on by inserting a finger. (As shown in the figure)

Measurement

1. After the pulse oximeter is turned on, the display interface will first display the product model and software version number, and then enter the measurement interface. After inserting your finger, you can start measuring.
2. You can directly read relevant data from the display screen. The display screen can show pulse oxygen saturation (% SpO_2), pulse rate (PR bpm), battery level, time, and pulse bar. When the Bluetooth connection is successful, the Bluetooth indicator is still displayed.
3. The pulse oximeter can achieve the display interface turning function by touching the button to facilitate to read data. See the figure below:



4. During the measurement, the display screen will automatically go off without any button operation; at this point, the display screen can be lit up by lightly touching the button.

Note:

- The thumb and index finger are recommended for measurement.

- If the circumference of the fingers to wear it is too small or too large, it may result in no or inaccurate readings. Please choose the appropriate finger for wearing and measuring based on the circumference of your fingers.
- The sensor must be in direct contact with the skin.
- Do not shake your fingers during use and try to keep your body still.
- In case of signal inadequacy (such as excessive signal noise, poor signal quality, or disappearance), the reliability of SpO_2 and pulse rate readings is low, and the display screen shows "?".
- When exposed to direct sunlight or bright light, the display screen may be difficult to view.

Vibration reminder

1. The pulse oximeter will vibrate when turned on, reminding that it has been turned on.
2. During the measurement, when the user's pulse oxygen saturation is below 93%, or the pulse rate is below 40 bpm or above 120bpm, the pulse oximeter will vibrate to alert the user.
3. Press and hold the button to enter the vibration reminder switch setting interface, press the button to select "  " or "  ", and after about 10 seconds of selection, it will automatically exit or exit the setting interface by pressing and holding the button.

Vibration reminder on the screen:

 Vibration reminder turned on;

Vibration reminder turned off;

Note: The vibration reminder function is only used to remind users to check their SpO_2 and pulse rate, and is not used as an alarm function. When users have questions about their SpO_2 and pulse rate, they must consult a doctor.

Shutdown

When there is no operation and no signal detected, the pulse oximeter will automatically shut down within 8 seconds (±3 seconds).

Bluetooth transmission

Scan the QR code on the back cover with your phone to download the application, and connect to the corresponding application via Bluetooth to view the detection data.

Data storage

During the measurement, the SpO_2 and pulse rate will be stored in the pulse oximeter.

VII. Battery

This product is powered by a rechargeable lithium battery (Model: 452019) and can be charged by connecting it to a USB power adapter through a charging cable.

1. Attach the magnetic suction head of the charging cable to the charging interface of the main unit, and plug the other end into the USB power adapter (input AC 100 V−240 V, output DC 5 V 1.0 A).
2. After connecting the power, the pulse oximeter enters the charging state, and the screen displays "", with the filling part dynamically displayed.

3. After the battery is fully charged, the dynamic display of the filling part stops, and it takes about 2.5 hours from "  " to "  ". At this time, the charging cable can be removed to stop charging.

Battery level display on the screen:

 Low battery level prompt, indicating that the battery is about to run out and needs to be charged in a timely manner, otherwise the device will automatically shut down.

 The filling part represents the remaining power.

 The battery is fully charged.

Warning:

- Do not charge near flammable and explosive materials to prevent fire or explosion.
- Do not charge at temperatures that are too high or too low, as this may affect the battery's service life and performance.
- Do not use the pulse oximeter while charging.
- After charging is completed, remove the charging cable in a timely manner. Do not charge the battery continuously for a long time to avoid damaging the battery.
- Do not disassemble, impact, squeeze, immerse, or put the battery into the fire to avoid battery explosion; if the battery swells, deforms, damages, leaks, or becomes moldy, please stop using it.
- Do not replace batteries without sufficient training to avoid the risk of

overheating, fire, or explosion.

Note:

- The USB power adapter should comply with the requirements of IEC 60601-1:2020 standard.
- After being fully charged, the battery can be used for about 20 hours. Considering the aging characteristics of lithium batteries, the usage duration may be slightly shortened, which is normal.
- When the expected single-use time is long, it is recommended to fully charge before use.
- If the device is not in use for a long time, please recharge every 6 months.
- The cycle life of the battery is ≥ 300 times.
- When the pulse oximeter crashes, it can be restarted by charging;

VIII. Cleaning and disinfecting

The pulse oximeter is a reusable non-sterile product. Please clean and disinfect according to the following methods.

Warning:

- Never immerse or soak the oximeter.
- We recommend cleaning and disinfecting the oximeter before or after each use, or in accordance with the policies established by the hospital, to avoid long-term damage to the oximeter and avoid cross-infection.
- Never use cleaning agents/disinfectants other than the recommended.
- The sensor component is not cleaned and disinfected during testing.

- Avoid the use of metals such as steel wire brush or polishing agent abrasive material which will damage the oximeter panel.

Cleaning

The recommended cleaning agents include: **Soap solution**.

1. Shut down the pulse oximeter.
2. Thoroughly wipe the device surfaces using non-linting cloth moistened (but not dripping) with soap solution for a minimum of three minutes, and then wipe them using non-linting cloth moistened (but not dripping) with bottled water for a minimum of three minutes.
3. After cleaning, dry thoroughly with a soft, clean, non-linting cloth.

Note:

- Prepare the cleaning solution in accordance with the detergent manufacturer's instructions. (using for example, Alconox® Powdered Precision Cleaner, 10 g/L).
- Pay particular attention to cracks, crevices, and hard to reach areas of the device.

Post-cleaning inspection

Inspect device visually after cleaning and prior to disinfection for cleanliness, damage, and missing or illegible device labeling or markings:

1. If there is any visible soil present, repeat the cleaning procedure.
2. Damaged device shall be removed from use. Damage may include but is not limited to corrosion, discoloration, excessive scratches, flaking, cracks, and wear.

3. Device that has missing or illegible device labeling or marking shall be removed from use.

Disinfecting

The recommended disinfectants include: **Isopropanol 70%**.

1. Clean the device before disinfection.
2. Wipe the device surfaces using non-linting cloth wetted (but not dripping) with 70% Isopropyl Alcohol (IPA).
3. Allow all surfaces to remain wet for a minimum of two minutes. If needed, use additional wipes to ensure the surfaces remain wet for the full duration.
4. After disinfection, dry thoroughly with a soft, clean, non-linting cloth.
5. Allow at least 5 minutes drying time before. Make sure device is clean and dry prior to use.

IX. Maintenance

The pulse oximeter (including charging cable) is expected to have a service life of 5 years and can be used for multiple patients. The device does not require special maintenance or calibration. When not in use for a long time, it is recommended to clean and disinfect this product once a week.

The electrical schematic diagram and component list are only provided to qualified maintenance stations or personnel confirmed by the manufacturer.

Warning:

- Do not disassemble, repair, or replace internal parts of this product without authorization;

- Please do not repair or maintain the device during use.
- Do not subject the pulse oximeter to high temperature, high pressure, or gas fumigation;

X. Transportation and Storage

Transportation and storage conditions:

Environmental temperature: -25℃～+70℃;

Relative humidity: ≤93%, no condensation;

Atmospheric pressure: 500 hPa～1060 hPa;

Note:

- This product should be stored indoors in a dry environment, without strong sunlight, corrosive gases, and good ventilation. A humid environment may affect the product's service life and even damage the product.
- Avoid exposure or direct sunlight, and avoid extreme radiation of infrared or ultraviolet rays.
- Avoid contact with organic solvents, mist, dust, and corrosive gases.
- When using and storing the product, prevent pets, insects, or children from causing damage to the product.

XI. Common Faults and Troubleshooting Methods

Warning:

- The cover of the pulse oximeter can only be opened by professional maintenance personnel, and there are no components inside that require adjustment by users.

- If it is uncertain whether the measurement value is accurate, please first use other methods to check the patient's pulse signal and determine whether the pulse oximeter can work normally.

Note: Do not splash, pour, or spill any liquid onto the pulse oximeter and its accessories, as it may damage the pulse oximeter.

Problem	Possible Causes	Resolution Methods
Unable to power on normally	Low or no battery power	Restart the device after charging.
	Product damage	Please contact the local customer service center
Abnormal or unstable measurement values	Incorrect placement of fingers	Re-insert the finger
	Excessive finger shaking or the human body being in motion	Please try to keep your body still as much as possible
	Excessively low finger perfusion index	Warm your fingers before retesting, or use another finger for testing
The measured value cannot be displayed normally	Not following the recommended steps to use a pulse oximeter	Please use the pulse oximeter properly according to the recommended steps
	The test area contains external pigments and substances	Remove external pigments and substances during measurement
	Finger circumference and pulse oximeter ring do not match	Choose the appropriate finger to wear
The display screen suddenly goes out	The product is set to automatically turn off the pulse oximeter screen during normal measurement without button operation.	Please lightly touch the button
	The battery level becomes low	Charge the device promptly.

XII. Accessory

Warning: To ensure the safety of the subject, please use components and accessories produced or recommended by the manufacturer. Using other accessories may cause injury or damage to the subject or operator of the pulse oximeter.

Charging cable: YX500-01 (Main material: TPE)

XIII. Electromagnetic Compatibility Instructions

Warning:

- To ensure electromagnetic compatibility, this product needs to be used according to the Manual.
- Keep the oximeter away from electrical equipment that emits radio frequencies to minimize radio interference. RF may result in inaccurate or inaccurate readings.
- Portable and mobile RF communication devices may affect the electromagnetic compatibility of this product.
- When using the pulse oximeter, please stay away from equipment that generates strong electric and magnetic fields (such as magnetic resonance equipment). Using this device in an inappropriate environment may cause interference to surrounding wireless devices or affect the operation of pulse oximeters. Electromagnetic interference sources include but are not limited to: Electrocautery devices, heat transfer devices, other mobile phones, wireless personal computers (PCs) and tablets, pagers, radio frequency identification (RFID) devices, magnetic resonance imaging (MRI), and electromagnetic safety

systems.

When there is interference, the product may exhibit abnormal phenomena such as unstable readings, shutdown, or other functional errors. If this situation occurs, it is necessary to inspect the usage site, identify the interference source, and take the following measures to eliminate it:

(1) Shut down the equipment in the vicinity and then re-open in order to identify interference equipment;

(2) To change the direction or location of the interference equipment;

(3) To increase the distance between the product and interference sources, the oximeter should keep a distance of not less than 30cm (12 inches) from electromagnetic interference source products.

(4) Interference from hidden RF emitters like RFID might be interrupted when working because of their interference. Move away from the hidden RF emitter or shut down and wait for the interference to disappear and retest if this happens.

- Use of the pulse oximeter adjacent to or stacked with other devices should be avoided because it could result in improper operation. If such use is necessary, the pulse oximeter and the other devices should be observed to verify that they are operating normally.
- If there is a fault in the charging cable of this product, please contact the Company for maintenance or replacement. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device

could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Cable information is as follows:

Cable Name	Cable Length (m)	Shield or not	Remarks
Charging cable	0.6	No	/

- The use should not use the oximeter and should inform the customer service, if the essential performance is lost or degraded due to EM disturbances.

The EMC environment for this product is the home healthcare environment and professional healthcare facility environment.

Basic performance determined:

The essential performance of this product is the accuracy of SpO_2 and pulse rate(SpO_2 Accuracy:±2% in the range of 70%-100% of SpO_2;Pulse rate Accuracy: ±2% or±2bpm(whichever is greater)).

Test Summary

Requirement-Test	**Result/Comments**	**Verdict**
Emissions		
Classification	-	-
Class A or B	Class B	-
Group 1 or 2	Group 1	-
CISPR 11, 14-1, 32 or CISPR 25	CISPR 11	-
Conducted Emissions	CISPR 11, Group 1, Class B	P
Radiated RF Emissions	CISPR 11, Group 1, Class B	P
Disturbance Power Emissions (if applicable)	N/A	N/A
Harmonic Distortion per IEC 61000-3-2 (Class A, B, C, D)	Class A	-
Voltage Fluctuations and Flicker per IEC	IEC 61000-3-3	P

61000-3-3		
Immunity		
Electrostatic Discharge	IEC 61000-4-2	P
Radiated RF EM Fields and Proximity fields from RF	IEC 61000-4-3	P
Electrical Fast Transients/Bursts	IEC 61000-4-4	P
Surges	IEC 61000-4-5	P
Conducted Disturbances Induced by RF fields	IEC 61000-4-6	P
Rated Power Frequency Magnetic Fields	IEC 61000-4-8	P
Voltage Dips and Interruptions	IEC 61000-4-11	P
Proximity Magnetic Fields	IEC 61000-4-39	P
Electrical transient conduction along supply lines	ISO 7637-2	P
Electrosurgery Interference	N/A	N/A

Table 1 - For ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – Radiated Emission				
Emissions test	**IEC60601 test level**		**Compliance level**	
Conducted Emissions	0.15MHz-0.5MHz 0.5MHz-5MHz 5MHz-30MHz	66dB-56dB 56dB 60dB	0.15MHz-0.5MHz 0.5MHz-5MHz 5MHz-30MHz	66dB-56dB 56dB 60dB

Table 2 - For ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – Radiated Emission		
Emissions test	**IEC60601 test level**	**Compliance level**
RF emissions CISPR 11	10m 30dB(μ V/m) 30MHz-230MHz 37dB(μ V/m) 230MHz-1000MHz	10m 30dB(μ V/m) 30MHz-230MHz 37dB(μ V/m) 230MHz-1000MHz

Table 3 - For ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – Radiated Emission		
Emissions test	**IEC60601 test level**	**Compliance level**

Voltage Fluctuations and Flicker per IEC 61000-3-3	Pst:≤1.0，Tp＝10min Plt:≤0.65，Tp＝2h dc:≤3.3% dmax:≤4% dt:≤3.3%，more than 500ms	Pst:≤1.0，Tp＝10min Plt:≤0.65，Tp＝2h dc:≤3.3% dmax:≤4% dt:≤3.3%，more than 500ms

Table 4 - For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – Electrostatic Discharge		
IMMUNITY test	**IEC60601 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ± 2 kV, ± 4 kV, ± 8 kV, ±15kV air	±8kV contact ± 2 kV, ± 4 kV, ± 8 kV, ±15kV air

Table 5 - For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture’s declaration – RF electromagnetic fields		
IMMUNITY test	**IEC60601 test level**	**Compliance level**
Radiated RF IEC 61000-4-3	3 V/m and 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	3 V/m and 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz

Table 6 - For ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture’s declaration – Electrical Fast Transients/Bursts		
Emissions test	**IEC60601 test level**	**Compliance level**
Electrical Fast Transients/Bursts	±2 KV 100 kHz repetition frequency	±2 KV 100 kHz repetition frequency

Table 7- For ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture’s declaration – Surge		
Emissions test	**IEC60601 test level**	**Compliance level**
Surge	±1 KV line to line	±1 KV line to line

Table 8- For ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – Surge		
Emissions test	**IEC60601 test level**	**Compliance level**
Conducted Disturbances Induced by RF fields	3V rms 150kHz to 80MHz	3V rms 150kHz to 80MHz

Table 9 - For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – Power-frequency Magnetic Fields		
IMMUNITY test	**IEC60601 test level**	**Compliance level**
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz and 60Hz

Table 10- For ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – Surge		
Emissions test	**IEC60601 test level**	**Compliance level**
Voltage Dips and Interruptions	＜5%UT(＞95% dip UT)for 300 cycles	＜5%UT(＞95% dip UT)for 300 cycles

Table 11 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**IMMUNITY Test LEVEL (V/m)**
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430-470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	28
710	704-787	LTE Band 13,17	Pulse modulation [b] 217Hz	9
745				
780				
810	800-960	GSM 800/900, TETRA 800, iDEN 820,	Pulse modulation [b] 18Hz	28
870				

930		CDMA 850, LTE Band 5		
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900 DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation [b] 217Hz	28
1845				
1970				
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217Hz	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217Hz	9
5500				
5785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.				

Table 12 - Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	**Modulation**	**IMMUNITY Test LEVEL (A/m)**	**Result**
30 kHz [a]	CW	8	Pass
134.2 kHz	Pulse modulation [b] 2.1 kHz	65 [c]	Pass
13.56 kHz	Pulse modulation [b] 50 kHz	7.5 [c]	Pass
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s., before modulation is applied.			

XIV. Packing List

S/N	Item	Quantity
1	Pulse oximeter	1
2	Charging cable	1
3	Manual (including a warranty card, a packing list, and a certificate of conformity)	1

XV. Terminology and definitions

Terminology	Definition
Accuracy	Closeness of agreement between a test result and an accepted reference value.
Data update period	Interval in which the pulse oximeter equipment algorithm provides new valid data to the display or the functional connection.
Displayed range	range of SpO_2 or pulse rate values that can be displayed by the pulse oximeter equipment.
Declared range	portion of the displayed range of SpO_2 and pulse rate values over which there is specified accuracy.
Normalized	Displayed at constant amplitude independent of the actual magnitude of the signal being displayed.
SpO_2	Estimate of SaO_2 made by pulse oximeter equipment.
SaO_2	Fraction of functional haemoglobin in arterial that is saturated with oxygen
Pulse rate (PR)	Pulse rate (PR), measured in beats per minute (bpm), is based on the optical detection of peripheral flow pulse.
Pulse bar	The amount of arterial blood in the fingertip tissue changes with your pulse(photoplethysmography). The amount of light absorbed by the varying quantities of arterial blood changes as well and the histogram is continuously used for tracing.

Warranty Card

Thank you very much for using our products.

FCC Statement

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.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment .

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.

CE 0123

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Due to the limited size of the label, the font is too small, please put it at a suitable location for viewing. All specifications and product configurations are subject to change without notification.

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