

Warning

- Warning, do not modify this equipment without authorization of manufacturer.
- Warning, the device has no Alarm System.
- Warning, keep away from the wet medical equipment such as drip or other similar liquid simulation as far as possible.
- Warning, do not use the Finger pulse oximeter on the same finger for over 30 minutes in one single use. Otherwise, it may cause skin damage, compressive necrosis, or inaccurate measurement readings.
- Warning, the device has been calibrated before leaving the factory. Except replacing batteries, devices do not require routine maintenance and calibration, etc. Daily measure ten times, ten minutes every time, devices can be used for five years.
- Do not use a functional tester to evaluate the accuracy of the Finger Pulse Oximeter. The functional tester shall only be used to check whether a unit is working properly.
- Warning, when discarding components (including the batteries) or this product, follow local regulations to avoid contamination.
- SpO₂ is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Warning, With the increasing number of radio devices or other noise sources from electric equipment in health care departments, our product may be interrupted when working because of their interference. The closer the distance between each other is or stronger the signal is, the more serious the interference will be. The electromagnetic interference sources in health care departments may include: (1).Electronic surgical instruments (2).Mobile Phones (3).Automotive two-way wireless communications equipment (4).Electronic apparatus (5).High-definition television
- In this interference, the measurement values may deviate, or the device may not work. When interfered, the product may produce abnormal phenomenon: unstable reading values, outages or other functions of error. If such a case, the use of the site should be checked to identify interference and the elimination of the following measures:
 - (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.
- Warning, do not put the battery close to the fire or into the fire to avoid the battery explosion. Do not use the battery when it leaks or molds.
- Warning, device conforms to the requirement of RoHS directive.
- Warning, device application component materials are certified for biological compatibility.
- Warning, please replace the battery when a low battery remind appears.
- Warning, nail polish will affect measurement accuracy.
- Warning, under the combined effects of the environment and the frequency of use, the product's shell temperature may exceed 41°C. Please use it carefully.
- Do not leave the oximeter unattended around children or infants. Small items such as the battery door, battery, and lanyard may become choking hazards if swallowed. Infants or children may be entangled in the lanyard, thus causing strangulation.
- The maximum skin surface temperature is below 41°C (106°F) when measured in a 35°C (95°F) environment, which has been verified by measuring the skin surface temperature via a Finger Pulse

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Oximeter under the reasonable worst conditions.

- Please pay attention to product storage to prevent damage caused by pets, pests or children.
- Please do not repair and maintain the equipment during use.
- This product can be operated by the patient, or by others to measure the patient's PR and SpO₂. The maintenance, operation and maintenance methods are the same.
- Do not stare at the light (the infrared is invisible) emitted from the oximeter, which is harmful to the eyes.
- Do not use the oximeter for purposes other than its intended use. Do not place the oximeter on edema or fragile tissues.
- Do not use the oximeter on the same hand/arm when using a blood pressure cuff or monitor.
- The effect of sensor and electrode degradation or electrode loosening may reduce the performance of the measurement or cause other problems.
- This product contains batteries and recyclable electronic waste. To protect the environment, do not dispose of it in the household waste, but take it to appropriate local collection points.

General Description

Oxyhemoglobin saturation is percentage of Oxyhemoglobin (O₂Hb) capacity, compounded with oxygen, by all combinative haemoglobin (Hb) Oxyhemoglobin (O₂Hb) capacity in blood. In other words, it is consistence of Oxyhemoglobin in blood. It is a very important ecological parameter for Respiratory Circulation System. Many respiratory diseases can result in oxyhemoglobin saturation being lowered in human blood. Moreover, the following factors can also lead to problems in oxygen supply, so that human oxyhemoglobin saturation might be reduced; Automatic Organic Regulation Malfunction caused by Anesthesia, intensive Postoperative Trauma, hurts resulted in by some medical examination and etc. In the situation, illnesses, such as dizziness, asthenia, emesis and etc, might happen to patients and even endanger the patient's life. Therefore, it is very important to know oxyhemoglobin saturation of patient timely in clinical medical aspects. So that doctors can find problems in time.

The finger pulse oximeter features in small volume, low power consumption, convenient operation and portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for measurement, and then the screen will display the measured value of oxyhemoglobin saturation. It has been proved in clinical experiments that it features in rather high precise and repeatability.

Measurement Principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer law according to Spectrum Absorption Characteristics of deoxyhaemoglobin (HHb) and Oxyhemoglobin (O₂Hb) in glow and near-infrared zones.

Operation principle of the instrument is 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 nail tip through perspective clamp finger-type 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.



Figure 1 Work Principle

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Equipment Symbols And Explain

Symbol	Definitions
	Warnings and precautions
	Serial Number
	Recyclable
	Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste
	EC-Representative
	Type BF applied part
	Manufacturer
	Date of effective use of the product
	Temperature for transportation and storage
	The Pulse Oxygen Saturation(%)
	Stand-by

Symbol	Definitions
	This item is compliant with Medical Device Directive 93/42/EEC
	Refer to instructions manual (Background: Blue; Symbol: White)
	Date of manufacture
	Protection from ingress of particulates than ≥12.5mm. Dripping water falling within 15° of vertical will not have a harmful effect on the pulse oximeter per IEC 60529
	The device has no Alarm System
	Humidity for transportation and storage
	Atmospheric pressure for transportation and storage
	Pulse rate (bpm: 1/min)
	Medical device
	Batch code
	Bluetooth

(The product you purchased may not contain all of the following symbols)

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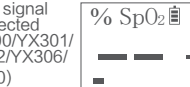
Product Scope Of Application

Intended use: The Finger Pulse Oximeter is a kind of non-invasive device which can measure and display SpO₂ and pulse rate. It is intended for adults and children and is expected for home and hospital inspection.

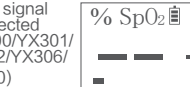
Contraindications: None.

Signal Undetected

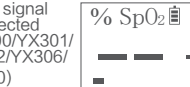
Wave signal undetected (YX300/YX301/YX302/YX306/YX310)



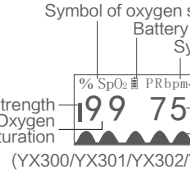
Signal inadequacy (eg: 1.Finger is out, 2.Device fault)



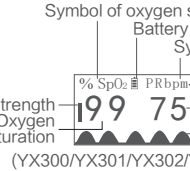
Wave signal undetected (YX102/YX103/YX110)



Display



(YX300/YX301/YX302/YX306/YX310)



(YX102/YX103/YX110)

Technical Parameters

- Display Type: LED (YX102/YX103/YX110) OLED (YX300/YX301/YX302/YX306/YX310)
SpO₂ Display range: 0% ~ 100%. Pulse Rate Display range: 25bpm ~ 250bpm.
- Power: Two AAA 1.5V alkaline batteries.
- Working Current: Less than 30mA at rated voltage 3V. (For YX300/YX301/YX302)
Less than 40mA at rated voltage 3V. (For YX102/YX103/YX110/YX306/YX310)
- Measurement accuracy:
SpO₂ Accuracy(A_{ms}): ±2% in the range of 70%~100% of SpO₂;
No definition for SpO₂ under 70%.

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Pulse rate: 25bpm ~ 250bpm, accuracy(A_{ms}): ±1% or ±1bpm (larger)

Note: The accuracy(A_{ms}) 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_{ms}) value.

5. Correct SpO₂, and pulse rate can be displayed when the simulation pulse wave amplitude is at 6%.
6. Anti-interference ability of ambient light: Deviation in blood oxygen content is less than ±1% when measured under indoor nature light / existing lighting and measured in the dark room.

7. The product will automatically shut down when there is no signal detected for about eight seconds.

8. Dimension: YX102/YX103/YX110/YX306/YX310: 60mm*38mm*35mm (LWH), Weight: 38g approximately (without batteries).

YX300: 56mm*31mm*27mm (LWH), Weight: 23g approximately (without batteries).

YX301: 66mm*35mm*30mm (LWH), Weight: 27g approximately (without batteries).

YX302: 66mm*37mm*37mm (LWH), Weight: 30g approximately (without batteries).

9. Working Environments: Ambient temperature: 5°C ~ 40°C; Relative humidity: ≤80%; Atmospheric pressure: 860hPa ~ 1060hPa.

10. Operation mode: Continuous operation.

11. Device response time: (See Figure 2)

12. Peak wavelengths and light output power:
For YX300/YX301/YX302: The wavelength range of Red light is from 619nm to 659nm and the luminous intensity is 27 mcd.

The wavelength range of Infrared light is from 895nm to 989 nm and the luminous intensity is 0.6 mW/sr (20mA).

For other models: Emission wavelength range 600nm ~ 1000nm, radiation intensity is less than 15mW/sr (20mA).

Information of wavelength range may be of especial use to clinical doctors.

13. Description of the effect on displayed and transmitted SpO₂ and Pulse rate data value:

1) data averaging and other signal processing.

2) the data update period: ≤3 pulse rate cycles, less than 30s.

Note: Data processing and update will not affect pulse rate and SpO₂.

14. The pulse waveform has been normalized, the measurement value is the best when the waveform is smooth and stable.

15. Internally Powered ME Equipment

16. TYPE BF APPLIED PARTS

17. Degrees of protection provided by enclosures (IP code): IP22.

18. Description of oximeter application management

YX110 and YX310 are equipped with Bluetooth function. Bluetooth

communication protocol module enables the oximeter to be equipped with

Bluetooth connection and the function of data exchange, which does not

involve patient privacy, mainly including pulse rate, blood

oxygen and other information.

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Bluetooth specification sheet:

Transmitting and receiving frequency range	2400 MHz~2483.5 MHz
Receive bandwidth	≤2 MHz
Transmit power	≤20 dB
Effective radiated power	≤0 dBm
Frequency characteristics	UHF
Modulation	GFSK

Product Properties

1. Operation of the product is simple and convenient.

2. The product is small in size, light in weight and portable.

3. The product features in low power consumption, YX300/YX301/YX302 can operate continuously for about 30 ~ 40 hours with 2 brand new AAA batteries, for other models, it is about 17 hours. (The operation time may vary due to the different performance of batteries.).

4. Low voltage prompt will appear on the display when the battery voltage is lower than the minimum value of normal working voltage range.

5. The product will automatically shut down when there is no signal detected for about eight seconds.

6. The technology used in Finger 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% SpO₂ against a laboratory co-oximeter.

7. The technology used in Finger Pulse Oximeter has been verified with the pulse rate accuracy of 25~250bpm range in the bench top test against simulator and the Finger Pulse Oximeter.

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Finger Pulse Oximeter

Please read the user manual closely before using!
(The picture is for reference only, please refer to the actual product.)

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Product Operation Steps

1. Install two AAA batteries into battery cassette before closing the cover.
2. Nip the clamp as diagram. (See Figure)

Note: During the measurement, the device is placed with the face up when the finger is inserted in.

3. Plug one finger into rubber hole of the Oximeter (it is best to plug the finger thoroughly) before releasing the clamp.

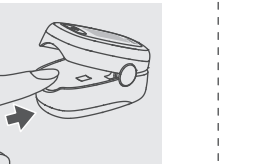
4. Press the switch button one time on the front panel. (For YX300/YX301/YX302/YX306/YX310)

The oximeter will start measurement once the finger is inserted in and the clamp is released. (For YX102/YX103/YX110)

5. Do not tremble while the oximeter is working. It's better that the whole body be in still status.

Note: For normal use after long interruptions, refer to the product operation steps.

6. Read corresponding data from display screen.



Battery Installation (Use YX306 as an example)

1. Pull the battery cover horizontally.

2. Put two AAA batteries into battery cassette in right polarities and push the cover back.

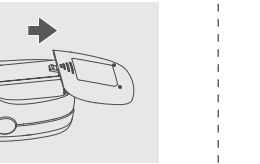
Note: Battery polarities must be correct. Otherwise, damage might occur to device.

Please put or remove batteries in right order, or it will damage the device bracket.

3. Install as the figures show. (See Figure)

⚠ Remove the battery from the product if it is not required for extended periods of time in order to avoid damage to the oximeter resulting from a leaking battery.

⚠ Do not use the new batteries with the old ones. Alkaline battery of long service is recommended, and do not use rechargeable batteries.

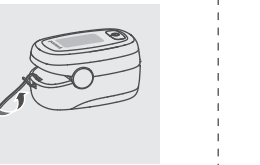


Lanyard Installation (Use YX306 as an example)

1. Thread thinner end of the lanyard through the hanging hole.

2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.

3. Install as the figures show. (See Figure)



Maintenance and Storage

● Under normal conditions there is no need for special protection and maintenance when using, please pay attention to the following points:

Caution: Using oximeter in required environment.

Caution: Avoid direct sunlight.

Caution: Avoid extreme infrared radiation or ultraviolet radiation.

Caution: Avoid organic solvent vapors, dust, and corrosive gas.

● Transportation and storage conditions:

Temperature range: -20°C ~ +55°C

Relative humidity: ≤93%, no condensation

Atmosphere pressure: 500hPa ~ 1060hPa

● It is recommended that the product should be kept in a dry environment anytime. Moisture might affect its lifetime and even damage the product.

Cleaning and disinfecting

● This product is a reusable non-sterile device. Please clean and disinfect according to the following methods.

⚠ Warning:

1. Never immerse or soak the oximeter.

2. 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.

3. Never use cleaning agents/disinfectants other than the recommended.

4. The sensor component is not cleaned and disinfected during testing.

5. 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: water

1. Shut down the finger pulse oximeter and remove the battery.

2. Clean the oximeter with cotton or soft cloth moistened with water.

3. After cleaning, wipe off the water with a soft cloth.

4. Allow the oximeter to air dry.

⚠ The most commonly used hospital cleaning and non-corrosive liquid detergent can be used to clean the oximeter. Pay attention to diluting cleaning detergent before use, following the manufacturer's instructions.

⚠ Avoid the use of ethanol-based, amino- or acetone-based cleaning agent. Oximeter shell should be maintained from dust pollution, use a soft cloth or lint-free cleaning agent with the sponge to wipe. Make sure no liquid will enter into the equipment.

● Disinfecting

The recommended disinfectants include: ethanol 70%, isopropanol 70%

1. Shut down the finger pulse oximeter and remove the batteries.

2. Clean the oximeter as instructed above.

3. Disinfect the oximeter with cotton or soft cloth moistened with one of the recommended disinfectants.

4. After disinfection, be sure to wipe off the disinfectant left on the oximeter with a soft cloth moistened with water.

5. Allow the oximeter to air dry.

Possible cases and solutions

⚠ Warning:

Caution: Oximeter cover can only be opened by a professional maintenance staff. No internal parts require opening by end users.

- If you are not sure about the measurement precision, please use other methods to check patient's pulse, to determine whether oximeter works.

⚠ Note: Do not splash, dump any liquid into the oximeter and attachments, switch and connections, which may damage the oximeter.

Problems	Possible reason	Solution
SpO ₂ or PR can not be shown normally	1. Put finger incorrectly. 2. Not used according to recommended steps 3. Nail polish or paste manicure	1. Try again 2. Try some more times, if you can make sure about no problem exiting in the product, please go to a hospital timely for exact diagnosis 3. Remove the nail polish or discharge manicure when measuring.
SpO ₂ or PR is shown unstably	1. Finger might not be plugged deep enough 2. Finger is trembling or patient is in movement status.	1. Retry by plugging the finger 2. Try not to move
The finger pulse oximeter can not power on	1. Power of batteries might be inadequate or not be there at all 2. Batteries might be installed incorrectly 3. The finger pulse oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact with local customer service center
Indication lamp are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. Battery Low	1. Normal 2. Replace the batteries

Electromagnetic interference

⚠ The EM environment for this product is the home/healthcare environment and professional healthcare facility environment.

⚠ The essential performance of this product is the accuracy of SpO₂ and pulse rate. When used directly near strong electromagnetic interference (for example: near mobile phones, microwave ovens, etc.), it may be temporarily inaccurate. If so, please keep the product away from interfering devices.

⚠ During measurement, The 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.

⚠ During measurement, 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 finger pulse oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 1 – For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – electromagnetic emissions	
The Finger Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Finger Pulse Oximeter should assure that it is used in such an environment.	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B

Table 2 – For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity		
The Finger Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Finger Pulse Oximeter should assure that it is used in such an environment.		
IMMUNITY test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8kV contact ± 15kV air
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz and 60Hz

Table 3 – For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity					
The Finger Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Finger Pulse Oximeter should assure that it is used in such an environment.					
IMMUNITY test	IEC 60601 test level	Compliance level			
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz			

Table 4 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY Test LEVEL (V/m)
385	380–390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						

1720	1700–1990	GSM 1800; TETRA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: 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, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Accessories

Lanyard: 1 pc

AAA batteries: 2 pcs

User Manual, Warranty card: 1 pc

APP Quick Usage Guide (For YX110 & YX310)

After unpacking, check the items according to the accessories list, and check whether the oximeter is mechanically damaged. If you find any problems, please contact the local customer service center immediately.

During the warranty service, if you need to provide circuit diagrams, necessary materials, and if there are any problems with the maintenance of electrical circuits, please contact the manufacturer.

Warranty Card

Thank you very much for using our products.

Product name: Finger pulse oximeter

Model: Refer to the specific model

S/N: _____

MFG. DATE: _____

JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.

Yunyang Industrial Park 212300 Danyang

Jiangsu PEOPLE'S REPUBLIC OF CHINA

www.yuwell.com

Please reserve the warranty card carefully.

European Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg Germany

Tel: 0049-40-2513175

Fax: 0049-40-255726

Notified Bodies:

Name: TÜV SÜD Product Service GmbH

Address: Ridlerstr. 65, 80339 München, Germany

JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.

Yunyang Industrial Park 212300 Danyang

Jiangsu PEOPLE'S REPUBLIC OF CHINA

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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.

Release date: Jan. 2022

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