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All specifications and product configurations are subject to change without notification.

730600-0A



yuwell



Fingertip Pulse Oximeter YX3 Series(YX300、YX301、YX302)

Please read the user's manual closely before using!

9.Warning, The water protection grade of device is IPX 1.

10.Warning, Please take out the batteries and do not burn or bury if the product is scrapped or discarded.

11.Warning, Device conforms to the requirement of RoHS directive.

12.Warning, Device application component materials are certified for biological compatibility.

13.Warning, A low battery remind please replace the battery after use.

14.Warning, Nail polish will affect measurement accuracy.

General Description

Haemoglobin saturation is percentage of Oxyhemoglobin (HbO₂) capacity, compounded with oxygen, by all combinativable haemoglobin (Hb) Oxyhemoglobin (HbO₂) 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 haemoglobin Saturation being lowered in human blood. Moreover, the following factors can also lead to problems in oxygen supply, so that human haemoglobin 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 light head, asthenia, vomitory and etc, might happen to patients and even endanger the patient' s life. Therefore, it is very important to know Hemoglobin saturation of patient timely in clinical medical aspects. So that doctors can find problems in times.

The fingertip pulse oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of hemoglobin 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 Reductive hemoglobin (R Hb) and Oxyhemoglobin (O₂ Hb) 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 (660nm glow and 940nm near infrared light) can be focused onto human nail tip through perspective clamp finger-type



Warning

- 1.Warning, Do not modify this equipment without authorization of manufacture.
- 2.Warning, The device has no Alarm System.
- 3.Warning, As far as possible away from the wet medical equipment such as drip or other similar liquid simulation.
- 4.Warning, Do not use the oximeter for more than 30 minutes without relocation the device to another finger, long term clip on the finger may lead to hand acid.
- 5.Warning, 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.
- 6.Warning, The pulse oximeter simulation can not be used to verify the accuracy of the calibration of the production.
- 7.Warning, Alkaline battery of long service life is recommended and do not use rechargeable batteries and battery reverse error operation will lead to the normal operation of the boot. Please follow local disposal and recycling laws for the oximeter and its components, including the battery.

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8.Warning, With the increasing number of radio devices or other noise sources from electric equipments in health care departments , our product may be interrupted when working because of their interference. The closer distance between each other or the more powerful sources, the more serious interference. 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 it does not work. When interfered, the product may produce abnormal performances: 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)The vicinity of the equipment shut down and then re-opens in order to identify interference equipment;
- (2)To change the direction of interference with equipment or location;
- (3)To increase the distance between the product and interference sources.

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

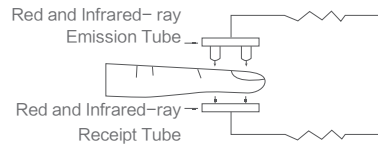


Figure 1: Work Principle

Equipment Symbols and explain

Symbol	Definitions	Symbol	Definitions
	Consult the manual		This item is compliant with Medical Device Directive 93/42/EEC
	Serial Number		Caution, consult accompanying documents

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Symbol	Definitions	Symbol	Definitions
	Batteries and electronic instruments must be disposed of In accordance with the locally applicable regulations , not with domestic waste		This Pulse Oximeter is protected against harmful effects of dripping water per IEC60529
	Type BF applied part		Power button
	Manufacturer		The device has no Alarm System
	Date of effective use of the product		Humidity for transportation and storage
	Temperature for transportation and storage		Atmospheric pressure for transportation and storage
	The Pulse Oxygen Saturation(%)		Recycle

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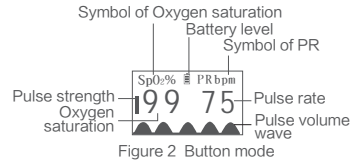
Product scope of application

Contraindications: None.

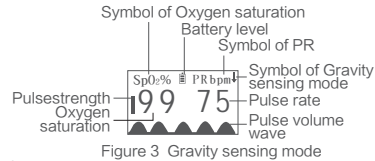
Intended Use: The Fingertip Pulse Oximeter is a kind of non-invasive detection adults and children SpO_2 and heart-rate detection of medical instrument which is expected for home and hospital inspection.

Applicable People: Normal adults and children, Vascular disease crowd, The respiratory system disease crowd, Middle-aged and old old man over the age of 60, athlete.

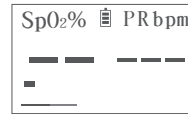
Display



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Wrong Mode Display



OLED display wrong mode when finger out or product failure.

Figure 4 Wave wrong mode

Technical Parameters

1. Display Type: OLED

SpO_2 Measurement rang: 70–100%, Accuracy: $\pm 2\%$, Pulse Rate Measure rang: 25–250BPM/min, Accuracy: $\pm 1BPM$ or $\pm 1\%$ (larger)

2. Power: Two AAA 1.5V alkaline Batteries, Voltage range: 2.6–3.6V

3. Working Current: Less than 30mA.

4. Measurement accuracy:

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acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

The pulse oximeter is intended for use in hospital, clinical institution, healthcare community

- 1) data averaging and other signal processing
- 2) the data update period

Product Properties

1. Operation of the product is simple and convenient.
2. The product is small in size, light in weight (total weight is about 54g including batteries) and portable.
3. The power of two AAA batteries can last for 45 hours.
4. Low voltage warning will be indicated in visual window when battery voltage is too low than normal operation of the oximeter might be influenced.
5. The product will automatically shut down when there is no finger entering for eight seconds.

Product Operation Scope

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The fingertip Oximeter can be used to measure human Haemoglobin Saturation and heart rate through finger, the product is suitable for family, hospital (including clinical use in internist/surgery, Anaesthesia, paediatrics, intensive sports (It can be used before or after sport. Operation in sport is not recommended) and etc.

The product is not suitable to monitor patient continuously.

Product Operation Scope

1. Installing two AAA batteries into battery cassette before closing the cover.
2. Nip the clamp as diagram.
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.
5. Do not tremble while the oximeter is working. It's better that the whole body be in silent status.
6. Read corresponding data from display screen.



Figure 5: Testing sketch diagram

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Spo₂ Accuracy: ± 2% in the range of 70%–99% of Spo₂

No definition for Spo₂ under 70%, Pulse rate: ± 1% or ± 1BPM/min(larger)

5.Measurement Performance in Low Perfusion Condition: 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 / existinglighting and measured in the dark room.

7.The product will automatically shut down when there is no finger entering for eight seconds.

8.Dimension: 58mm*32mm*34mm(LWH), Weight: 54g approximately(including two AAA batteries).

9.Working Environments:

Ambient Temperature: 5~40℃, Relative humidity: <80%, Atmospheric pressure: 860hPa~1060hPa.

Transportation And Storage Environments : -40℃ ~ 55℃(OLED Use: -20℃ ~ +55℃),

Relative humidity: <93%, Atmospheric pressure: 500hPa~1060hPa.

10.Operation mode: Continue operation.

11.Patient population: The personal application are adult patient(weight:>30kg) and pediatric patients

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(weight:20~30kg).We recommend index finger, middle finger and ring finger are suitable position for monitor. The pulse oximeter is NOT design for newborn and infant.

For adults, it recommended that the finger thickness should between 8~25.4mm. The probe is the hole in the middle of the equipment to which the finger insert. The device is intended for spot-checking or attended-care monitoring.

12.Peak wavelengths and light output power:

The wavelength range of Red light is from 619nm to 659 nm 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).

13.Transmitted SpO₂ and Pulse rate data value:

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 Characteristic of Reductive hemoglobin(Hb) and oxyhemoglobin(HbO₂) in glow & near-infrared zones. Operation Principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning Recording Technology, So that two beams of different wavelength of lights by a photosensitive element, information

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Battery Installation

1.Put the two AAA batteries into battery cassette in right polarities.

2.Pull the battery cover horizontally.

Notes: Battery polarities must be correctly installed .Otherwise, damage might occur to device.

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

Please remove the battery if the oximeter will not be used for long time.

3.Install as the figures show. (See Figure 6–9)



Figure 6: Along the direction of the arrow to open the battery cover



Figure 7: Open the battery cover



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Figure8: Close the battery cover

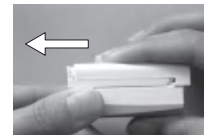


Figure 9: Along the direction of the narrow to Close the battery cover

Lanyard installation

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 10, 11, 12)

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Figure 10



Figure 11



Figure 12

Maintenance and Storage

- Clean the surface of the fingertip oximeter before it is used in diagnosis for patients.
- The most commonly used hospital cleaning and non-corrosive liquid detergent can be used to clear the oximeter. Pay attention to diluting cleaning detergent cleaning before use, by 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, using a soft cloth or lint-free cleaning agent

with the sponge to wipe infiltration. Make sure no liquid inside the equipment.

- ⚠️ Avoid the use of metals such as steel wire brush or polishing agent abrasive material which will damage the oximeter panel .
- ⚠️ Under normal conditions there is no need for special protection and maintenance when using, please pay attention to the following points:
 - ⌚ Using oximeter in required environment.
 - ⌚ Avoid direct sunlight exposure.
 - ⌚ Avoid extreme infrared radiation or ultraviolet radiation.
 - ⌚ Avoid organic solvent vapors, dust, and corrosive gas exposure.
- ⚠️ Warning: Do not put oximeter in disinfection or in liquid.
- Please remove the battery if the oximeter will not be used for long time.

Transportation and storage conditions:

Temperature range: -20°C ~ +55°C

Relative humidity: ≤93%, no condensation

Atmosphere pressure: 500hPa ~ 1060hPa

Possible cases and solutions

- ⚠️ Warning:
 - ⌚ 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. Do not put finger correctly	1. Try again
	2. Patient Oxyhemoglobin value is too low to be measured	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. Nail polish or paste Manicure	3. When measuring the nail polish remover or discharge Manicure
SPO ₂ or PR is shown unstably	1. Finger might not be plugged deep enough	1. Retry by plugging the finger
	2. Finger is trembling or patients body is in movement status	2. Try not to move
The Oxyhemoglobin can not be power on	1. Power of batteries might be inadequate or not be there at all	1. Please replace batteries
	2. Batteries might be installed incorrectly	2. Please reinstall the batteries
	3. The Oxyhemoglobin might be damage	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	1. Normal
	2. Finger quantity of the batteries is start being inadequate	2. Replace the batteries

- It is recommended that the product should be kept in a dry environment anytime. Moisture might affect its lifetime and even might damage the product.
- Electrical schematics and component list is only available to the professional manufacturer or qualified repair station personnel.
- Do not use the new batteries with the old ones. Alkaline battery of long service life is recommended, and do not use rechargeable batteries. Batteries must be disposed of in accordance with the locally applicable regulations, not with domestic waste. Batteries must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

Cleaning and disinfecting

⚠ Warning:

1. Never immerse or soak the oximeter.
2. We recommend that the oximeter be cleaned and disinfected after use every time or determined by your hospital's policy, to avoid long term damage to the oximeter.
3. Never use cleaning agents/disinfectants other than the recommended.

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

The recommended cleaning agents include: water

1. Shut down the 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

- Disinfecting

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

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

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Electromagnetic interference

As a result of radio frequency transmission devices and noise of electrical source, the machine may stop working, interfered by strong radio frequency, or because of close distance. Medical places may have the following EMI pollution sources:

1. Electronic surgical instruments
2. Mobile phones
3. Automotive two-way wireless communications equipment
4. Electronic apparatus
5. High-definition television

In the designed oxygen using environment, EMI may make the pulse not obvious. In this interference, the measurement values may become too large, or oximeter does not work. Performance under interference: unstable reading, interruption, other function errors. As to the above mentioned cases, please check the places to find out the interferences, and take the following measures:

1. Turn off the nearby equipment, and restart, to find out interference equipment.
2. Change the direction and location of interference equipment.

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3. Keep a distance between our equipment and interference equipment.

Oximeter and radiation generates radio frequency energy and if we do not press the "Manual" use, may also be other devices in the vicinity of harmful interference.

Guidance and MANUFACTURER'S declaration - ELECTROMAGNETIC EMISSIONS - for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration - electromagnetic emissions		
The [Finger Pulse Oximeter YX300, YX301, YX302] is intended for use in the electromagnetic environment specified below. The customer or the user of the [Finger Pulse Oximeter YX300, YX301, YX302] should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CLSPR 11	Group 1	The [Finger Pulse Oximeter YX300, YX301, YX302] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CLSPR 11	Class B	The [Finger Pulse Oximeter YX300, YX301, YX302] is suitable for use in all establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.


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Guidance and MANUFACTURER' S declaration - ELECTROMAGNETIC IMMUNITY - for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture' s declaration - electromagnetic immunity			
The [Finger Pulse Oximeter YX300, YX301, YX302] is intended for use in the electromagnetic environment specified below. The customer or the user of the [Finger Pulse Oximeter YX300, YX301, YX302] should assure that it is used in such an environment.			
IMMUNITY test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC61000-4-2	± 6KV contact ± 8KV air	± 6KV contact ± 8KV air	Floors should be wood, oncrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) magnetic field C	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Guidance and MANUFACTURER' S declaration - ELECTROMAGNETIC IMMUNITY - for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture' s declaration - electromagnetic immunity			
The [Finger Pulse Oximeter YX300, YX301, YX302] is intended for use in the electromagnetic environment specified below. The customer or the user of the [Finger Pulse Oximeter YX300, YX301, YX302] should assure that it is used in such an environment.			
IMMUNITY test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the [Finger Pulse Oximeter YX300, YX301, YX302] including cabled, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d = 1.2 \times \text{square root}(P)$, 80MHz to 800 MHz $d = 2.3 \times \text{square root}(P)$, 800MHz to 2.5GHz 

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NOTE1 At 80MHz and 800MHz the higher frequency range applies
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Waste, residue from processing

- Of waste, waste handling should be consistent with the corresponding national laws and regulations.
 1. Fingertip Pulse Oximeter: 1pc
 2. Lanyard: 1pc
 3. AAA batteries: 2pcs
 4. User's Manual, Warranty card: 1pc

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Warranty Card

Thank you very much for using our products.

Product name: Fingertip pulse oximeter Model: YX300, YX301, YX302

S/N: _____ MFG.DATE: _____

JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.

Sales Center Address: Huanyuan East Road No.1, Xuzhuang Software Park, Nanjing, Jiangsu Province, P.R. China, 210000

Manufacturing Address: YunYang Industrial Park, DanYang, Jiangsu Province, P.R. China, 212300
<http://www.yuwell.com>

Please reserve the warranty card carefully.

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