（CE版）通用指夹式脉搏血氧仪说明书印刷要求：
色彩：准确、单色,层次分明
纸张：70克双胶纸
印后加工：印后成品尺寸60x118mm,
展开尺寸240x472mm，行折3折，列折3折

## 20.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.
Manufacturer Address: No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA
www.yuwell.com
Please reserve the warranty card carefully.

CE 0123

EC REP Metrax GmbH
Rheinwaldstr. 22, D-78628 Rottweil, Germany

JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO.,LTD.
No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA
www.yuwell.com

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.

YY-BOM0001C-01(A/0)
Release date：Nov. 2023

yuwell


# Finger Pulse Oximeter

Model: YX102/YX105/YX106/ YX110/YX301/ YX306/YX310

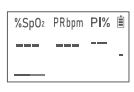
Please read the user manual closely before using!
(The picture is for reference only, please refer to the actual product.)

| | | | |
|---|---|---|---|
| | Type BF applied part | | Alarm inhibit |
| | Manufacturer | | Humidity limitation |
| | Use-by date | | Atmospheric pressure limitation |
| | Temperature limit | | Keep dry |
| | Fragile, handle with care | MD | Medical device |
| LOT | Batch code | | This way up |
| PR bpm | Pulse rate (bpm:1/min) | | Bluetooth |
| | Refer to instruction manual (Background: Blue; Symbol: White) | EC REP | Authorized representative in the European Community |
| PI% | Perfusion index(%) | UDI | Unique device identifier |

## 5.Product Scope Of Application

Intended purpose: The Finger 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.
Contraindications: None.

## 6.Signal Undetected




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

Wave signal undetected


(It is only a schematic diagram, and the specific functions are mainly based on real objects.)

## 1.Warning

1. Do not modify this equipment without authorization of manufacturer.
2. The device has no Alarm System. So do not use the finger pulse oximeter in situations where alarms are required. If the product is used in a situation where an alarm is required, there is a risk that the patient's abnormal status will not be obtained in a timely manner.
3. Keep away from the wet medical equipment such as drip or other similar liquid simulation as far as possible.
4. 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.
5.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.
6. 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. Pulse oximeter can use FLUKE INDEX2 simulator, select specific curve (PALCO 300), and verify the accuracy and repeatability of $SpO_2$ or pulse rate by setting fixed $SpO_2$ value or pulse rate value.
7. When discarding components (including the batteries) or this product, follow local regulations to avoid contamination.
8.$SpO_2$ is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
9.Keep the oximeter away from electrical equipment that emits radio frequencies to minimize radio interference. RF may result in inaccurate or inaccurate readings.
The electromagnetic interference sources may include but are not limited to the following:
electrocautery equipment, diathermy equipment, other cellular telephones, wireless PC and tablets, pagers, RFID devices, MRI, and electromagnetic security systems.
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, the oximeter should keep a distance of not less than 30 cm (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.
10. 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.
11. Device conforms to the requirement of RoHS directive.
12. The material in contact with human body has been tested for biocompatibility.
13. Please replace the battery when a low battery remind appears.
14. Nail polish will affect measurement accuracy.
15. Under the combined effects of the environment and the frequency of use, the product's shell temperature may exceed 41℃. Please use it carefully.
16. Do not use oximeter if it appears or is suspected to be damaged. Damage to internal parts can result in no or inaccurate reading.
17. 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. This kind of interference may result in no or inaccurate reading.
18. Place the oximeter out of reach of children or infants to avoid suffocation caused by swallowing small objects or lanyard around the neck. Children should use the oximeter under the supervision of adults. Adults should not use the lanyard during activities where it may become wrapped around the neck, strangulation may occur.
19. The maximum skin surface temperature is below 41℃ (106°F) when measured in a 35℃ (95°F) environment, which has been verified by measuring the skin surface temperature via a Finger Pulse Oximeter under the reasonable worst conditions.
20. Please pay attention to the use and storage of products to prevent damage caused by pets, pests or children.
21. Please do not repair and maintain the equipment during use.
22. This product can be operated by the patient, or by others to measure the patient's PR and $SpO_2$. The maintenance, operation and maintenance methods are the same.
23. Do not stare at the light (the infrared is invisible) emitted from the oximeter, which is harmful to the eyes.
24. Do not use the oximeter for purposes other than its intended purpose. Do not place the oximeter on edema or fragile tissues.
25. Do not use the oximeter on the same hand/arm when using a blood pressure cuff or monitor.
26. The aging of the sensor may reduce the performance of the measurement or cause other problems.
27. This product is easy to operate. The operator only needs to have a certain reading ability (e.g. People who have received 8 years of education) and can operate without additional training.
28. Oximeter cover can only be opened by a professional maintenance staff. No internal parts require opening by end users.
29. This product is calibrated to display functional oxygen saturation.
30. When the ambient temperature is 20 ℃, the time required for the oximeter to warm/cool from the minimum/maximum storage temperature to the normal operating temperature is approximately 30 minutes.
31. Properly apply and avoid using the oximeter under high ambient light sources, fluorescent lights, infrared heating lamps and direct sunlight to minimize the interference that may result in no or inaccurate reading.
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.

## 2.General Description

Oxyhemoglobin saturation is percentage of Oxyhemoglobin ($O_2Hb$) capacity, compounded with oxygen, by all combinativable haemoglobin (Hb) Oxyhemoglobin ($O_2Hb$) 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.

## 3.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 ($O_2Hb$ ) 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.

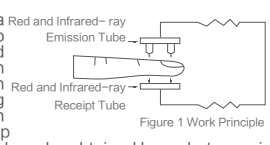


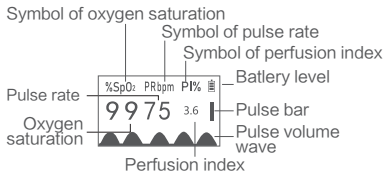

Figure 1 Work Principle

## 4.Equipment Symbols and Explain

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

| Symbol | Definitions | Symbol | Definitions |
|---|---|---|---|
| | Caution | CE 0123 | This device is compliant with Medical Device Regulations 2017/745 |
| SN | Serial Number | | Stand-by |
| | General symbol for recovery / recyclable | | Date of manufacture |
| | Waste from electrical and electronic equipment (WEEE) | IP22 | Protected against solid foreign objects of 12.5 mm ϕ and greater. Protection against vertically falling water drops when ENCLOSURE tilted up to 15° |
| MR | MR Unsafe (Background color: white; Circular frame and diagonal bar: red; Letters 'MR': black) | % $SpO_2$ | Oxygen Saturation(%) |

## 7.Display



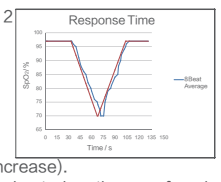


(It is only a schematic diagram, and the specific functions are mainly based on real objects.)

## 8.Technical Parameters

1.Display Type: LED (YX102/YX105/YX106/YX110) ; OLED (YX301/YX306/YX310)
2.Display range: $SpO_2$ Display range: 0%～100%. Pulse Rate Display range: 25bpm～250bpm.
PI Display range：0.5%-20% (For YX301/YX306).
3.Power: Two AAA 1.5V alkaline batteries.
4.Working Current: Less than 40mA at rated voltage 3V.
5.Measurement accuracy:
$SpO_2$ Accuracy (Arms): ±2% in the range of 70%-100% of $SpO_2$;No definition for $SpO_2$ under 70%.
Pulse rate: 25bpm～250bpm, accuracy($A_{rms}$): ±1% or ±1bpm (whichever is greater)
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.
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/YX110/YX306/YX310:60mm*88mm*35mm(LWH), Weight:38g approximately (without batteries).
YX105:58mm*33mm*34mm (LWH), Weight:36g approximately (without batteries)
YX106:65mm*38mm*35mm (LWH), Weight:40g approximately (without batteries).
YX301:69mm*36mm*33mm (LWH), Weight:36g approximately (without batteries).
9.Working Environments:
Ambient temperature: 5℃～40℃;
Relative humidity: 15%～90%, no condensation;
Atmospheric pressure: 700hPa～1060hPa
10.Operation mode: Continuous operation.
11.Device response time. (See Figure 2)

Figure 2




12.Peak wavelengths and light output power：
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.Data averaging and signal processing delay the display and transmission of data values for $SpO_2$. The measurement data update cycle is less than 30 seconds (when the signal is weak, weak perfusion or other disturbances occur, the time for taking the dynamic mean value will increase).
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 date exchange, which does not involve patient privacy, mainly including pulse rate, blood oxygen and other information.

(Android) (iOS)

| Bluetooth specification sheet: | |
|---|---|
| Transmitting and receiving frequency range | 2402 MHz-2480 MHz |
| Receive bandwidth | 1 MHz, 2 MHz |
| Transmit power | ≤10 dBm |
| Frequency characteristics | UHF |
| Modulation | GFSK |

## 9.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, it is can operate continuously for about 17 hours with 2 brand new AAA batteries. (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.Flicker prompt: When the measured value of $SpO_2$ is below 90%, the display area of $SpO_2$ value will flicker to prompt; when the measured value of pulse rate exceeds the range of 40-120bpm, the display area of pulse rate will flicker to prompt. (For YX301/YX306).
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% $SpO_2$ against a laboratory co-oximeter. Graphical Plot of $SaO_2$ versus error ($SpO_2$ - $SaO_2$) (See Figure 3、4)

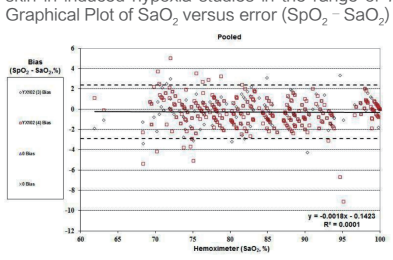



Figure 3 YX102

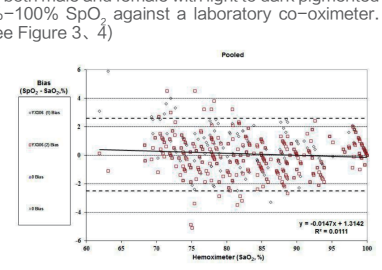



Figure 4 YX306

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

## 10.Product Operation Scope

The Finger Pulse Oximeter is designed for fingers(not thumb) between 0.3 and 1.0 inch (0.8-2.54cm) thick. And the finger shall be inserted into the sensor position which is in the middle of the device.
The pulse oximeter is not design for newborns and infants.
We recommend using index finger, middle finger and ring finger. It is recommended for people who weigh more than 30kg. And this device is more recommended for the vascular disease crowd, the respiratory system disease crowd, middle-aged people, men over the age of 60 and athletes.
The product is not suitable for monitoring patients continuously, but intended for spot-checking. It is also not suitable for use during motion and low perfusion.

## 11.Product Operation Steps

1.Install two AAA batteries into battery cassette before closing the cover.
2.Nip the clamp as diagram. (See Figure)
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 YX105/ YX106/YX301/ YX306/YX310)

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

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

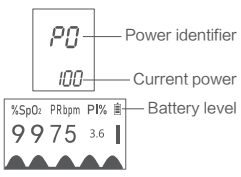
Note: For normal use after long interruptions, refer to the product operation steps.

6.Read corresponding data from display screen.

## 12.Battery Installation

1.Battery Reminder:

For YX102/YX105/YX106/YX110: After the product is powered on, the product model and software version number interface, battery power display interface and measurement interface will be displayed in sequence (the battery power display interface is shown in the figure). Users need to confirm the battery level by rebooting. When the " " symbol on the screen is always on, please replace the battery in time.




For YX301/YX306 /YX310: The battery power can be displayed on the measurement interface of the product (See Figure). The state of the internal electrical power source will display a different icon depending on the battery capacity. When the screen only displays the symbol " ", prompt to replace the battery as soon as possible; when the symbol " " is displayed, replace the battery immediately.

2.Battery Installation:

(1) Open the battery cover as instructed in the figures. (Pay attention to the specific model), put two AAA batteries into battery cassette in right polarities.

(2) Close the cover back.

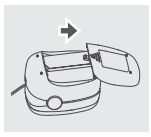
Notes: Battery polarities must be correct. Otherwise, damage might occur to device.

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

⚠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.

For YX106



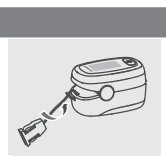
For other Models

## 13.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.



## 14.Maintenance and Storage

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

⚠ 1. Using oximeter in required environment.

2. Avoid direct sunlight .

3. Avoid extreme infrared radiation or ultraviolet radiation.

4.Avoid organic solvent vapors, dust, and corrosive gas .

●Transportation and storage conditions：

Temperature range: −25℃ ~ +70℃

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.

## 15.Cleaning

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

Warning:

1.Never immerse or soak the oximeter.

2.We recommend cleaning 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 other than the recommended.

4.The sensor component is not cleaned 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.

## 16.Possible cases and solutions

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

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

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

| Problems | Possible reason | Solution |
|---|---|---|
| $SpO_2$ or PR can not be shown normally | 1. Put finger incorrectly. | 1. Try again |
| | 2. Not used according to recommended steps | 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. Remove the nail polish or discharge manicure when measuring. |
| When the oximeter appears "−−", it indicates that the signal is inadequacy at this time, which may be caused by the above three circumstances. | | |
| $SpO_2$ or PR is shown unstably | 1.Finger might not be plugged deep enough | 1. Retry by plugging the finger |
| | 2. Finger is trembling or patient is in movement status. | 2. Try not to move |
| | 3. Hardware failure | 3.Please contact with local customer service center |
| The finger pulse oximeter can not 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 finger pulse oximeter might be damaged | 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. Battery Low | 2. Replace the batteries |

## 17.Electromagnetic Interference

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

⚠The essential performance of this product is the accuracy of $SpO_2$ and pulse rate($SpO_2$ Accuracy ($A_{rms}$): ±2% in the range of 70%−100% of $SpO_2$, No definition for $SpO_2$ under 70%; Pulse rate: 25bpm～250bpm, accuracy($A_{rms}$): ±1% or ±1bpm (whichever is greater)). 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.

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 | – | N/A |
| Radiated RF Emissions | – | P |
| Disturbance Power Emissions (if applicable) | N/A | N/A |
| Harmonic Distortion per IEC 61000−3−2 (Class A, B, C, D) | Class A | N/A |
| Voltage Fluctuations and Flicker per IEC 61000−3−3 | – | N/A |
| **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 | N/A |
| Surges | IEC 61000−4−5 | N/A |
| Conducted Disturbances Induced by RF fields | IEC 61000−4−6 | N/A |
| Rated Power Frequency Magnetic Fields | IEC 61000−4−8 | P |
| Voltage Dips and Interruptions | IEC 61000−4−11 | N/A |
| Proximity Magnetic Fields | IEC 61000−4−39 | P |
| Electrical transient conduction along supply lines | ISO 7637−2 | N/A |
| Electrosurgery Interference | IEC XXXXX−X−XX: XXXX Clause XXX | N/A |

Table 1 − For all ME EQUIPMENT and ME SYSTEMS

| Guidance and manufacturer's declaration − Radiated Emission | | | |
|---|---|---|---|
| Emissions test | IEC60601 test level | Compliance level | Result |
| RF emissions CISPR 11 | 10m<br>30dB( μ V/m) 30MHz−230MHz<br>37dB( μ V/m) 230MHz−1000MHz | 10m<br>30dB( μ V/m) 30MHz−230MHz<br>37dB( μ V/m) 230MHz−1000MHz | Pass |

Table 2 − For all ME EQUIPMENT and ME SYSTEMS

| Guidance and manufacturer's declaration − Electrostatic Discharge | | | |
|---|---|---|---|
| IMMUNITY test | IEC60601 test level | Compliance level | Result |
| Electrostatic discharge (ESD) IEC 61000−4−2 | ± 8kV contact<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15kV air | ± 8kV contact<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15kV air | Pass |

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

| Guidance and manufacture's declaration − Radio−frequency Electromagnetic Field | | | |
|---|---|---|---|
| IMMUNITY test | IEC60601 test level | Compliance level | Result |
| Radiated RF IEC 61000−4−3 | 3 V/m and 10 V/m<br>80 MHz to 2.7 GHz<br>80 % AM at 1 kHz | 3 V/m and 10 V/m<br>80 MHz to 2.7 GHz<br>80 % AM at 1 kHz | Pass |

Table 4 − For all ME EQUIPMENT and ME SYSTEMS

| Guidance and manufacturer's declaration − Power−frequency Magnetic Fields | | | |
|---|---|---|---|
| IMMUNITY test | IEC60601 test level | Compliance level | Result |
| Power frequency (50/60Hz) magnetic field IEC 61000−4−8 | 30 A/m<br>50Hz or 60Hz | 30 A/m<br>50Hz and 60Hz | Pass |

Table 5 − 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] 217 Hz | 9 |
| 745 | | | | |
| 780 | | | | |
| 810 | 800−960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation[b] 18 Hz | 28 |
| 870 | | | | |
| 930 | | | | |
| 1720 | 1700−1990 | GSM 1800, CDMA 1900, GSM 1900, DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation[b] 217 Hz | 28 |
| 1845 | | | | |
| 1970 | | | | |
| 2450 | 2400−2570 | Bluetooth, WLAN, 802.11 b/g/n RFID 2450, LTE Band 7 | Pulse modulation[b] 217 Hz | 28 |
| 5240 | 5100−5800 | WLAN 802.11 a/n | Pulse modulation[b] 217 Hz | 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 7 − 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.

## 18.Accessories

Lanyard: 1 pc (Except YX105 & YX106)

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.

If necessary, please contact the manufacturer or the manufacturer's representative when the LAY operator or the LAY responsible organization needs assistance in setting up, using or maintaining the ME equipment; or when reporting unexpected operations or events.

## 19.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. |
| 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. |
| Perfusion Index (PI) | The Perfusion Index (PI) is the ratio of the pulsatile blood flow to the non−pulsatile or static blood in peripheral tissue. PI thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter. |
| 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. |
| Pulse volume wave | 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 curve is continuously used for tracing. |