YIMI LIFE CE 0598

# Fingertip Pulse Oximeter User Manual

Revision number: 1.2
Release time: June. 2025

© Copyright Shenzhen Yimi Life Technology Co.,Ltd . All rights reserved.

## Chapter 1 Safety

### 1.1 Warnings

- Rx only:Federal (U.S.) law restricts this device to sale by or on the order of a physician.
- Please check the product before use. In case of abnormal operation, please stop using immediately.
- The product is only used as an aid in diagnosis. Please observe the clinical status and symptoms for comprehensive judgment.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with a healthcare professional.
- The product is not for therapy.
- Explosion hazard: DO NOT use the product in the environment with tinder such as anesthetic.
- DO NOT use the product while the patient is being scanned by MRI or CT.
- Do not use the product in an environment that generates strong electric and magnetic fields. Using the product in an inappropriate environment may cause interference to the surrounding radio devices or affect the operation of this product.
- For some special patients, check the measuring parts more carefully. Don't place the product on swollen or fragile tissues.
- Continuous use will cause discomfort or tenderness, especially for patients with microcirculation disorders. It is better to measure continuously at the same location for no more than 2 hours.
- Do not look directly at the red light and infrared light emitter of this product with your eyes (infrared light is invisible light), even if the maintenance personnel do not look directly at it, otherwise it may be harmful to your eyes.
- Although all parts expected to contact the human body have been evaluated biologically, and the biological safety meets the standard requirements, very few people may have allergic reactions, and patients with allergic reactions should stop using them.
- The lanyard is made of non-sensitive materials. People who are extremely sensitive to the lanyard should not use it. Do not break the lanyard; otherwise, it may not be used around the neck, or the product may fall and be damaged due to the damaged lanyard when used around the neck. Do not wrap the lanyard around your neck to avoid asphyxiation.
- Keep away from children, pets and insects during storage to avoid impact on product performance.
- Do not place the product in a place where it is exposed to direct sunlight,



high temperature, humidity, cotton, dust and easy to splash to avoid affecting the machine performance.

- To prevent environmental pollution, the scrapping of this product and its accessories and the disposal of packaging waste should follow local laws and regulations.
- The interference of electrosurgical equipment will affect the measurement accuracy.
- Carbon monoxide poisoning will be over evaluated, and it is not recommended to use.
- The intended operator of this product may be a patient.
- Do not maintain the pulse oximeter when it is in use.
- The maintenance of this product is only carried out by qualified maintenance personnel designated by the manufacturer. Users are not allowed to repair this product and refit it.
- Any serious incident that occurs in relation to the fingertip pulse oximeter should be reported to both the manufacturer and the competent authority of the Member State where you (the user and/or patient) are established.

### 1.2 Cautions

- Before use, ensure that the product is in normal working condition and operating environment.
- This series of products is applicable to adults over 18 years old and children over 3 years old. Do not use this device for newborns and infants.
- The adult version of this equipment can be measured with a finger about 8-25mm thick (diameter); Children's models can be measured with fingers about 7~12mm thick (diameter).
- This product may not be applicable to everyone. If it cannot meet the requirements of satisfactory measurement, please give up using it.
- For more accurate measurement, this product should be used in a quiet and comfortable environment. During measurement, the fingers should be placed flat and kept quiet, and the human body should not be in a state of motion. Fingers facing down or moving will affect the accuracy of measurement.
- The product cannot be used as a monitoring device for continuous measurement.
- Do not use the product immediately when changing from cold to warm and humid environment. It is recommended to wait at least 4 hours.
- Do not use sharp things to operate the product.
- Please do not sterilize the product under high temperature, high pressure, gas fumigation or liquid immersion. Please refer to the manual section (6.1) for cleaning and disinfection. Please remove the internal battery before cleaning and disinfection.



- Data averaging and signal processing cause delays in displaying and transmitting data values for SpO2. The update period of the measurement data is less than 30 seconds. In case of signal attenuation, weak perfusion or other disturbances, the time for obtaining dynamic averages will increase, depending on the pulse rate value.
- Volumetric waveform display has been normalized. When SpO2 and PR values are not measured or are incorrect, "--" is an invalid value as an indicator to remind the user.
- The product has no alarm system and does not provide the alarm function for exceeding the limit of blood oxygen saturation and pulse rate. It is not applicable to the places where the alarm function for exceeding the limit of measured value is required.
- The device is not intended to monitor any clinical parameters of a patient which could lead to death or severe deterioration of the patient's state of health.
- The maximum temperature of the contact surface between the product and the human body shall not exceed 41 ℃, which is measured by the temperature measuring instrument.
- When some abnormalities appear on the screen during measurement, pull out your finger and re-insert it for measurement.
- The measuring part should not have external colorants, such as nail polish, colorants or colored skin care products, or the measurement will be affected.
- Fingers are too cold, thin or nails are too long, which may affect the measured value; When measuring, please fully insert the thicker finger (thumb or middle finger is recommended) into the finger clip.
- Measurement performance under weak perfusion: accuracy of blood oxygen value and pulse rate value will be affected when blood perfusion is less than 0.5%.
- Fingers should be placed correctly. Improper placement or contact position with the sensor will affect the measurement.
- The light between the light-emitting tube and the receiving tube of the pulse oximeter must pass through the micro-arterial blood vessels of the person being measured. There should be no obstructions such as adhesive tape at the positions through which the light path passes, otherwise, it may lead to inaccurate measurement values.
- Too high ambient light will affect the measurement, such as surgical lamp, bilirubin lamp, fluorescent lamp, infrared heating lamp and direct sunlight. In order to prevent the interference of ambient light, the sensor must be properly placed, and the sensor part must be shielded with opaque materials.



- The frequent movement and violent activities of the person being measured will affect the measurement accuracy.
- Do not place the sensor on the limb with blood pressure cuff, arterial catheter or intracavitary pipeline.
- The product has no anti defibrillation function, and the measured value may be inaccurate during and after defibrillation.
- The measurement is based on small artery pulsation, and the measured person must have the minimum pulsating blood flow. The weaker the pulse perfusion and the smaller the plethysmography waveform due to shock, cold or hypothermia, massive blood loss, arterial obstruction or the use of vasoconstrictor drugs, the more sensitive the measurement is to interference.In such circumstances, healthcare professionals should be consulted.
- Intravascular colorants (such as indigo blue, cyan green or methylene blue) and skin pigmentation will affect the measurement.If the readings don't match your physical condition,consult a healthcare professional promptly.
- If the patient has anemia or dysfunction of hemoglobin content (such as carboxyhemoglobin, methemoglobin, sulfmethemoglobin), the measurement result may seem normal, but the patient may be hypoxic. It is recommended to conduct further assessment in combination with clinical symptoms and signs.
- Pulse oxygen is only of reference significance for anemic hypoxia and toxic hypoxia, because some severe anemia patients can still display good pulse oxygen measurement value.In case of such situations, consult a healthcare professional promptly.
- Please read the measure value when the waveform on screen is uniform and stable. The measurement value is optimal value, and the waveform at the moment is the standard one.

### 1.3 Notes

Provides application tips or other useful information to ensure that you get the most from your product.

## Chapter 2 The Basics

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so-called the O2 concentration in the blood. It is an important bio-parameter for respiration. A number of diseases relating to respiratory system may cause the decrease of SpO2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment,



damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body. And the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. serious symptoms might bring danger to human's life. Therefore, prompt information of patients SpO2 is of greats help for the doctor to discover the potential danger, and is of great importance in the clinical of medical field.

### 2.1 Principle

The measurement principle of the pulse oximeter is based on the absorption spectral properties of reduced haemoglobin (Hb) and oxyhaemoglobin (Hb02) in the red and near infrared light regions, using Lambert Beer's law to establish empirical formulas for data processing. The device works on the principle of photoelectric haemoglobin detection combined with volumetric wave tracing technology, using two beams of light of different wavelengths (e.g. 660m red light and 905nm near infrared light) to irradiate the human fingertips through a lens.

Pulse oximeter sensors have red and infrared low voltage light emitting diodes (LEDs) wich serve as light sources. The emitted light is transmitted through the tissue, then detected by the photodetector and sent to the microprocessor of the pulse oximeter. All constituents of the human body, venous and arterial blood, and tissue absorb light. The pulsating of arterial blood results in changes in the absorption to added hemoglobin (Hb) and oxygenated hemoglobin (HbO2) in the path of the light. Since HbO2 and Hb absorb light to varying degrees, this varying absorption is translated into plethysmographic waveforms at both red and infrared wavelengths. The relationship of red and infrared plethysmographic signal amplitude can be directly related to arterial oxygen saturation.

### 2.2 Introduction

#### 2.2.1 Intended Purpose

The Fingertip Pulse Oximeter is a reusable device and intended for spot-checking of oxygen saturation(SpO2) and pulse rate(PR) for use with the finger of adult or pediatric patients in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.

Warnings
- Do not use the oximeter during sports activities.
- Do not use the oximeter for continuous monitoring of patients.



Cautions
- The pulse oximeter is NOT design for newborn and infant.

#### 2.2.2 Intended User

Both Healthcare Professional and Lay person.

#### 2.2.3 Intended Patient Population

Adult or pediatric patients.

#### 2.2.4 Intended Use Environment

Both Hospital/home Healthcare Facility.

#### 2.2.5 Medical indications

The Fingertip pulse oximeter can effectively estimate and predict the blood oxygen concentration in the periphery of the body by non-invasive operation, so as to achieve the role of monitoring the changes of the respiratory disease with using the finger pulse oxygen as the monitoring index.

#### 2.2.6 Contraindications

No known Contraindications.

#### 2.2.7 Components

The oximeter consists of probe, electronic circuits, and display and plastic enclosures.

**Notes:**
**The probe is the hole in the middle of the oximeter to which the finger insert. The probe is the Applied Part of the oximeter.**

#### 2.2.8 Features

1)The fingertip pulse oximeter is small in volumes, light in weight and ease to carry.
2)Automatically Balance of performance and power consumption.
3)One button and ease to operation.
4)Multiple display directions can be rotated.
5)Auto turn off after 8 seconds when there no signal.
6)Bluetooth function (only YM401,YM402,YM403,YM501,YM502,YM503,YM504 models).



### 2.3 Product model list

| No. | Model | Display type | Appearance Type |
|---|---|---|---|
| 1. | YM101 | 1.5" LED(red) | YM01（Basic） |
| 2. | YM102 | 1.5" LED(green) | |
| 3. | YM103 | 1.5" LED(white) | |
| 4. | YM104 | 1.5" LED(blue) | |
| 5. | YM201 | 0.96" OLED | |
| 6. | YM301 | 1.3" OLED | |
| 7. | YM202 | 0.96" TFT | |
| 8. | YM302 | 1.14" TFT | |
| 9. | YM111 | 1.3" LED(red) | YM02（small waist） |
| 10. | YM112 | 1.3" LED(multi colour) | |
| 11. | YM113 | 1.3" LED(white) | |
| 12. | YM114 | 1.3" LED(blue) | |
| 13. | YM211 | 0.96" OLED | |
| 14. | YM212 | 0.96" TFT | |
| 15. | YM314 | 1.14" TFT | |
| 16. | YM601 | 0.96" OLED | |
| 17. | YM602 | 0.96" TFT | |
| 18. | YM401 | 0.96" OLED | YM03（Female） |
| 19. | YM402 | 0.96" TFT | |
| 20. | YM403 | 1.14" TFT | |
| 21. | YM501 | 0.96" OLED | YM04（Male） |
| 22. | YM502 | 0.96" TFT | |
| 23. | YM503 | 1.3" OLED | |
| 24. | YM504 | 1.14" TFT | |
| 25. | YM603 | 0.96" TFT | YM06（Children） |



### 2.4 Functions

| Function | YM101/YM102/YM103/YM104/YM111/YM112/YM113/YM114 | YM201/YM211/YM401/YM501/YM601 | YM301/YM503 | YM202/YM212/YM402/YM502/YM602/YM302/YM314/YM403/YM504/YM603 |
|---|---|---|---|---|
| Display | 1.5"LED/1.3" LED | 0.96" OLED | 1.3"OLED | 1.14"TFT/0.96"TFT |
| SpO2 parameter measurement | √ | √ | √ | √ |
| Pulse rate measurement | √ | √ | √ | √ |
| Bar graph display | √ | √ | √ | √ |
| Battery display | √ | √ | √ | √ |
| Automatic power-off function | √ | √ | √ | √ |
| Pulse beat sound | × | √ | √ | √ |
| Pulse sound On/Off function | × | √ | √ | √ |
| Pulse waveform display | × | √ | √ | √ |
| Multiple direction display | √ | √ | √ | √ |
| PI parameter measurement | √ | √ | √ | √ |
| Bluetooth function | Applicable to YM401,YM402,YM403,YM501,YM502, YM503,YM504 | | | |

### 2.5 Symbols

| Symbol | Definition | Symbol | Definition |
|---|---|---|---|
| %SpO2 | The Pulse Oxygen Saturation(%) | —— | Uninserted finger/Search pulse/Lack of signal |
| PRbpm | The Pulse Rate(beat per minute) | | Power Button |



| Symbol | Definition | Symbol | Definition |
|---|---|---|---|
| PI% | Perfusion index (%) | | Buzzer is ON |
| | The device has no Alarm System | | Buzzer is OFF |
| | Date of Manufacture | | Battery Indicator |
| | Manufacturer | | Low Voltage Indicator |
| | Use-by date | + | Battery Positive Electrode |
| SN | Serial Number | — | Battery Negative Electrode |
| LOT | Batch code | | Fragile, handle with care |
| | BF Type Applied Part | | This side up |
| IP22 | Degree of Protection Provided by Enclosures per IEC60529 | | Keep dry |
| | Caution | 10% 95% | Humidity Limitation |
| | Caution, Consult Accompanying Documents | -20°C 60°C | Temperature Limitation |
| CE 0598 | CE mark | 50.0kPa 107.4kPa | Atmospheric Pressure Limitation |
| EU REP | Authorized representative in the Europe | | WEEE logo |
| MD | Medical Device | | |

(**Note:** Your device may not have all the symbols in the table above.)



## Chapter 3 Operating Guide

### 3.1 Front View

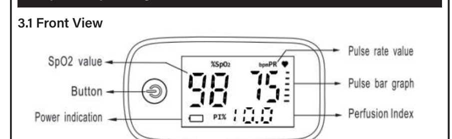



Figure 3-1: LED display

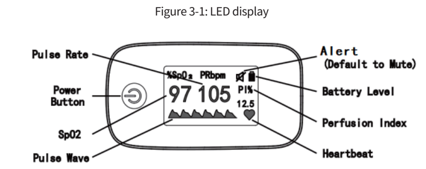



Figure 3-2: TFT/OLED display

### 3.2 Operation Method

1. Remove the battery cover, install two AAA batteries in the correct direction, and install the battery cover.
2. Press the clamp to open the device, and insert the finger until it touches the inside.
3. Press the button to turn on the oximeter.
4. After about 8 seconds, the measured value will be displayed on the display.
5. The displayed value may be unstable. Please confirm that the displayed value is stable for more than 4 seconds before reading the measured value.
6.Remove the finger from the oximeter, and the oximeter will automatically shut down.



⚠ **Caution**: When inserting the finger, the light from the sensor must shine directly on one side of the nail. Please select a finger that fits the oximeter. If you feel too loose or too tight, change to a suitable finger. During use, Please do not shake the finger being measured, and the body should not move. When measuring, insert your finger correctly so that it covers the entire sensor. (Refer to Figure 3-3)

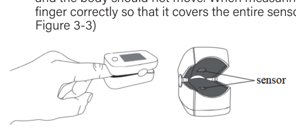



Figure 3-3: Finger placement diagram

### 3.3 Battery Installation

1. Open the battery cover on the back of the product. (See Figure 3-4, Figure 3-5).
2. Install two AAA alkaline batteries in the correct direction according to the polarity indicator of the oximeter battery compartment.
3. After the batteries are installed, close the battery cover.

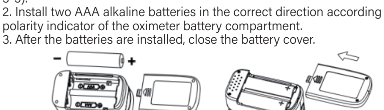


Figure 3-4:Applicable appearance types :YM01/YM02/YM06

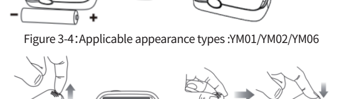


Figure 3-5:Applicable appearance types :YM03/YM04



⚠ **Caution**: Ensure batteries are correctly installed according to their polarities; oximeter may become damaged if batteries are incorrectly installed.

Remove batteries if oximeter will not be used for an extended period of time.

### 3.4 Lanyard installation

1. Pass the thinner end of the lanyard through the hanging hole;
2. Pass the thicker end of the lanyard through the thinner end and tighten the lanyard (Figure3-6).

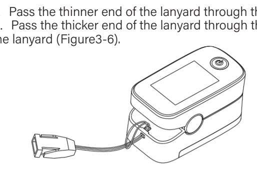


Figure 3-6: Lanyard Installation

## Chapter 4 Function and menu operation

Cautions: The device does not have the alarm system. When the measured value(SpO2 or PR) exceeds upper or lower limit, the device provides sound prompt (alert) to notify the user. This is for informational purposes only and should not be interpreted as a medical alarm.

#### 4.1The button operation rules

After the oximeter is turned on, various operations can be performed through the unique key. The basic operations of the key are as follows:
① · Long press - press the key for 2 seconds to enter or exit the main menu or lower menu, and modify the attribute value of the menu.
② · Short press - press for less than 0.5 seconds to start the machine,



browse through the menu items, and change the parameter values.
③ · Double click - press twice continuously to switch the display direction.

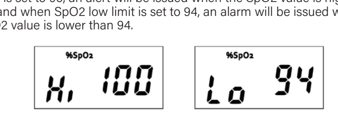
#### 4.2 Menu operation（LED display）

**Active the menu**

After the oximeter is turned on, long-press the power button to activate the menu, then short- press the button to view the setting values of each item. If the user wants to change the setting value of the item, long-press to enter the item's submenu, the parameter value starts to flash, short-press to traverse the parameter value until the parameter value required by the user is selected, long press to confirm and exit the submenu.

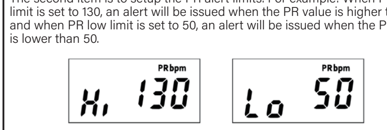
**1. Setup the SpO2 Alert Limits**

The first item is to setup the SpO2 alert limits. For example: When SpO2 High limit is set to 96, an alert will be issued when the SpO2 value is higher than 96, and when SpO2 low limit is set to 94, an alarm will be issued when the SpO2 value is lower than 94.




**2. Setup the PR Alert Limits**

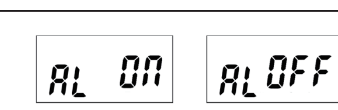
The second item is to setup the PR alert limits. For example: When PR High limit is set to 130, an alert will be issued when the PR value is higher than 130, and when PR low limit is set to 50, an alert will be issued when the PR value is lower than 50.




**3.Turn Alert ON or OFF**

The third item is long-press to turn Alert ON or OFF.






**4. Check the software version**

The forth item is view the software version.

#### 4.3 Menu operation(OLED/TFT display)

**4.3.1 Storage interface**

1. Press the button to turn on the oximeter,the oximeter will enter the storage interface.Short press the button to select the page to view the previous historical test data,without pressing the button ,this page will remain for 3 seconds.
2. The first measurement data (data with countdown record) after each startup will be stored,and the data at the front of the storage interface is the latest test data.

```
                DATA REVIEW(1/4)
Storage group      M1  M2  M3  M4  M5
Spo2 %          02: 97  97  99  97  --
Pulse rate      PR: 75  75  81  85  --
```

Storage Interface

**4.3.2 Menu**

1. After turning on the oximeter,press and hold the button for about 2seconds.The oximeter will display the settings menu.Short press to move "*"to a corresponding option,and hold the button to confirm your selection.
2. Quickly press the power button twice to rotate the display.

```
       MENU
* GENERAL SETUP  ENTER
  ALERT SETUP    ENTER
  DATA REVIEW    ENTER
  EXIT
```



**4.3.3 General setup**

MENU→ GENERAL SETUP:
【ALERT】-ON: When the alert is set to ON and the measured SpO2 or PR Values go beyond the upper or lower limits,the oximeter will sound an alert.
【ALERT】-OFF: When the alert is set to OFF and the measured Values go beyond the limits,the oximeter will not sound an alert.
【SOUND】-ON: When sound is set to ON,the oximeter plays a sound indicating the pulse rate during the measurement.
【SOUND】-OFF: When sound is set to OFF,No pulse rate sound is played.
【BRIGHTNESS】: The brightness level can be adjusted from 1 to 5.
【DEFAULTS】: While the "*" is on the default option,hold the button to restore factory settings.
【EXIT】: Press and hold to return to the upper menu or the main measurement interface.

```
   GENERAL SETUP
* ALERT        ON
  SOUND        OFF
  DEMO         PLAY
  BRIGHTNESS   3
  DEFAULT      RESTORE
  EXIT
```

**4.3.4 Alert setup**

1. Press the button to switch between options.On this screen,you can set the upper limit and lower limit of the SpO2 and PR alerts.
2. Select the corresponding option and hold the button to change the upper or lower limit.
3. Move "*" to the Exit option and hold the button to return to Measurement Mode.

```
    ALERT SETUP
* SPO2 ALT HI   100
  SPO2 ALT LO   94
  PR ALT HI     120
  PR ALT LO     50
  EXIT
```



## Chapter 5 Technical Specifications

| | |
|---|---|
| **1. Classification** | |
| Type of protection against electric shock | Internally powered |
| Degree of protection against electric shock | Type BF-Applied part (non-defibrillation proof) |
| Grade of Enclosure protection | IP22 |
| Pollution Degree | 2 |
| Mode of operation | Continuous operation |
| **2. Power Requirement** | |
| Operating voltage | 3Vdc, 2×1.5V AAA batteries |
| **3. Physical specifications** | |
| Overall size（length×width×height）mm | Appearance YM01 and YM02：57×30×31mm<br>Appearance YM03：62×34×35mm<br>Appearance YM04：63×36×37mm<br>Appearance YM06：54×32×31mm |
| Max.Weight | <35 g (without the batteries) |
| **4. Display** | |
| Display type | LED /OLED/TFT |
| Display content | See "Section 2.4 Functions" |
| **5. SpO2 Measurement specification【Note 1】** | |
| Measurement range | 35~100% |
| Measurement accuracy | 70~100%：The accuracy is not more than ±2%;<br>35~69%：undefined. |
| Resolution | 1% |
| **6. PR Measurement specification** | |
| Measurement range | 30~250bpm |
| Measurement accuracy | ±3bpm |
| Resolution | 1bpm |
| Data update period | ＜30s |



| | |
|---|---|
| **7. Environmental conditions** | |
| Operating conditions：<br>Temperature:10 ℃~40 ℃<br>Relative humidity:15%~95%(non-condensing)<br>Atmospheric pressure:70kPa-106kPa | Transportation and Storage conditions：<br>Temperature：-20 ℃~60 ℃<br>Relative humidity：10%~95%(non-condensing)<br>Atmospheric pressure：50kPa-107.4kPa |
| **8. Optical sensor specification【Note 2】** | |
| Red Led | The wavelength of red light is about 660nm, output power: 9-13mW |
| IR Led | The wavelength of infra-red light is about 905nm, output power:3-6mW |
| **9. Use-life** | Five years |

**【Note 1】:**
(a) The claim of accuracy of blood oxygen saturation should be supported by clinical research measurement covering the whole range.
The accuracy test method of blood oxygen saturation is to select healthy subjects who meet the conditions, conduct induced blood oxygen lowering test and conduct arterial blood sampling. Record the measured value (SpO2) of the test equipment while taking the blood sample, measure the SaO2 of the arterial blood sample taken by the calibrated blood gas analyzer and compare it with the measured value (SpO2) of the test equipment, so as to evaluate the accuracy of the pulse oxygen saturation measurement function of the test equipment.
Because PULSE OXIMETER EQUIPMENT measurements are statistically distributed, only about two - thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ± Arms of the value measured by a CO - OXIMETER.
(b) The subjects were healthy non-smoking individuals who volunteered to participate in the clinical trial, including women and men from light skin to dark skin, and the age was between 18 and 45 years old.
(c) The functional test equipment cannot be used to evaluate the accuracy of oximeters. However, the oximeter products manufactured by our company have a specific calibration curve, and the functional test equipment can measure the portion of the overall error of the oximeter system that comes from the product itself based on this curve, so the functional test equipment will also be able to test the accuracy of the oximeter that replicates this calibration curve.
【Note 2】: Optical sensors are luminous components, which will affect other medical devices using this wavelength range. This information may be useful to clinicians who perform optical therapy. For example, clinicians operate photodynamic therapies.



## Chapter 6 Clinical Information

### 6.1 Clinical benefits

The fingertip pulse oximeter provides the following clinically validated benefits to patients:
- The blood oxygen saturation (SpO2) value can be monitored in time, especially for people with low blood oxygen state and cardiovascular disease, and the measurement data provided can be used by doctors as a reference for medical diagnosis in time, and applied to the diagnosis of cardiovascular disease, which has positive impact on clinical outcome.
- Patients can monitor blood oxygen saturation(SpO2) and pulse rate (PR) at home at any time, greatly reducing the number of visits to the hospital, reducing the risk of travel and improving the quality of patient's life.

The fingertip pulse oximeter can realize the clinical benefit by monitoring the clinical outcome parameters (SpO2 and PR).Full parameter specifications are detailed in Chapter 5.

### 6.2 Graphical Plot of All Sampled Data Points

(1) Model：YM101

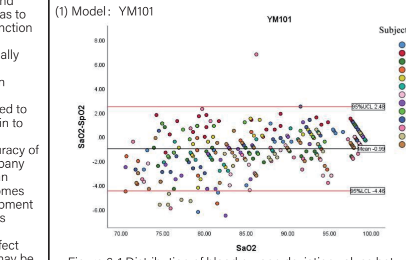



Figure 6-1:Distribution of blood oxygen deviation values between YM101 test equipment and reference equipment



(2) Model：YM201

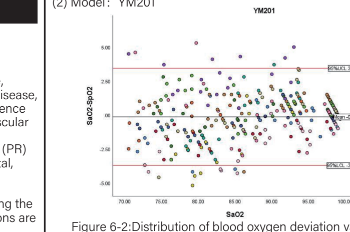



Figure 6-2:Distribution of blood oxygen deviation values between the YM201 test device and the reference device

(3)Model：YM403

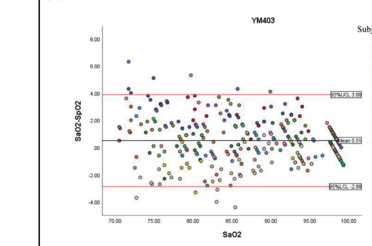



Figure 6-3:Distribution of blood oxygen deviation values between the YM403 test device and the reference device



(4) Model：YM503

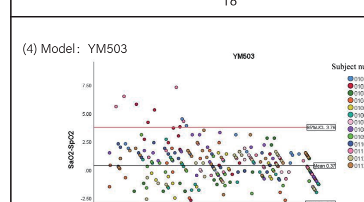



Figure 6-4:Distribution of blood oxygen deviation values between the YM503 test device and the reference device

(5) Model：YM603

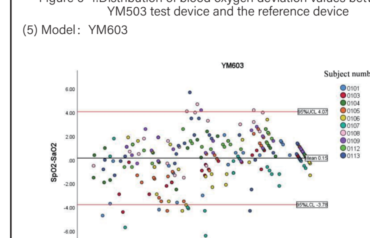



Figure6-5:Distribution of blood oxygen deviation values between YM603 test equipment and reference equipment



### 6.3 Assessing the Validity of a SpO2 Reading

You can check the quality of the pleth wave and the stability of the SpO2 values on the Patient Monitor to assess whether the sensor functions properly and whether the SpO2 readings are valid. Always use these two indications simultaneously to assess the validity of a SpO2 reading.

**NOTE:**
1.The SpO2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies composed of local healthy men and women from age 20 to 27, with variations of skin pigmentations.
2.The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).
3.Generally, the quality of the SpO2 pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO2 values also reflects the signal quality. Different from varying SpO2 readings caused by physiological factors, unstable SpO2 readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO2 readings, try to limit patient movement.

### 6.4 Accuracy of the Pulse Oximeter in the healthly adult volunteer hypoxia study

(1)Accuracy of the Pulse Oximeter of YM101/YM102/YM103/YM104/YM111/YM112/YM113/YM114

| SaO2 Range (%) | 70-100(Overall) | 70-80 | 80-90 | 90-100 |
|---|---|---|---|---|
| # of data pairs | 315 | 76 | 107 | 132 |
| Bias | -0.99 | -1.97 | -1.18 | -0.26 |
| Arms | 1.99 | 2.85 | 2.08 | 1.13 |

(2)Accuracy of the Pulse Oximeter of YM201/YM202/YM301/YM302/YM311/YM212/YM314/YM601/YM602



| SaO2 Range (%) | 70-100(Overall) | 70-80 | 80-90 | 90-100 |
|---|---|---|---|---|
| # of data pairs | 315 | 76 | 107 | 132 |
| Bias | -0.15 | -0.67 | -0.48 | 0.43 |
| Arms | 1.79 | 2.35 | 1.88 | 1.28 |

(3)Accuracy of the Pulse Oximeter of YM403/YM401/YM402

| SaO2 Range (%) | 70-100(Overall) | 70-80 | 80-90 | 90-100 |
|---|---|---|---|---|
| # of data pairs | 315 | 76 | 107 | 132 |
| Bias | 0.51 | 0.91 | 0.36 | 0.40 |
| Arms | 1.76 | 2.33 | 1.86 | 1.20 |

(4)Accuracy of the Pulse Oximeter of YM503/YM501/YM502/YM504

| SaO2 Range (%) | 70-100(Overall) | 70-80 | 80-90 | 90-100 |
|---|---|---|---|---|
| # of data pairs | 315 | 76 | 107 | 132 |
| Bias | 0.37 | 0.59 | 0.58 | 0.77 |
| Arms | 1.73 | 2.60 | 1.62 | 1.06 |

(5)Accuracy of the Pulse Oximeter of YM603

| SaO2 Range (%) | 70-100(Overall) | 70-80 | 80-90 | 90-100 |
|---|---|---|---|---|
| # of data pairs | 242 | 56 | 84 | 102 |
| Bias | 0.15 | -0.69 | 0.01 | 0.72 |
| Arms | 1.96 | 2.28 | 2.25 | 1.45 |

### 6.5 Accuracy of the device in the skin pigmentation and gender subgroups

The pulse oximeter accuracy was tested in thirteen healthy subjects(aged 20-27), with skin tones varying from Fitzpatrick II-V. Of these,4 subjects had dark skin with Fitzpatrick V, 4 subjects had lighter skin with Fitzpatrick II, 4 subjects had Fitzpatrick IV, and 1 subject had Fitzpatrick III.



## Chapter 7 Maintenance

### 7.1 Cleaning

The internal battery must be removed before cleaning the product, and the product must not be immersed in liquid. Users can use 75% medical alcohol to wipe and disinfect, and then air dry or clean the product with a clean and dry cloth. Do not directly spill liquid on the product during cleaning to avoid liquid infiltration into the product.

### 7.2 Maintenance

The designed service life of the oximeter is 5 years. To ensure the service life of the product, please pay attention to maintenance.
1)Check regularly to ensure that the product has no obvious damage that may affect safety or monitoring performance. It is recommended to check at least once a week. If there is obvious damage, stop using this product.
2)Clean the product surface before use, wipe it with alcohol, and then air dry or wipe it dry.
3)The operating environment shall be free of combustible substances, and high or low temperature or humidity shall be avoided.
4)If the oximeter is splashed or condensed with water, stop the operation.
5)Please replace the battery in time when low voltage prompts.
6)If the product is not used for a long time, please take out the battery to avoid leakage.
7)Non professional maintenance personnel are not allowed to open the instrument housing for maintenance. If the product needs to be repaired, it can be repaired by qualified maintenance personnel designated by the manufacturer. The manufacturer can provide maintenance personnel with product technical data such as product circuit diagrams, component lists, and illustrations. These data can refer to the technical specifications. Please contact the manufacturer's technical personnel to provide them.
8)The display function of this product has been calibrated before leaving the factory, so users do not need to calibrate again during use.
9)This product does not need to be calibrated during maintenance.

### 7.3Transportation and storage

1)The packaged products shall be transported according to the conventional transportation requirements or the transportation contract. During the transportation, severe impact, vibration, rain and snow shall be avoided, and the products shall not be mixed with toxic, harmful and corrosive substances.
2)The packaged products shall be stored in an environment of - 20 to 60 ℃,



10% - 95% relative humidity, without corrosive gas and in a well ventilated room.
3)It is recommended to store the oximeter in a dry and cool environment. Humidity will shorten its service life and even damage the oximeter.

### 7.4 Disposal

Dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations.

## Chapter 8 Accessories

1.One lanyard;
2.Two AAA batteries(optional);
3.One user manual;

## Chapter 9 Troubleshooting

Warnings: Necessary maintenance must be performed by qualified service personal ONLY.
Users are NOT permitted to maintain the oximeter by themselves.
There are NO replaceable components in the oximeter.

| Trouble | Possible Reason | Solution |
|---|---|---|
| The oximeter can't be turned on. | The battery is drained away or almost drained away. | Please replace battery. |
| | The battery installation is incorrect. | Install the battery over again. |
| | The malfunction of the oximeter. | Please contact the local service center. |
| The display is off suddenly. | The oximeter is set to shut down automatically in 8 seconds when there is no correct physiological Signals. | Normal |
| | The battery is almost drained away. | Please replace battery. |



| Trouble | Possible Reason | Solution |
|---|---|---|
| The Spo2 and Pulse Rate are not displayed stably. | The thoroughfare from photo detector to light emitting diode was sheltered by some object. | Check and clean the inside of the probe especially the two windows of sensors, |
| | The finger is shaking or the patient is moving. | The patient try to keep still. |
| | The finger is not placed inside deep enough. | Place the finger properly and try again. |
| | The finger's size is too big or too small. | Select the correct size finger to measure. |
| | Excessive ambient light | Avoid the excessive ambient light irradiation. |
| | Pulse rate value of the cyclical fluctuations. | The measurement is normal, and the patient is arrhythmia. |
| The Spo2 and Pulse Rate can't be displayed normally. | The finger is not properly positioned. | Place the finger properly and try again. |
| | The patient's Spo2 is too low to be detected. | Try again, go to a hospital for a diagnosis if you are sure the oximeter works all right. |
| Pulse sound can't be turned off | The key is bad. | Check the key and press again. |
| | The press time is not right. | Make sure the press time is 2~3 seconds. |

## Appendix A EMC

**The Fingertip Pulse Oximeter complies with the requirement of standard IEC60601-1-2:2014+AMD1:2020 "Electromagnetic disturances – Requirements and tests".**

### Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.



**Warning**: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

**Warning**: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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

**Warning**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Fingertip Pulse Oximeter (YM101,YM102,YM103,YM104,YM201,YM202,YM301,YM302,YM111,YM112,YM113,YM114,YM211,YM212,YM314,YM401,YM402,YM403,YM501,YM502,YM503,YM504,YM601,YM602,YM603),including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

**If any**: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

### Technical description

1.All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2.Fingertip Pulse Oximeter do not contains magnetically sensitive electronic components and circuitry.



3.Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

**Table 1**

| Guidance and manufacturer's declaration - electromagnetic emissions | |
|---|---|
| Emissions test | Compliance |
| RF emissions CISPR 11 | Group 1 |
| RF emissions CISPR 11 | Class B |
| Harmonic emissions IEC 61000-3-2 | N/A |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | N/A |

**Table 2**

Guidance and manufacturer's declaration - electromagnetic Immunity

| Immunity Test | IEC 60601-1-2 Test level | Compliance level |
|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air |
| Electrical fast transient/burst IEC 61000-4-4 | Power supply lines：±2 kV<br>100 kHz repetition frequency | N/A |
| Surge IEC 61000-4-5 | line(s) to line(s)：±1 kV. | N/A |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% 0.5 cycle<br>At 0°, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 °<br>0% 1 cycle<br>And<br>70% 25/30 cycles<br>Single phase: at 0<br>0% 300 cycle | N/A |
| Power frequency magnetic field IEC 61000-4-8 | 30 A/m<br>50Hz/60Hz | 30 A/m<br>50Hz/60Hz |



| Immunity Test | IEC 60601-1-2 Test level | Compliance level |
|---|---|---|
| Conduced RF * IEC61000-4-6 | 150KHz to 80MHz：<br>3Vrms<br>6Vrms (in ISM and amateur radio bands)<br>80% Am at 1kHz | N/A |
| Radiated RF IEC61000-4-3 | 10 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz | 10 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz |
| Proximity magnetic fields IEC 61000-4-39 | 30 kHz: 8A/m<br>134.2 kHz: 65A/m<br>13.56 MHz: 7.5A/m | 30 kHz: 8A/m<br>134.2 kHz: 65A/m<br>13.56 MHz: 7.5A/m |

NOTE UT is the a.c. mians voltage prior to application of the test level.
Remark: "*" : Only test for Patient Coupling line.

**Table 3**

Guidance and manufacturer's declaration - electromagnetic Immunity

| | Test Frequency (MHz) | Band (MHz) | Service | Modulation | Maximum Power(W) | Distance (m) | IEC 60601-1-2 Test level (V/m) | Compliance level (V/m) |
|---|---|---|---|---|---|---|---|---|
| Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment | 385 | 380 – 390 | TETRA 400 | Pulse modulation 18 Hz | 1，8 | 0，3 | 27 | 27 |
| | 450 | 430 – 470 | GMRS 460, FRS 460 | FM ± 5 kHz deviation 1 kHz sine | 2 | 0，3 | 28 | 28 |
| | 710 | 704 – 787 | Banda LTE 13, 17 | Pulse modulation 217 Hz | 0，2 | 0，3 | 9 | 9 |
| | 745 | | | | | | | |
| | 780 | | | | | | | |
| | 810 | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 2 | 0，3 | 28 | 28 |
| | 870 | | | | | | | |
| | 930 | | | | | | | |



| | Test Frequency (MHz) | Band (MHz) | Service | Modulation | Maximum Power(W) | Distance (m) | IEC 60601-1-2 Test level (V/m) | Compliance level (V/m) |
|---|---|---|---|---|---|---|---|---|
| | 1720 | 1 700 – 1 990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz | 2 | 0，3 | 28 | 28 |
| | 1845 | | | | | | | |
| | 1970 | | | | | | | |
| | 2450 | 2 400 – 2 570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0，3 | 28 | 28 |
| | 5240 | 5 100 – 5 800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 0，2 | 0，3 | 9 | 9 |
| | 5500 | | | | | | | |
| | 5785 | | | | | | | |

**Tabla 4**

Guidance and manufacturer's declaration - electromagnetic Immunity

| Test frequency | Modulation | IMMUNITY TEST LEVEL (A/m) |
|---|---|---|
| 30 kHz | CW | 8 |
| 134,2 kHz | Pulse modulation a 2,1 kHz | 65 b |
| 13,56 MHz | Pulse modulation a 50 kHz | 7,5 b |

a)The carrier shall be modulated using a 50% duty cycle square wave signal.
b)r.m.s., before modulation is applied.



**Contact Information**

Manufacturer: Shenzhen Yimi Life Technology Co.,Ltd.
Address: 302 Building C,YouLiTong Technology Industrial Plant,No.56 Qingsong Road , Laokeng Community, Longtian Street , Pingshan District ,518118 Shenzhen ,China
TEL +86 755-89369909
Email: hnpsd@myspo2.com

**EU REPRESENTATIVE**

Share Info GmbH
Address: Am Schulzentrum 12, 41564 Kaarst, Germany.
Email: eu-rep@share-info.com