File Type	Tech File	Class of Confidentiality	confidential
File No.	H-25-02-0001	File Version	1.0
Project Code	YM20 series	Scope of application	Fingertip pulse Oximeter

User Manual

prepared by:	Review:	approve:
date:	date:	date:

Revision history

Version	Overview of revisions	Revised by	Revision date
1.0	Initial release	Fu Qin	2022-06-01

CE Marking

CE 0123

The product bears CE mark indicating its conformity with the provisions of the EU Medical Device Regulation 2017/745 concerning medical devices and fulfils the essential requirements of Annex I of this Regulation.

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

- Revision number: 1.0
- Software revision: Refer to the boot interface of the oximeter
- Release time: June. 2022

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
FAX +86 755-89369909
Email: hnpsd@myspo2.com

EC REPRESENTATIVE

Shanghai International Holding corp. Gmbh(Europe)
Address: Eiffestrasse 80, 20537, Hamburg, Germany
Email: shholding@hotmail.com

Preface

Dear users，thanks you very much for purchasing the Fingertip Pulse Oximeter.

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

FCC Caution.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Contents

Chapter1 Safety

1.1 Warnings

- This product should be operated by trained medical personnel or instructed non medical personnel.
- Please check the pulse oximeter before use. In case of abnormal operation, please stop using immediately.
- This product is only used as an aid in diagnosis. Please observe the clinical status and symptoms for comprehensive judgment.
- The oximeter is not a therapeutic device.
- Explosion hazard: Do not use this product in an environment with flammable substances such as anesthetic.
- Do not use this product at the same time during MRI and CT examinations, because the induced current may cause burns.
- Do not use this product in an environment that generates strong electric and magnetic fields. Using this product in an inappropriate environment may cause interference to the surrounding radio devices or affect the operation of this product.
- For some special patients, the measuring parts need to be examined more carefully, and this product should not be placed on edema 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.
- Please do not open the pulse oximeter to directly look at the light emitting device with your eyes (infrared light is invisible light), 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 itself is made of non sensitive substances, but people who are extremely sensitive to the lanyard should not use it. Do not break the lanyard, or the lanyard is considered damaged during use, causing the product to fall and be damaged. 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.

1.2 Cautions

- Before using this product, ensure that it is in normal working condition and operating environment.
- This series of products is applicable to adults (age>18 years old, weight>50kg) and children (3<age<18 years old, weight 15-50kg). 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 6~12mm 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.
- This product cannot be used as a monitoring device for continuous measurement.
- Do not use this 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 this 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 delay the display and transmission of data values of SpO2. The measurement data update period is less than 30 seconds. When signal attenuation, weak perfusion or other disturbances occur, the time for taking dynamic mean value will increase, depending on the pulse rate value.
- Volumetric waveform display is normalized,. When SpO2 and PR values are not measured or are incorrect, "--" is an invalid value as an indicator to remind the user.
- This 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 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.
- In the process of measurement, when there are some abnormalities on the screen, pull out the finger and re insert the 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 photoelectric receiver tube and the luminous tube of the blood oximeter must pass through the small artery of the person being measured, and the place where the light path passes through must not have light barriers such as adhesive tape, otherwise the measured value may be inaccurate.
- 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 measurement accuracy will be affected by the frequent movement and violent activities of the measured person.
- Do not place the sensor on the limb with blood pressure cuff, arterial catheter or intracavitary pipeline.
- This 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.
- Intravascular colorants (such as indigo blue, cyan green or methylene blue) and skin pigmentation will affect the measurement.
- If the tested person is anaemic or has hemoglobin with equivalent dysfunction (such as carboxyhemoglobin, methemoglobin and thiohemoglobin), the measured value may seem normal, but the tested person may be anoxic, so it is recommended to further evaluate in combination with clinical manifestations and symptoms.
- 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.
- Contraindications: None.

1.3 Notes

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

Chapter2 The Basics

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so-called the O_2 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 principle of pulse oximeter is based on the red and infrared light absorption characteristics of oxygenated and deoxygenated hemoglobin. Oxygenated hemoglobin absorbs more infrared light and allows more red light to pass through. Deoxygenated (or reduced) hemoglobin absorbs more red light and allows more infrared light to pass through. Red light is in the 600-750 nm wavelength light band. Infrared light is in the 850-1000 nm wavelength light band.

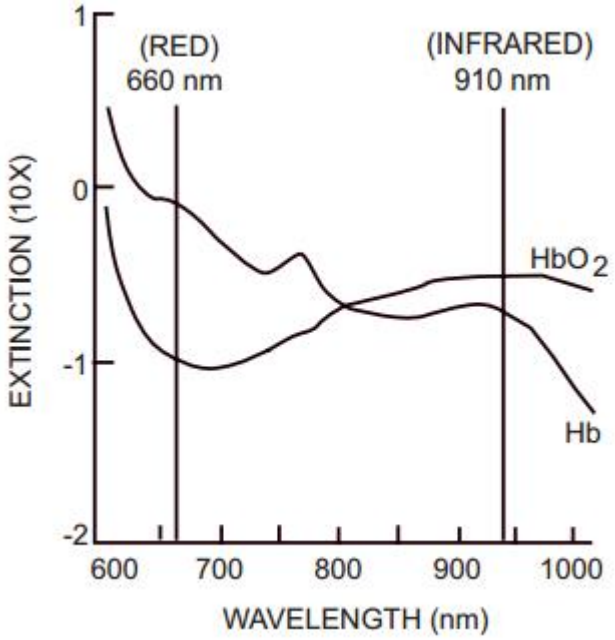


Figure 1 : Absorption spectra of HbO2 and Hb for red and infrared wavelengths

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 (Figure 2). The pulsating of arterial blood results in changes in the absorption to 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.

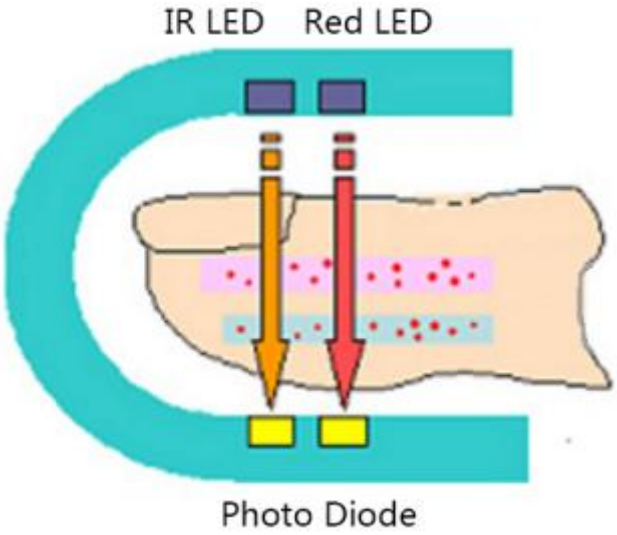


Figure 2: Oximeter‘s schematic illustration

2.2 Introduction

2.2.1 Intended Use

The pulse oximeter is a reusable device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult or child 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. For adults and children, it recommended that the finger thickness should between 8-25mm.**

2.2.2 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.**

2.2.3 Features

- The fingertip oximeter is small in volumes, light in weight and ease to carry.

- Automatically Balance of performance and power consumption.
- One button and ease to operation.
- Multiple display directions can be rotated.
- Auto turn off after 8 seconds when there no signal.
- Bluetooth function (only male and female 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(multicolour)	
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	

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
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	√	√	√	√

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
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		Humidity Limitation
	Caution, Consult Accompanying Documents		Temperature Limitation
CE 0123	CE mark		Atmospheric Pressure Limitation
EC REP	Authorized representative in the Europe		WEEE logo

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

Chapter3 Operating Guide

3.1 Front View

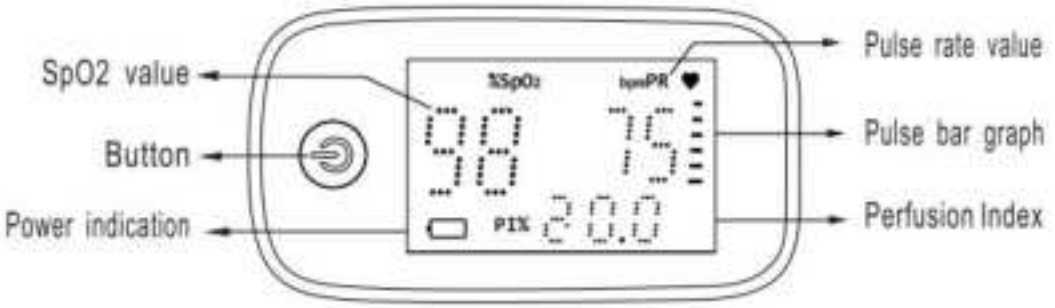


Figure 3: LED display

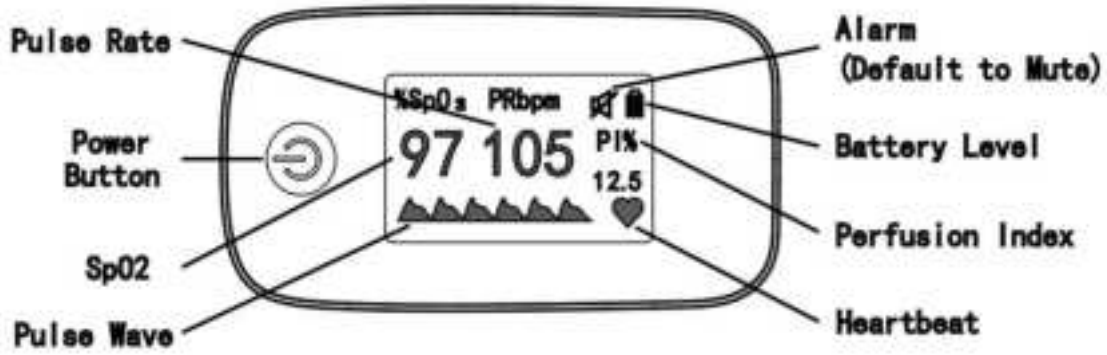


Figure 4: TFT/OLED display

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.

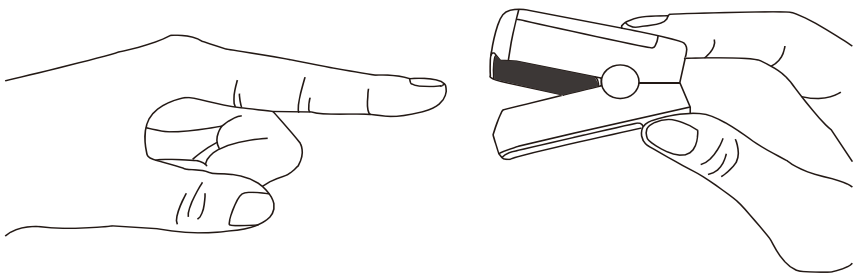


Figure 5

3. Press the function key to turn on the power of the device.
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 device, and the oximeter will automatically shut down.

Caution： When inserting a finger, the light from the sensor must directly shine on one side of the fingernail. Please select a finger that is suitable for this device. If it feels too loose or tight, please replace it with a suitable finger.
During use, it is better not to shake the measured finger, and the human body should not be in motion. Please install it correctly when measuring, so that your fingers cover the entire sensor. (Refer to Figure 6)

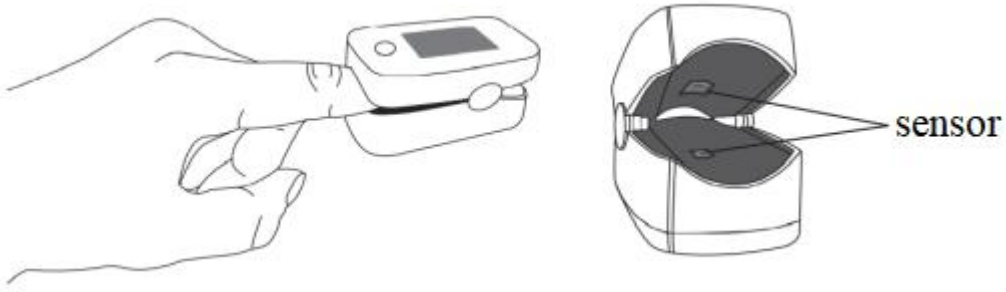


Figure 6 Finger placement diagram

3.3 Battery Installation

1. Open the back cover of the battery compartment on the back of the product (refer to the following table).
2.Insert two AAA batteries into battery compartment according to correct polarities as shown in the figure below.
3.After installing the battery, close the battery cover.

No.	Appearance type	Applicable model	Battery installation
1.	YM01（Basic）	YM101/YM102/YM103/YM104 /YM201/YM202/YM301/YM302	
2.	YM02(Small waist） YM03（Female） YM04（Male）	YM111/YM112/YM113/YM114/YM211/YM212/YM314/YM601/YM602 YM401/YM402/YM403 YM501/YM502/YM503/YM504	

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 (Figure7).

Figure 7: Lanyard Installation

Chapter4 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 and light prompt.This article about alarm writing is for people to understand.

4.1 The button operation rules

After the equipment 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.

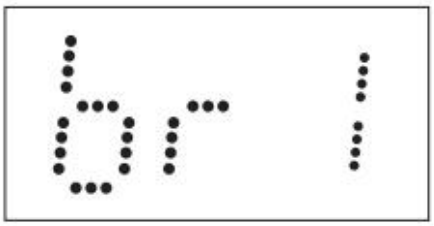
4.2 Menu operation（LED display）

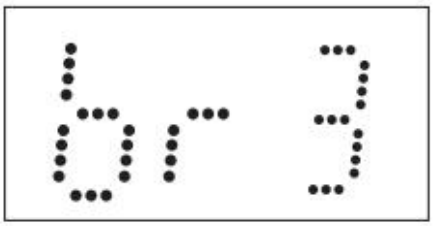
Active the menu

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 LED display brightness

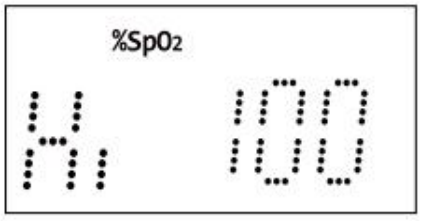
The first item is to setup the display brightness. Long-press the button to select a brightness level ranging from 1 to 3. The greater the value, the greater brightness of the display.

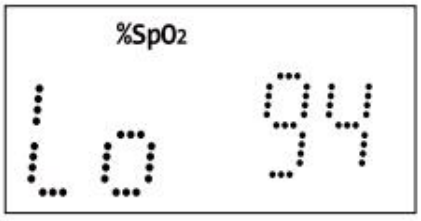




2.Setup the SpO2 Alarm Limits

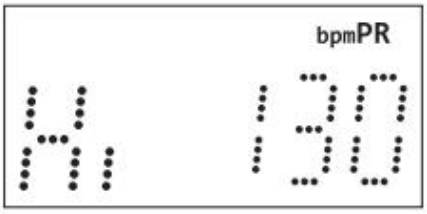
The second item is to setup the SpO2 alarm limits. For example: When SpO2 High limit is set to 96, an alarm will be issued when the SpO2 value is higher than 96, and when SpO2 low limit is set to 94, an alarm will be issued when the SpO2 value is lower than 94.

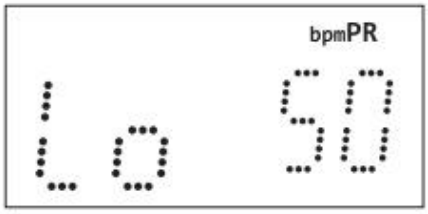




3.Setup the PR Alarm Limits

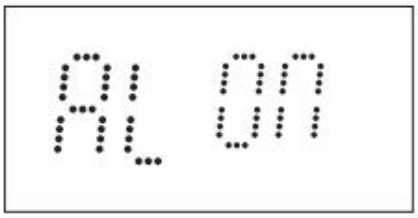
The third item is to setup the PR alarm limits. For example: When PR High limit is set to 130, an alarm will be issued when the PR value is higher than 130, and when PR low limit is set to 50, an alarm will be issued when the PR value is lower than 50.

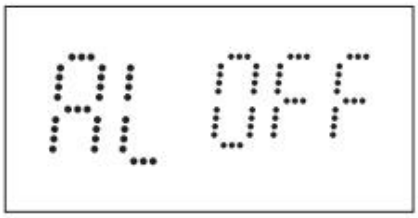




4.Turn Alarm ON or OFF

The forth item is long-press to turn Alarm ON or OFF.





5.Check the software version

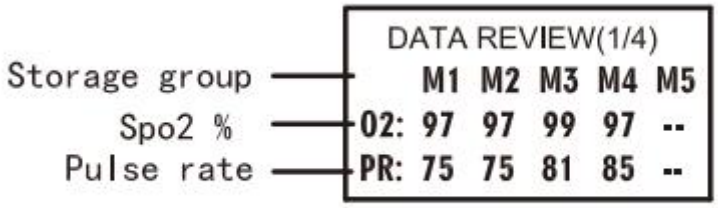
The fifth item is view the software version.

4.3 Menu operation(OLED/TFT display)

4.3.1 Storage inteface

1．Press the power button,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.



Storage Interface

4.3.2 Menu

1．After turning on the oximeter,press and hold the power 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 to rotate the display.

4.3.3 General setup

MENU→ GENERAL SETUP：

【ALARM】-ON： When the alarm is set to ON and the measured SpO2 or PR Values go beyond the upper or lower limits,the oximeter will sound an alert.

【ALARM】-OFF： When the alarm 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.

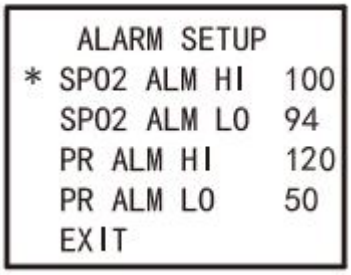
【EXIT】： Press and hold to return to the upper menu or the main measurement interface.

4.3.4 Alarm 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 alarms.

2. Selcet 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.



Chapter5 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 Appearance YM03：62×34×35mm Appearance YM04：63×36×37mm	
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%; 0~69%：undefined.	
Resolution	1%	
6、PR Measurement specification		
Measurement range	30~250bpm	
Measurement accuracy	±3bpm	
Resolution	1bpm	
Data update period	＜30s	
7、Environmental conditions		
Operating environmental conditions： Operating temperature:10~40℃ Relative humidity:15~95% Atmospheric pressure:70kPa-106kPa		Operating environmental conditions： Operating temperature：-20~60℃ Relative humidity：10~95% Atmospheric pressure：70kPa-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 red light is about 905nm,output power:3-6mW	

【Note 1】： The above measurement accuracy is derived from the blood oxygen simulator。

SpO2 Measurement accuracy: in 70%-100% measurement range，Arms≤3%（For the definition of Arms, see ISO80601-2-61）。

(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 the blood oxygen measurement value is published with statistical probability, only about 2/3 of the blood oxygen measurement value falls within ± Arms of the value measured by the carbon monoxide blood gas analyzer.

(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 function tester cannot be used to evaluate the accuracy of the oximeter. However, the blood oximeter products produced by our company have a specific calibration curve, and the functional test equipment can measure the part of the overall error of the blood oximeter system that comes from the product itself according to this curve, so the functional tester can also test the accuracy of the blood oximeter that copies 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.

Chapter6 Maintenance

6.1 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.

6.2 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.

6.3 Transportation 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.

6.4 Disposal

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

Chapter7 Accessories

1. One lanyard;
2. Two AAA batteries;
3. One user manual;
4. One certificate card

Notes

- **For particular configuration of accessories please refer to the product package list.**

Chapter8 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.
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 Professional healthcare facility environment 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), 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 A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance

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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV 100 kHz repetition frequency	Power supply lines：±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s)：±1 kV.	line(s) to line(s)：±1 kV.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And

	70% 25/30 cycles Single phase: at 0 0% 300 cycle	70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz： 3Vrms 6Vrms (ISM bands between) 80% Am at 1kHz	150KHz to 80MHz： 3Vrms 6Vrms (ISM bands between) 80% Am at 1kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	Not application
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Maximum Power**(W)	**Distance** (m)	**IEC 60601-1-2 Test level** (V/m)	**Compliance level** (V/m)
	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	LTE Band 13,	Pulse modulation	0,2	0.3	9	9
	745							

	780		17	217 Hz				
	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							
	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							