

Wrist Pulse Oximeter User Manual

Version :A00
Revision date:2022-9
ENSMWP01202209237WHH/13.14.001.0158/23051115.010

1.Product Introduction

This Wrist Pulse Oximeter is a kind of innovated medical device with non-invasive features for artery SpO2 and PR detection. Being portable, it is able to measure SpO2 and PR values quickly and precisely.

1.1 General Description
Haemoglobin Saturation is the percentage between the capacity of Oxyhemoglobin (HbO2) that compounded with oxygen and that of all combinativable haemoglobin (Hb) in blood. In other words, it is the saturation of Oxyhemoglobin in blood. It is a very important physiological parameter for Respiratory and Circulation Systems. Many respiratory diseases could reduce haemoglobin saturation in human blood. Moreover, factors such as Automatic Organic Regulation Malfunction caused by anaesthesia, trauma resulted from major operation and some medical examination can also cause problems in oxygen supply, which might reduce human haemoglobin saturation. As a result, such symptoms as megrim, vomiting and asthenia might appear to patients. Hence, it is very important to know hemoglobin saturation of patient timely in clinical medical aspects.

The Wrist Pulse Oximeter features in small volume, low power consumption, convenient operation and portability. It is only necessary for patient to put one finger into fingertip photoelectric sensor for diagnosis, and the display screen will directly show measured value of hemoglobin saturation. It has been proved in clinical experiments that it possesses rather high precision and repeatability.

1.2 Intended use
The Wrist Pulse Oximeter can be used to measure human haemoglobin saturation and pulse rate through finger , it can be used in hospitals, families, schools and medical centers.

1.3 User Group
People who need blood oxygen measurement .

1.4 Contraindication
not found

1.5 Product include
main machine and SpO2 sensor.

1.6 Measurement principle
The principle of the oximeter is as follows: An experience formula of data process is established by exerting Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin and oxyhemoglobin (HbO2) in red light and infrared light zones. Operation principle of the instrument is to combine Photoelectric Oxyhemoglobin Inspection Technology with Capacity Pulse Scanning and Recording Technology, so that two lights with different wavelength (660nm red light and 905nm infrared light) can be focused onto human nail through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of diodes through process in electronic circuits and microprocessor.

-1-

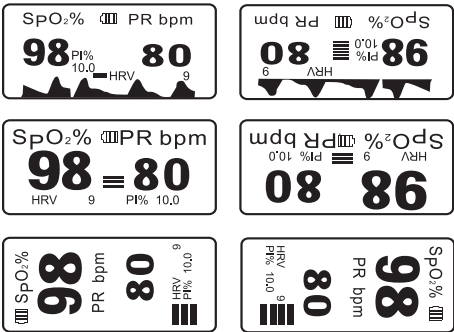
- 10)Significant levels of dysfunctional hemoglobins (such as carboxyl-hemoglobin or methemoglobin) may cause inaccurate reading.
- 11)Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate reading.
- 12)SpO2 measurements may be adversely affected in the presence of high ambient light. Please shield the sensor area (with a surgical towel or direct sunlight, for example) if it is necessary.
- 13)Unexpected action may cause inaccurate reading.
- 14)Medical signal with high frequency or interference caused by defibrillator may lead to inaccurate reading.
- 15)Venous pulsations may cause inaccurate reading.
- 16)It may cause inaccurate reading when the positions of sensor and blood pressure cuff are on the same arterial catheter or intravascular line.
- 17)Hypotension, severe vasoconstriction, severe anemia, or hypothermia may cause inaccurate reading.
- 18)It may cause inaccurate reading by giving use of cardiotonic to patient after his cardiac arrest or when he is in quiver.
- 19)Bright nail or painted nail may cause inaccurate SpO2 reading.
- 20)Do not use this product if you are allergic to ABS, black silicone pad and other materials.
- 21)If the performance is inconsistent with the description or changes, stop using immediately and contact the manufacturer.
- 22)Measuring function should not be used to evaluate oximeter accuracy.
- 23)Please place the oximeter in a place where children, pets, etc. can not be touched, so as to prevent falling, biting and affecting the product performance.
- 24)Do not use beyond the service life of the product, otherwise the accuracy of the instrument will be affected.
- 25)No modification of this equipment is allowed.
- 26)Oximeter should be avoided in places with poor ventilation and high dust and lint content.
- 27)Avoid direct sunlight and strong light sources.
- 28)Oximeter cannot be serviced and maintained during use.
- 29)The Wrist Pulse Oximeter can be maintained and calibrated once every two years, and the basic safety and basic performance of the Wrist Pulse Oximeter have been guaranteed.

3.Operation Instructions

3.1 Battery charging

- 1)The oximeter is powered by an internal lithium battery, the status of which is indicated by an icon in the screen.
- 2)When the battery is too low, you need to charge the battery, otherwise the oximeter will automatically turn off.

-3-



Keys function description: in standby mode, start the key instrument into the working state.Push down this button under working state, can change the display mode.

- Note**
- 1.The image in the instruction may have slight differences with the actual instruments.
 - 2.Technical parameters and appearance change, without prior notice.
 - 3.The machine profile picture only for your reference use, specific in kind prevail.

3.6 Parameter setup
Press start button (>3s) , into parameter setup .As menu ①:
1)In menu ①, When the “*” signal is shown on the “Alm Setup”, press the button (>3s) and enter into the menu ②. Press the button (<1s) can select item, then press button (>3s) to set the on/off for prompt ,beep,demo and screen brightness adjustment (optional “1” ,” 2 ”, 3 ”and” 4 ”). When the “*” signal is shown on the “Restore”,press the button (>3s) and all the settings are back to the factory settings.
2) In menu ②, When the “*”signal is shown on the “Sounds Setup”, press the button (>3s) and enter into the menu ③,Press the button (<1s) can select item ,then press the button (>3s) to setup data.choose “+” or “-” to plus or minus values.

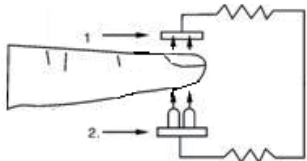
Settings		Settings	
Alm Setup	*	System Setup	*
Alm	on	SpO2 Alm Hi	100
Beep	off	SpO2 Alm Lo	85
Demo	off	PR Alm Hi	130
Restore	OK	PR Alm Lo	50
Brightness	3	+/-	+
Exit		Exit	

Menu ①

Menu ②

-6-

1.7 Diagram of Operation Principle



1. Red-ray and Infrared-ray receiving diode
2. Red-ray and Infrared-ray transmitting diode

1.8 Features

- Product adopts OLED display
- Low-power consumption, continuously work for about four hours with one rechargeable lithium battery.
- Low voltage indicator
- In the absence of signals, the product will be power-off automatically;
- When the oximeter test value exceeds the limit, it will vibrate.
- Small in volume, light in weight, and convenient to carry.

2.Precautions for use

- 1)Do not use the Wrist Pulse Oximeter together with MRI or CT equipment.
- 2)Explosion hazard: Do not use the Wrist Pulse Oximeter in an explosive atmosphere.
- 3)The Wrist Pulse Oximeter is intended only as an adjunct in patient assessment. Doctors should make diagnosis in conjunction with clinical manifestation and symptoms.
- 4)Check the Wrist Pulse Oximeter sensor application site frequently to make sure that the circulation and skin integrity of patient are under good condition.
- 5)The sensor of the oximeter is not suitable for contacting the adhesive tape, which may lead to the error of measurement data or mistaking that there are blisters on the tested skin.
- 6)Please read the manual carefully before your operation.
- 7)The Wrist Pulse Oximeter has no SpO2 alarm.
- 8)When used for a long time, it will produce discomfort or tenderness, especially for patients with microcirculation disorders.Please change the test sites periodically according to different situations of patients.The test site must be changed and the skin integrity and circulation condition of the patient must be checked at least every 2 hours, and the correct adjustment must be made.
- 9)Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.

-2-

- 3)When using the oximeter for the first time, please charge it for about 2 hours, and then use it when fully charged.

3.2 Charging method

- 1)Connect one end of the USB cable to the charging port of the oximeter;Connect the other end of the USB cable plug to the adapter jack;
- 2)Insert the adapter into the socket, in the charging process, the electric quantity display symbol flashes according to the electric quantity. When the battery is full, the battery icon stops flashing.
- 3)When charging is complete, remove the adapter from the socket.Remove the USB cable from the oximeter.

Attention

- 1)Please use a power adapter that meets the safety certification standards.
- 2)The battery's power supply time depends on the device configuration and operation. If the use times are greatly reduced after the battery is fully charged, it is recommended to contact the manufacturer to replace the internal dedicated battery.
- 3)When the adapter is connected to charge, the oximeter will automatically enter the charging state.
- 4)When the oximeter is working, it cannot be charged.

3.3 Wrist strap installation

- 1)Place the OLED screen of the host facing down,Hold the front of the wristband in your hand.
- 2)Put the metal connector on the left side of the wrist strap into the positioning hole on the left side of the wrist strap, move the toggle switch of the metal connector to the left, and align the right side of the metal connector with the positioning hole on the right side of the wrist strap. Release the toggle switch. The wristband is assembled.As figure 1.



figure 1

-4-

Attention

- Using devices outdoors or under strong light, please adjust the screen brightness to a higher proper level for observation.
- It's better for user to choose a lower brightness to conserve battery power.

4.Main technical parameters

- 1)Display Type: OLED display
- 2)SpO2: Measurement range :70%~100%
Accuracy: 80%~100%: ±2% (Including 80%);
70%~79%: ±3% ;
Below 70% no requirement;
Resolution: 1%
- 3)PR: Measurement range: 30BPM~250BPM
Accuracy: ≤100BPM , ±1BPM
>100BPM , ±2BPM
- 4)Parameters of LED probe

	wavelength	radiation power
RED	Approx. 660nm	1.8mW
IR	Approx. 905nm	2.0mW

This parameter can be especially useful to clinicians.

- 5)Power: Lithium battery 3.7V 300mAh, DC 5.0V
- 6)Low electrical parameters: 3.15V-3.3V showing low power
- 7)Automatic standby: the product shuts off by itself when no finger is in the product about 8 seconds
- 8)Data transmission: The measurement data can be transmitted to the terminal device in real time through Bluetooth;
- 9)Pl index: measurement scope: 0%-20%
- 10)HRV index: measurement scope: 0-999
- 11)Dimension: about 42mm × 50mm × 16mm
- 12)Weight: about 20g
- 13)**Operation environment:**
Temperature: 5 °C ~ 40 °C
Humidity: 15% ~ 80%, no condensing
Atmospheric pressure: 70kPa ~ 106kPa
Transport, storage environment:
Temperature: -10 °C ~ 40 °C
Humidity: 10%~ 95%, no condensing
Atmospheric pressure: 70kPa ~ 106kPa, non-corrosive gas and well-ventilated

-7-

3.4 Operation Instructions

- 1)Plug the blood oxygen probe into the USB port of the oximeter.
 - 2)Plug one finger into rubber hole of the blood oxygen probe (it is best to plug the finger thoroughly) before releasing the clamp with the nail upwards.As figure 2.
 - 3)Press button on the side panel;
 - 4)Don't tremble your finger when the Oximeter is working. Your body is not recommended on moving status.
 - 5)Read relevant datum from display screen.
 - 6)Please charge in time when OLED indicates the batteries are in low power.
- Note: When plugging your finger into the Blood oxygen probe, your nail surface must be upward.

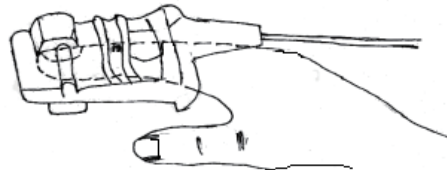
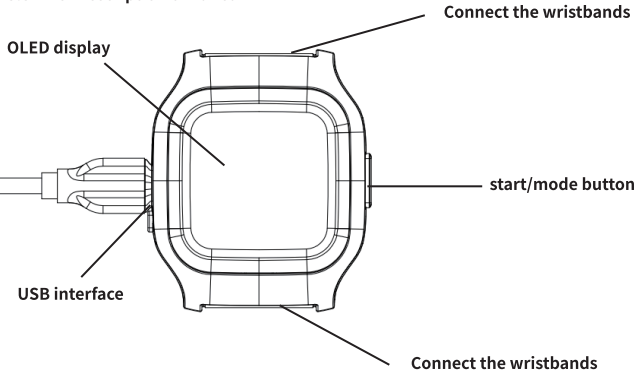


figure 2

Declaration: Please use the medical alcohol to clean the rubber before each test and clean the tested finger with alcohol before and after the test. (The rubber inside of the Blood oxygen probe adopts medical rubber, which has no toxin, no harm, and brings no side effect such as allergy to the our skin).

3.5 Brief Description of Panel



-5-

- environment.
- 14)Declaration: EMC of this product comply with IEC60601-1-2 standard.
 - 15)This equipment has no alarm function.
 - 16)Data averaging and signal processing delay the display and transmission of SpO2 data.The date update period : <12S
 - 17)Applied parts specified: Probe and its circuit
 - 18)Using life: 5 years

5.Maintenance and Preservation

- 1.Clean the surface of Blood oxygen probe before use.
- 2.Do not attempt to disassemble or repair the inside yourself,It can lead to unacceptable risks.
- 3.It would be better to preserve the product in -10~40°C (14-104°F) and humidity is 10%-95%.
- 4.It is recommended that the product should be kept dry anytime. A wet ambience might affect its lifetime and even damage the product.
- 5.**Cleaning frequency**
If the oximeter is dirty when used at home, it is recommended to clean the enclosure and blood oxygen probe after each use.If the oximeter is not dirty, simply clean the black silicone pad before and after each use.
When used in a medical institutions, clean it after each use.

6.Cleaning method

When the oximeter is used at home, wipe and disinfect with 75% alcohol, then dry naturally or clean the product with dry cloth. Clean at least twice a week.
When using in medical institutions, clean the tested finger with 75% alcohol before use. After each measurement, wipe and disinfect the blood oxygen probe with 75% alcohol.
7.The oximeter can display functional arterial oxygen saturation and pulse rate after calibration.
8.The name of the simulator is FLUKE Index2 simulator, and the version number is 3.00.
9.The Blood oxygen simulator is calibrated to display functional oxygen saturation.
10.The maximum temperature of the contact surface between the product and human body does not exceed 41 °C.

6.Waste disposal

- 1.Please follow local laws to dispose of waste scrap.
2. Follow local ordinances and recycling instructions regarding to disposal or recycling of the device and device components, including used batteries and packaging box

-8-

7.Manufacturer’s Declaration of the EUT

Statement:

1.The equipment or user should use the product in the electromagnetic environment specified in the following table, otherwise it may cause abnormal operation of the product.

2. Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas)should be used no closer than 30cm(12 inches)to any part of the equipment,including cables specified by the manufacturer.Otherwise, degradation of the performance of this equipment could result.

3. Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper observed to verify that they are operating normally.

4.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 impropre operation.

Guidance and manufacturer’s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer’s declaration – electromagnetic emission	
2	The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of equipment should assure that it is used in such an environment.	
3	Emissions test	Compliance
4	RF emissions CISPR 11	Group 1
5	RF emissions CISPR 11	Class B
6	Harmonic emissions IEC 61000-3-2	Class B
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance

-9-

5240	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0.3	9
5500						
5785						

NOTE:
If necessary to achieve the immunity test level, the distance between the transmitting antenna and the me equipment or me system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

8.Possible Problems and Resolutions

Problem	Possible reason	Solution
SpO2 or PR can not be shown normally	1. Finger is not plugged correctly 2.Patient's Oxyhemoglobin value is too low to be measured	1. Retry by plugging the finger 2. Try more times. If you can make sure there is no problem in the product, please go to hospital timely for exact diagnosis
SpO2 or PR is shown unsteady	1. The finger might not be plugged deep enough 2. Finger is trembling or the patient is on movement status	1. Retry by plugging the finger 2. Please remain at rest
The Oximeter can not be turned on	1. Inadequate power or power off 2. Batteries might be installed incorrectly 3. The Oximeter might be damaged	1. Please replace the batteries 2. Please reinstall the batteries 3.Please contact with local customer service centre
Indication lamps are suddenly off	1. The product automatically shuts off when no signal is detected in 8 seconds 2. Inadequate power	1. Normal 2. Please charge in time

-12-

3.Operation Instructions

3.1 Register login

When the user accesses for the first time, the user shall register through the following steps

①“Click "click to login" → SMS login → enter mobile phone number → Click to obtain verification code → login

②Click "click to login" → email login → enter email → Click to obtain verification code → login

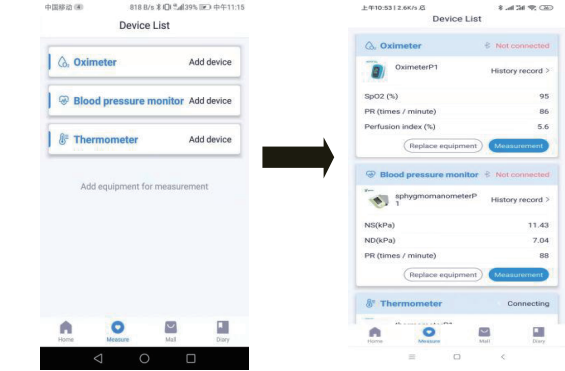
③Click "click to login" → third party login → Facebook or wechat

3.2 Account and information

Sex, nickname, height, weight, country and region can be set in Account and information.

3.3 Device addition

On the [measure] page, you can add equipment for measurement, click "Devicet List" and select the corresponding required blood oxygen equipment. After selecting the device, click "bind", and then click "Measurement" after "bind successfully" is displayed.



3.4 Real time synchronous data

Click "Measure" to jump to the blood oxygen detection interface, display the real-time blood oxygen dynamic curve, and play the heartbeat sound at the same time.

-15-

Guidance and manufacturer's declaration –electromagnetic immunity – for all EQUIPMENT AND SYSTEMS

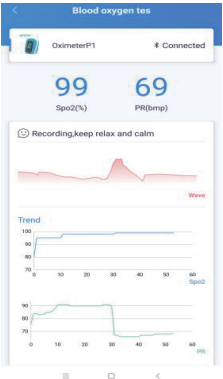
Guidance and manufacturer’s declaration – electromagnetic immunity		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Immunity test	EN 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15kV air
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lnes	± 2 kV for power supply lines
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	±1kV differential mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m
NOTE UT is the a. c. mains voltage prior to application of the test level.		

-10-

9.Appendix

	BF type application part		This device has no alarm function
	Up toward		Humidity range
	Reference manual		Keep dry
	Cautions		Lot number
	Serial number		Temperature range
	Date of manufacture		Avoid sunlight
	Manufacturer		Consult instructions for use
	Model number		Use-by date
	To protect the environment, dispose of empty batteries at appropriate collection sites according to national or local regulations.	IP22	First characteristic numeral 2: Against ingress of solid foreign objects:≥12.5mm diameter Second characteristic numeral 2 Against ingress of water with harmful effects:dripping(15° tilted)
	signal inadequacy		Medical device
	①Indication of probe faults (open circuit condition or close circuit condition) ②Indication of Probe cable faults ③Indication of Probe cable extender faults		

-13-



3.5 View SPO2 measurement history

After the test, display the device information, Bluetooth link status (not connected, connected, connected) and view the blood oxygen measurement history at the top of the [Device list].

The status during connection is: the blue and white Bluetooth signs flash alternately, and the blue and white flashes alternately once per second. After the connection is completed, it becomes a display.

Pull down and refresh, click "Measurement", jump to the "blood oxygen test" interface and continue the test.

3.6 Replace equipment

On the [Device list] page, click "replace equipment" to add equipment again, jump to the "blood oxygen equipment" interface, add new equipment and continue testing.

3.7 Maintenance

On the [Home] , you can click the " " symbol in the upper left corner to set "Account and information", "Health Choice", "Goal", "Remind", "unit", "Kinematics", "Help center", "About the platform", "Language setting ", "life and sports status", etc.

3.8 Health trends

On the [Home], you can view the status of SPO2, PRand weak perfusion index. On the page, light green is displayed in the low range, red is displayed in the high range, dark green is displayed in the normal range, and the triangular indication points to different areas according to the corresponding values.

Draw the health trend chart according to the different selection of "recent", "week", "month" and "year" date types.

-16-

Guidance and manufacturer’s declaration –electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer’s declaration – electromagnetic immunity		
The Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Pulse Oximeter should assure that it is used in such an environment.		
Immunity	EN 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0, 15 MHz -80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0, 15 MHz -80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz 3 V 0, 15 MHz -80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz -2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz -2,7 GHz 80 % AM at 1 kHz

Table 9 - Test specifications for enclosure port immunity to RF wireless communications equipment						
Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity TEST LEVEL
385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0.3	27
450	430-470	GMRS 460, FRS 460	FMc) ± 5 kHz deviation	2	0.3	28
710	704-787	LTE Band 13,17	Pulse modulation b) 217 Hz	2	0.3	9
745						
780						
810	800 - 960	GSM 800/900. TETRA 800,iDEN 820,CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800;CDMA 1900;GSM 1900; DECT;LTE Band 1, 3 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28
1845						
1970						
2450	2400-9570	Bluetooth,WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28

-11-

II . APP

1.APP download

YonkerCare is now available on the three largest platforms: Android app stores, APP STROE, GOOGLE PALY. The download methods for the different platforms are described below.

APP STORE

Enter APP STROE on the IPHONE mobile phone and search for the app name YonkerCare.Click on Install.

Android Market

1) Through the Android phone directly open its own app market, 91 assistant, Android market APP, search YonkerCare.

Enter the mobile browser to enter the Android market official website to search for the oximeter.Find the APP as shown in Fig, and click to download.

2) Directly scan the QR code below.Download the installation.



GOOGLE PLAY

Open the google software market directly and search for YonkerCare.Find the APP as shown, and download the installation.

2.APP Software running environment

Equipment	Minimum configuration requirements
software environment	Client Android 6.0 and above compatible versions; Apple IOS 6.0 and above The browser supports H5
hardware configuration	Client Smartphone, with minimum screen resolution of 640x1136px and memory of more than 4G
Network conditions	Mobile phone 4G and above

-14-

3.9 Diet Diary

In the diet diary, breakfast, lunch and dinner can be set, and eggs, vegetables, meat, staple foods and desserts can be selected to help regulate the development of health.

4. Possible problems and solutions in app

Question	Possible causes	Solution
App terminal blood oxygen or heart rate cannot be displayed normally	1.Fingers not properly placed 2.Bluetooth connection failed	1. Put your finger correctly and try again 2. Reconnect the device
App side software crashes during operation	There is a hardware problem with the mobile phone Not the latest version	1.Contact the mobile phone manufacturer 2.Go to the corresponding application mall and download the latest app version
The app end cannot be connected to the oximeter	1.The mobile phone version is not compatible with Android 6.0 or above; Or apple IOS 6.0 and above 2.Not the type of finger clip pulse oximeter specified	1.Update the mobile phone version to Android 6.0 and above compatible version; Or apple IOS 6.0 and above 2.Use finger pulse oximeter of the specified type
App cannot be opened normally or flash back	App is not the latest version	Go to the corresponding application mall and download the latest app version

III. Product Accessories

Inventory list	Quantity
The host	1 set
Blood oxygen probe	1 pc
User manual	1 pc
USB line	1 pc
Wrist strap	1 set

-17-