Instructions to User

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

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly.Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

This product is medical device, which can be used repeatedly.

WARNING:

- **Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the special patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not stare at the light.**
- **Testee can not use enamel or other makeup.**
- **Testee's fingernail can not be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

CONTENTS

1 Safety

1.1 Instructions for safe operations

✧ Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the device.

✧ Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.

✧ The oximeter cannot be used together with devices not specified in User's Manual.Only the accessory that appointed or recommendatory by manufacture can be used with this device.

✧ This product is calibrated before leaving factory.

1.2 Warning

Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.

DO NOT use the oximeter while the testee measured by MRI and CT.

Please do not break the wristband, for fear it becomes out of use, or the unexpected drop of the device which is due to the looseness of the wristband in the process of using. Users who are allergic to the wristband is not recommended to use it.

The person who is allergic to rubber can not use this device.

The disposal of scrap instrument and its accessories and packings(including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.

Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.

Please choose the accessories and probe which are approved or manufactured by the manufacturer, or else it may damage the device.

Please choose the battery chagers which should be ensured compliance with the requirements of IEC 601-1, or else it may damage the device.

Please don't use the device in the course of charging.

The device can only be matched with the compatible probe.

Please don't measure this device with functional tester for the device's related information.

1.3 Attention

Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.

If the oximeter gets wet, please stop operating it.

When it is carried from cold environment to warm or humid environment, please do not use it immediately.

DO NOT operate keys on front panel with sharp materials.

High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter (7.1)for instructions of cleaning and disinfection.

Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.

When cleaning the device with water, the temperature should be lower than 60℃.

- As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients' SpO_2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enought into the probe.
- The pulse oximeter can be used to adult or infant. Whether the device is used to adult or infant,it depends on the probe selected.
- Whether the device is used to adult or infant,it depends on the probe selected.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- Please read the measured value when the waveform on screen is equably and steady-going, This measured value is optimal value. And the waveform at the monment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal useful life for three years since the first electrified use.
- This device has the function of alarming, users can check on this function according to chapter 6.1 as a reference.
- The device has the function of limits alarming, when the measured data is beyond the highest or lowest limit, the device would start alarming automatically on the premise of the alarming function is on.
- The device has the function of alarming, this function can either be paused, or closed for good, please check the chapter 6.1 as a reference.
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.

2 Overview

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration. A number of diseases relating to respiratory system may cause the decrease of SpO_2 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' SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable.It is only necessary for patients to put one of his fingers into a probe for diagnosis, and a display screen will directly show the measured value of pulse oxygen saturation with the high veracity and repetition.

2.1 Features

A. Operation of the product is simple and convenient.

B. The product is small in volume, light in weight and convenient in carrying.

C. Low power consumption

2.2 Major applications and scope of application

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through

finger. The product is suitable for being used in family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports, and it is not recommended to use the device during the process of having sport) and etc.

⚠**The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.3 Environment requirements

Storage Environment

a) Temperature :-40℃～+60℃
b) Relative humidity :5%～95%
c) Atmospheric pressure :500hPa～1060hPa

Operating Environment

a) Temperature:10℃～40℃
b) Relative Humidity :30%～75%
c) Atmospheric pressure:700hPa～1060hPa

3 Principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

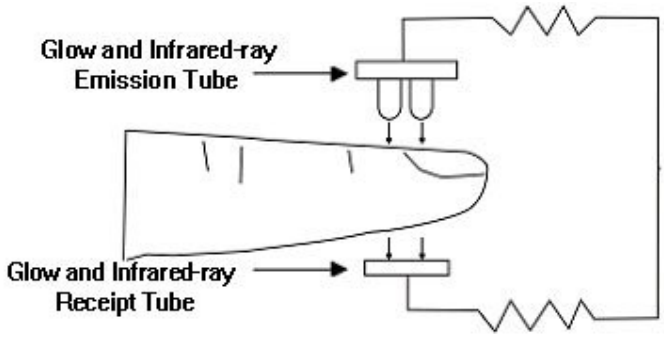

Figure 1.

4 Technical specifications

4.1 Main performance

A. SpO_2 value display
B. Pulse rate value display, bar graph display

C. Pulse waveform display

D. Low-voltage indication: low-voltage indicator appears before working abnormally which is due to low-voltage

E. The display mode can be changed

F. Screen brightness can be changed

G. A pulse sound indication

H. With alarm function

I. With SpO_2 value and pulse rate value of storage, the stored data can be uploaded to computers

J. It can be connected with an external oximeter probe

K. Real-time data can be transmitted to computers

L. With clock function

4.2 Main Parameters

A. Measurement of SpO_2

Measuring range: 0%～100%

Accuracy:

When the SpO_2 measuring range is 70%～100%,the permission of absolute error is ±2%;

below 70% unspecified

B. Measurement of pulse rate

Measuring range:30bpm～250bpm

Accuracy: ±2 bpm or ±2% (select larger)

C. Resolution

SpO_2: 1%, Pulse rate: 1bpm.

D. Measurement Performance in Weak Filling Condition

SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).

E. Resistance to surrounding light

The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

F. Power supply requirement: : 3.6 V DC ~ 4.2V DC.

G. Optical Sensor

Red light (wavelength is 660nm，6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

H. Adjustable alarm range:

SpO_2 ： 0%~100%

Pulse Rate: 0bpm~254bpm

5 Installation

5.1 View of the front panel

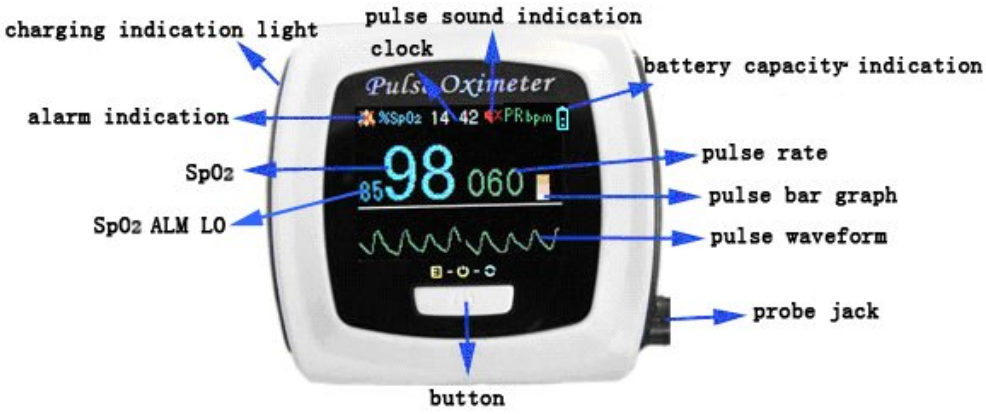

Figure 2. front view

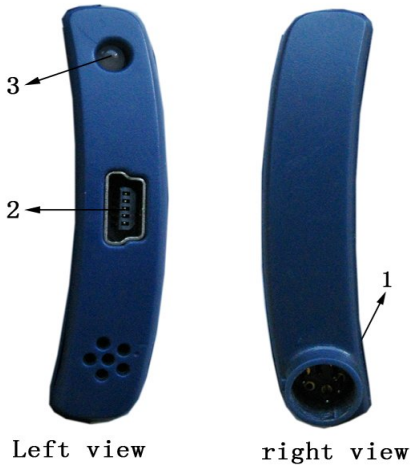

Figure 3. left and right view

1. Probe jack : It is used to connect a SpO_2 sensor to measure the oxygen saturation and pulse rate.
2. USB port :It is used to connect a personal computer to export the trend data or charge the lithium battery via a data line.
3. Charging indication light. When the device is in the state of battering charging, the indication light appears to be orange, and when the battery status is full, the light turns to green.

5.2 Wristband installation and probe connection

A. Put one side of the wristband on which there is no ring through the belt hole above the device, then put it through the other belt hole under the device.

B. Make the alignment signs on the probe in accordance with the alignment signs on the device, then plug the probe into the jack.

C. It appears as the following figure after installation.

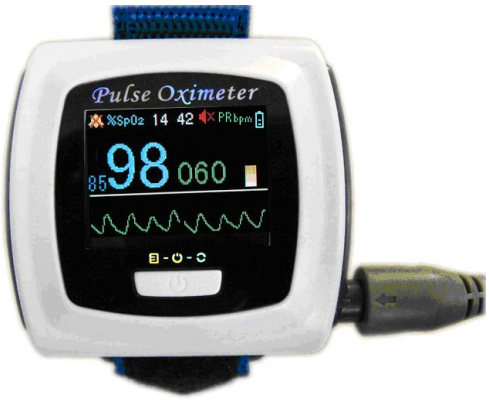

Figure 3.

5.3 Accessories

A. a wristband
B. a User Manual
C. a power adapter
D. a data line
E. a disk (PC software)
F. An adult-oximeter probe（Model:CMS04）
An infant-oximeter probe (May purchase selectively)

6 Operating Guide

6.1 Application method

A. Install the wristband according to the instructions of chapter 4.2.

a) Put the suitable probe into the jack on the right side of the oximeter. (The probe is limited to be produced by our company; never replace it with the similar ones by other manufacturers).
b) Put the finger into the probe.
c) Turn on the device by long pressing the button on the panel.
d) Do not shake the finger and keep the patient in a stable state during the process.
e) The data can be read directly from the screen on the measuring interface.

⚠ **Fingernails and the luminescent tube should be on the same side.**

⚠ **If the alarm function is on,the device will provide midium-priority alarm signal when probe or finger is out. Intermittent alarm will occur and the user interface presents "FINGER OUT".**

Medium priority indicating that prompt operator response is required.

Figure 4.

（Actual probe may be different with the probe as figure 4,please accept the actual probe with the device ）

Attention:

CLICK = short press of power button and **PRESS** = prolonged push of power button (1sec)

B. Change display direction

On the measuring interface, enter the clock interface by Click the button, and then Click the button to change the display direction within 30 seconds.

C. Enter and exit the clock interface

a) On the measuring interface, Click the button in order to enter the clock interface, and it will automatically return to the measuring interface if there is no more operations within 30 seconds.

b) On the measuring interface, Press the button for about 10 seconds in order to enter the clock interface, and the device would return to the measuring interface by Press the button for about 10 seconds again.

D. Pause alarm

a) Alarm including the alarm of measure data's going beyond the limits, the alarm of low-voltage, the alarm of probe or finger's out of position.

b) On the measuring interface, if the alarm function is on, during the period of alarming,you can pause it by Click the button, but the function will be renewed in about 60 seconds.

c) If you want to turn off the alarm for good, you should enter the menu for operation.

E. Menu operations

When the device is under the measuring interface, Press the button for about 1 second in order to enter the menu interface shown as figure 5. Users can adjust the setting through the main menu, such as backlight, alarm, clock, data transmission (with the data line), data storage, and power off. The specific operation methods are as the following:

Figure 5. Main Menu Interface

a) Backlight adjustment

On the main menu interface, Click the button to select "Brightness", Press the power button and hold to adjust the backlight brightness.

b) Alarm setting

On the main menu interface, click the button to select "Alarm", Press the power button (1sec) to enter the alarm setting interface as shown in Figure 6:

a. Adjusting the high and low limits of alarms

Click the button to select "Direction", then Press the button to choose Up or Down. (this will be the direction the value of the high-low limits of SpO_2 and pulse rate will be adjusted)

To raise the SpO_2 and pulse rate limit, choose "Direction" as 'up', then Click the button to highlight the parameter to be adjusted: SpO_2 high limit (SpO_2 ALM HI), SpO_2 low limit (SpO_2 ALM LO), Pulse rate high limit (PR ALM HI), Pulse rate low limit (PR ALM LO), Press the button and hold to adjust the selected limit to the desired higher value and release the button once the higher limit has been reached.

To lower the SpO_2 and pulse rate limit, choose "Direction" as 'down', then Click the button to choose the parameter to be adjusted. Press the button and hold to adjust the selected limit to the desired lower value and release the button once the lower limit has been reached.

⚠ **If the alarm function is on,the device will provide midium-priority alarm signal when the data of SpO_2 or pulse rate is beyond the limit. Intermittent alarm will occur and the measurement shows in yellow.**

Medium priority indicating that prompt operator response is required.

b. The alarm state setting

Click the button to select "Alarm", then Press the button to choose alarm on or off, press " on" to turn on the alarms and " off" to turn off the alarms.

Figure 6.Alarm Setting Menu

c. Pulse sound indication setting

Click the button to select "Pulse Sound", then Press the button to choose to have the Pulse Sound (heart beat) alarm "on" or "off".

d. Exit the Alarm settings

Click the button to select "EXIT", then Press the button to exit the Alarm Settings Menu.

c）Clock setting

On the main menu interface, Click the button to select "Clock", then enter the clock setting interface by press the button.

Figure 7. Clock Setting Menu

a. When entering the clock setting menu, the menu choice bar would be on the item of "set time", and the state would always be "no" whenever it enters the clock setting menu on the purpose of avoiding unexpected changes of time due to improper operation. You can change the state by press the button, choose "yes" to reset the time, choose "no" to forbid time resetting.

b. Click the button to select the parameter that you want to change, then adjust the data by press the button.

c. Click the button to select "Exit", then exit the clock setting menu by press the button. If you have reset the time or date ,when exiting the clock setting menu, firstly the renewed time and date

would be displayed on the screen, then it returns to the main menu; if you did't reset the time and date , when exiting the clock setting menu, the device would return to the main menu directly.

d）Real-time data transmission setting

Firstly, please install the affiliated software into the computer, and two icons would appear on the desktop after installation. The icon of "SpO2 "is a program for receiving real-time data which is shown as figure 8; the icon of "SpO2 Review" is a program for receiving stored data which is shown as figure 9.

a. Please connect the device to computer with the affiliated data line , then double click the "SpO2 "icon to start the program.

b. On the main menu interface, Click the button to select "Usb", then Press the button to choose whether transmit the real-time data to computer which displays the data synchronously or not, choose "on" to permit transmission, choose "off" to forbid transmission

c. When you unplug the data line from computer, there is a dialog box "Save data at view" appearing on the desktop, in which you can input some patient's basic information.

Figure 8. SpO2 program

Figure 9. SpO2 Review program

⚠**If the users choose to turn on the synchronizing display function on computer, it would probably take several seconds for the data to appear on the computer screen.**

e）Data storage setting

This instrument has the ability to store 24 hours worth of data. It can store the measured pulse rate and SpO_2 value accurately, transfer the data to the computer, display the data and print reports (with the included SpO_2 Software - Green Heart)

a. On the main menu interface, Click the button to select "Record", then Press the button to choose whether store the data or not, choose "Yes" to permit storing, choose "No" to forbid storing.

b. The device can storage starting time automaticly.

c. If the data storage function is being turned on, when return to the measuring interface, a red "REC"sign and a flashing red dot would appear on screen, which means the device is in a state of storing.

d. In the state of storing, whatever interface the device is on (measuring interface, menu interface,clock interface), the sign "Recording" would appear on the screen in 30 seconds, then the clock interface would appear in succession after several seconds.and then the screen will be automatically shut down. If short press the button at this moment, the sign "Recording" would appear on the screen, and then the screen will be automatically shut down again; if long press the

button, the device would return to the former interface.

e. If turning on the data storage function, the former data storage will be automatically removed.

f. In the state of data storing, after the screen is automatically shut down, the pulse sound indication would be off for saving power.

g. When the storage space is full, it displays “Memory is full” on the screen, and then shut down in a few seconds. But it will still display “Memory is full” by the next time you turn on the device on the purpose of warning the user, if Click the button again, it will enter the measuring interface.

f）Uploading the data to the PC after recording

a. Please connect the device with computer by the data line which is equipped with the device, then double click "SpO2 Review" icon to open"SpO2 Review" program, click the ‘New Session’ Icon in the software, enter the patient data and then click ‘ok’. The Software will then display “device connected, waiting for data”.

b. At this time , Press the button to enter the “Main Menu” and then Click the button to select “Upload”. Press the button to select “on” then the data will be transferred to your computer.

c. In the state of storing, it is not applicable for the users to upload the stored date to computer.

d. When the upload of stored data is finished, the menu choice bar will move to "Exit" automatically .

g） Power off

On the main menu interface, Click the button to select "Power off", then Press the button to shut down the device.

h） Exit the main menu

On the main menu interface, Click the button to select "Exit", hen Press the button to exit the main menu.

F. Charge

There are two kinds of charging methods:

a） Connect the device with computer by data line, then the device should be under charging state.

b) Connect the device with power supply by power adaptor, then the device should be under charging state.

c) When the device is in the state of battering charging, the indication light appears to be orange, and when the battery status is full, the light turns to green.

⚠**If the alarm function is on, the device will provide high-priority alarm signal when the battery is in low power status .Intermittent alarm will occur and the battery icon turns red in the state of flashing.**

High priority indicating that immediate operator response is required.

6.2 Attention for operation

A. Please check the device before using, and confirm that it can work normally.

B. The finger should be in a proper position (see the attached illustration of figure 4 for reference), or else it may result in inaccurate measure.

C. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject' s arteriole in a position there between.

D. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.

E. Do not fix the SpO_2 sensor with adhesive or else it may result in venous pulsation and inaccurate measure of SpO_2 and pulse rate.

F. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.

G. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

H. Testee can not use enamel or other makeup.

I. Please clean and disinfect the device after operating according to the User Manual(7.1).

6.3 Clinical restrictions

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

B. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.

C. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measure.

D. As the SpO_2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

7 Maintain、transportation and storage

7.1 Cleaning and Disinfecting

Using medical alcohol to disinfect the device, nature dry or clean it with clean soft cloth.

7.2 Maintain

A. Please clean and disinfect the device before using according to the User Manual(7.1).

B. Please recharge the battery when the screen shows  .

C. Recharge the battery soon after the over-discharge. The device should be recharged every six months when it is no regular used. It can extend the battery life following this guidance.

7.3 Transportation and storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. The device can not be transported mixed with toxic, harmful, corrosive material .

B. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40℃~60℃; Humidity: ≤95%

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm
The device can not be turned on	1. The batteries are drained or almost drained. 2. The device's malfunction	1.Please recharge the battery 2. Please contact the local service center.
The display is off suddenly	1. The device's malfunction. 2. The battery is drained away or almost drained away.	1. Please contact the local service center. 2.Please recharge the battery
The device can not be used for full time after chagre	1、The battery is not full charged. 2、The battery is broken	1、Please recharge the battery 2、Please contact the local service center.
The battery can not be full charged even after 10 hours charging time.	The battery is broken	Please contact the local service center.

9 Key of Symbols

Signal	Description
	Warning – See User Manual
	The pulse oxygen saturation(%)
	Pulse rate (bpm)
	Full-voltage
	Low-voltage
	Close the alarm sound indication
	Pause the alarm sound indication

	Open the alarm sound indication
	Close the pulse sound indication
	Open the pulse sound indication
	menu button/power button/function button
	Type BF
SN	Serial number
	1. the finger clip falls off (no finger inserted)] 2. Probe error 3. Signal inadequacy indicator
IPX1	Ingress of liquids rank
	WEEE (2002/96/EC)

10 Function Specification

Information	Display Mode
The Pulse Oxygen Saturation（SpO_2）	2-digit digital OLED display
Pulse Rate（PR）	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
SpO_2 Parameter Specification	
Measuring range	0%～100%, (the resolution is 1%).
Accuracy	70%～100%：±2% ,Below 70% unspecified.
Average value	Calculate the Average value in every 4 measure value. The deviation between average value and true value does not exceed 1%.
Pulse Parameter Specification	
Measuring range	30bpm～250bpm, (the resolution is 1bpm)
Accuracy	±2bpm or±2% (select larger)
Average pulse rate	Moving calculate the Average pulse rate every 4 cardio-beat's cycle. The deviation between average value and true value does not

	exceed 1%
Safety Type	Interior Battery， B F Type
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
Voltage 3.7 rechargeable lithium battery × 1	
Battery working life	
Charge and discharge no less than 500 times.	
Power Adapter	
Input Voltage	100 to 240 VAC, 50/60 Hz
Output voltage	5 VDC
Output current	250mA
Output power	1.25 W
Oximeter Probe	
Wavelength:660nm 880nm	
Dimensions and Weight	
Dimensions	61(L) × 56(W) × 24 (H) mm
Weight	About 50g (with the lithium battery*1)

Appendix 1

State	Alarm condition delay	Alarm signal generation delay
Low voltage alarm	0.6s	20ms
Spo_2 alarm	400ms	20ms
Pulse rate alarm	400ms	20ms
Probe error alarm	400ms	20ms