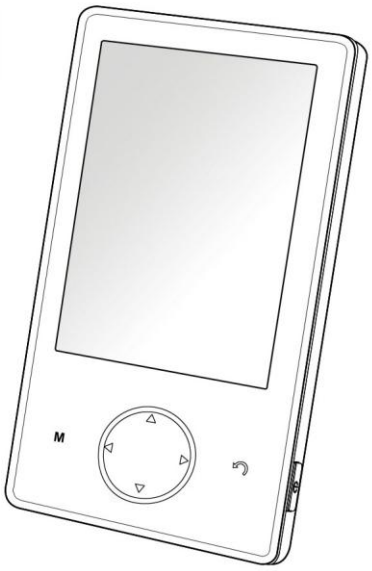
Pulse Oximeter

User Manual



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. It is recommended that the device should be inspected weekly 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 is 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 the environment with tinder such as anesthetic .

DO NOT use the oximeter while the patient is being scanned by MRI or CT.

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

The disposal of scrap instrument and its accessories and packing (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.

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, tinder, 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℃.

The fingers which are too thin or too cold may affect the measure accuracy, please clip the thicker finger such as thumb and middle finger deeply enough into the probe.

The pulse oximeter can be used to adult or children.Whether the device is used to adult or children, 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 moment 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 life for three years since the first electrified use.

🔔 The device has alarm function, users can check on this function according to chapter 6.1 as reference.

🔔 The device has the function of limit alarm, when the measure data is beyond the highest or lowest limit, the device would start to alarm automatically on the premise of the alarming function is on.

🔔 The device has alarm function.This function can either be paused, or closed for good.This function could be turned on through menu operation if you need.Please check the chapter 6.1 as 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 is small in volume,convenient in operation and portable.It is only necessary for patient to put one his finger into probe for diagnosis,and display screen will directly show the measure value of pulse oxygen saturation with the high veracity and repetition.

2.1 Features

A. Operation is simple and convenient.

B. 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.

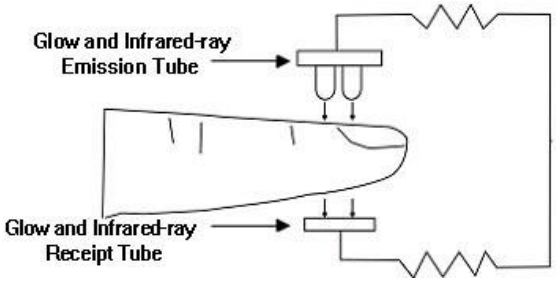


Figure 1.

4 Technical specifications

4.1 Main performance

- SpO_2 value display
- Pulse rate value display, bar graph display
- PI value display
- Pulse waveform display
- Low-power indication: low-power indication symbol appears before working abnormity which is due to low-power.
- Review function
- Screen brightness can be adjusted
- Pulse sound indication
- With alarm function
- With data record function of multiuser, continuous record 24 hours data for each user, and the record data can be uploaded to computer.
- It can be connected with adult,child,infant oximeter probe

- With clock function
- With locking touch key 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 Measurement of PI

Range: 0%～20％

D Resolution

SpO_2 : 1%, Pulse rate: 1bpm

E 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).

F 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%.

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

H Optical Sensor

Red light (wavelength is 660nm,6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

I Adjustable alarm range:

SpO_2 : 0%~100%

Pulse Rate: 0bpm~254bpm

5 Installation

5.1 View of the front panel

Figure 2. Front View

Probe jack : It is used to connect oximeter probe to measure the oxygen saturation and pulse rate.

USB port :It is used to connect a personal computer to export the trend data by a data line.

5.2 Left View and Right View

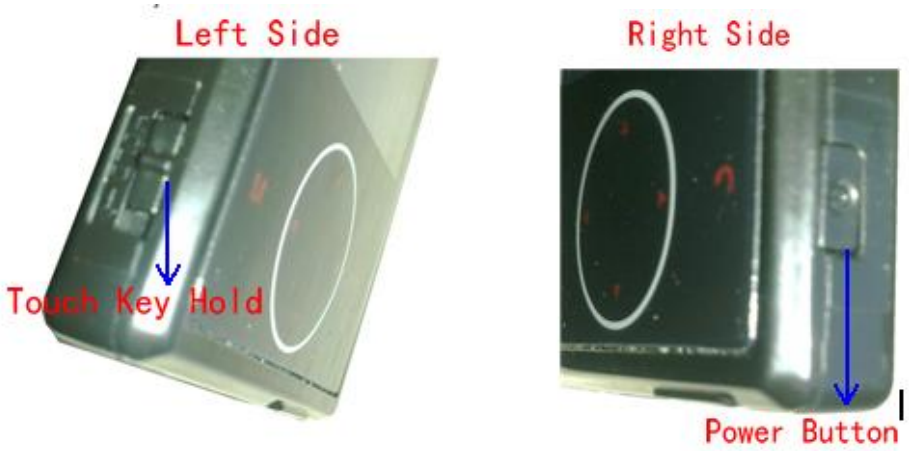


Figure 3. Left View and Right View

5.3 Probe connection

Figure 4. Installation

Inserting the oximeter probe into the USB port of the pulse oximeter as figure 4. (The probe is limited to the one that is produced by our company; and can't be replaced with the similar one by other manufacturers).

5.4 Accessories

A. A User Manual
B. A power adapter
C. A data line
D. A disk (PC software)
E. An oximeter probe

6 Operating Guide

6.1 Application method

6.1.1 Connect the probe well according to the method introduced in chapter 5.3,then put the finger into the probe. Refer to Figure 5.

A Long press the "power button", until the device turns on.
B Do not shake the finger and keep the patient in a stable state during the process.
C The data can be read directly from the screen on the measuring interface.

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

⚠ **If the alarm function is on, the device will provide medium-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 5.

（Actual probe may be different with the probe as figure 5,please accept the actual probe with the device）

6.1.2 Pause alarm

A Alarm including the alarm of measure data's going beyond the limits, the alarm of low-voltage, the alarm of finger out.

B When alarm is on,short press the “power button” can pause the alarm, it can renew alarm after period of time, alarm pause time can be set by menu.

C Only alarm sound can be closed,the prompt information displayed can't be closed.

6.1.3 Menu operations

In the measuring interface, press the “menu button” can enter the main menu interface of figure 6.

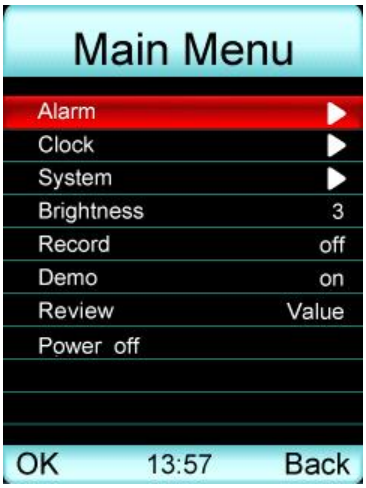


Figure 6. Main Menu Interface

A Alarm setting

In the main menu interface, move the choice bar to "Alarm” item, then press “right button” to enter the alarm setting menu of figure 7:

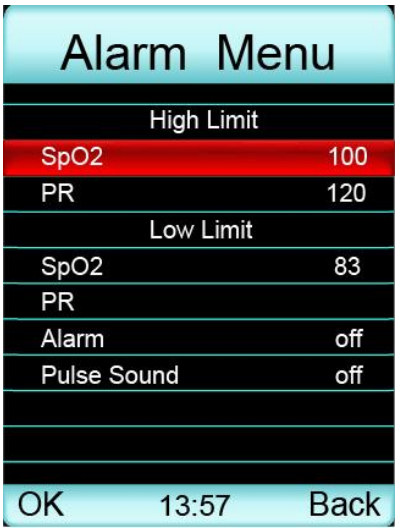


Figure 7. Alarm Setting Menu

a The high/low limit of alarm setting

In alarm setting menu,you can set the high/low limit of alarm.Move the choice bar to the menu item that you want to set, and press “right button" to begin to set value.Press "menu button" for affirming.

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

Medium priority indicating that prompt operator response is required.

b The alarm state setting

In alarm setting menu,move the choice bar to the "Alarm" item, then set the alarm state by pressing "right button".Choose “on “to turn on the alarm, and choose “off” to turn off the alarm.

c Pulse sound indication setting

In alarm setting menu,move the choice bar to the "Pulse Sound" item, then press "right button" to set state, choose “on “to turn on pulse sound, and choose “off” to turn off pulse sound.

B Clock setting

In the main menu interface, move the choice bar to “Clock” item, then press the “right button” to enter the clock setting menu of figure 8:

Figure 8 clock setting menu

Move the choice bar to the menu item that you want to set, and press “right button" to begin to set.Press "menu button" for affirming.After resetting time,press "return button",and the prompt information whether to affirm setting will appear.The interface will return to main menu after choosing.

C System setting

In the main menu interface, move the choice bar to the "System" item, then press the “right button” to enter the System setting menu as figure 9:

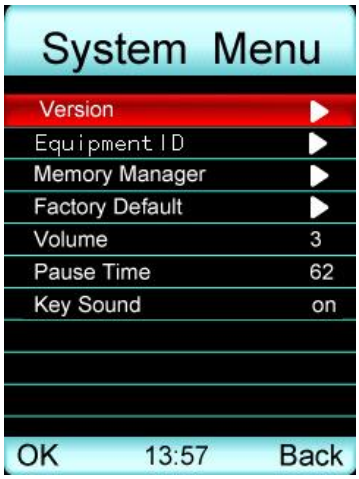


figure 9.System setting menu

a In "System Menu" interface,move the choice bar to the "Version" item,then press the “right button” to see the edition information of hardware and software.

b In "System Menu" interface,move the choice bar to the "Equipment ID" item,then press the “right button” to see the ID information of device.The ID of the device can be set by the PC software.Please refer to <SpO_2 Assistant user manual> for detail.

c Move the choice bar to the "Memory Manager" item,then press the “right button” to enter "Select ID" interface as figure 10.Select the patient ID that you want to delete,then press menu button to delete the patient ID and storage data.

figure 10. Select ID interface

d In "System Menu" interface,move the choice bar to the "Factory Default" item and press the “right button” to choose "Yes",then press menu button,and the device will resume leave-factory state.

e In "System Menu" interface,move the choice bar to the "Volume" item, then you can set the volume of voice.

f In "System Menu" interface,move the choice bar to the "Pause Time" item, then you can set the pause time of alarm.The default of pause time is 60 seconds,and press the “right button” to adjust the pause time of alarm.

g In "System Menu" interface,move the choice bar to the "Key Sound" item,and press the “right button” to turn on/off the key sound.

D Brightness adjustment

In the main menu interface, move the choice bar to the "Brightness" item,then press the "right button" to adjust the brightness of screen.

E Data storage setting

a In the main menu interface, press the “up button" or "down button" to select "Record", then press "right button",here the "off" will turn to black display.Press "right button" again,and the black "off" will turn to black "on".Press menu button to enter the "Input ID" interface as figure 11.

figure 11. Input ID interface

b In "Input ID" interface,press menu button to input new ID,here aglimmer cursor will appear in the ID input box and the red choice box will appear in the alphabet as figure 12.Press direction key to choose the letter which is wanted to input and press menu button to input.You can input 4 letters most. After inputting the letters,move the choice box to the enter sign and press menu button to confirm input,here there is not aglimmer cursor in the ID input box.Press menu button again to begin recording and return to measure interface.

figure 12. Input new ID interface

c In "Input ID" interface,press direction key to choose the existent ID for data storage, here the ID input box will turn to blue,at the same time there will be a red choice box on the first ID in the ID listing as figure 13.Press direction key to move the red choice box to the ID which is wanted to choose,then press menu button, here prompt information whether to erase the storage data for this ID will appear.Choose "Yes" to erase the ID data, at the same time begin to record and return to the measure interface;choose "No" to return the "Input ID" interface.

figure 13. Choose existent ID

d Every patient ID could save 24-hour data,the device could save 16 patient ID.

e In the state of storing, whatever interfaces the device is in(measure interface,menu interface,clock interface) ,if there is no operation in 30 seconds,the display screen will closed automatically.If pressing power button,the device will return the measure interface.

f After the display screen closed automatically,the pulse sound will close automatically too for saving electricity under recording state.

F Demo function setting

In the main menu interface, move the choice bar to the "Demo" item,then press the "right button" to turn on demo mode.

G Review function setting

In the main menu interface, move the choice bar to the "Review" item,then press the "right button" to choose review mode.There are two review mode of value and trend.
Under value review mode as figure 14,press "left button" or "right button" to page up or page down,press "up button" or "down button" to page up or page down quickly.The displayed time on the right top is the total recording time.

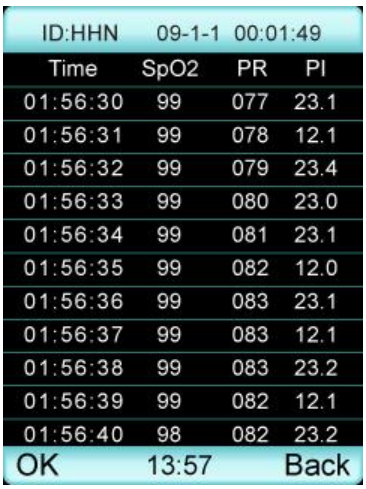


figure 14. Value review mode

Under trend review mode as figure 15,the white number on the left bottom is current recording time point,the middle blue number is SpO2 value,green number is pulse rate value,the white number on the right bottom is PI value.Press "up button" or "down button" to page up or page down;press "left button" or "right button" to move the red triangle.

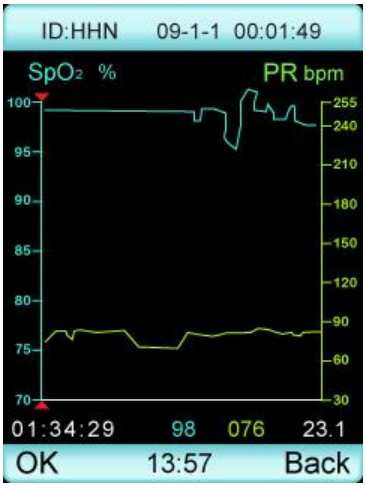


figure 15. Trend review mode

H Close the device

a In the main menu interface, move the choice bar to the "Power off" item,then press menu button to close the device.If the storage function has been opened,the prompt interface of "Recording..." will appear when closing the device.It means that the device is in the state of storing,can't be closed.

b In the state of boot-strap,long press power button could close the device too.

⚠ **If "finger out" appearing and no turning on record function and no operation in 10 minutes,the device will close automatically**

6.1.4 PC software operation

Please connect the device to the computer by USB data line ,which is affiliated with the device, then double click "SpO2 Assistant" icon to run the PC software.The functions such as uploading record data and change device ID could be carried out by the software.Please refer to <SpO_2 Assistant user manual> for detail.

⚠**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.(If there is no data on the computer screen ,unplug USB data line,then repeat step "6.1.4" again .)**

6.1.5 Charge

There are two kinds of charge method:

A Connect the device to computer with data line, then the device should be in charge state.

B Connect the device to power supply with power adaptor, then the device should be in charge state.

When pressing power button,if the device is closed,the charge icon will display,and when the battery

status is full,the icon of full power will display.If there is no operation in 30 seconds,the display will closed automatically.here short press power button to turn on display.When charging,long press power button to turn on the device,here the battery status icon on the right top will display dynamically.It means that the device is charging up.When the battery status is full,the icon of full power will display.

⚠**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 .**
High priority indicating requires that operator responds immediately.

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 5 for reference), or else it may result in inaccurate measure.

C.The ray between luminescent tube and photoelectric receiving tube must get across subject's arteriole.

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

E. Ensure nothing, such as a plaster, can impede the light passage., or else it may result in inaccurate measure of SpO_2 ,pulse rate and PI..

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

G. Exquisite 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 device may be inaccurate.

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

D. As the SpO_2 value serves as a reference value for judgment 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 red aglimmer "Battery Too Low" alarm information.
C Recharge the battery soon after the over-discharge. The device should be recharged every six months when it is not regular used. It can extend the battery life following this guidance.
D The device needs to be calibrated once a year (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

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°C~60°C; Relative Humidity: 5%～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 battery is drained away or almost drained away. 2.The malfunction of the device.	1. Please recharge the battery 2. Please contact the local service center.
The display is off suddenly	1. The device is damaged. 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 charge	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)
	Perfusion Index (%)
	The battery power is full
	The lack of battery power （Please change batteries in time for exact measuring ）
	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
	Open the demo mode
	Power on/off button
	Type BF
IPX1	Ingress of liquids rank
	USB
	Touch key switch
RST	Restoration orifice
SN	Serial number

▬ ▬ ▬	1. the finger clip falls off (no finger inserted)] 2. Probe error 3. Signal inadequacy indicator
	WEEE (2002/96/EC)

10 Function Specification

Information	Display Mode
The Pulse Oxygen Saturation（SpO_2）	2-digit digital TFT display
Pulse Rate（PR）	3-digit digital TFT display
Pulse Intensity (bar-graph)	bar-graph TFT display
PI (perfusion index)	3-digit digital TFT 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-beats cycle. The deviation between average value and true value does not exceed 1%
Perfusion Index Specification	
Range	0%～20% (The resolution is 0.1%))
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse.

Safety Type	Interior Battery，BF Type
Battery Requirement	
Voltage 3.7 rechargeable lithium battery × 1 (The red wire on the battery denotes anode,the black wire on the battery denotes cathode.)	
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
Dimensions and Weight	
Dimensions	94.25(L) × 55.32(W) × 9.6(H) mm
Weight	About 80g (with a lithium battery)

11 Factory default

	default	unit
brightness	3	
Key sound	on	
Pulse sound	off	
Alarm sound	off	
Alarm pause time	60	second
Spo_2 alarm high limit	100	%
Spo_2 alarm low limit	85	%
Pulse rate alarm high limit	120	bpm
Pulse rate alarm low limit	50	bpm