Handheld Pulse Oximeter

User Manual

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Disclaimer Statement

The information in this manual is true and complete to the best of company’s knowledge.Therefore all recommendations are made without any form of guarantee on the part of the company. The company disclaims any liability in connection with the use of this manual, installation and operation of the product and does not assume any legal liability for incidental or consequential damages.The contents contained in this manual are protected by the copyright law. All rights are reserved, and without prior written permission of the company, any part of this manual cannot be reproduced, photographed, copied, or translated into other languages.

The company can only be considered responsible for the reliability, security and performance of the instrument under the following circumstances, namely; assembly operation, expansion, readjustment, performance improvement and repair, all of which are performed by the personnel or institutions authorized by the company; relevant electrical devices are in line with national standards; the instrument is operated in accordance with the guidance in this manual.

The contents of this manual may be changed without notice.

Before using the product, please read the contents of this manual carefully for proper use of the product. Please keep this manual after reading it, so as to access at any time when needed.

Manual version：V1.0

The latest revision date: 04-2025

Foreword

This manual describes in detail the purpose, function and operational use of the product. Before using this product, please carefully read and understand the contents of this manual to ensure proper use of this product, and to ensure the patient and operator safety.

The manual introduces this product according to the most complete configuration, so some contents may not apply to your purchased product. **I**f you have any questions, please contact the company.

Please place this manual near the product, so as to be able to conveniently and timely access it when needed.

Applicable objects

This instrument is suitable for home users or professional clinical staffs, and users shall read the manual carefully before using this instrument.

Illustrations

All illustrations in this manual are provided only for reference, and settings or data in the illustrations may not be entirely consistent with the actual display you see on the product.

Warranty and maintenance services

Scope of Free Services:

Any device in compliance with the range of the company's warranty service can enjoy free services.

Scope of Paid Services:

(1) The company will implement the paid services for any device beyond the range of the company’ s warranty service;

(2) Even during the warranty period, the product needs to be repaired due to the following reasons: human damage; grid voltage exceeding the specified range of device; irresistible natural disasters.

The company is irresponsible for the direct, indirect or final damage and delay caused under the following circumstances (including but not limited to):

Component disassembly, stretching and re-commissioning; replacement of accessories without permission of the company or the machine repair by non-authorized personnel of the company.

Return of goods

Return process

If the product is needed to be returned, take the following steps:

1. The acquired right of return: Contact our customer service department, informing of the product serial number; if the serial number is non-legible, the return of goods will not be accepted. Please specify the product model, serial number, and brief reason for return.
2. Freight: The device is shipped to the company for maintenance, and meanwhile users have to bear the shipping cost (including customs fees)

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Chapter I Overview

1.1 Safety Information

⚠Warning
Tip：potentially dangers or unsafe operations, and if they are not avoided, it could result in death or serious personal injury or property damage.

⚠Caution
Tip：potentially dangers or unsafe operations, and if they are not avoided, it could result in slight personal injury, product failure, damage or property loss.

⚠Attention
Highlight important considerations, and provide instructions or explanations to make better use of this product.

This product is not involved in the information on danger level.

1.1.1 Warning

⚠Warning

- Users, before using this Handheld Pulse Oximeter, should follow the instructions set out in this manual; or else, any incorrect operation may result in serious injury. The company will assume no warranty for improper use of this device.
- Before use, users must check the device, cables, and accessories to ensure that they can properly work safely.
- The device is not available in the presence of flammable gases or other flammable anesthetic gases, in order to avoid explosion.
- Do not open the housing of the oximeter, to avoid the risk of electric shock. If necessary, please only the company's staff should maintain the oximeter.
- To prevent delays in treatment, make full Alarm settings for each patient, while Alarm sound should also be ensured when Alarming.
- The physiological waveforms, physiological parameters and Alarm information and others displayed by the device are for user’ s reference, but cannot be directly used as the basis for clinical treatment.

- Note to place all cables to avoid the hazard of strangling patients or tripping other personnel.
- To avoid personal injury, in addition to qualified technicians, other persons cannot repair the device.

1.1.2 Caution

⚠Caution

- To ensure patient safety, please use the accessories designated by the company.
- When the product and accessories described in this manual are about to exceed the period of use, they must be treated in accordance with relevant product specifications. If you want to learn more information, please contact the company or its representative
- Do not use a mobile phone near the oximeter, because the mobile phone will generate too strong radiation field, which thus interferes with the oximeter function.
- Before the device is powered on, make sure that the voltage and frequency of the power supply are in line with the requirements specified on the device label or in this manual.
- Please properly install or carry the device to prevent the device from falling or being damaged due to collision, receiving strong shock or other mechanical force.

1.1.3 Attention

⚠Attention

- Mount the device at the place where it is easy to observe, operate and maintain.
- Place this manual near the device so as to be able to easily and timely access when needed.
- Before use, verify and correct and ensure that the device is working properly.
- If a liquid is spilled into the enclosure of the device, disconnect the power supply immediately, and contact the maintenance personnel at once.
- The manual introduces the product according to the most complete configuration, and the product you purchase may not have some of the configurations or functions.
- Remove nail polish or artificial nails before oxygen probes are used. Nail polish or artificial nails may cause inaccurate oximeter readings.

1.2 Symbol and Description

	BF type applied part	LOT	Batch code
	Caution	#	Model name
	Manufacturer		Temperature limit
SN	Serial number		Up toward
	Keep dry		Use-by date
	Humidity limitation	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)
	Refer to operation manual		
MD	Medical device		
	Keep away from sunlight		
	Not made with natural rubber latex		To protect the environment, dispose of empty batteries at appropriate collection sites according to national or local regulations.
	Date of manufacture		

Chapter II Product Overview

2.1 Introduction

2.1.1 Intended use

The Handheld Pulse Oximeter is suitable for both home care and hospital use to monitor patients' vital sign parameters, blood oxygen saturation and pulse rate .Handheld Pulse Oximeter is a novel, compact and easy-to-carry device. This device can be used in home care and other occasions.

2.1.2 Environmental Requirements

Normal operating conditions

Ambient temperature：5°C～ 40°C
Relative humidity：15% ～ 80%
Atmospheric pressure：86.0kPa ～ 106kPa

Storage and transportation temperature

Ambient temperature：-20°C～ 50°C
Relative humidity：10% ～ 95%
Atmospheric pressure：55.0kPa ～ 106kPa
The operating environment of this device must comply with the requirements of the environment specification in this manual.

When the device is moved from one scene to another, due to differences in temperature or humidity which may cause the device condensation, you must wait until the condensation condition disappears before you start to use the device.

⚠ Warning

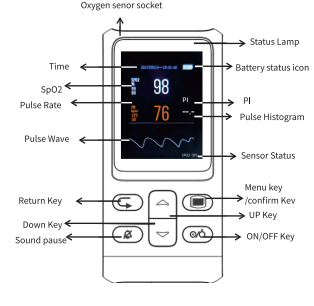
- Please ensure that the device is operated under specified environmental conditions; otherwise, it will not meet the technical specification claimed in this manual, and may lead to unpredictable consequences, which may bring damages to the device.

2.1.3 Contraindications

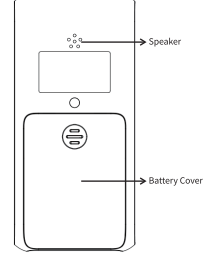
None

2.2 Appearance

2.2.1 Front View



2.2.2 Rear view



1. Display screen

◆2.4-inch color TFT display screen

2.On/Off key: In different situations, the key has different functions.

◆Start: After the battery is installed, short press the button to turn on the monitor.
◆Shutdown: in the startup state, long press the button for 2 seconds to turn off the monitor.

3. Right[↻] key

◆Press this key to enter the menu screen or select an option.

4. Left[▣] key

◆ Pressing this key can return to the measurement main interface;

5. Up key

In different situations, the key has a different function. Press this key to move the cursor upward, to increase the value of a menu option or to increase the pulse volume and to complete other operations. The key also has an Alarm pause function.

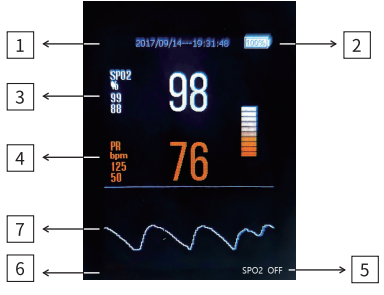
6. Down key

In different situations, the key has different functions. Press this key to move the cursor upward, to reduce the value of a menu option or to decrease the pulse volume and to complete other operations.

7. Oxygen sensor socket

◆ Connect with the oxygen saturation probes to achieve oxygen detection.

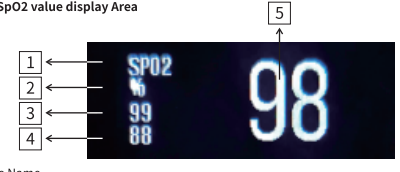
2.3 Screen Display



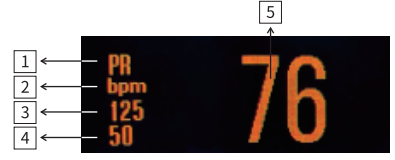
The following diagram shows the screen display interface.

1. Time area
2. Battery status icon
3. SpO2 value display area
4. PR value display area
5. Alarm status area: indicates the Alarm sound turned off.
6. Physiological and technical Alarms area
Display Alarm information, tips and information on the operating mode.
Circle display when coming with multiple messages.
7. Waveform area: Shows plethysmography (Pleth) waveform

2.3.1 SpO2 value display Area

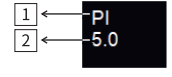


1.Value Name
2.Unit
3.High Alarm limit
4.Low Alarm limit
5.SpO2 value



2.3.2 PR parameter area
1. Value Name
2. Unit
3. High Alarm limit
4. Low Alarm limit
5. PR value

2.3.3 PI parameter area
1. Value Name
2. PR value



Chapter III Preparation before Use

3.1 Unpacking and Inspection

Take out the Handheld Pulse Oximeter and accessories from the box carefully, and store the packaging in case of future shipping or other use. Check the accessories according to the packing list. If any damage happened, please contact our company's after-sales department or agency immediately.

⚠ Warning

- Keep packaging material out of children's reach. Concerning Disposal packaging materials, waste disposal system must comply with relevant local regulations or hospital's claim.

3.2 Power On

1. Before starting, check whether the Handheld Pulse Oximeter is mechanically damaged.
2. Make sure the battery has enough capacity.
3. Insert the Handheld Pulse Oximeter cable into interface jack.
4. Press the power switch, and enter the boot screen.
5. Enter into the main interface after the boot screen disappearance.

⚠ Warning

- If find any function of this oximeter damaged, or get an error Alarm, stop using this oximeter and contact company's maintenance engineer.

3.3. Shutdown

Please refer to the following steps to turn off the oximeter:
1. Confirm that the work of monitoring patient comes to an end.
2. Disconnect the oximeter and oximeter cable.
3. Press the power switch and hold for two seconds to turn off the oximeter.

Chapter IV Menu Settings

The oximeter is designed with a flexible configuration. Both monitoring and Alarm setting could be freely performed by the user. Press the Menu key【 ■ 】to bring up the main menu shown in Figure 4-1.
The Right【 ↵ 】key will be written to [Menu] in following paragraphs.

Figure 4-1

4.1 Alarm
Select "ALARM" in the main menu, and pop out a menu as shown in Figure 4-2:

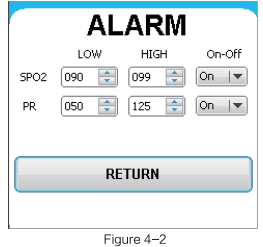


Figure 4-2

4.1.1 SPO2 Alarm
Choose SpO2 in alarm menu
●SPO2 adjustable range: Max: 100, Min: 1
●SPO2 alarm：On/Off
●Adjustment method：
Moving cursor via pressing【▲,▼】, Choosing item as your need, then press Right【 ↵ 】key ,Increase or decrease via pressing【▲,▼】. After your adjustment, pressing Right【 ↵ 】key to ensure it.

4.1.2 PR Alarm
Choose PR in alarm menu
●PR adjustable
●range: Max: 255, Min: 0
●SPO2 alarm：On/Off
●Adjustment method same as 4.1.1

4.2 Setup
In the main menu, select [Setup], set up menu appears as Figure 4-3 below. In the settings menu there are[Brightness],[Alarm Vol], [Pulse Vol] ,[Language] and [Time Setting].

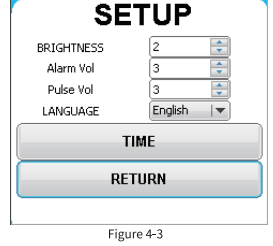


Figure 4-3

Users can modify the Pulse and Alarm Volume, Time Setting as needed.
●Choose【Brightness】in【SETUP】, adjusting via pressing【▲,▼】. Options have nice levels as “1” , “2” , “3” , “4” , “5” , “6” , “7” , “8” , “9” .
●In the [Setup] menu, select the [Alarm vol], Press【▲,▼】to select the level of the Alarm volume . The options have five levels as "1", "2", "3" , "4", "5".
●In the [Setup] menu, select the [Puls vol], Press【▲,▼】to select the level of the pulse volume . The options have five levels as "1", "2", "3" , "4", "5".
●In the [Setup] menu, select the [Language], Press【▲,▼】to select the English, Spanish or French.
●In the [Setup] menu, select the [Time], showed as Figure 4-3 Time Setting below Time Setting, You can set the year, month, day, hour, minute, and second.

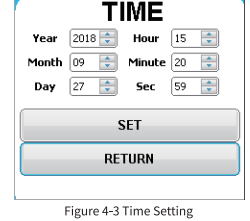


Figure 4-3 Time Setting

⚠ Attention

- Use the Alarm Off Button if you need to turn off the Alarm function.
- If used outdoors or ambient light, please increase the screen brightness for observation

The system time setting should be selected at power-on (if the user needs to set it), otherwise, it may provide incorrect time information when reviewing content with time Alarm information!

4.3 System Setup

Select "SYSTEM" from the main menu, the system menu appears as shown in Figure 4-4 System Menu.

The 『System』 menu include [Review], [default], [Return] and [Maintain].

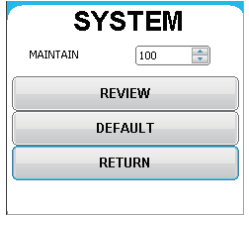


Figure 4-4 System Menu

4.3.1 Review

Choose【Review】in【SYSTEM】, you will see menu as Figure 4-5. You can setup record Open or Close, and the recording period (Time) in【Review】menu.

Figure 4-5 Review

Choose【Trend】in【Review】, you will see menu as Figure 4-6.

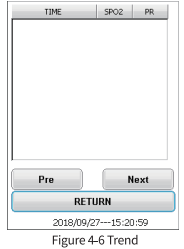


Figure 4-6 Trend

This device can review 500groups history data.

Choose【Previous Page】in【Trend】, you will see menu as Figure 4-7.

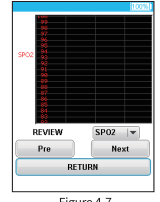


Figure 4-7

You can choose SpO2, PR, in【Review Open】read.

【PRE】to read the previous page

【NEXT】to read the next page

Choose【Delete Record】in【Review】, you will see menu as Figure 4-8.

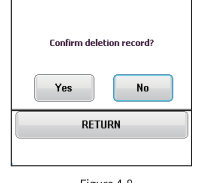


Figure 4-8

4.3.2 Default Setup

In the system menu, selecting Default will show up the "Recover factory set" dialog box, as shown in Figure 4-9.

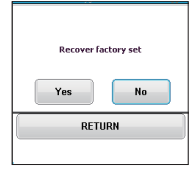


Figure 4-9

Select【Yes】to recover factory set.

Select【No】to quit the current operation, and the system remains unchanged original configuration.

4.3.3 Manufacturer Maintenance

In the [System], select the [Maintain] item, and pop out a dialog box, as shown in Figure 4-10.

Users can input specific user password to activate advanced settings in user maintenance menu. The entry password is 108.

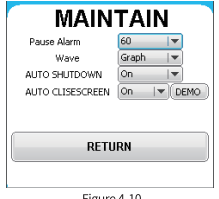


Figure 4-10.

In the Maintain function can choose【PAUSE Alarm】、【WAVE】、【AUTO SHUTDOWN】、【AUTO CLOSESCREEN】to set up.
【PAUSE Alarm 】Alarm time setting can be made, range is 60S~180S
【WAVE 】There are two options to choose from:【Graph】【Fill】
【AUTO SHUTDOWN 】There are two options to choose from:on off【ON】【OFF】
【AUTO ClOSESCREEN】There are two options to choose from:on 【ON】【OFF】

⚠ **Attention**

When exiting the [manufacturer maintenance], it will return to the sub-dialog box [Setup] menu; besides, all dialog boxes will exit to the [main menu].

Chapter V Alarm

Alarm refers to tips made by the monitor to medical staff through sound, light and other means when abnormal vital signs or changes are observed, or patients cannot be monitored smoothly due to the failure of the oximeter itself.

5.1 Alarm Type

Alarm can be classified into two categories which are physiological Alarm and technical Alarm. When the Alarm comes from the changes in the patient's vital signs, namely, the physiological parameters of the patient being under care exceed a specific range or the patient’ s physiological abnormalities cannot be attributed to one single physiological parameter beyond the range, it can be referred to as physiological Alarm; when the Alarm is from the machine itself, namely, when technical barriers existed in the Alarm or the machine itself breaks down, as a result, the patient cannot be observed accurately, it is referred to as technical Alarm.

Patient or machine	Alarm category
Heart rate of the patient is 114BPM, beyond the range of heart rate Alarm which is set by the user.	Physiological Alarm
SpO2 measurement module fails	Technical Alarm

■Physiological Alarm: the Alarm light is normally on and the parameters on the screen will flash with sound Alarms accompanied.
■Technical Alarm: the Alarm light is normally on with sound Alarms accompanied.

5.2 Alarm Status Icon

Besides the Alarm types mentioned above, the following Alarm icons will appear on the screen which means different Alarm states.
: the state when Alarm tone stops.
: the state when Alarm turns off.

5.3 Alarm Pause

■Press the【▲】button, the Alarm tone can be paused:
■The Alarm is suspended while the Alarm light and Alarm information continue to display.
■The state bar on the screen shows the left time of the Alarm tone.
■The state bar on the screen shows icon.

After the Alarm pause time (the system defaults to 120s), the instrument will automatically cancel the Alarm sound pause. You can also press the “▲” key to manually cancel the Alarm sound pause. However, in the event of a new Alarm, the system automatically clears the Alarm sound pause.

5.4 Set Alarm Sound

Select the Right【 】key →【Setup】→【Alarm Volume】→ adjust the volume (Max 5, Min 1).
After the oximeter is turned off and restarted, the minimum Alarm volume set will not change.

⚠ Warning

●When the Alarm volume is adjusted to 0, the Alarm sound is off.
●Patients cannot be monitored and cared only by the sound Alarm system. When the Alarm sound is adjusted to a relatively small volume, patients can be in a dangerous condition. Users should pay close attention to the actual clinical condition of patients.

5.5 Countermeasures to The Alarm

In case that the oximeter sends out an Alarm, please refer to the following steps to take appropriate measures:

1. Check the patient's condition.
2. Verify that the parameters of the ongoing Alarm or the types of Alarm.
3. Identify the reasons for the Alarm.
4. Remove the reasons of the Alarm.
5. Check whether the Alarm is eliminated.

For the specific treatment measures for each Alarm, please refer to Appendix C Alarm information.

Chapter VI SpO2

6.1 Overview

A continuous and non-invasive pulsation oximeter quantitative method is adopted for SpO2 measurement. It measures the specific wavelength of light from the light source of oxygen saturation probes, and after it is absorbed by oxyhemoglobin in the patient’ s tissue and reaches the luminous flux of photodetector end, thus to get oxygen saturation and pulse rate. The oximeter has been calibrated and is used to display functional oxygen saturation. The interface is as shown in Figure 6-1

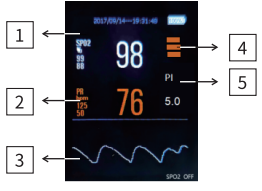


Figure 6-1 SpO2 measurement interface

Measurements provide:

1. Arterial oxygen saturation (SpO2): the percentage of oxyhemoglobin in the total hemoglobin.
2. Pulse rate (PR): the number of pulse detected per minute (obtained from plethysmography waveform).
3. Plethysmography (Pleth) waveform: the strength of the patient's pulse signal does not affect the amplitude of Pleth waveform.
4. Perfusion bar graph: proportional to the intensity of pulse.
5.**PI**:The Perfusion **I**ndex (Pi) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. Pi thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter.

6.2 Safety Information

⚠Warning

- **I**nfluence from carboxyhemoglobin, methemoglobin or dye dilution chemicals will cause biased SPO2 value.
- Do not use any other SpO2 probe except the specified model in this manual. Furthermore,ensure that all operations are under the instruction of the manual. Observe all warnings and precautions.
- Before starting to monitor and care, firstly check whether the oxygen probe is normal. **I**f the oxygen probe packaging or the probe has been damaged, do not use this oxygen probe.
- **I**f a patient has a tendency to hypoxia, the oximeter should be used to analyze the oxygen probe, because the induced current may cause serious burns of the patient.
- When the patient is under continuous long-term monitoring, finger position in the oxygen probe should be checked once every two hours, meanwhile, move patient's hand every 4 hours or when a change occurred to patient's skin. Continuous long-term monitoring may increase risk of patient's unpredictable skin changes, such as allergies, reddening, and blistering or oppression necrosis.
- The cables of electrosurgical devices cannot be entwined with oximeter cable.
- Do not mount and place the oxygen probe on the limbs with arterial ducts or intravenous tubes.
- Do not place the oxygen probe and blood pressure cuff on the same limb.
- Do not use the device when the ambient temperature above 40 °C to avoid burning the skin.
- **I**f the sensor packaging or sensor has been damaged, do not use this Sp02 sensor, and it should be returned to the manufacturer.

6.3 Monitoring steps

1. Select the appropriate oxygen probe according to the patient's type.
2. Clean the measurement site, such as colored nail polish.
3. Place the oxygen probe at the measurement site.
4. Connect the oximeter and oximeter cable.

6.4 On/ Off Parameter Alarm

1. Select the [Menu] → [Alarm]→[SPO2 Alarm]
2. Set SPO2 or PR Alarm to:
   [On]: When the measured parameter has an Alarm event, the machine will have Alarm indication;
   [Off]: No Alarm indication when the menu is set to off. Alarm sound, light, and indication will be closed at the same time. There will be a sign ⚠ in the SPO2 or PR parameter area.

6.5 Set Alarm Limits

1. Select the [Menu] → [Alarm]→[SPO2 Alarm]
2. Set the [High Limit] of SpO2 or PR: When the measured parameter value is above the high Alarm limit, a physiological Alarm of too high parameters will be triggered.
3. Set the [Low Limit] of SpO2 or PR: When the measured parameter value is below the low Alarm limit, a physiological Alarm of too low parameters will be triggered.

In case that a parameter Alarm occurs, the measured value of the parameter will flash and the appropriate Alarm light will be triggered.

6.6 Measuring Influence Factors

If the accuracy of the measurement results is suspected, first use other methods to examine the patient's vital signs, and then test the oximeter and oxygen probe. **I**n the measurement process, the following factors may affect the accuracy of measurements:

- ■Outside light radiation
- ■Body movement (active or passive patient movement)
- ■Diagnostic test
- ■Weak perfusion
- ■Electromagnetic field effects, such as nuclear magnetic resonance device
- ■Electrosurgical devices
- ■Concentration of non-functional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
- ■Presence of certain dyes, such as methylene blue and indigo rouge, inappropriate placement of oxygen probe or incorrect use of oxygen probe
- ■Shock, anemia, low temperature or application of vasoconstrictor drugs leads to reduced pulse blood flow in the water that can not be measured

Chapter VII Battery

7.1 Overview

The icon in the top right corner of the screen shows the status of the batteries.
When the battery is too low to display, you must to replace battery, after a period of time. Otherwise, oximeter will automatically shut down.

⚠ Warning
Keep out of the reach of children.

⚠ Note
The battery's power supply time depends on the device configuration and operation.

⚠ Warning
Do not remove the battery, do not put it into a fire or short circuit. Battery burn, explode or leak may cause personal injury.

Chapter VIII Maintenance

Please merely use the materials and methods listed in this section for cleaning or disinfecting of the device. The company does not provide any guarantee for damage or accidents caused by other materials or methods.
The company does not bear any responsibility for the effectiveness of the chemicals or methods listed as a means of infection control. About the method for infection control, please consult the hospital’ s infection prevention department or epidemiologist.

Please keep your devices and its’ accessories free of dust. To prevent damage to the device, be sure to observe the following:

■Please dilute the cleaning agent and disinfectant according to the manufacturer's instructions, or use the lowest possible concentrations.
■Do not immerse the device in the liquid.
■Do not pour liquid onto the device or accessories.
■Do not allow liquid to enter the enclosure.
■Do not use abrasive materials (such as steel wool or silver polish), and any strong solvents (such as acetone or acetone-containing cleaning agents).

⚠ Warning
- Before cleaning the device, you must turn off the oximeter.

⚠ Caution
- If you pour liquid onto the device or accessories due to incaution, please contact the maintenance personnel or the company immediately.

⚠ Attention
- To clean or disinfect reusable accessories, please refer to the manual provided along with the accessories.

8.1 Inspection

Before the oximeter is used for the first time, and after it is repaired or upgraded, or at least every two years, a comprehensive inspection on it should be conducted by qualified maintenance personnel to ensure the normal operation and work of the oximeter.

Inspection items should include:

■The environment and power supply meet the requirements.
■The device and accessories are not mechanically damaged.
■The power line is not worn, with good insulation properties.
■Use the specified accessories.
■The Alarm system functions properly.
■Battery performance.
■The monitoring function is in good working condition.

If you find any damage or unusual phenomenon, please do not use the oximeter, and immediately contact the company’ s maintenance personnel.

8.2 Cleaning

The device should be cleaned on a regular basis, and the frequency of cleaning should be increased in the areas suffering from serious environmental pollution or heavy sand. Please consult or learn about the hospital’ s regulations on the device cleaning before cleaning.

The following cleaning agents are available for selection:

■Diluted soapy water and diluted ammonia
■Sodium hypochlorite (bleaching power for washing)
■Hydrogen peroxide (3%)
■Ethanol (70%)
■Isopropanol (70%)

When cleaning the device:

1. Turn off the oximeter.
2. Use a soft cotton ball and absorb the right amount of cleaning agent, and wipe the display screen.
3. Use a soft cloth ball and absorb the right amount of cleaning agent, and wipe the surface of the device.
4. Use a dry cloth to remove excessive cleaning agent when necessary.
5. The device is placed in the ventilated, shade and dry environment.

8.3 Disinfection

Disinfection operation may produce some degree of damage to the oximeter. **I**t is recommended to perform disinfection only when deemed necessary in your hospital maintenance plan.
The device should be cleaned before disinfection.
The recommended disinfectants are: 70% ethanol, 70% isopropyl alcohol and 2% glutaraldehyde solution.

⚠Caution

- Do not use gas (EtO) or formaldehyde for disinfection.

8.4 Scrap

To avoid contamination or infection to others, environment or other devices, before scrapping the oximeter, follow the state relevant laws or regulations for its disinfection and purification.
For the oxygen probe, please follow the relevant provisions of the local hospital on waste scrap

Chapter IX Accessories

⚠ Warning

- Use only the accessories specified in this manual. The use of other accessories may damage the oximeter.
- Disposable accessories can only be used once. This is because repeated use can cause performance degradation or cross-infection.
- **I**f accessory packages or accessories are damaged, do not use the accessories.
- The blood oxygen saturation probe in the chapter complies with biocompatibility requirements.

Blood oxygen saturation probe

Model	Applicable object	Wavelength *
DB9 adult finger clip	Adult	660nm 940nm

A Product Specification

According to the classification standard of China's State Food and Drug Administration,
the oximeter belongs to Class **II** device.

Safety specification (in accordance with IEC60601-1 classification)		
Protection type of electric shock	Class II (including internal power supply)	
Protection class of electric shock	BF (anti-defibrillator)	
Explosion protection class	Ordinary device, explosion protection not provided	
Protection class of inlet liquid	IP22	
Movement grade	Handheld	
Working mode	Continuous	
Environmental specification	Work	Storage
Temperature (°C)	5℃～40 ℃	-20℃～50℃
Relative humidity (non-condensing)	15%～80%	10%～95%
Atmospheric pressure (kPa)	86.0kPa～106kPa	55.0kPa～106kPa
AC charger		
Input voltage	100～240 VAC 、50/60 Hz	
The output voltage	5 VDC	
Output current	2.0A	
Output Power	10 W	

Power	3*1.5V AAA
Physical specification	
W × H ×T	128×60×30 mm
Maximum weight	Appr.130g (net weight)
Hardware specification	
Display screen	Color TFT, 2.4-inch, dot matrix: 240× 320
Speaker	1, Alarm sound (45 ~ 85dB), multi-level volume function;
Alarm indicator light	yellow
Power indicator light	yellow
Blood oxygen probe interface	1, D 9-pin socket
Measurement specification	
SpO2	
Confirm the accuracy of measurements: the accuracy of SpO2 is already confirmed in human trials by comparison with the reference value of arterial blood sample measured by CO- oxygen pressure gauge. The measurement results of pulsation oxygen meter meet statistical distribution, and compared with the measurement results of CO- oxygen pressure gauge, only about two-thirds of the measurement results is expected to be within the specified precision.	

Measuring range	0～100%	
Resolution	1%	
Precision	70～100%：± 4% (adults, in the non-moving state) 0%～69%：not defined	
PR		
Measuring range	30～240 bpm	
Resolution	1 bpm	
Precision	±3 bpm (in the non-moving state)	
Update cycle	1 s	
PI		
Measuring range	0～100%	
Alarm limit specification		
Alarm limit	Range (%)	Step length (%)
SpO2 high limit	(low limit +1) ～100	1
SpO2 low limit	70～ (high limit -1)	
Alarm limit	Range (bpm)	Step length (bpm)
PR high limit	(low limit +1) ～240	1
PR low limit	0～ (high limit -1)	

B Default factory settings

This chapter lists some of the most important default factory settings of the oximeter. If users can not change the factory settings, but when needed, the default factory settings of the oximeter can be restored.

B.1 Alarm

Alarm setting	Default factory settings
Alarm volume *	2
Pause time for Alarm tone	120 s
Alarm switch	Open
Probe off	Low
SPO2 Alarm	Open
PR Alarm limit	Open

B.2 SpO2

SpO2 Settings	Adults
SpO2 high Alarm limit	99
SpO2 low Alarm limit	90
PR Settings	Adults
PR high Alarm limit	125
PR low Alarm limit	50

C Alarm Information

This chapter lists some of the most important physiological and technical Alarm information, but some Alarm information is not necessarily listed.
For each Alarm information, appropriate countermeasures are given out. If the problem persists after operations following the countermeasures, contact the maintenance personnel.

C.1 Physiological Prompt information

Alarm information	Reasons and countermeasures
SpO2 too high	Check the physiological condition of the patient, and confirm whether the patient type and Alarm limit settings are applied to the patient.
SpO2 too low	
PR too high	
PR too low	
No pulse found	If the patient's pulse signal is too weak, the system can not analyze. Check the patient's condition, oxygen probe, and measurement site.

C.2 Technical Alarm information

Alarm information	Reasons and countermeasures
Probe off	If the oxygen probe is off from the patient or host, if it fails, or an oxygen probe not specified in this manual is used, check whether the oxygen probe type and installation position are correct and whether the oxygen probe is damaged. Reconnect the oxygen probe or use a new oxygen probe.
Inadequate battery capacity	When the low battery voltage is below the Alarm voltage, Please replace the battery again.

D Manufacturer' s Declaration of the EUT

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

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

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

Guidance and manufacturer's declaration – electromagnetic immunity		
The Handheld Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulse Oximeter 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 lines	± 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	30 A/m
NOTE U_T is the a. c. mains voltage prior to application of the test level.		

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

Guidance and manufacturer´s declaration – electromagnetic immunity		
The Handheld Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulse Oximeter should assure that it is used in such an environment.		
Immunity test	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
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 (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM[c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13,17	Pulse modulation [b] 217 Hz	0,2	0.3	9
810 870 930	800 - 960	GSM 800/900.TETRA 800, iDEN 820,CDMA 850,LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
1 720 1 845 1 970	1 700-1 990	GSM 1800;CDMA 1900; GSM 1900;DECT;LTE Band 1, 3 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
2 450	2 400-2 570	Bluetooth,WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240 5 500 5 785	5 100-5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0.3	9

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.

Precautions for use

According to IEC60601-1-2, Handheld Pulse Oximeter complies with all applicable electromagnetic compatibility (EMC) requirements. It may have harmful interference with other devices if you do not follow the instructions. However, there is not certain it has not interference with other devices if you following the instructions. If it does have interference with other device, you can amend interference by the following methods.

1.Enlarge the distance between this device and other device.
2.Connect the two devices with different power socket.
Essential performance and basic safety testing should be done every two years. If your device needs to be done, please contact your provider or Yongkang. This device only can be tested by the provider who has be authorized.

Components

Components	Quantity
Handheld pulse oximeter	1pc
User manual	1pc
Battery (Optional)	1pc
Oxygen probe , adult ,DB9	1pc