Mini Handheld Pulse Oximeter

User’s Manual

Disclaimer Statement

The company does not in any form guarantee the errors in this manual, installation errors and operator errors, and does not assume any legal liability for incidental or consequential damages.

The company only considers to be 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.

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 can be, and to ensure that 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. If you have any questions, please contact with the company.

Please place this manual near the product, so as to be able to convenient and timely access 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 by 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

The company is really necessary to be returned, follow these 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 Palm 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.

- **The device is used in the medical field, and measurement results serve only as reference.**
- **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 the company's staff maintain.**
- **The oximeter is suitable for the occasions where an electrosurgical device is used; where it shares with an electrosurgical device, the user (doctor or nurse) should ensure the safety of the patient under intensive care.**
- **During defibrillation, do not touch patients; or else, it may cause serious injury and death.**
- **To prevent delays in treatment, make full alarm settings for each patient, while alarm sound should also be able to be ensured when alarming.**
- **The physiological waveforms, physiological parameters and alarm information and others displayed by the device are for doctor’s reference, but can not be directly used as the basis for clinical treatment.**
- **Note to place the power line and all cables to avoid the hazard of strangling patients or tripping other personnel.**
- **To avoid personal injury, in addition to qualified technicians, other persons can not 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 bodies.**
- **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 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 oximetry readings.**

1.2 Symbol and Description

Symbol	Description	Symbol	Description
	BF type applied part		Refer to operation manual
	Cautions, please refer to attached documents	IP22	Level of protecting against liquid inlet
	Manufacturer		Date of manufacture
SN	Serial number		Recycled separately from other household waste under the WEEE directive
	Keep dry		Keep away from sunlight

Chapter II Product Overview

2.1 Introduction

2.1.1 Intended use

The oximeter is suitable for both home care and hospital use to monitor patients' vital sign parameters, including blood oxygen saturation, pulse rate and body temperature (body temperature is optional) .Palm Pulse Oximeter is a novel, compact and easy-to-carry device. This device can be used in Emergency Room, home care and other occasions.

2.1.2 Environmental Requirements

Temperature

Operating temperature 5(°C)～40(°C)

Transportation and storage temperature -20(°C)～ 50(°C)

Humidity

Operating humidity 15%～ 85%

Transportation and storage humidity ≤ 90 %

Atmospheric pressure

86.0kPa～106.0kPa；

Altitude

Working altitude -500 ～ 4,600m (-1,600 ～ 15,000 ft)

Transportation and storage altitude -500 ～ 13,100m (-1,600 ～ 43,000 ft)

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 one, due to differences temperature or humidity, which may cause the device condensation. At this point, you must keep waiting until the condensation condition disappears 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.**

⚠Attention⚠

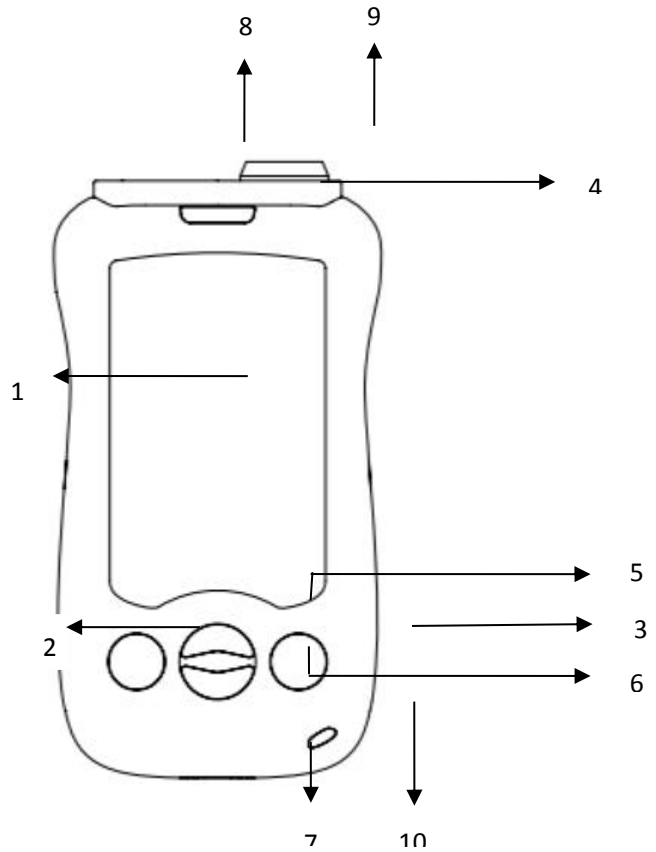
- **The oximeter can be used in hospitals, emergency room and ambulance, as well as for home care.**

2.1.3 Contraindications

None

2.2 Appearance

2.2.1 Front View



1. Display screen
   - 2.4-inch color LCD display screen
2. Power switch: 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. Menu key
   - Press this key to enter the menu screen or select an option.
4. Alarm Indicator light

- Yellow and normally on

5. Up key

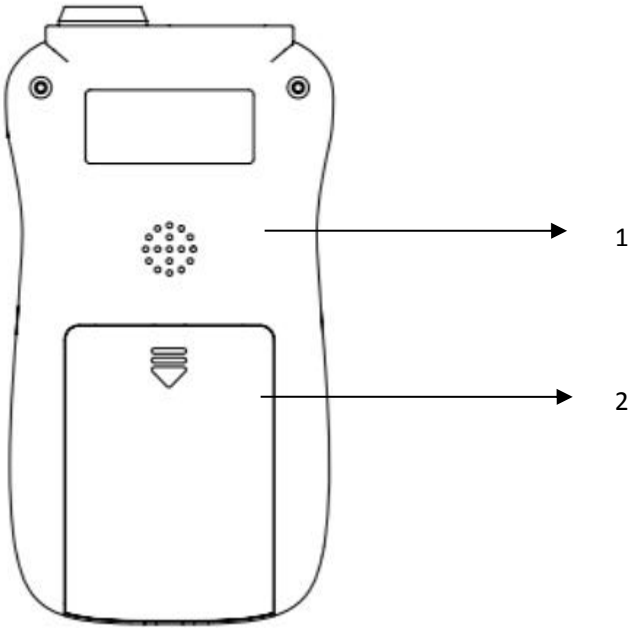
In different situations, the key has a different function. Press this key to move the cursor upward, to increase the value of a menu option or to increase the pulse volume and to complete other operations. The key also has an alarm pause function.

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. Micro USB interface
   - Connect the adapter
8. Oxygen sensor socket
   - connects with the oxygen saturation probes to achieve oxygen detection.
9. Temperature sensor interface
   - Connected to the temperature probes to achieve temperature measurement.
10. Power indicator
    - Green: Connecting the AC power adapter, the oximeter being powered.
    - Off: the oximeter is not connected to AC

2.2.2 Rear view

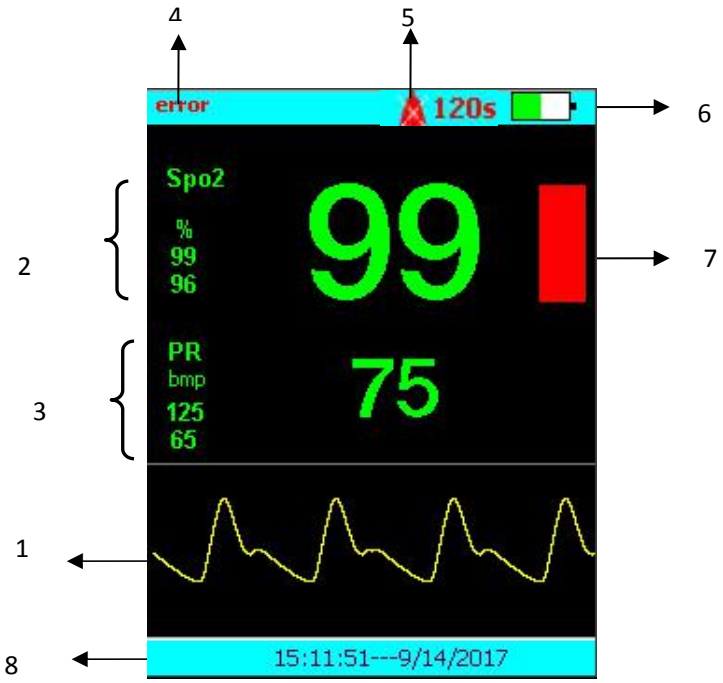


1. Speaker

2. Battery cover

2.3 Screen Display

The following diagram shows the screen display interface.



1. Waveform area: Shows plethysmography (Pleth) waveform

2. SpO2 value display area

3. PR value display area

4. Physiological and technical alarms area

Display alarm information, tips and information on the operating mode.

Circle display when coming with multiple messages.

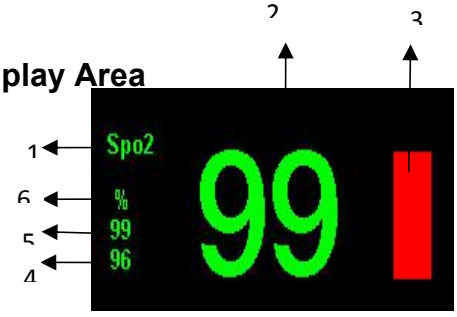
5. Alarm status area:  indicates the alarm sound turned off.

6. Battery status icon

7. PI bar diagram

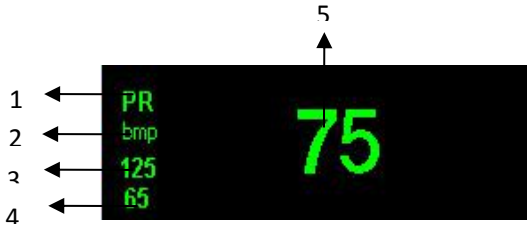
8. Time area

2.3.1 SpO2 value display Area



1. Value Name
2. SpO2 value
3. PI bar graph
4. Low alarm limit
5. High alarm limit
6. Unit

2.3.2 PR parameter area



1. Value Name
2. Unit
3. High alarm limit
4. Low alarm limit
5. PR value

Chapter III Preparation before Use

3.1 Unpacking and Inspection

Take out the 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 oximeter is mechanically damaged.
2. Make sure the battery has enough capacity.
3. Insert the 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 damage of oximeter, or get an error promotion, stop using this oximeter anymore. And contact the biomedical engineer in hospital or company's maintenance engineer.**

3.3Shutdown

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 free performed by user. Press the Menu key to bring up the main menu shown in Figure 4-1.

Figure 4-1

4.1 Alarm

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

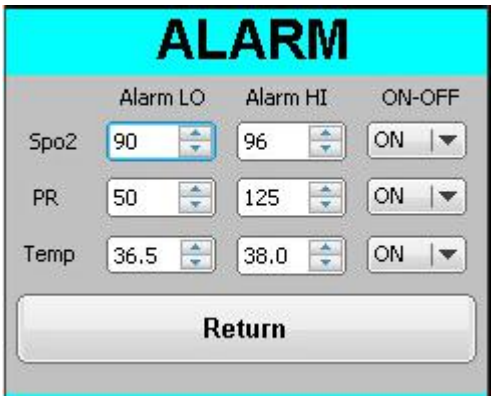


Figure 4-2

4.1.1 SPO2 Alarm

Choose SpO2 in Alarm menu

- SPO2 adjustable range: Max: 100, Min:70
- SPO2 Alarm：On/Off
- Adjustment method：

Moving cursor via pressing 【▲,▼】, Choosing item as your need, then press【M】, Increase or decrease via pressing【▲,▼】. After your adjustment, pressing 【M】to ensure it.

4.1.2 PR Alarm

Choose PR in Alarm menu

- PR adjustable range: Max: 254, Min: 0
- SPO2 Alarm：On/Off
- Adjustment method same as 4.1.1

4.1.2 Temp Alarm (optional)

Choose Temp in Alarm menu

- Temp adjustable range: Max: 50, Min: 20
- 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 [Pulse Vol] , [Alarm Vol] and [TEMP Unit].

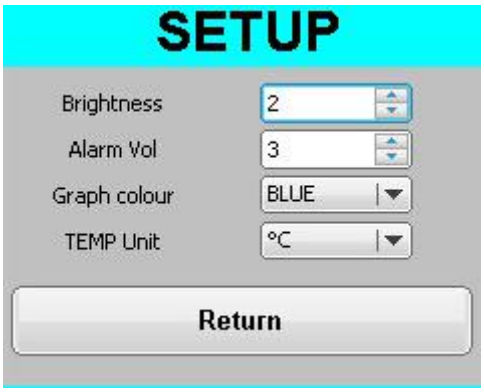


Figure 4-3

Users can modify the pulse and alarm volume, Temp unit 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 [TEMP unit] ，Press【▲,▼】to modify TEMP unit. The options include “℃”and“℉”

⚠Attention⚠

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

4.3 System Setup

Select "SYSTEM" from the main menu, the system menu appears as shown in Figure 4-4. The 『System』 menu include [Review], [default] and [Return] three options.

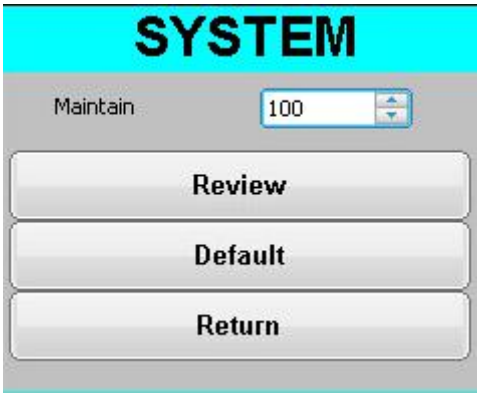


Figure 4-4

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.

图4-5 历史回顾

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

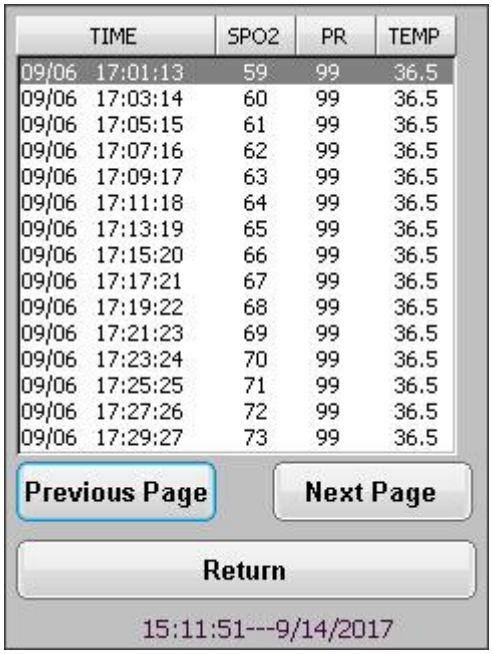


图4-6 Trend

This device can review 500groups history data.

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

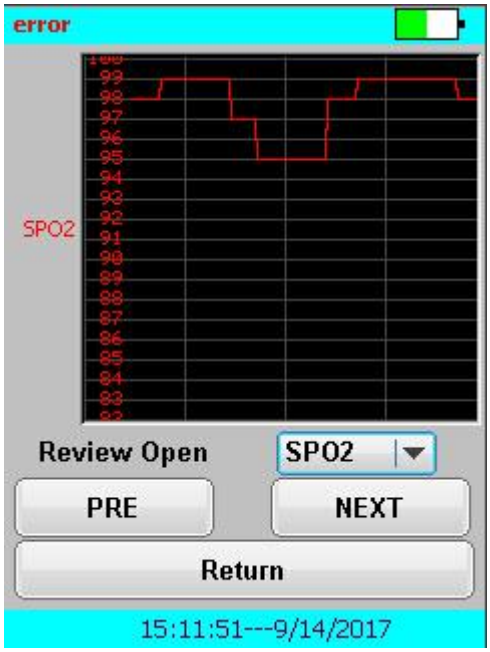


图4-7 Review

You can choose SPO2, PR, TEMP in【Review Open】read.

【PRE】to read the previous page

【NEXT】to read the next page

4.3.2 Default Setup

In the system menu, selecting Default will pop up the "Recover factory set" dialog box, as shown in Figure 4-8.

Figure 4-8

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 Setup], select the [Maintenance] item, and pop out a dialog box, as shown in Figure 4-9.

Users can input specific user password to active advanced settings in user maintenance menu.

“Factory Maintenance” function only opens to the company's designated maintenance personnel.

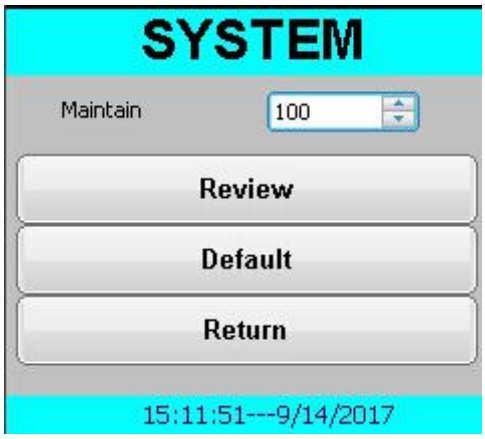


Figure 4-9

4.4 Time Setup

Choose【Time Set】in【SETUP】, menu as Figure 4-10.

Figure 4-10

⚠**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 change is observed, or patients cannot be monitored smoothly due to the failure of the monitor 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 attribute 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 there are 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 display.
- The state bar on the screen shows the left time of the alarm tone.
- The state bar on the screen shows  icon.

5.4 Set Alarm Sound

Select the 【Menu】 → 【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 adjust 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 of 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 7-1

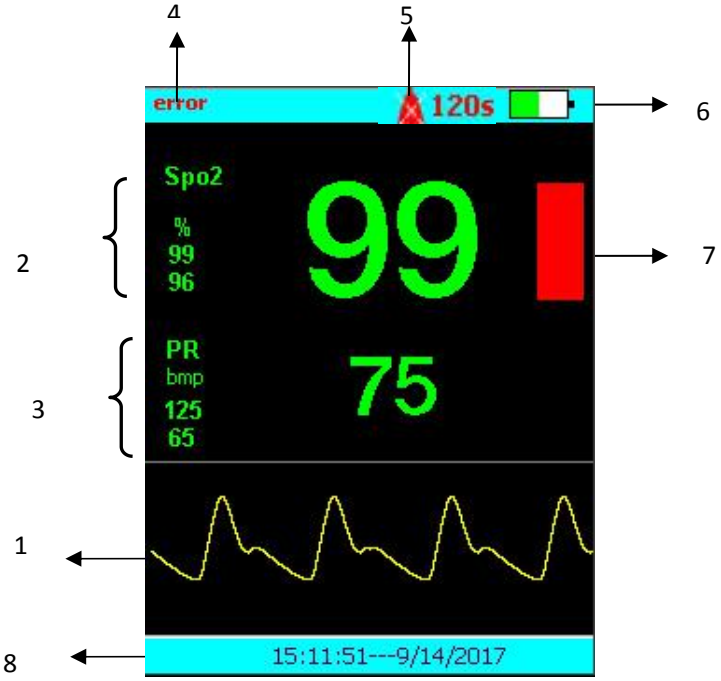


Figure 7- 1 SpO2 measurement interface

Measurements provide:

1. Arterial oxygen saturation (SpO2): the percentage of oxyhemoglobin in the total hemoglobin.

2. Perfusion bar graph: proportional to the intensity of pulse.

3. Pulse rate (PR): the number of pulse detected per minute (obtained from plethysmography waveform).

4. Plethysmography (Pleth) waveform: the strength of the patient's pulse signal does not affect the amplitude of Pleth waveform.

6.2 Safety Information

⚠**Warning**⚠

- **Influence 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, as well 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. If the oxygen probe packaging or the probe has been damaged, do not use this oxygen probe.**
- **If 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, 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.**
- **For the patients younger than one-year-old, do not use the device when the ambient temperature above 40 degrees Celsius to avoid burning baby's skin.**
- **If the sensor packaging or sensor has been damaged, do not use this $Sp0_2$ sensor, and it should be returned to the manufacturer.**

6.3 Caring Stepsbin

1. Select the appropriate oxygen probe according to the patient's type and weight.

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 alarm event, the machine will have alarm indication;

[Off]: No alarm indication when the menu is seted to off. Alarm sound, light and indication to 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. In 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 of temperature (TEMP) (optional)

7.1 Temperature Monitoring Operation Steps (Optional)

Oximeter temperature probe can be used to measure the body temperature data.

1. If you are using a disposable temperature probe, insert the cable's right side into socket and connect the other side with probe. For reusable temperature probe, you can plug it directly into the socket.
2. The temperature probe firmly attached to the patient.
3. Connect the oximeter and temperature cable.

Temperature measurement interface shown in Figure 8-1.

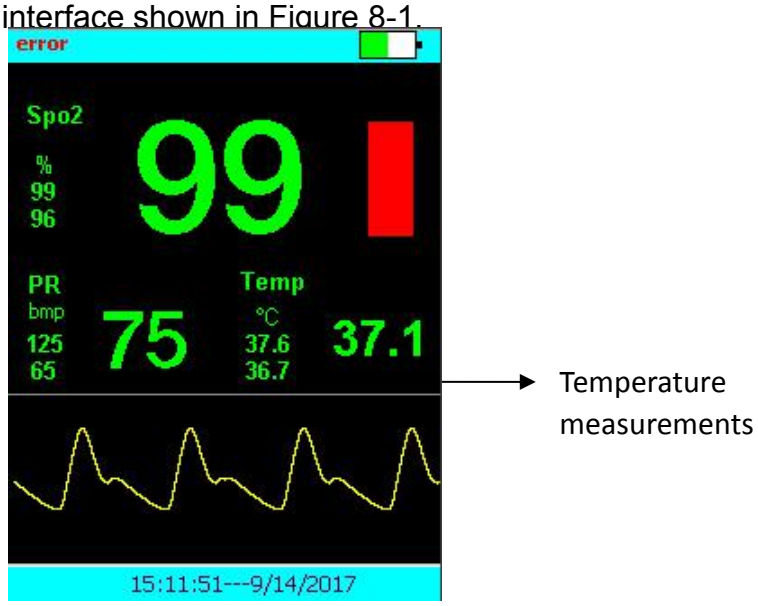


Figure 8-1 temperature measurement interface

7.2 Safety Information

⚠**Warning**⚠

- Should be tested before the start of the measurement probe cable is normal. Unplug the temperature probe cable from the jack, the screen will display the error message "T sensor off" and an alarm sounds. Similar to other channels.
- Place carefully temperature probe and cable when not in use, probe and cable should be rolled into a loose ring. If the inside of the wire pull too tight, it will cause mechanical damage.
- Must biennial temperature measuring instrument calibration (or according to hospital protocol indicates the time).

⚠Note⚠

Disposable temperature probe can only be used once. To protect the environment, disposable temperature probe should be recycled or properly

disposed of.

- During the measurement temperature measurement function self-test automatically once per hour. Self-Test for 2 seconds, will not affect the normal operation of the oximeter.

7.3 On / Off Parameters Alarm

1. Select【Menu】→【Alarm】→【Alarm temperature alarm】
2. Set the 【Alarm Temp】as follows:

【Open】：When this parameter alarm occurs, the oximeter will alarm-related parameters;

【Off】：oximeter without alarm-related parameters, alarm sounds, alarm lights and alarms are turned off, the display Temp parameter shows “  ” icon.

7.4 Set the Alarm Limit

1. Select【Menu】→【Alarm】→【Alarm temperature alarm】
2. Set Temp The【High Limit】: When the measured parameter value is above the high alarm limit, an alarm will be triggered physiological parameters too high.
3. Set Temp the【Lower limit】：When the measured value is below the low alarm limit parameters, low physiological parameters will trigger an alarm. When a parameter alarm occurs, This value will flash and corresponding trigger an alarm lamp.

7.5 Setting The Temperature Unit

Select【Menu】→【Settings】→【TEMP unit】，options are "℃" and "℉"

Chapter VIII Battery

8.1 Overview

The oximeter main power supplied is alkaline batteries. Icon in the top right corner of the screen shows the battery status of the batteries.
When the battery is too low to display, you must replace the batteries or use the AC adapter for power, after a period of time. Otherwise, oximeter will automatically shut down. In the case of measuring the patient cannot be interrupted, you can oximeter with the adapter and AC power.

⚠Note⚠

Remove the batteries before shipping oximeter or not use for a long time.

AC adapter power supply is available simultaneous use when you are using batteries.

⚠Warning⚠

Keep out of the reach of children.
Use only the battery specified by the manufacturer.

8.2 Installing The Batteries

1. Hold the battery cover, push it down, remove the battery cover.
2. Install the batteries:
   1) Press the batteries correct polarity into the batteries compartment;
   2) The batteries cover on the top of the batteries, push up, install the battery cover.

⚠Be careful⚠

Do not use different types of alkaline batteries.

⚠Note⚠

Battery run time depends on the device configuration and operation.

8.3 Battery Recycling

If the battery is visibly damaged, or if the battery runs out of energy, should be replaced, and properly recycled. When disposing of used batteries, should follow the appropriate regulations.

⚠Warning⚠

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

Chapter Ⅸ Maintenance and Cleaning

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 power supply and disconnect the power line and charger base.**

⚠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.**

9.1 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 hospital's medical engineer or the company’s maintenance personnel.

9.2 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 adsorb the right amount of cleaning agent, and wipe the display screen.
3. Use a soft cloth ball and adsorb 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.

9.3 Disinfection

Disinfection operation may produce some degree of damage to the oximeter. It 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.**

9.4 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 Ⅹ Accessories

⚠**Warning**⚠

- **Use only the accessories specified in this manual, and the use of other accessories may damage the oximeter**
- **Disposable accessories can only be used once, because repeated use can cause performance degradation or cross-infection.**
- **If accessory packages or accessories are damaged, do not use the accessories.**
- **The blood oxygen saturation probe in the chapter complies with biocompatibility requirements and meets the standards ISO 10993-1 and ISO 10993-5 and ISO 10993-10.**

Blood oxygen saturation probe

Model	Applicable object	Wavelength *
DB9 adult finger clip	Adult	660nm 940nm
DB9 newborn wrap	Newborn	660 nm 905 nm

Others

Name	Model
Body temperature probe (optional)	Two core plastic plugs
Lithium battery	1.5V AAA

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	IPX2	
Movement grade	Handheld	
Working mode	Continuous	
Environmental specification	Work	Storage
Temperature（℃）	0～40	-20～60
Relative humidity (non-condensing)	15％～95％	10％～95％
Atmospheric pressure (mmHg or kPa)	425 ～ 809 mmHg or 70.0 ～ 106.0 kPa	120 ～ 809mmHg or 22.0 ～ 107.4 kPa

Alkaline battery	

Quantity	3 pcs
Standard	1.5V AAA
Supply time	6h, using the new and fully charged battery at the ambient temperature 25℃, with a typical configuration (SpO2 continuous measurement, the backlight set to minimum brightness, and the sound turned off all the time).
Shutdown delay	At most 10 minutes(since the first low battery capacity alarm)

Physical specification	
W × H ×T	127×67×27 mm
Maximum weight	110g（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 sound in line with the requirements of IEC 60601-1-8 standard
Alarm indicator light	1, yellow
Power indicator light	1, green
Blood oxygen probe interface	1, D 9-pin socket
Temperature probe interface	1 (optional)
Micro USB interface	1, connect adapter

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％: ± 2% (adults, in the non-moving state) ± 3% (in the moving state) 0％～69％：not defined	
Update cycle	1 s	
PR		
Measuring range	18～300 bpm	
Resolution	1 bpm	
Precision	±3 bpm （in the non-moving state） ±5 bpm（in the moving state）	
Update cycle	1 s	
Alarm limit specification		
Alarm limit	Range（％）	Step length（％）
SpO2 high limit	（low limit +1）～100	1
SpO2 low limit	50～（high limit -1）	
Alarm limit	Range（**bpm**）	Step length（**bpm**）
PR high limit	（low limit +1）～300	1
PR low limit	18～（high limit -1）	
Measurement specification		

TEMP		
Measuring range	0~50 ℃	
Resolution	0.1 ℃	
Precision	±0.1 ℃	
Alarm limit specification		
Alarm limit	Range（℃）	Step length（%）
TEMP high limit	（low limit+1）～50	1
TEMP 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 *	1
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	100
SpO2 PR low alarm limit	90

PR Settings	Adults
PR high alarm limit	120
PR low alarm limit	50

Temp setting	adults
Temp high alarm limit	38.0
Temp ow alarm limit	35.5

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.

Alarm information	Reasons and countermeasures
SpO2 too high	Check the physiological condition of the patient, and confirm whether the
SpO2 too low	

PR too high	patient type and alarm limit settings are applied to the patient.
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.
Temp too high	Check the physiological condition of the patient, and confirm whether the patient type and alarm limit settings are applied to the patient.
Temp too low	

C.1 Physiological alarm information

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, if the battery in use is alkaline battery, replace the battery immediately. If the battery in use is a lithium battery, connect the charger base and AC power supply to recharge the lithium battery, and then use the battery to supply power as needed.

D Manufacturer's Declaration of the EUT

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

1	Guidance and manufacturer´s declaration – electromagnetic emission		
2	The Palm Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Palm Pulse Oximeter should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment - guidance**
4	RF emissions CISPR 11	Group 1	The Palm Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	The Palm Pulse Oximeter is suitable for use in all establi shments, including domestic establishments and those dir ectly connected to the public low-voltage power supply ne twork that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	N/A	
7	Voltage fluctuations /flicker emissions IEC 61000-3-3	N/A	

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

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Palm Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Palm Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Palm Pulse Oximeter requires continued operation during power mains interruptions, it is recommended that the Palm Pulse Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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

<table>
<tr><td colspan="4">Guidance and manufacturer´s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The Palm Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Palm Pulse Oximeter should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>EN 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF

IEC 61000-4-6</td><td>3 Vrms

150 kHz to 80 MHz</td><td>N/A</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the Palm Pulse Oximeter including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = [\frac{3.5}{V_1}]\sqrt{P}$
$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz
where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b]
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF

IEC 61000-4-3</td><td>3 V/m

80 MHz to 2.5 GHz</td><td>3 V/m</td><td></td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones</td></tr>
</table>

and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Palm Pulse Oximeter is used exceeds the applicable RF compliance level above, the Palm Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Palm Pulse Oximeter.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Palm Pulse Oximeter

The Palm Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Palm Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Palm Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.