Pluse Oximeter Instruction Manual

MD300C316
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Safety Information

Please read this manual thoroughly before using the pulse oximeter! Keep it in hand for future reference.

Warnings alert the user to potential serious outcomes, such as injury or adverse events to the patient or user.

Cautions alert the user to exercise care necessary for the safe and effective use of the pulse oximeter.

Notes contain important information that may be overlooked or missed.

Warnings!

● DO NOT strike or needle the battery.
● Keep away from source of fire and/or heat.
● DO NOT disassemble the oximeter or its accessories.
● DO NOT use the pulse oximeter in an MRI or a CT environment
● DO NOT use the pulse oximeter in the presence of flammable anesthetics.
● Explosion hazard: DO NOT use the pulse oximeter in an explosive atmosphere.
● Chemicals from a broken OLED panel are toxic when ingested. Use caution when the oximeter has a broken display screen.
● The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
● Check the pulse oximeter application site frequently to determine the positioning of the measurement and circulation and skin sensitivity of the patient.
● Although the pulse oximeter has alarms, it is not suggested for long time continuous monitoring.
● Prolonged use or the patient’s condition may require changing the measurement site periodically. Change measurement site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

● Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

● Only the authorized service personnel can replace the battery or repair this device. This device uses a fixed lithium-ion battery inside. Do not try to replace the battery by yourself at any time. For longer battery life, only charge the battery when the battery power is empty.

Cautions!

➢ Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause inaccurate readings.

➢ Significant levels of dysfunctional hemoglobins (such as carbonxy- hemoglobin or methemoglobin) may cause inaccurate readings.

➢ Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate readings.

➢ SpO₂ measurements may be adversely affected in the presence of upper ambient light. Shield the sensor area (with a surgical tower, or direct sunlight, for example) if necessary.

➢ Excessive patient movement may cause inaccurate readings.

➢ Upper-frequency electrosurgical interference may cause inaccurate readings.

➢ Venous pulsations may cause inaccurate readings.

➢ Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line may cause inaccurate readings.
The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia may cause inaccurate readings.

Operation of the pulse oximeter may be affected by the use of an electrosurgical unit (ESU).

The pulse oximeter must be able to measure the pulse properly to obtain an accurate $\text{SpO}_2$ measurement. Verify that nothing is hindering the pulse measurement before replying on the $\text{SpO}_2$ measurement.

The patient is in cardiac arrest or is in shock may cause inaccurate readings.

Fingernail polish or false fingernails may cause inaccurate $\text{SpO}_2$ readings.

Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.
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CHAPTER 1 General Information

The pulse oximeter is intended to measure SpO₂% and PR. The oximeter is designed with the measurement, storage, review, audible and visible alarms, vibration alert and data transmission (optional).

Note: The illustrations used in this manual may differ slightly from the appearance of the actual product.

1.1 Measuring 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 (HbR) and Oxyhemoglobin (HbO₂) in red light and near-infrared light zones. The photoelectric oxyhemoglobin inspection technology is adopted in accordance with capacity pulse scanning and recording technology, so that two beams of different wavelength of lights (660nm red light and 940nm near infrared light) 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 two groups of LEDs through process in electronic circuits and microprocessor.

Diagram of Operation Principle:

1. Red and Infrared light emission diodes
2. Red and Infrared photodiode
1.2 Product Features

- Compact and light in weight
- Four display modes
- Low power consumption
- Battery low indicator
- Rechargeable lithium-ion battery
- Visible, audible and vibration alarms.
- USB data transmission.
- Automatically power off after finger out for 8 seconds.

1.3 Intended Use

The Fingertip Pulse Oximeter is indicated for spot check monitoring of functional arterial oxygen saturation (SpO₂) and pulse rate of adult and pediatric patients in hospital, hospital type facilities, transport and mobile environments as well as in home care environment. The Oximeter is not indicated for long time continuous monitoring although it has alarm functions.

The Oximeter requires no periodic calibration or special maintenance other than charge the battery.
1.4 Appearance Introduction

Description:

1: **Display screen**: OLED display

2: Power switch & function button

**Short press**: press this button for about 0.5 second to power on or change the select item.

**Long press**: Press this button for about 1.5 seconds to confirm your selection and enter into the submenu.

3: **USB cable port**: It is used to connect the USB cable with the pulse oximeter.

**NOTE**: The pulse oximeter will return to the measuring screen, when no operation lasts for 8 seconds.
### 1.5 Description of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
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<tbody>
<tr>
<td><img src="image" alt="Power or function button" /></td>
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<td><img src="image" alt="Return icon" /></td>
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<tr>
<td><img src="image" alt="Alarm Set/Alarm On icon" /></td>
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<td><img src="image" alt="Battery power indicator" /></td>
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CHAPTER 2 Date, Time and ID setting

Always set the ID number, date and time before using the oximeter for the first time.

Set the ID number for different users. Make sure that the date and time are correct before using the unit, reset them if necessary. The ID number, date and time are important indicators when a measurement is taken.

2.1 ID setting

Press the ⬑ button to power on the oximeter, and then the initial screen is as follows:

![Fig.4](image1.png)  ![Fig.5](image2.png)

After the initial self-diagnose, the main menu will appear as Fig.5 shown. Long press the ⬑ button to enter the main menu screen.

And then short press the ⬑ button to select the ID setting icon (Fig.7), and then long press the ⬑ button to enter the ID setting screen, refer to the figure 8.
In Fig. 7 long press the button to set the ID number, the range is 01 to 99. After finishing setting, short press the button to select the “Return” item and long press the button to return to the previous menu.

2.2 Date and Time setting

In the main menu short press the button to select the Date and Time icon, refer to Fig. 9, and then long press the button to enter the “Date and time” setting screen, refer to Fig. 10.

In figure 10, short press the button to select the item you want to set, and then long press the button to adjust the date and time value.
The displaying mode:
Date: Year-Month-Day
Time: Hour: Minute: Second

The setting range:
Year: 2008～2028  Month: 1～12  Day: 1～31
Hour: 0～23  Minute: 0～59  Second: 0～59

CAUTION:
In the Date and Time setting screen, BE SURE TO select the “Return” item and long press the button to return to the previous menu. Otherwise, the settings will not be saved.
CHAPTER 3 Take a measurement

After the ID, date and time setting. Return to the main menu and then short press the button to select the “Return” item and long press the button to confirm your selection to return to the measuring screen.

Open the clamp and insert a finger into the oximeter as illustrated in the figure 11 before releasing the clamp.

Caution: When your finger is plugged into the oximeter, your nail surface must be upward.

![Fig.11]

The figure 12 is shown the recommended measuring fingers:

Note: Keep your tested hand still and do not move during the measurement.

![Fig.12]
The measurement screen refers to figure 13:

**Description of figure 13:**
1—Time display: The current time is 22:10.
2—SpO₂% area of display
3—Measured SpO₂%
4—The SpO₂% Plethysmograph
5—Measured pulse rate.
6—Pulse amplitude indicator.
7—Pulse rate unit.
8—Battery power indicator: When battery power is low the icon will be empty and turn to red.
9—Alarm status area of display: The current alarm status is alarm on.
During the measuring, each time you press the button short, the oximeter will switch to another display mode, there are 4 display modes shown as follows:

![Fig.14](image1)
![Fig.15](image2)
![Fig.16](image3)
![Fig.17](image4)

**NOTE:**

Please use the medical alcohol to clean the rubber, touch the finger inside of the oximeter with a soft cloth dampened with 70% isopropyl alcohol, and clean the test finger using alcohol before and after each measurement.

Do not pour or spray and liquids onto the oximeter, and do not allow any liquid to enter any openings of the device. Allow the oximeter to dry thoroughly before use.
CHAPTER 4 Battery Charge

4.1 Power Supply
Battery Model: SP080
Battery Type: One 3.7V Lithium Ion Rechargeable Battery

4.2 Battery charge
4.2.1 Connect the oximeter with attached the USB cable, as shown in Fig.18.
4.2.1 Connect the other end of the USB cable with the attached charger or a computer’s USB port.

Charging temperature: 0°C ~ 40°C (32°F to 104°F)
Charging Voltage: 110 Vac ~ 240 Vac, 50Hz ~ 60Hz.

It will take about 4 hours to complete charging not more than 6 hours.

Note: The battery indicator icon is active until the charge process is completely.
Warning!

✧ Keep away from source of fire and/or heat.
✧ Avoiding the strongly impacting to the oximeter.
✧ Avoid the oximeter exposure straightly to the strongly sunlight.
✧ DO not leave the oximeter in the sealed car.
✧ DO NOT open or disassemble the device, opening and disassembly may cause damage to the oximeter.
✧ ONLY USE the attached battery charger, DO NOT USE other chargers. If not that may cause damage even danger to the Oximeter or person.
✧ **DO NOT charge the battery for more than 5 hours, otherwise that may cause damage to it.**
✧ DO NOT charge or preserve the battery in too hot or cold environment, the proper temperature is 0~30℃ for charging, The details refer to the section “CHAPTER 9 Specifications”.
✧ Please charge the oximeter in time, when the low power indicator appears. Otherwise, there maybe cause influence to the specification of the Pulse oximeter.
✧ Avoiding water ingress, keep the oximeter in the specified environment. The rechargeable lithium-ion battery will be exposure when the water ingress the oximeter or in the high temperature environment.
✧ If the snow, rain, sweat and so on ingress the oximeter. Please stop using the oximeter, or else the oximeter may cause flaming. Please contact with the local service center for help.
✧ Not recommended that using the oximeter during charging.

**NOTE:** It is suggested that charge or discharge the battery once every three months, if the oximeter will be not used for a long time.

Due to influences of ambient humidity and non-absolute insulation environment, batteries have a phenomenon of self-consumption. So it is quite normal that the capacity of the battery declines along with use.
CHAPTER 5 Data Manage

In the main menu (shown as Fig.20), select the “Data Manage” icon and long press the button to enter into Fig.21 to review, clear all the data and look over the used space for data storage.

- **Data review:**
  In Fig.20 long press the button to review the stored data, refer to the Fig.21. Long press the button to enter the Fig.22. If there is no stored data, the screen will be Fig.23. Short press the button to turn page up or down. Long press the button to return to the previous menu as shown in Fig.21.

- **Look over storage space:**
  Used Space: 10% — The percent of occupied storage space is 10%, refer to figure 24.
◆ Clear Data:

Short press the button to select the “Clear Data” item and then long press the button to conform your selection, and then the screen as shown in Fig.26 will be appear. Short press the button to select “Yes” or “No” and then long press the button to confirm your selection.

![Fig.25](image1)

![Fig.26](image2)

After finishing “Data Manage”, short press the button to select the “Return” item and then long press the button to confirm the selection.

![Fig.27](image3)
CHAPTER 6 Alarm set

The Alarm limits display allows you to adjust the upper and lower saturation and pulse rate limits. When the measured values exceed the setting limits, the visible, audible or vibratory alarms will occur according to the alarm setting.

In the main menu short press the button to select the “Alarm Set” icon, and long press the button to confirm your selection and enter into the Alarm Set screen, refer to figure 29.

◆ SpO₂% alarms setting:

Upper alarm limit setting:

The SpO₂% upper alarm limit range is 71% to 99%. The low value of the SpO₂% upper alarm limit is limited to the SpO₂% lower alarm limit. The SpO₂% upper alarm limit cannot be set equal to or lower than the SpO₂% lower alarm limit.

SpO₂ ALMHI (Upper alarm limit): Short press the button to select the “SpO₂ ALMHI” and then long press the button to increase the upper alarm limit. If you long press the button, the number will be cycled displaying.

Note: The default SpO₂% upper alarm is 99%.
**Lower alarm limit setting:**

![Alarm Set]

The SpO₂% lower alarm limit range is 70% to 98%. The upper value of the SpO₂% lower alarm limit is limited to one number lower than the SpO₂% upper alarm limit. The SpO₂% lower alarm limit cannot be set equal to or higher than the SpO₂% upper alarm limit.

SpO₂ ALMLO (lower alarm limit): Short press the button to select the “SpO₂ ALMLO” and then long press the button to decrease the lower alarm limit. If you long press the button, the number will be cycled displaying.

**Note:** The default SpO₂% lower alarm limit is 90%.

**PR alarms setting:**

**Upper alarm limit setting:**

The pulse rate upper alarm limit range is 31 to 235. The low value of the pulse rate upper alarm limit is limited to one number above the pulse rate lower alarm limit. The pulse rate upper alarm limit cannot be set equal to or lower than the pulse rate lower alarm limit.

**Note:** The default PR upper alarm is 100 bpm.
PR ALMHI (Upper alarm limit): Short press the button to select the “PR ALMHI” and then long press the button to increase the upper alarm limit. If you long press the button, the number will be cycled displaying.

**Lower alarm limit setting:**
The pulse rate lower alarm limit range is 30 to 234. The upper value of the pulse rate lower alarm limit is limited to one number lower than the pulse rate upper alarm limit. The pulse rate lower alarm limit cannot be set equal to or higher than the pulse rate upper alarm limit.

PR ALMLO (Lower alarm limit): Short press the button to select the “PR ALMLO” and then long press the button to increase the lower alarm limit. If you long press the button, the number will be cycled displaying. **Note: The default PR low alarm limit is 60bpm.**
Alarm mode setting:

Mode: There are three alarm modes for selection: OFF, ON and Sound Off.

“OFF”: The alarm function is off, the audible, visible and vibratory alarms are ineffective.

“ON”: The alarm function is on, the audible, visible and vibratory (if vibration is on) alarms are effective.

“Sound Off”: The audible alarm will be ineffective, but the visible and vibratory alarms are still effective.

Short press the button to select the “Mode” and then long press the button to change the alarm mode, refer to the figure 33.

⚠️ WARNING: Do NOT silence the audible alarm function, if patient safety could be compromised.

After finishing the alarm mode setting, short press the button to select the “Return” item and then long press the button to confirm the settings and returns to the main menu, as shown in the figure 34.

Note: When the oximeter is turned off, the alarm limits of the settings in the last time are restored. When the oximeter is turned on, you should set alarm limits again if necessary.
CHAPTER 7 System Set

In System Set menu, you can set the brightness of backlight, beep, power save, vibration alert and so on.

In the main menu short press the button to select the “System Set” item refer to figure 35, and then long press the button to confirm your selection and enter into the sub menu of System Set, refer to figure 36.

- **Brightness**: Adjust the backlight brightness, in the figure 36, long press the button to adjust the brightness of the backlight. The brightness level is 1 to 7.

- **Beep**: Set the pulse beep “ON” or “OFF”.

**Notes:**

- The pulse beep volume is ineffective in the Power Save ON mode.
- The pulse beep volume level is proportion to the measured SpO₂ value, when the measured SpO₂ value is larger than 80%. The pulse beep volume is still when the measured SpO₂ value is no larger than 80%.
◆ Power Save: “ON” or “OFF” setting.

When setting “Power save: ON”, the beep is ineffective automatically.

NOTE: If the “Power Save” is on, the display screen will turn black. Long press the button to return to the displaying screen, short press the button the following screen will appear showing the oximeter is in process of measuring.

![measuring...](image)

Fig.37

◆ Vibration: “ON” or “OFF”

Short press the button to select the “Vibration” item and then long press the button to set the vibration alert “ON” or “OFF”. If vibration is on, the oximeter will vibrate along with the alarms.

NOTE: If the vibration is set to “ON”, the audible alarm is ineffective when the finger is out. When the vibration mode is set to “OFF”, the audible alarm is effective when the finger is out.
CHAPTER 8 Data transmission (optional)

Please be sure to register the pulse oximeter before transmission. Connect our company for registration.

The measurement results saved in the pulse oximeter can be uploaded to a computer for review or management.

**USB cable transmission:**

Power on the Pulse Oximeter. Connect the USB cable to a computer.

Fig.38
CHAPTER 9 Specifications

Display:
Display type: OLED display
SpO₂ display range: 0~99%
PR display range: 30~235 BPM
PR display mode: Bar amplitude graph
Data update period: <15s

LED Wavelengths and Output Power:
Red: approximately 660nm @0.8mW maximum average
Infrared: approximately 940nm @0.8mW maximum average

Battery:
Model: SP080
Nominal Voltage: 3.7V
Typical lithium ion battery: 300 cycles.
Charging temperature: 0℃~40℃ (32℉ to 104℉)

Resolution:
SpO₂ %: ±1%
Pulse rate: ±1BPM

Measurement Accuracy:
SpO₂: 70%~99% ±3%; ≤69% unspecified.
PR: 30~99 bpm ±2 bpm; 100~235 bpm ±2%.
Physical Characteristics:

Dimensions: 56.5mm x 36mm x 26mm (2.2” x 1.4” x 1.4”)
Weight: 43g (0.09 lbs.) (including the lithium ion battery)

Environment Conditions:
Operating Temperature: 5°C ~ 40°C (41°F to 104°F)
Storage Temperature: -20°C ~ 30°C (-4°F to 86°F) for 1 year.
                          -20°C ~ 45°C (-4°F to 113°F) for 3 months.
Humidity: 20%-85% in operation, non condensing
          <85% in storage, non condensing

EMC of this product comply with IEC60601-1-2 standard.

The device meets the Essential Requirements of the Medical device Directive 93/42/EC.

Accessories:

USB Cable.................................................................1piece
AC/DC Adapter................................................................1piece
Instruction Manual........................................................1piece
Lanyard.........................................................................1piece
MedView Software CD(Optional)......................................1piece
CHAPTER 10 Maintenance And Calibration

10.1 Please charge the battery in time when the power low indicator flashes.
10.2 Clean the surface of the fingertip Oximeter before it is used in diagnosis for patients.
10.3 It is best to preserve the product in the environment specified in this manual.
10.4 It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the device. Please follow the law of the local government to deal with used oximeter and the accessories.

Cleaning the PULSE OXIMETER:

- Please use 70% isopropyl alcohol to clean the inside rubber surface of the probe.
- Moisten a soft cloth with the alcohol and clean the finger probe, before and after each test.
- Do not pour or spray and liquids onto the oximeter or probe, and do not allow any liquid to enter any gaps in the device or probe. In case moisture enters the oximeter or probe, be sure to dry thoroughly before reuse.
- Do not use abrasive cleansers to clean the screen or body of the device. Only use alcohol wipes to remove soil and to disinfect the surfaces of the device.

Calibration:

The functional tester cannot be used to assess the accuracy of the oximeter. The test methods used to establish the SpO₂% accuracy is clinical testing. The oximeter used to measure the arterial haemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-oximeter.

Index 2 that made by Bioteck company is a function tester. Set Tech to 1, R curve to 2, then user can use this particular calibration curve to measure the oximeter.
# CHAPTER 11 Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Solution</th>
</tr>
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| SpO₂% or pulse rate does not display. | 1. Finger is not plugged correctly.  
2. Patient's SpO₂ value is too low to be measured. | 1. Retry by plugging the finger.  
2. There is excessive illumination.  
3. Measure other patients to make sure that no problem exists in the product. Go to a hospital in a timely manner for an exact diagnosis. |
| SpO₂% or PR is shown unstably. | 1. Finger might not be plugged deep enough into the clamp probe.  
2. Excessive patient movement. | 1. Retry by inserting the finger to the end.  
2. Stop moving the finger, hand or body. |
| The Oximeter can not be powered on. | 1. No battery or low power of battery.  
2. Battery might be installed incorrectly.  
3. The Monitor might be damaged. | 1. Please replace battery.  
2. Please reinstall the battery.  
3. Please contact with local customer service centre. |
| Display suddenly turns off. | 1. The oximeter is automatically powered off when no signal is detected longer than 8 seconds.  
2. The batteries power is too low to work. | 1. Relocate the probe on another finger or restart the oximeter and be sure the signal strength is strong enough for stable display.  
2. Please charge in time. |
| Error 1                        | ROM error                                                            | Please contact with local customer service centre.                                                |
| Error 2                        | RAM error                                                            | Please contact with local customer service centre.                                                |
| Error10                        | EEPROM damaged or dry joint                                         | Please contact with local customer service centre.                                                |
Manufacture: Beijing Choice Electronic Technology Co., Ltd.
Address: Rm. 1127-1128, Fuxing Road, A36, Bailangyuan Building B,
100039, Beijing, People’s Republic of China.
Tel: (+86)10- 88204188、68221006 、88203520
Fax: (+86)10-88204632
www.choicemmed.com
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