Pluse Oximeter

Instruction Manual

CE 0123

VER2.0C318

Pulse Three

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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 when 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.
- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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 carbonyl- hemoglobin or methemoglobin) may cause inaccurate readings.
- Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate readings.
- SpO_2 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 SpO_2 measurement. Verify that nothing is hindering the pulse measurement before replying on the 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 SpO_2 readings.
- Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.
- All Choice devices are designed to be compliant with rules and regulations in locations they are sold and will be labelled as required.
- Any changes or modifications to choice equipment, not expressly approved by choice, could void the user's authority to operate the equipment.

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CHAPTER 1 General Information

The pulse Oximeter is integrated with Bluetooth® technology allowing the user to transfer measurement data any time and anywhere. 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 (HbO_2) 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

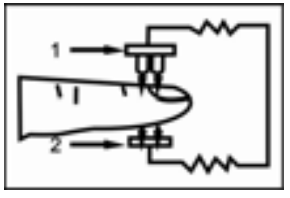

Fig.1

1.2 Product Features

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

1.3 Intended Use

The Fingertip Pulse Oximeter is indicated for spot check monitoring of functional arterial oxygen saturation (SpO_2) 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 calibration or special maintenance other than charge the battery.

1.4 Appearance Introduction

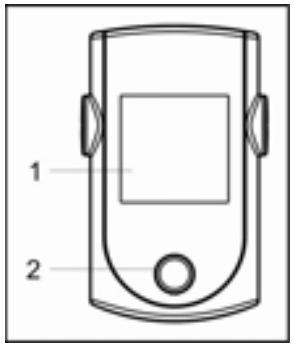

Fig.2

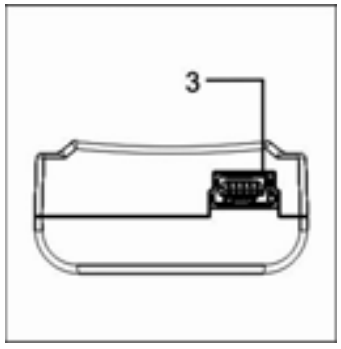

Fig.3

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

Symbol	Description	Symbol	Description
	Power or function button		System Set icon
	Data Manage Set icon		Return icon
	Alarm Set/Alarm On icon		Bluetooth® Transmission Mode indicator
	ID Set icon		Battery power indicator
	Date and Time Set icon		Power low indicator
	Europen union approval		Sound alarm off indicator
	Non AP equipment		Alarm Off indicator
	Type BF Applied Part		Resitant to liquid ingress
	Date of Manufacture		See Instructions for Use

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

Fig.5

After the initial self-diagnose, the main menu will appear as Fig.5 shown. Long press the ⏻ button to enter into 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 into the ID setting screen, refer to the figure 8.

In figure 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.

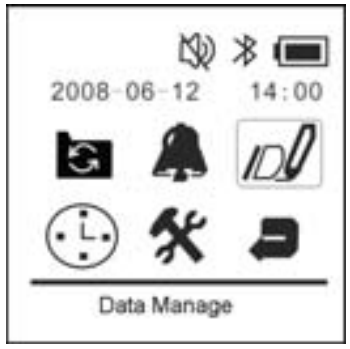

Fig.7

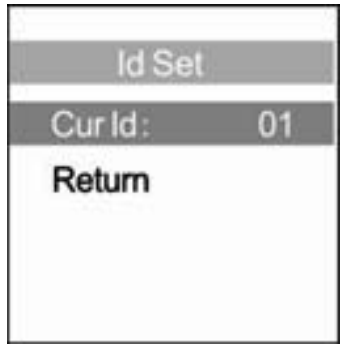

Fig.8

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 into the “Date and time” setting screen, refer to Fig.10.

Fig.9

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.

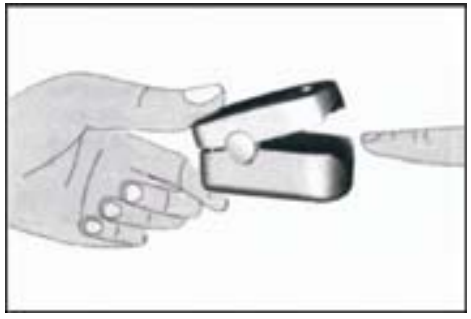

Fig.11

The figure 12 is shown the recommended measuring fingers:

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

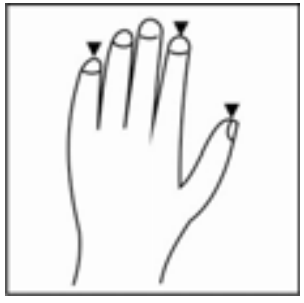

Fig.12

The measurement screen refers to figure 13:

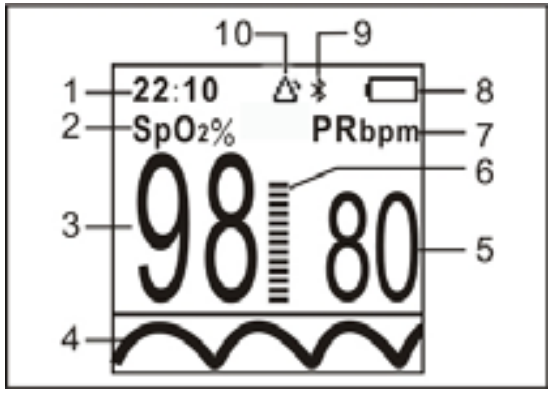

Fig.13

Description of figure 13:

1—Time display: The current time is 22:10.

2—SpO_2% area of display

3—Measured SpO_2%

4—The SpO_2% 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—Data transmission mode area of display the current transmission mode is Bluetooth®.

10—Alarm status area of display: The current alarm status is alarm on.

During the measuring, each time you press the ⏻ button the Oximeter will switch to another display mode, there are 4 display modes shown as follows:

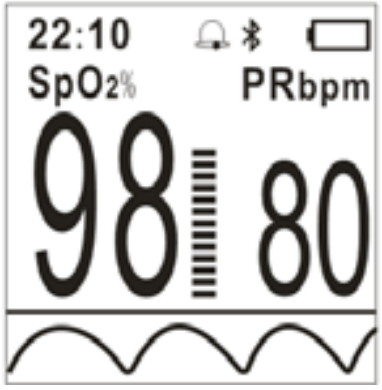

Fig.14

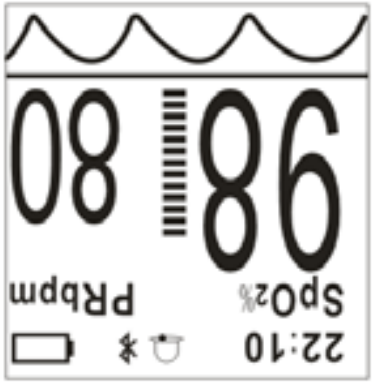

Fig.15

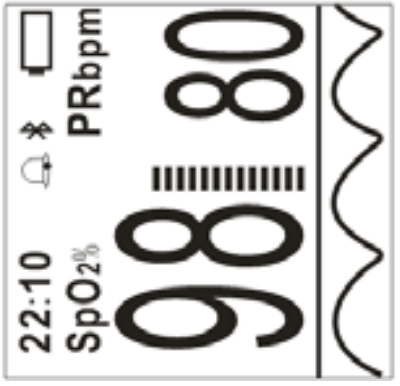

Fig.16

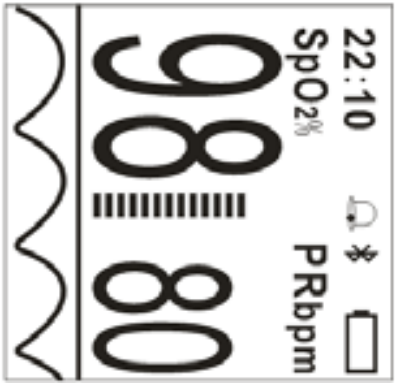

Fig.17

NOTE:

Please use the medical alcohol to clean the rubber, touching the finger inside of 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 liquids onto the Oximeter, and do not allow any liquid to enter any openings in the device. Allow the Oximeter to dry thoroughly before reusing.

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.

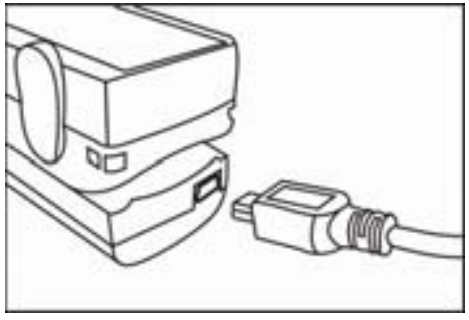

Fig.18

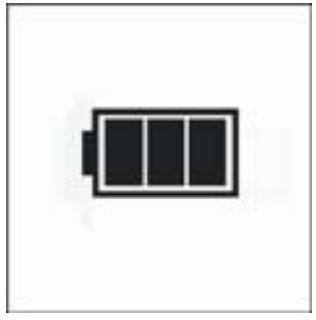

Fig.19

Charging temperature: 0℃～40℃

Charging Voltage: 110Vac～240 Vac, 50Hz～60Hz.

It will take about 4 hours to complete charging no more than 5 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 power low 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 the data and look over the used space for data storage.

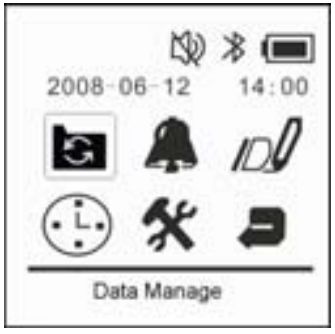

Fig.20

Fig.21

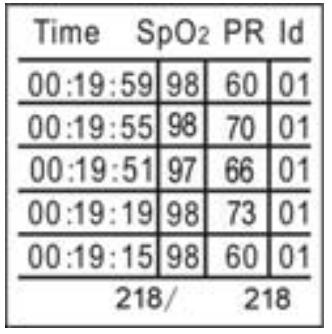

Fig.22

Fig.23

◆ **Data review:**

In figure 20, long press the ⏻ button reviews the stored data, refers to the figure 21. Short press the ⏻ button turns page up or down. If there is no stored data the screen will be the figure 22. Long press the ⏻ button you will exit from the Data Review and return to the previous menu refers to figure 20.

◆ **Look over storage space:**

Used Space: 10% — Percent of occupied storage space is 10%, refer to figure 24.

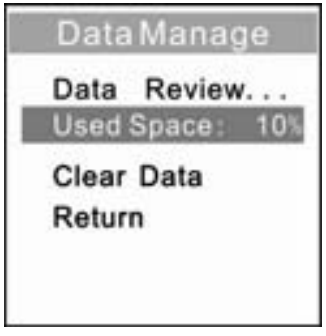

Fig.24

◆ **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

Fig.26

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

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.

Fig.28

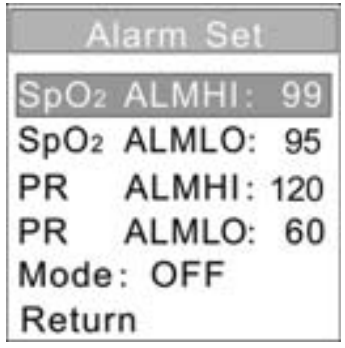

Fig.29

- **SpO_2% alarms setting:**

Upper alarm limit setting:

The SpO_2 %upper alarm limit range is 71% to 99%. The lower value of the SpO_2% upper alarm limit is limited to the SpO_2% low alarm limit. The SpO_2% upper alarm limit cannot be set equal to or lower than the SpO_2 %low alarm limit.

SpO_2 ALMHI (Upper alarm limit): Short press the ⏻ button to select the “SpO_2 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 SpO_2% upper alarm is 99%.

Lower alarm limit setting:

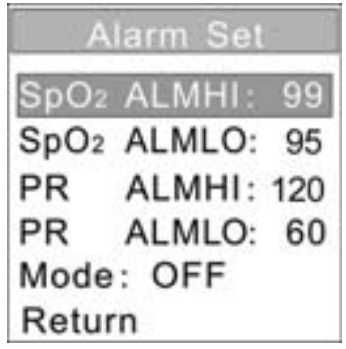

Fig.30

The SpO_2% low alarm limit range is 70% to 98%. The upper value of the SpO_2% low alarm limit is limited to the SpO_2% upper alarm limit. The SpO_2% low alarm limit cannot be set equal to or higher than the SpO_2% upper alarm limit.

SpO_2 ALMLO (lower alarm limit): Short press the ⏻ button to select the "SpO_2 ALMLO" and then long press the ⏻ button to decrease the low alarm limit. If you long press the ⏻ button, the number will be cycled displaying.

Note: The default SpO_2% low alarm 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 low alarm limit. The pulse rate upper alarm limit cannot be set equal to or lower than the pulse rate low alarm limit. Refer to Fig.31.

Note: The default PR upper alarm is 100.

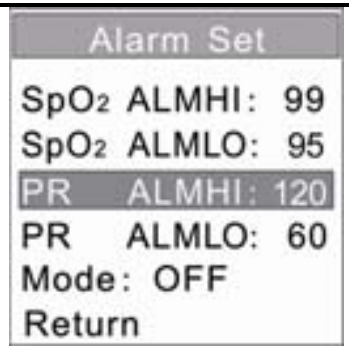

Fig.31

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

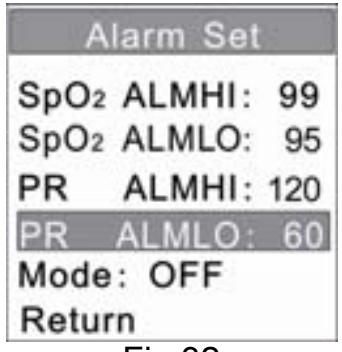

Fig.32

PR ALMLO (Low alarm limit): Short press the ⏻ button to select the “PR ALMLO” and then long press the ⏻ button to increase the low alarm limit. If you long press the ⏻ button, the number will be cycled displaying.

Note: The default PR low alarm is 60.

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 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.**

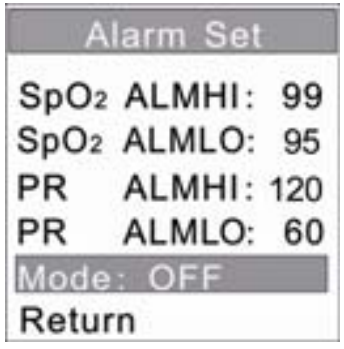

Fig.33

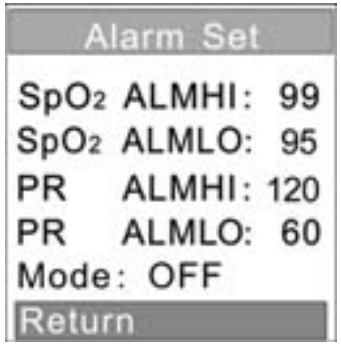

Fig.34

After finishing the alarm mode setting, short press the ⏻ button to select the "Return" item and then long press the ⏻ button to confirm and return to the main menu refer to figure 34.

Note: When the Oximeter is turned off, the alarm limits of the last time set 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, BlueTooth® mode, 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.

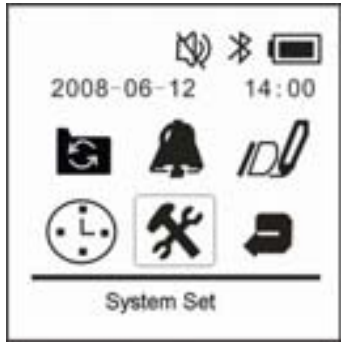

Fig.35

Fig.36

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

BlueTooth: Short press the ⏻ button to select the "Blue Tooth" item and then long press the ⏻ button to select "ON" or "OFF".

Beep: Set the pulse beep "ON" or "OFF".

Notes:

- The pulse beep volume is ineffective in the Power Save ON mode.
- The beep volume level is proportion to the measured SpO_2 value, when the measured SpO_2 value is larger than 80%. The pulse beep volume is still when the measured SpO_2 value is no larger than 80%.

Power Save: “ON” or “OFF” setting.

When setting “Power save: ON”, the “BlueTooth” will be set “OFF” automatically and the beep is ineffective.

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

Fig.37

Vibration: “ON” or “OFF”

Short press the ⏻ button selects the “**Vibration**” item, and then long press the ⏻ button sets the vibration alert “ON” or “OFF”. If vibration is on, the Oximeter will vibrate along with the alarms.

NOTE: Under the “Power Save: ON” mode, If the vibration is set to “ON”, the audible alarm is ineffective when the finger is out. Contrarily 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. Contact our company for registration.

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

The modes of Data transmission are Bluetooth® transmission and USB calbe transmission. Please refer to the "software user manual" for the details of data transmission. The data transimission screen is shown in Fig.38.

- **USB cable transmission:**

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

- **Bluetooth transmission:**

Power on the Pulse Oximeter. Set the Pulse Oximeter to "**Bluetooth: ON**" in the System Set menu.

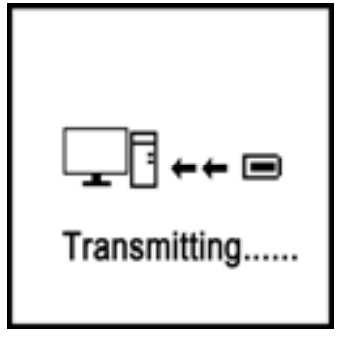

Fig.38

CAUTION:

The Bluetooth® transmission may be influenced in different environments, such as: walls, metallic doors, steel wire netting and an MRI or a CT environment and so on.

CHAPTER 9 Specifications

Display:
Display type: OLED display
SpO_2 display range: 0～99%
PR display range: 30～235 BPM
PR display mode: Amplitude Bar
Data update period: <15 s

Resolution:
SpO_2: ±1%
Pulse rate: ±1BPM

Measurement Accuracy:
SpO_2: 70%--99% ±3%; ≤69% unspecified.
PR: 30～99 bpm ±2 bpm; 100～235 bpm ±2%.

Antenna Information:
Antenna Type/Patten: Internal
Frequency Range: 2402 to 2480 MHz

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

Wireless transmission distance: 0～10m

Physical Characteristics:

Dimensions: 56mm x 38mm x 40mm (2.2”x 1.5”x 1.6”)

Weight: 51g (0.11 lbs.)（including the lithium-ion battery）

Battery life:

Typical lithium ion battery: 300 cycles.

Charge temperature: 0℃～40℃(32℉H to 113℉H)

Environment Conditions:

Operating Temperature: 5℃～40℃ (41℉H to 104℉H)

Storage Temperature: -20℃～30℃ (-4℉H to 86℉H) for 1 year;
-20℃～45℃ (-4℉H to113℉H) 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.

Accessories:

USB Cable……1 piece

AC/DC Adapter……1 piece

Instruction Manual……1 piece

Lanyard……..1 piece

MedView Software CD (Optional)……..…...1 piece

USB Dongle (Optional)……1 piece

CHAPTER 10 Maintenance And Calibration

10.1 Please charge the battery timely 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 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 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.

Calibration:

The functional tester cannot be used to assess the accuracy of the Oximeter. The test methods used to establish the SpO_2% 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

Problem	Cause	Solution
SpO2% or pulse rate does not display.	1. Finger is not plugged correctly. 2. Patient's SpO_2 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.
SpO_2% 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. Replace the battery.
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.

CHAPTER 12 Declaration

FCC-ID: WWIMD300C318

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. There limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

--Reorient of relocate the receiving antenna.

--Increase the separation between the equipment and receiver.

--Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

--Consult the dealer or an experienced radio/TV technician for help.

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

Guidance and manufacture's declaration – electromagnetic emissions-
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The *MD300C318 PULSE OXIMETER* is intended for use in the electromagnetic environment specified below. The customer of the user of the *MD300C318 PULSE OXIMETER* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *MD300C318 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.
RF emission CISPR 11	Class B	The *MD300C318 PULSE OXIMETER* is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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

Guidance and manufacture's declaration – electromagnetic immunity			
The *MD300C318 PULSE OXIMETER* is intended for use in the electromagnetic environment specified below. The customer or the user of *MD300C318 PULSE OXIMETER* should assure that it is used in such an environment.			
Immunity test	**IEC 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 floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *MD300C318 PULSE OXIMETER* requires continued operation during power mains interruptions, it is recommended that the *MD300C318 PULSE OXIMETER* be powered from an uninterruptible power supply.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/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 manufacture's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The *MD300C318 PULSE OXIMETER* is intended for use in the electromagnetic environment specified below. The customer or the user of *MD300C318 PULSE OXIMETER* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the *MD300C318 PULSE OXIMETER*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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).

			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: 

NOTE 1 At 80 MHz and 800 MHz, 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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones 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 *MD300C318 PULSE OXIMETER* is used exceeds the applicable RF compliance level above, the *MD300C318 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 *MD300C318 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 or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *MD300C318 PULSE OXIMETER*

The *MD300C318 PULSE OXIMETER* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *MD300C318 PULSE OXIMETER* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *MD300C318 PULSE OXIMETER* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.74**
1	**1.17**	**1.17**	**2.33**
10	**3.69**	**3.69**	**7.38**
100	**11.67**	**11.67**	**23.33**

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.

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