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**Contents**

<b>1 Introduction</b> .....	<b>2</b>
1.1 Brief Introduction .....	2
1.2 Safety Information .....	2
1.3 Intended use .....	4
1.4 Electromagnetism Interference .....	4
1.5 Explanation of Symbols .....	5
1.6 Product Features .....	5
<b>2 General Descriptions</b> .....	<b>6</b>
2.1 Appearance .....	6
2.2 Rear Panel .....	9
2.3 Power Supply .....	9
<b>3 Install SpO<sub>2</sub> Probe</b> .....	<b>11</b>
<b>4 Setting ID, Date and Time</b> .....	<b>12</b>
4.1 Date & Time Settings .....	12
4.2 ID number Setting .....	13
<b>5 Take a Measurement</b> .....	<b>14</b>
<b>6 Other Settings</b> .....	<b>17</b>
6.1 Alarm Setting .....	17
6.2 Data Management .....	18
6.3 System Setting .....	22
<b>7 Maintain and Repair</b> .....	<b>25</b>
7.1 Maintenance .....	25
7.2 Safety Checks .....	25
7.3 Calibration and Verification .....	27
7.4 Trouble Shooting .....	28
7.5 Warranty and Repair .....	28
7.6 Storage and Transportation .....	30
<b>APPENDIX A Specifications</b> .....	<b>30</b>

## 1 Introduction

### 1.1 Brief Introduction

Thank you for purchasing the pulse oximeter. The main functions of the device include Haemoglobin Saturation (SpO<sub>2</sub>) and pulse rate (PR) measurements, visual and audible alarm, batteries charging, data storage and review, USB cable and Bluetooth® for data transmission, etc. Please read this manual carefully before using the device.

**Note: The illustrations applied in the manual may differ slightly from the actual unit.**

### 1.2 Safety Information

#### Conception of Warning, Caution and Note

The Warning, Caution and Note at this document are special information in favor of user's operation.

- Warning - Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.
- Caution - Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.
- Note - Provides application tips or other useful information to ensure that you get the most from your product.

#### Warnings

- Users should follow all instructions listed in this manual. Our company will assume no warranty for using this equipment improperly.
- Do not use the oximeter in the presence of flammable anesthetics, vapors or liquids.
- Do not use the oximeter in an MRI or CT environment.
- This equipment is intended only as an adjunct in patient assessment, and the measurement results only serve as a reference for any relevant treatment.
- Connect the probe correctly; please see the directions for use of any accessories.
- Prolonged use of the probe/sensor or the patient's condition may require changing the sensor site periodically. Change the sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours. Prolonged use may cause blisters,

skin deterioration, and discomfort.

- When connecting this device to other peripherals, make sure that you are qualified to operate this device. Any peripheral must be certified according to the protocol of IEC 950 and IEC 601-1-1. Any input/output device should follow the protocol of IEC 601-1-1.
- The malfunction of probe or worn-out data cables may cause inaccurate measurement results, so the user should inspect them frequently and make sure that they are in good working state.
- Do not touch the AC adapter with wet hands, otherwise, you may suffer electric shock.
- The disposable accessories should not be cycled.

#### **Cautions**

- Clean the probe with an H<sub>2</sub>O solution and a neutral detergent.
- Don't submerge the probe into any liquid. Do not use in autoclave (sterilizer).
- Before cleaning or disinfecting the probe, unplug it from the oximeter to prevent probe or oximeter from being damaged, and to protect user under safety situation.
- To avoid an electrical hazard, never immerse the unit in any liquid or attempt to clean it with liquid cleaning agents. Always disconnect the device from AC adapter before cleaning.
- Alarm must be set up according to different situations of individual patient. Make sure that alarm sound can be activated when alarm function begins to work.
- The materials that contact with human bodies are all non-toxic.

#### **Notes**

- Application of this device in the background of electromagnetic areas may influence the measuring accuracy such as in the environment of electro-surgery.
- SpO<sub>2</sub> measurements may be adversely affected in the presence of high ambient light. Shield the probe area (with a surgical towel, for example) if necessary.
- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein, may adversely affect the accuracy of the SpO<sub>2</sub> reading.
- Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause a failure to determine accurate pulse rate and SpO<sub>2</sub> readings.

- Remove fingernail polish or artificial fingernails before applying SpO<sub>2</sub> probes. Fingernail polish or artificial fingernails may lead to inaccurate SpO<sub>2</sub> readings.
- Optical cross talk can occur when two or more probes are located in adjoining area. It can be eliminated by covering each site with opaque material. Optical cross talk may adversely affect the accuracy of the SpO<sub>2</sub> readings.
- Obstructions or dirt on the probe's red light or detector may cause a probe failure. Make sure there are no obstructions and the probe is clean.
- The AC adapter and accessories used with the device should be complied with the requirement of IEC60601-1.
- For routine equipment maintenance, please refer to the service procedures at the associated section as indicated in the manual.
- Dispose of the device or its accessories end of life in accordance with the local ordinances and regulations, otherwise, discarding them as you like may cause pollution to the environment.
- **It is not recommended to take measurements during battery charging.**
- Our company will only provide the schematic, components list, legend and correction details for the qualified technical personnel authorized by our company.
- The device is only for prescription use, federal law restricts this device to sale by or on the order of a physician.
- As to the other concerns for attention, please carefully look through the specific chapter in this instruction.

### 1.3 Intended use

The MD300K3 handheld pulse oximeter is a portable, non-invasive device intended for **continuous monitoring, spot checking of** functional arterial oxygen saturation(SpO<sub>2</sub>) and pulse rate of adult and pediatric patients in hospital and home care. The application site are fingers.


























### 1.4 Electromagnetism Interference

This oximeter is designed and tested in compliance with the EMC standard, complying with the international standard for the EMC of the electronic medical device - IEC 60601-1-2. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (e.g. cellular phones, mobile two-way radios, electrical appliances), it is possible that high

levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

This apparatus complies with the IEC 60601-1-2 international standard. The requirements of this international standard are: CISPR11, GROP1, and CLASS B.

### 1.5 Explanation of Symbols

Symbol	Explanation	Symbol	Explanation
	Type BF applied part	IPX1	Protected against dripping water
<i>IDI</i>	ID indication		Battery power indication
	Audible alarm on		Audible alarm inhibition
	Pulse Beep on		Pulse Beep off
	Keyboard is unlocked		Keyboard is locked
	USB cable is connected.		USB cable disconnected
	SpO <sub>2</sub> probe is inserted		SpO <sub>2</sub> probe off
	Bluetooth® activated		Bluetooth® inactivated
	SD card is inserted		The adapter is connected
	Printer		The SD card socket
	Alarm inhibition		Power on/off
	Prevent from rain	<b>SN</b>	Serial number
	Storage temperature and relative humidity		Attention, consult the accompanying documents.
	Date of Manufacture		Manufacturer's information

**1.6 Product Features**

- ◇ Simple to use and easy to operate.
- ◇ Portable and compact in design.
- ◇ TFT display screen with adjustable backlight.
- ◇ Up to 127 patients' ID and 72-hour records can be saved.
- ◇ Visual and three-level audible alarms, low battery power alarm.
- ◇ Data transfer to PC by USB cable or Bluetooth®.
- ◇ Powered by four AA alkaline/Ni-MH batteries/power adapter.
- ◇ Battery charge function with adapter (optional).
- ◇ Suitable for adult and pediatric patients.

**2 General Descriptions**

The pulse oximeter adopts 2.8 inch TFT screen, which can display the SpO<sub>2</sub>% and pulse rate value, other indication parameters, such as time, ID number, pulse bar and battery power status, alarm limits and the connection of probe, etc.

**2.1 Appearance**

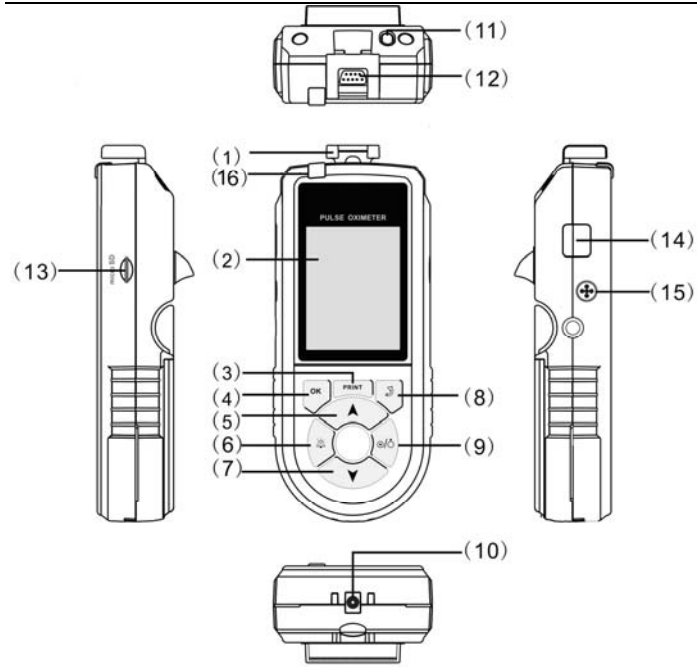









Fig.2-1

**Description of Fig.2-1:**

- (1) **Fixing clip for the SpO<sub>2</sub> probe.**
- (2) **Displaying screen.**
- (3)  **Print Button:** Press this button to turn on/off the function of printing.
- (4)  **OK Button:** Press this button to enter menu items or confirm the selection/setting.



- (5)  **Up Button:** Press this button shortly to increase the value by one unit. You can press and hold the button extendedly to speed up the adjustment of values.
- (6)  **Alarm inhibition button:** Press this button to close alarm sound for 120 seconds. You can open the alarm sound in the process of alarm inhibition by pressing the button again.
- (7)  **Down button:** Press this button shortly to decrease the value by one unit. You can press and hold the button extendedly to speed up the adjustment of values.
- (8)  **Return/Lock button:** On the measuring screen, it serves as Lock button. You can lock the keyboard by long pressing it and press it again to unlock; On the menu and sub-menu screen, it serves as Return button.
- (9)  **Power button:** Press and hold it for about 3 seconds to power the device on, and for about 4 seconds to turn the device off.
- (10) **Adapter socket:** For connecting the power adapter.
- (11) **Paper Feed button:** When the printing function is turned on, you can press the button to start printing.
- (12) **SpO<sub>2</sub> socket:** For connecting the SpO<sub>2</sub> probe with the oximeter and connecting USB cable with your computer for data transmission.
- (13) **micro SD:** The socket for installation of the SD memory card.
- (14) **USB socket:** It is designed to update the software of the device and only serves engineers.
- (15) **Speaker:** The speaker for alarm and beep, its volume can be adjusted.
- (16) **Alarm lamp/ Charge indicator:** When SpO<sub>2</sub> or/and PR alarm occurs, it flashes in yellow. When the unit is being charged, the lamp will flash in green; when it is charged to full, the lamp will keep light without flashing.

**Notes:**

- ◇ **When the keyboard is locked, all the keys will be inactivated.**
- ◇ **You can set auto power-off mode through system setting.**
- ◇ **The SpO<sub>2</sub> socket and data transmission share a common interface, so you can't take a measurement when the unit is uploading data to PC.**
- ◇ **You should refer to the corresponding chapter about the specific operation of printing.**

## 2.2 Rear Panel

- (1) Paper Feed button: when the printing function is on, press this button you can start printing.
- (2) Outlet: the outlet for printing paper.
- (3) The groove for installing the printing paper.
- (4) The cover of battery compartment.

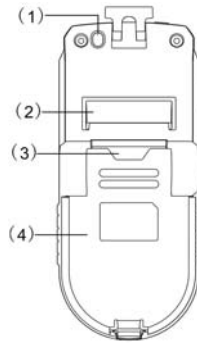


Fig.2-2

## 2.3 Power Supply

The device can be powered by 4 AA alkaline batteries, Ni-MH batteries or power adapter.

### 2.3.1 Powered by batteries

#### Batteries Installation:

- 1) Open the battery cover and you can see the battery polarities as shown in Fig.2-3.
- 2) Install 4 AA alkaline batteries (or 4 AA Ni-MH batteries) lightly as indicated by the polarity signs in battery compartment.

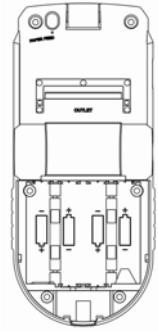


Fig.2-3

**Warnings!**

- ◇ **DO NOT USE Ni-MH rechargeable and alkaline batteries together, otherwise, that may damage the device or injury users.**
- ◇ **Make sure the polarities of the batteries are correct.**

3) Close the battery cover.

**Battery life**

When the battery power is lower than  $4.5V \pm 0.1V$  the battery indicator will become empty and at the same time its frame will become red, which means little of battery capacity remains. You should replace the batteries with new ones in time.

The unit will shut down when the battery voltage is lower than  $4.4V \pm 0.1V$ .

**Cautions!**

- ◇ Do not use batteries not specified for this unit.
- ◇ Do not dispose of batteries in fire.
- ◇ If battery fluid gets on your skin or clothing, rinse with plenty of clean water immediately.
- ◇ Remove the batteries from this unit when you are not going to use it for a long period of time (approximately one month).

- ◇ Do not use batteries of different types together.
- ◇ Do not use new and used batteries together.
- ◇ Dispose of batteries in accordance with the local ordinances and regulations.
- ◇ Regular maintenance of rechargeable batteries is required, such as periodic charge and discharge.
- ◇ The charging time shouldn't be too long, otherwise, it may reduce batteries performance and shorten batteries' life.

### 2.3.2 Charging Batteries through adapter (optional)

To charge batteries, please ensure the installed batteries are Ni-MH ones. Firstly connect the adapter with the oximeter and secondly with the wall outlet, and then press and hold the power switch for 3 seconds to power the device on.

A prompt window will appear inquiring you "Are the batteries Ni-MH ones?". Select "Yes" to charge them by wall outlet or "No" to abandon charge.

#### Notes:

1. To avoid the device from being damaged due to short circuit, please make sure the adapter is firstly connected with the oximeter and secondly with the wall outlet. While disconnected the connection, please make sure the adapter is firstly disconnected from the wall outlet and then disconnected from the oximeter.
2. During battery charge, the "Power Auto" and "Brightness" items can not be accessible.
3. It is not recommended to take a measurement during the oximeter is powered by wall outlet or being charged, for damages and injuries may be caused to the device or users.
4. DO NOT charge when the non-rechargeable batteries are installed, otherwise damages or injuries may be caused to the device or users.
5. You can cut off the power of the device through unplug the adapter.
6. It is not recommended to charge batteries while the battery power is sufficient. If you perform the charging action at this time, the device will detect the battery voltage and terminate the charging automatically to protect the batteries. In this case the prompt window will not appear.

## 3 Install SpO<sub>2</sub> Probe

Set the fixing clip for SpO<sub>2</sub> probe, and then insert the SpO<sub>2</sub> probe to the SpO<sub>2</sub> socket as

shown in Fig.3-1. When the SpO<sub>2</sub> probe is connected well, please set the fixing clip up to ensure the probe well connected.

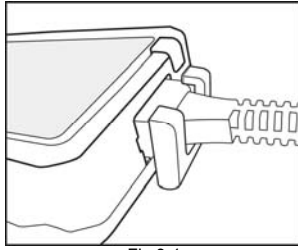




Fig.3-1

The indicator  will be shown on the display screen when the probe is well connected. If the probe is disconnected from the unit, the indicator  and the prompt "Probe Off!!!" will appear in the status column.

The socket is also used for USB cable connected with the PC for data transmission. For more information on data transmission and data management, refer to the corresponding software instruction manual.

## 4 Setting ID, Date and Time

**Always set the date and time before using the unit for the first time. Set different ID numbers for different users.**

Check the date and time are correct before using the unit, and reset them if necessary. The date and time are important indicators when a measurement is taken.

### 4.1 Date & Time Settings

**Set the correct time according to the following steps:**

- 1) Press the power switch for 3 seconds to power on the oximeter and then press the menu button to enter the main menu, refer to Fig.4-1.

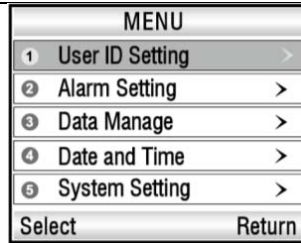


Fig.4-1

2) Press the Down button to select the "Date and Time" item, and then press the Menu button to enter the time setup screen, refer to Fig.4-2.

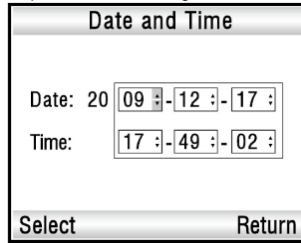


Fig.4-2

Pick different sub-items to set and press the OK button to highlight it and then using the Up or Down button to adjust the value. At last, press the OK button to confirm your settings.

#### 4.2 ID number Setting

Enter the "User ID Setting" item from the main menu screen, refer to Fig.4-3. Press the OK button to make the "User ID number" highlighted, and then press the Up or Down button to increase or decrease the ID number, and then press the OK button again to confirm your settings. The range of ID number is: 001-127.

**Note:** The user ID cannot be changed; you may get the prompt information saying

that "Cannot change!!!", if you attempt to change it when taking a measurement.

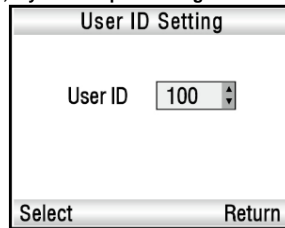


Fig.4-3

## 5 Take a Measurement

### Warnings!

- **The measurement would not be performed if the following instances come across in operation:**
  - Shock
  - Low temperature of hand
  - Have taken vascular activity medicine
  - Anemia
  - carboxyhemoglobin
  - methemoglobin
  - methylene blue
  - Indigo carmine
- **Only use the SpO<sub>2</sub> probes provided by the manufacturer, other SpO<sub>2</sub> probes may cause improper performance.**
- **Do not use the SpO<sub>2</sub> probe with exposed optical components.**
- **Excessive patient movement may cause inaccurate measurements.**
- **Tissue damage can be caused by incorrect application of the probe, for example by wrapping the probe too tightly. Inspect the probe site to ensure skin integrity and correct positioning and adhesion of the probe. More frequently inspection should be taken depend on different patients if necessary.**
- **Inaccurate measurements may be caused by:**
  - Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin);
  - Intravascular dyes such as indocyanine green or methylene blue;
  - Exposure to excessive illumination, such as surgical lamps (especially ones with a

xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight;

- High-frequency electro surgical interference and defibrillators;
  - Venous pulsations;
  - Placement of a probe on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
  - The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
  - There is arterial occlusion proximal to the probe;
  - The patient is in cardiac arrest or shock.
- **Loss of pulse signal can occur in any of the following situations:**
- The probe is too tight
  - There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight
  - A blood pressure cuff is inflated on the same extremity as the one to which an SpO<sub>2</sub> probe is attached

**Note:** SpO<sub>2</sub> probe should obviate the light source, e.g. radial lamp or infrared lamp.

**Before taking a measurement:**

- Select a suitable probe in terms of type and dimension.
- Plug the probe into the SpO<sub>2</sub> socket on top of the pulse oximeter.
- Clip the patient finger to the rational position of the probe as the illustration as Fig.5-1.

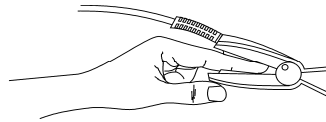


Fig.5-1 Placement of the probe

**Note:** If no finger is in the probe, the words "Finger Out!!" will be shown.

There are two display modes as shown in Fig.5-2&5-3.



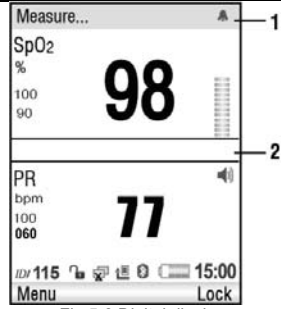


Fig.5-2 Digital display

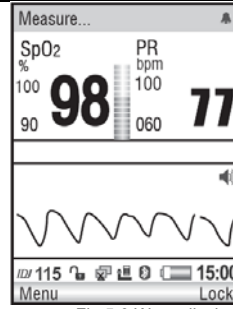



Fig.5-3 Wave display

- ◇ Status bar 1: The status of the oximeter is shown on the bar (Measure... , Finger out!!, Probe off!! and so on).
- ◇ Status bar 2: If the measured SpO<sub>2</sub>% or PR value exceeds the alarm limits, there will be corresponding information.
- ◇ **SpO<sub>2</sub>%**: SpO<sub>2</sub> area of display
  - ◆ It shows the oxygen saturation level of functional hemoglobin during normal measurement.
  - ◆ The color of the SpO<sub>2</sub> value will become red when the SpO<sub>2</sub> value exceeds the alarm limits.
  - ◆ It shows two dashes throughout probe off and finger out conditions.
- ◇ **100**: SpO<sub>2</sub>% high alarm limit indicator; **90**: SpO<sub>2</sub>% low alarm limit indicator.
- ◇  Pulse amplitude bar:
 

It indicates the dynamic pulse amplitude and rate. As the detected pulse becomes stronger, more bars are illumined with each pulse. The reverse is true for weak pulses.
- ◇ **100**: PR high alarm limit indicator; **60**: PR low alarm limit indicator.
- ◇ **PR**: PR area of display
  - ◆ It shows the pulse rate in beats per minute during normal measurement.

- ◆ The color of the PR value will become yellow when the PR value exceeds the alarm limits.
  - ◆ It shows three dashes throughout probe off and finger out conditions.
- ◇ **15:00**: The current time.

## 6 Other Settings

### 6.1 Alarm Setting

From the main menu, select and enter the "Alarm setting" screen, refer to Fig.6-1.

#### 1) SpO<sub>2</sub> alarm setup

To set SpO<sub>2</sub> alarm high limit in the "Alarm setting" screen, press the Up or Down button to select the "High limit (SpO<sub>2</sub>)". And then press the OK button to highlight the item. Press the Up or Down button to adjust its value, and then press the OK button again to confirm the setting of SpO<sub>2</sub> high limit. The range of SpO<sub>2</sub> high limit is 71%-100%.

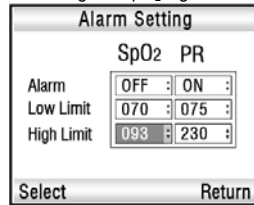


Fig.6-1

Set the low limit for SpO<sub>2</sub> alarm as the above steps of SpO<sub>2</sub> high limit settings. The range of SpO<sub>2</sub> alarm low limit is 70%-99%.

#### 2) PR alarm setting

The limits settings of PR are performed as similarly as the SpO<sub>2</sub> limits. The range of High limit is 31bpm-235bpm, the range of low limit is 30bpm-234bpm.

#### 3) Alarm on/off

In the Alarm Setting screen, press the Up or Down button to select the Alarm (SpO<sub>2</sub> or PR) sub-item, and press the OK button to highlight it. Then press the Up or Down button to select ON or OFF. And at last press the OK button to confirm your setting. If you set the SpO<sub>2</sub> and/or PR alarm off, the corresponding limits on the measurement display is crossed

with "x".

**Note: Please caution the alarm off item, it may cause damages to users.**

### ALARM PRIORITY

Alarms of the oximeter include technical and physiological alarms. All the three priorities are divided by built-in module and can not be changed by users.

**High priority:** indicates the patient is in the very dangerous situation.



**Medium priority:** indicates the warnings should be paid attention to.

**Low priority:** indicates the technical alarm caused by the device itself.

#### Assignment of priority:

	High	Medium	Low
Parameter	SpO <sub>2</sub>	PR	
Value	Red	Yellow	
Alarm lamp	Flashing with yellow	Flashing with yellow	
Lamp Frequency	1.5Hz	0.5Hz	
Audiblesound	Di- Di - Di ----- Di - Di	Di - Di - Di	Di
Alarm cycle	3 s	5 s	20 s
Alarm info	SpO <sub>2</sub> too high/low	PR too high/low	Probe off/Finger out

#### AUDIBLE ALARM INHIBITION:

Short press the  button to silence the audible alarm for 120 seconds, the audible alarm indicator will be displayed as , together with the countdown from 120s to 0s, short press it again, you can cancel alarm inhibition.



#### Warnings!

**When an alarm occurs, check patients' conditions immediately.**

- Check which parameter is alarming or which alarm is going on.
- Check patient's condition.
- Search for the source of alarm.
- Make the alarm mute if necessary.

### 6.2 Data Management

From the main menu screen, select and enter the "Data Manage" screen, refer to Fig.6-2. The unit can store 72-hour records. If the storage is full you should delete the old records

manually for free space.

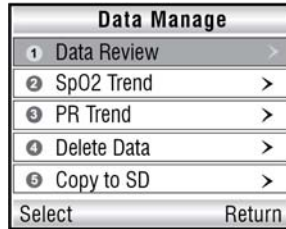


Fig.6-2

**6.2.1 Data Review**

Pick and enter the "Data Review" sub-item, the screen as shown in Fig.6-3 will appear. You can move the rolling bar to view all the records that have saved in the unit by pressing the Up or Down button.

Press the OK button, a dialog box will pop up, refer to Fig.6-4. After selecting a ID number, press the Up or Down button to select "Delete" or "Review" and then press the OK button to confirm, you can delete or review all the records saved under this ID.

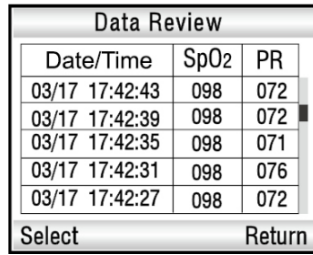


Fig.6-3

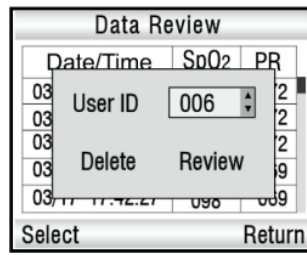


Fig.6-4

**6.2.2 SpO<sub>2</sub> Trend**

Pick and enter the "SpO<sub>2</sub> Trend" sub-item, and the screen as shown in Fig.6-5 will appear.

Press the OK button, a dialog box will pop up, refer to Fig.6-6. After selecting a ID number, press the Up or Down button to select "Delete" or "Review" and then press the OK button to confirm, you can delete or review all the SpO<sub>2</sub> trends saved under this ID.

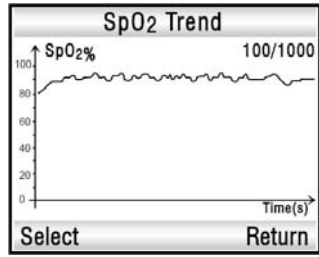


Fig. 6-5

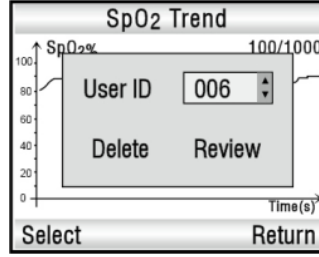


Fig. 6-6

**6.2.3 PR Trend**

The specific operations are as the same as "SpO<sub>2</sub> Trend", please refer to 6.2.2 SpO<sub>2</sub> Trend.

**6.2.4 Delete Data**

Pick and enter the "Delete Data" sub-item, a dialog box will pop up, refer to Fig.6-7. Press the Up or Down button to pick "Yes" or "No" and then press the OK button to determine whether to delete all the records.

**Note:** Pay attention to data deletion, as you make the deletion, the data will not be restored again.

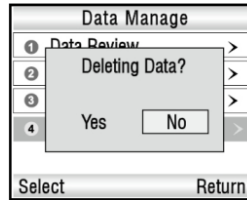


Fig.6-7

In the data management screen, the upper half screen will display the maximum, minimum and average values of SpO<sub>2</sub> and PR for the current ID. Refer to Fig.6-8.

Measure...			
ID# 006	Min	Avg	Max
SpO <sub>2</sub>	93	97	099
PR	065	073	087


Fig.6-8

### 6.2.5 Copy to SD

The SD card is only as a transfer media for data transmission from the unit to PC.

By entering this item you can copy the saved data in the unit to the inserted SD card manually, and then through the SD card reader transfer data to PC. You can browse the data through the PC software of MedView. That can save the time of uploading data.

#### Inserting a SD card

Insert a SD card into the micro SD socket located in the right side of the unit, then the SD (  ) mark will be displayed in the middle status bar of the screen. Do not insert the SD card hard.

#### Ejecting the SD card

Press the card, the lock is released and the card is ejected lightly. Remove the SD card.

#### Formatting a SD card

Insert the SD card into the SD card reader; then connect the SD card reader with a computer's USB interface. Click the SD card icon on your desktop by pressing the right button of mouse, select the "fat" item to start formatting the SD card.

#### NOTES:

- > It is recommended to use the approved micro-SD cards and Readers.
- > If the prompt information "Do not support this file system. Please format SD card with "fat16" appears, format the SD card on a computer.

### 6.3 System Setting

From the main menu, select and enter the System Setting screen, refer to Fig.6-9&6-10. Press the Up or Down button to pick the different sub-items to set and press the Select button to enter.

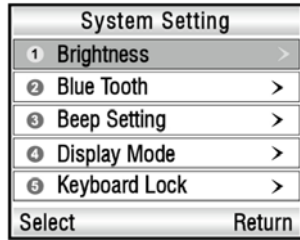


Fig.6-9

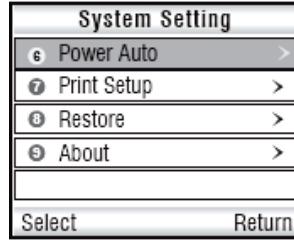


Fig.6-10

#### 6.3.1 Brightness

Pick and enter the Brightness sub-item from the System Setting screen, and set the brightness level and bright time.

Brightness level: 1-7

Bright time: ON, 15, 30, 45, 60, 75, 90,105,120 seconds.

**Note: The brightness cannot be set in the charging process.**

#### 6.3.2 Bluetooth®

Enter Bluetooth® setting screen from the System Setting screen, and set the Bluetooth® ON or OFF before transferring data to a PC. For details, refer to the attached software instruction manual.



**Note:** When the Bluetooth® is free from transferring data for 2 minutes, the Bluetooth® will be closed.

#### 6.3.3 Beep Setting

Enter Beep setting screen from the System Setting screen, you can set the beep level and on/off.

Beep level: 1-7

Beep(checkbox): on or off.

The beep on or off can be displayed in the main screen by the symbol  and .

#### 6.3.4 Display Mode

You can set the display mode Digital or Wave by entering the Display Mode sub-item. First press the OK button to highlight it and then press the Up or Down button to select Digital or Wave item, last press the OK button again to confirm your selection.

This two display modes are shown in Fig.5-2&5-3.

#### 6.3.5 Keyboard Lock

Enter Keyboard lock screen from the System Setting screen, and set the lock function on/off. If set to on, long press the Lock button, all the keys but the Return/Lock button will be deactivated.

To unlock the keyboard, long press the Lock button again.

#### 6.3.6 Power Auto

Enter Power Auto screen from the System Setting screen, and set the auto power-off time and the auto power-off on/off.

Auto power-off time: Set the time that no operation lasts before the device automatically powers off.

Time: 1,2,3,4,5...15 minutes.

Auto: Set the auto power-off function on or off.

**Note: The auto power off time cannot be set in the charging process.**

#### 6.3.7 Print Setup

Enter Print Setup screen from the System Setting screen, you can set the Print ON /OFF and the Print Item. Press the Up or Down button to select the item that you want to set, and press the OK button to highlight it. Press the Up or Down button to change its value, and then press the OK button again to confirm your setting.

**Note: Only in the interface of Data Review as shown in Fig.6-3 the data can be printed.**

**Provided that the printing paper has installed correctly, the steps for printing are as follows:**

1. Set the Print ON in the system setting menu firstly.
2. Press the PRINT button on the front panel secondly.



3. Press the Paper Feed button on the top of the rear panel, then the unit will begin printing.

You can end the current printing by pressing the PRINT button.

**If the printing paper is not installed, the steps for printing are as follows:**

1. Set the Print ON in the system setting menu firstly.
2. Press the PRINT button on the front panel secondly.
3. Press the Paper Feed button and then begin installing paper as shown in Fig.6-11.

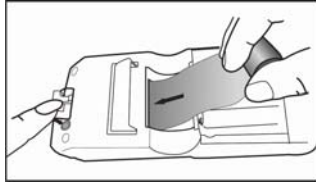


Fig.6-11

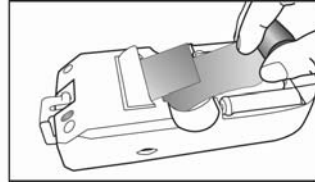


Fig.6-12

4. When the paper comes out from the outlet as shown in Fig.6-12, it means that the printing paper is installed well. The unit will perform printing.

#### 6.3.8 Restore

Enter Restore screen from the System Setting screen, and the oximeter can restore the default configurations.

**Note: The oximeter cannot restore the factory defaults configurations when measuring.**

##### Default configuration:

Audio alarm: ON;

Beep: ON; Level: 4;

Display Mode: Wave;

Brightness Level: 4; Bright time: On

SpO<sub>2</sub> alarm limit: low limit 90%; high limit 100%;

PR alarm limit: low limit 60bpm; high limit 100bpm;

Auto power off time: 60 seconds.

**Note: After changing batteries, the default settings will resume.**

**6.3.9 About**

Enter the About screen from the System Setting screen, the version of software is displayed.

**7 Maintain and Repair****7.1 Maintenance**

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.

We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

- Always dilute according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse any part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

**Caution:** If you spill liquid on the equipment or accessories, contact us or your service personnel.

**Note:** To clean or disinfect reusable accessories, refer to the instructions delivered with the accessories.

**7.2 Safety Checks**

Before every use, or after your pulse oximeter has been used for 6 to 12 months, or whenever your pulse oximeter is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability. Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.

- Make sure that only specified accessories are applied.
- Inspect if the alarm system functions correctly.
- Make sure that the batteries meet the performance requirements.
- Make sure that the pulse oximeter is in good working condition.

In case of any damage or abnormality, do not use the pulse oximeter. Contact your hospital's biomedical engineers or your service personnel immediately.

#### **Cleaning**

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

- Mild soap (diluted)
- Ammonia (diluted)
- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

1. Shut down the pulse oximeter and take the batteries out of the battery compartment.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry your equipment in a ventilated, cool place.

#### **Disinfecting**

The applied parts touching the patients' body are required to be disinfected once after each use. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.

Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule. Clean the pulse oximeter before disinfecting it.

**Caution:** Never use EtO or formaldehyde for disinfection.

**Battery maintenance**

- Please take out battery if you will not use the monitor for a long time.
  - Please charge the battery fully if you will not use it for a long time.
  - Please charge over 14 hours at the first time, or may reduce the battery life.
- If any abnormal phenomena occurs, should stop using immediately and reuse after inspection by technical person.
- f) Inspect the equipment and accessories for mechanical and functional damages.
  - g) Inspect the safety relevant labels for legibility.
  - h) Verify that the device functions properly as described in the instructions for use.

**7.3 Calibration and Verification**

The performance should be checked every one year and after maintenance and repair.

Required Test Equipment: SpO<sub>2</sub> signal Simulator.

**Note:** The simulator cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter.

**7.3.1 Control Key Verification**

Press Menu key, display the history data.

**7.3.2 Sound Verification**

- a. Set the oximeter sound ON.
- b. The simulated heart beep sound will be issued.

**7.3.3 SpO<sub>2</sub> & PR Measurement Value Verification**

- a). Connect SpO<sub>2</sub> Probe to the SpO<sub>2</sub> connector on the unit.
- b). Insert the operator's finger into the finger probe, the measured value of healthy person should be from 95% to 99%, and the pulse rate is as the same as heart rate.
- c). If SpO<sub>2</sub> Simulator is available, verify the accuracy of Oxygen Saturation Value with probes as follows:

Oxygen Saturation	Tolerance
96%	±3%
86%	±3%
70%	±3%

**7.3.4 SpO<sub>2</sub> & PR Alarm Verification**

- a). Connect SpO<sub>2</sub> Probe to the SpO<sub>2</sub> connector on the oximeter.
- b). Insert the operator's finger into the finger probe, the SpO<sub>2</sub> measured value of healthy person should be more than 96%.
- c). Set the SpO<sub>2</sub> high limit as 90, low limit as 80.
- d). Verify the SpO<sub>2</sub> visual and auditory alarms, the background color of the SpO<sub>2</sub> data should be red and "dudu" voice should be heard.

**7.4 Trouble Shooting**

- a) Can't power on the oximeter  
Please check the batteries voltage.
- b) "Probe OFF" alarm  
Please check if the probe was connected with the oximeter correctly. If the probe is with extension cable please check if the extension cable is connected with the probe correctly.

**7.5 Warranty and Repair****7.5.1 Maintenance Method**

- a) Maintenance responding time: 9:00am~17:30pm, Monday to Friday
- b) Service support: Our company will offer user telephone and e-mail technology support and parts change.  
Parts change: our company will change parts if it is necessary free of charge in the warranty period.  
Because parts are the sources of maintenance, user should send them back to our company if not specified.
- c) Update the system software free of charge.

**7.5.2 Exempt and Limitation**

- a) Our company isn't responsible for such damage caused by natural disaster. For example: fire, thunder flash, flood, cyclone, hail, earthquake, house collapse, commotion, plane failing and traffic accident, deliberate damage, lack of fuel or water,

labor and capital bother, strike and stop-working etc.

b) No-service offer

The corresponding fee and insurance fee of disassembly, refurbishment, repackaging and conveying of the oximeter or the part of it doesn't comply with the instruction manual.

The damage is caused by the third company which is not commended by our company adjusting, installing or replacing the parts of the oximeter.

The damage and failure caused by user or its representative doesn't comply with the instruction manual.

c) The oximeter is installed or connected with such external device without our company permission as printer, computer, internet line and lead to oximeter failure. Our company will charge for the maintenance.

d) Responsibility limitation

During the period of maintenance contract validity, if user changes the parts manufactured by other manufacturers without our company permission, our company is entitled to stop contract.

### 7.5.3 User Guarantee

a) Please read the instruction manual completely before operation.

b) Please operate and make daily maintenance as request of manual and guarantee.

c) Power supply and environment.

### 7.5.4 No-guarantee Principle

There is no-dispelled smut and not-original mark in the crust.

- There is physical damage on oximeter and its accessory.
- There are liquid leftover and eyewinker on oximeter and lead to short circuit and plugboard failure.
- All the probe and accessories belong to consumption and beyond free change range.
- Such damage of probe caused by mechanical force doesn't belong to free change range.
- During measurement of SpO<sub>2</sub>, principle leads to measure value difficult or inaccurate measurement.
- Maintenance seal of oximeter are not opened.

●Not-original package lead to oximeter during transportation

●Not-professional person operation leads to oximeter failure. Not our company professionals or authorized personnel disassemble oximeter and lead to oximeter failure.

●Not carefully read manual and so wrong operation lead to oximeter damage and failure.

#### **7.5.5 User's Special Request for Guarantee Time**

Our guarantee constitution for oximeter complies with electronic product after-sale service standard regulated by national laws. The guarantee time of mainboard regulated by our company is one year and all the accessories are three months. If users request the guarantee time beyond our regulated guarantee time, we should take it into consideration. Because electronic product has such a character of changing quickly, for such user asking more than three years guarantee time, our company will not buy oximeter parts during maintenance. Our company will upgrade oximeter or change new maintenance methods, for this, we charge the lowest price for new oximeter with user permission.

#### **7.5.6 Repackage**

●Take all the accessories and put them into plastic cover

●Try to use original package and packing material. user will be responsible for such damage caused by bad package during transportation.

●Please offer guarantee list and copy of invoice to standby with the period of guarantee.

●Please describe failure phenomenon in detail and altogether offer oximeter.

#### **7.6 Storage and Transportation**

Storage: Storage Temperature -20~55℃, Relative Humidity ≤93%, no condensation

Transportation: Transport by airline, train or vessel after packing according to request.

Package: We pack the product with the hard bag. We put the foam between the inner box and the cartoon to alleviate the shake.

### **APPENDIX A Specifications**

#### **Notes:**

- Specifications may be changed without prior notice.
- The circuit diagrams, the list of components, the illustrations of diagrams, and the detailed rules of calibration are provided exclusively to professional

personnel authorized by our company.

#### Display

Data: SpO<sub>2</sub>%, PR, pulse bar, plethysmogram;  
 Others: connection status of probe and other alarm information;  
 Data update time: less than 5 seconds;

#### SpO<sub>2</sub>

Display range: 0%~100%  
 Measurement range: 70%~100%  
 Resolution: 1%  
 Accuracy: 70-100%: ±3%; <70%: unspecified;

Probe LED Specifications:

	Wavelength	Radiant Power
RED	660±2nm	1.8mW
IR	940±10nm	2.0mW

#### Pulse Rate

Display range: 0~254 bpm  
 Measurement range: 30~235 bpm  
 Resolution: 1 bpm  
 Accuracy: ±2 bpm or 2% (The larger)

#### Alarm

Alarm: SpO<sub>2</sub>% and PR value, probe off, finger out, battery exhausted;  
 Alarm mode: audible alarm, visual alarm and prompt information.  
 Default alarm limits: SpO<sub>2</sub> high 100%, low 90%; PR high 100 bpm; low 60 bpm

#### Power adapter

Input Voltage: AC 100~240V  
 Input Frequency: 50~60Hz  
 Output Voltage: DC 9V±5%  
 Output Current: 2A MAX

#### Bluetooth® adapter

Data transmission rate: 3Mbps



Working Distance: 20-100m  
Interface: USB 1.1  
Operation system: Windows98®, 2000®, XP®

**Classification**

**According to the type of protection against electric shock:**

Internal powered equipment and class II equipment;

**According to the degree of protection against electric shock:**

Type BF applied part;

**According to the degree of protection against ingress of water:**

IPX1;

**Operation mode:**

Continuous running mode.

**Environment Requirements**

Operation temperature: 5~40℃

Operation humidity: ≤80%,no condensation

Storage temperature: -20~55℃

Storage humidity: ≤93%, no condensation

Power supply: Four AA alkaline or Ni-MH batteries or adapter

Working time: work for 16 hours continuously (NO printing)

**Store and replay**

Store and replay 72-hour SpO<sub>2</sub>% and Pulse rate value, the interval of every two records is 4 seconds.

**Outline of product**

**Dimension:** 170mmX75mmX35mm

**Weight:** 250g (excluding the batteries)

**Accessories:****● Standard accessories:**

1. Four AA alkaline batteries.
2. One instruction manual.
3. One finger clip sensor for adult: Model: **M-50E**.
4. One software CD.
5. One USB Cable.

6. One roll of Printing paper.

7. One Bluetooth® adapter.

8. One 2GB SD card.

● **Optional accessories:**

1. One Power adapter.

2. Four AA Ni-MH batteries.

3. One disposable sponge wrap sensor for adult: Model: **M-50J**.

**Manufacturer address: Beijing Choice Electronic Technology Co., Ltd.**

**Bailangyuan Building B**

**Rm. 1127-1128, Fuxing Road, A36**

**100039 Beijing**

**PEOPLE'S REPUBLIC OF CHINA**

**FCC ID: WWIMD300K3**

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.

changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: 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. These 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 or 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.