PULSE OXIMETER INSTRUCTION MANUAL

V1.0M122

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V1.0M122

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Content

1 Introduction

1.1 Brief Introduction

Thank you for purchasing the handheld pulse oximeter. The main functions of the device include SpO_2 and PR measurements, visual and audible alarm, batteries charging, data storage and review and USB cable&Bluetooth transferring, etc. Please read this manual carefully before using the device.

Intended use：

The pulse oximeter is intended for spot checking, displaying, storing and transmitting Haemoglobin Saturation and pulse rate of single adult, pediatric and neonatal patient in hospital (including clinical use in surgeries, anesthesia, intensive care and etc.), in home care environment, and social medical organizations.

Notes：

- **The illustration applied in the manual may differ slightly from actual device.**
- **The device is designed of handheld structure and please be sure not to turn upside down when using it.**

1.2 Safety Information

Conception of Warning, Precaution and Note

The Warning, precaution and Notice 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

- The handheld pulse oximeter should be confined to sophisticated operator exclusively. Prior to application, users should follow instructions listed in this manual, otherwise any wrong operation may cause serious damage. 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 for use in the medical field, and measurement results only serve as a reference for any relevant treatment.
- Connect the probe correctly; please see the directions for use of any accessories.
- Please follow the doctor's suggestions when starting to monitor the vital sign parameters.
- 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.
- Considering the probe is a sensitive device so please strictly follow the probe application instructions.
- The malfunction of probe may cause inaccurate data which serves as a foundation to treat patients, so make sure to pay more attention to the probe and inspect it usually.
- The worn-out data cables may cause inaccurate data which is used as a reference to treat patients, so please pay attention to the data cable and check it frequently.
- Do not touch the AC adapter with wet hands. Otherwise，You may suffer electric shock.
- The disposable accessories should not be cycled.
- 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

- Clean the probe with an H_2O solution and a neutral detergent. Don't submerge the probe. Do not use in autoclave (sterilizer).
- This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.
- 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 performing cleaning of maintenance.
- Alarm must be set up according to different situations of individual patient. Make sure that chime sound can be activated when alarm function begins to work.

Notes

- Application of this device may influence the measuring accuracy in the background of electromagnetic areas such as electro-surgery environment.
- SpO_2 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_2 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_2 readings.
- Remove fingernail polish or artificial fingernails before applying SpO_2 probes. Fingernail polish or artificial fingernails may lead to inaccurate SpO_2 readings.
- Hazards arising from software errors have been minimized. Hazard analysis conforms to meet ISO14971: 2000 and EN60601-1-4: 1996. Significant levels of dysfunctional hemoglogins, such as carboxyhemoglogin or methhemoglobin, will spawn an affection of the accuracy of the SpO_2 measurement.
- 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_2 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.
- As to the other concerns for attention, please carefully look through the specific chapter in this instruction.

1.3 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.

2 General Descriptions

The handheld pulse oximeter adopts 2.8 inch TFT screen, which can display the SpO2% and pulse rate value, other indication parameters, such as time, ID number, pulse amplitude bar and battery power status, alarm limits and the connections of Bluetooth and probe, etc.

2.1 Appearance

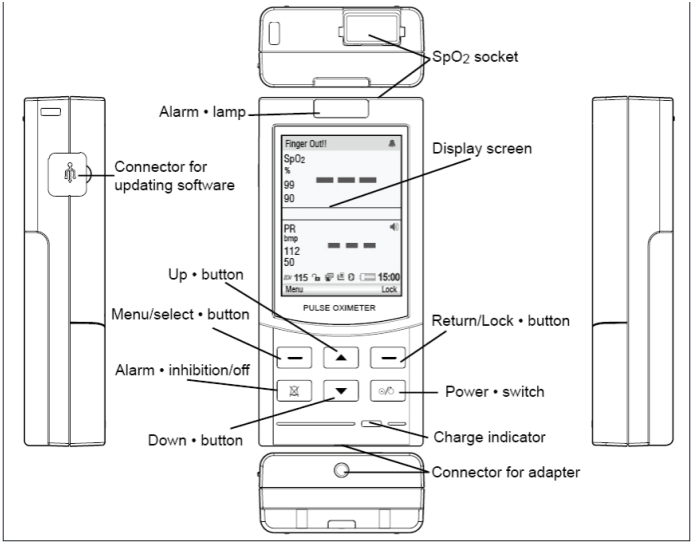

Fig.2-1

Description of Fig.2-1：

SpO_2 socket: for connecting the SpO_2 probe with the oximeter.

Alarm lamp: When SpO_2 or/and PR alarm occurs, It flashes（the color of the lamp is yellow）.

Up button: press this button to increase the value by **one** increment. Or press it and hold

it down to continuously increase the value.

Down button: press this button to decrease the value by **one** decrement. Or press it and hold it down to continually decrease the value.

Menu/Select button: for entering main menu, or confirming the selection/setting.

Alarm inhibit/off button: Press this button to inhibit alarm sound for 120 seconds. And long press the button, power off the alarm.

Return/Lock button：On the measuring screen, it serves as Lock button；On the menu and sub-menu screen, it serves as Return button.

Power switch: Press and hold it down for about 3 seconds to power it on, and for about 4 seconds to turn it off.

Charge indicator: During the oximeter is being charged, the lamp is flashing; when it is charged to full, the lamp is lighted without flashing; And the lamp is not lighted when it is not charged.

Adapter socket: for connecting the power adapter.

USB socket：designed to update the software of the device and only serves engineer.

Measurement screen:

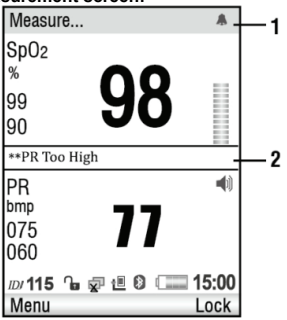

Fig.2-2 Digital display

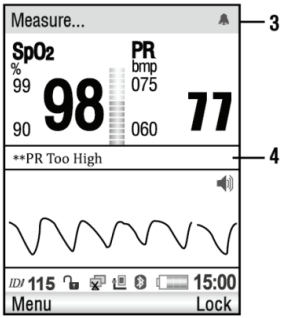

Fig.2-3 Wave display

1. Status bar 1&3: The status of the oximeter is shown on the bar.

2. Status bar 2&4: If the measured SpO_2% or PR value exceeds the alarm limits, there will be the corresponding information.

3 SpO_2%：SpO_2 area of display

◆It shows the oxygen saturation level of functional hemoglobin during normal measurement.

◆The background color of the SpO_2 value is red when the SpO_2 is outside the alarm limits.

◆It shows two dashes throughout probe off and finger out conditions.

4：99: SpO_2% upper alarm limit indicator

5：90: SpO_2% lower alarm limit indicator

6： Pulse amplitude bar.

It indicates the dynamic pulse amplitude and rate. As the detected pulse becomes stronger, more bars is illumined with each pulse. The reverse is true for weak pulses.

7：75: PR upper alarm limit indicator

8：60: PR lower alarm limit indicator

9：PR: PR area of display

◆It shows the pulse rate in beats per minute during normal measurement.

◆The background color of the PR value is yellow when the PR is outside the alarm limits.

◆It shows three dashes throughout probe off and finger out conditions.

10.15:00: The current time.

2.2 Explanation of Symbols

Symbol	Explanation	Symbol	Explanation
	Type BF applied part	**IPX1**	Protected form dripping water
	ID indication		Attention, consult ACCOMPANYING DOCUMENTS
	Audible alarm on		Audible alarm off/inhibition It indicates alarm inhibition when the countdown of 120s displayed
	Pulse Beep on		Pulse Beep off
	The adapter is connected		Battery power indication

	Keyboard is unlocked		Keyboard is locked
	USB cable is connected		USB cable disconnected
	SpO_2 probe is inserted		SpO_2 probe off
	Bluetooth activated		Bluetooth deactivated

2.3 Power Supply

2.3.1 Powered by batteries

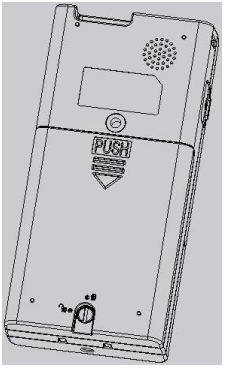

Fig.2-4

Batteries Installation :

1) Open the battery cover: Rotate the fixing screw slightly in the rear panel to the position which is marked with " " and then push the cover as indicated by arrowhead, as shown in Fig.2-4.

2) Install 3 batteries lightly as indicated by the polarity signs in battery housing.

Note: Make sure the polarities of the batteries are correct.

3) Close battery housing cover

Close the battery housing cover and rotate the screw to the position which is marked with

. And the batteries are locked.

Battery life and replacement

There are five shapes of the indicator: the centre with 4 bars(full), 3 bars, 2 bars, 1 bar, empty and the frame in red. That the frame of indicator become red means few of battery capacity remains. You should replace the batteries with new ones timely. Or else, the indicator displays with a red frame constantly until battery capacity reaches critical condition (the battery voltage is 3.5V±1V) at which time the unit shuts down.

Cautions!

- ✧ Be sure to install batteries with correct polarities.
- ✧ Only the approved batteries are recommended to be used..
- ✧ 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.

2.3.2 Charging Batteries through adapter

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

A prompt window appears enquiring you “Are the batteries NI-MH ones?”, select “Yes” to charge them or “No” to abandon charge and the device can be powered by wall outlet.

2.3.3 Charging Batteries by charger stand

The device can also be charged by charger stand provided with the oximeter. For more information, refer to “Charger Stand Instruction Manual”.

Note:

1. To avoid the device from being damaged due to shot circuit, please keep the adapter is firstly connected with the oximeter and secondly with the wall outlet. While disconnected the connection, please keep the adapter is firstly disconnected from the wall outlet and then disconnected from the oximeter.

2. During battery charge, the “Power Auto” and “Brightness” item can not be accessed.

3. It is not recommended to measure SpO_2 during the oximeter is powered by wall outlet or being charged, for the damages and injuries may be caused to the device or users.

4. DO NOT charge when the non-rechargeable batteries are installed, otherwise, the damages or injuries may be caused to the devices or users.

2.4 Product Features

- ✧ Simple to use and easy to operate.
- ✧ Compact, light in weight and convenient to carry.
- ✧ TFT display with adjustable backlight displays SpO_2, pulse rate, pulse amplitude bar, etc.
- ✧ Up to 127 patients' ID and 72-hour records storage.
- ✧ Visual and three-level audible alarms, Battery power low alarm.
- ✧ Adjustable pulse beep and backlight.
- ✧ Data transfer to PC for review by Bluetooth or USB cable
- ✧ Powered by three AA alkaline/ NI-MH batteries.
- ✧ Battery charge function with adapter or charge stander(optional).
- ✧ Suitable for adult, pediatric and neonatal users.

3 Install SpO_2 Probe

The SpO_2 Probe is shown in the following figure:

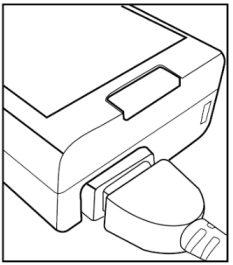

Fig.3-1

Insert the SpO_2 probe to the socket, as shown in Fig.3-1. Then indicator is shown on the display (refer to Fig.2). If the SpO_2 probe is disconnected from the unit，the indicator appears and the prompt "Probe Off!!! " appears 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 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 the fig.4-1.

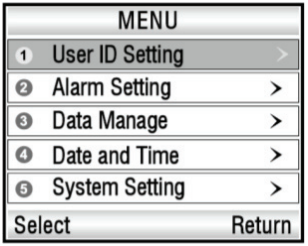

Fig.4-1

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

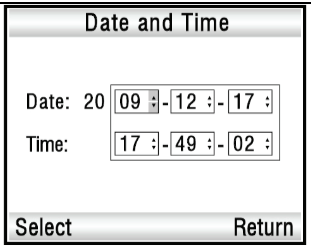

Fig.4-2

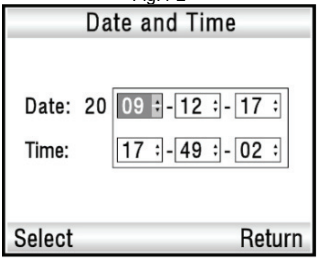

Fig.4-3

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

Set other sub-items of data and time according to the "Year setting" illustrated in the above figures 4-2&4-3.

4.2 ID number Setting

Enter the "User ID Setting" from the main menu screen, refer to Fig.4-4. Press the Select 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 Select button to confirm your settings. The range of ID number is: 001-127.

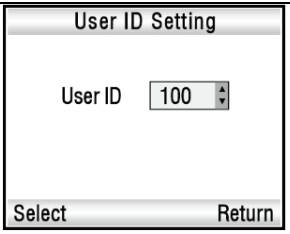

Fig. 4-4

5 Take a Measurement

Before taking a measurement:

- Select the suitable probe in terms of type and dimension.
- Plug probe into SpO_2 socket on top panel of pulse oximeter.
- Clip the patient finger to the rational position of the probe as the illustration as Fig.5-1.

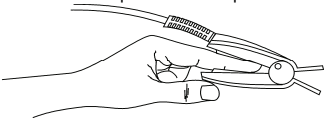

Fig.5-1 Placement of the probe

Note：If the finger is not in the probe, "Finger Out！！ " will be shown.

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_2 probes provided by manufacturer for SpO_2 measurements. Other SpO_2 probes may cause improper performance.**
- **Do not use the SpO_2 probe with exposed optical components.**
- **Excessive patient movement may cause inaccurate measurements.**
- **Tissue damage can be caused by incorrect application or use of 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:**
  - Incorrect application or use of probe
  - 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 is in 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_2 probe is attached

Note：SpO_2 probe should obviate the light source, e.g. radial lamp or infrared lamp.
The measured results are recorded into the memory of the oximeter, and Store up to 72-hours SpO_2% and Pulse rate value, the time interval is 4 seconds. When the memory is full, a prompt window of "Space Expire!" appears. To recorded the newest measurements, you can delete the old ones for free space.

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_2 alarm setup

To set SpO_2 alarm high limit, In the "Alarm setting" screen, press the Up or Down button to select the "High limit（SpO_2）". And then press the Select button to highlight the value. Press the Up or the Down button to adjust the value, and at last press the Select button to finish the setting of SpO_2 high limit. The range of SpO_2 high limit is 71%-100%.

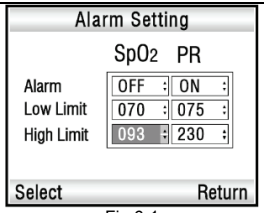

Fig.6-1

Set the low limit for SpO2 as the above steps of SpO2 high limit settings. The range of SpO2 lower limit is 70%-99%.

2) PR alarm setting

Also, the limits settings of PR are performed as similarly as the SpO2 limits. The range of High limit is 31bpm-235bpm. And the range of low limit is 30bpm-234bpm.

3) Alarm on/off

In the Alarm Setting screen, press the Up or Down button to move the cursor to the Alarm(SpO2) or Alarm(PR) sub-item, and press the Select button to it highlighted. Press the Up or Down button to select ON or OFF(refer to Fig.6-2). And then press the Select button to confirm your settings. If you set the SpO2 and/or PR alarm off, the corresponding limits on the measurement display is crossed with "x".

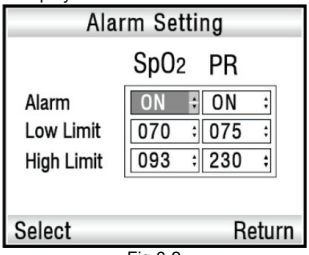

Fig.6-2

ALARM PRIORITY:

There are three-level priorities for selection.

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.

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 user.

Assignment of priority:

	High	Medium	Low
Paramter	SpO_2	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_2 too high/low	PR too high/low	Probe off/Finger out

Notes:

1. The alarm sound will go on until alarm disappears or is turned off.
2. After silencing the alarm, the corresponding indicator will indicate this.
3. The power low alarm: the corresponding indication lamp will be flashing with a red frame.

AUDIBLE ALARM INHIBITION/OFF:

Short press the button to silence the audible alarm for 2 minutes, 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; Long press the button, the audible alarm indicator will be displayed as which indicates the audible alarm off. And then long press the button, you can activate the audible alarm again.

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.
- Check the alarm when no warning.

6.2 Data Management

From the main menu screen, select and enter the "Data Manage" screen, refer to fig.6-3.

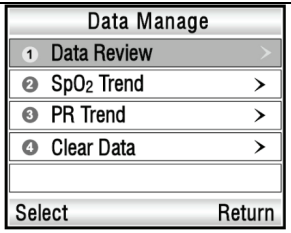

Fig.6-3

Press the Up button or Down button select the sub-item to set, and then press the Select button to confirm or Return button to return to the previous screen.

6.2.1 Data Review

Pick "Data Review" sub-item and enter by pressing the Select button. The screen as in fig.6-4 will appear.

Press the Select button again, a dialog box will pop up, refer to fig.6-5. After selecting a ID number, press the Up or Down button to select "Delete" or "Review" and then press the Select button to confirm, you can delete or review all the records saved under the ID.

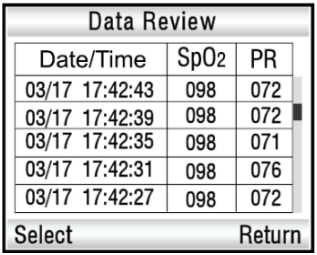

Fig.6-4

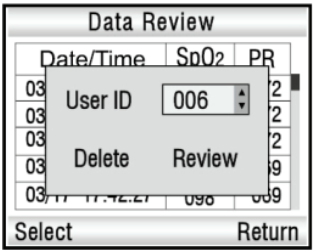

Fig.6-5

6.2.2 SpO_2 Trend

Pick " SpO_2 Trend" sub-item and enter by pressing the Select button. The screen as in fig.6-6 will appear.

Press the Select button again, a dialog box will pop up, refer to fig.6-7. After selecting a ID number, press the Up or Down button to select "Delete" or "Review" and then press the

Select button to confirm, you can delete or review all the SpO_2 trends saved under the ID.

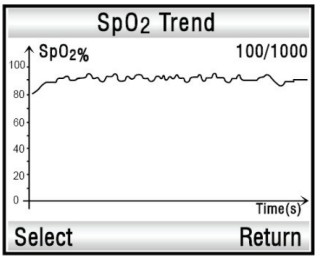

Fig. 6-6

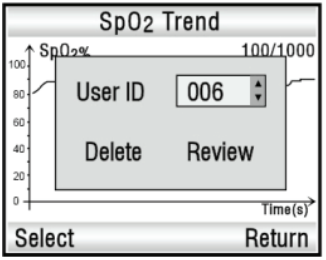

Fig. 6-7

6.2.3 PR Trend

The operation is referred to *6.2.2 SpO_2 Trend*.

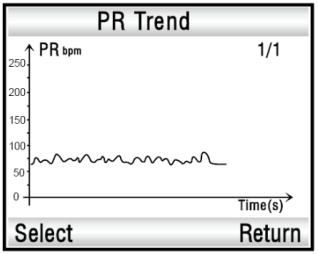

Fig.6-8

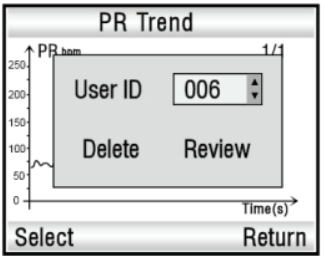

Fig.6-9

6.2.4 Clear Data

Pick "Clear Data" sub-item and enter by pressing the Select button. A dialog box will pop up, refer to fig. 6-10. Press the Up or Down button to pick the Yes or No and then press the Select 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.

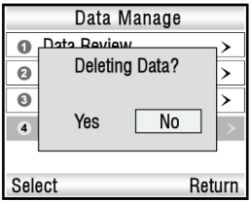

Fig.6-10

6.2.5 In the data management screen, the upper half screen will display the maximum, minimum and average values of SpO2 and PR for the current ID. Refer to fig.6-11.

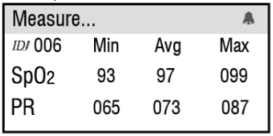

Fig.6-11

6.3 System setting

From the main menu, select and enter the System Setting screen, refer to Fig.6-12&6-13. Press the Up or Down button to pick the different sub-items to set and press the Select button to enter.

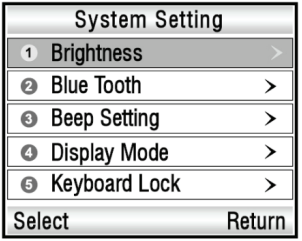

Fig.6-12

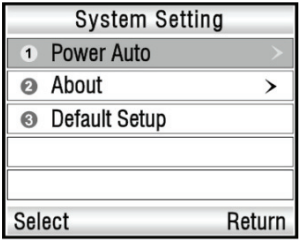

Fig.6-13

6.3.1 Brightness

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

Brightness level: 1-7

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

6.3.2 Bluetooth

Enter BlueTooth screen from the System Setting screen, and set the Bluetooth on or off before transferring data to software for reviewing or analyzing data.

Notes:

- ✧ For details, refer to attached Software Instruction Manual.
- ✧ 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, and set the beep level and on/off.

Beep level: 1-7

Beep(switch): on or off.

6.3.4 Display mode

Enter Display Mode screen from the System Setting screen, and select the display mode for measurement screen from Wave and digital.

Select 'Wave", SpO_2 plethysmogram will be displayed on the lower screen of the measurement screen.

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， the Menu/select, Up and Down, Alarm inhibition buttons on front panel will be deactivated，except the Alarm off，power switch and lock buttons.

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 set the auto power-off on/off.

Auto power-off time: Set how long not any operation is taken before the device automatically power off.

Time: 1,2,3,4,5…15 minutes.

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

6.3.7 About

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

6.3.8 Default Setup

Enter Default Setup screen from the System Setting screen, and you can restore the default configurations.

Default configuration includes:

ID: 001

SpO_2 low limit: 90% SpO_2 high limit: 100% SpO_2 alarm: on

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

Brightness Level：3 Bright time: On

Bluetooth: Off

Beep level: 4 Beep(switch): on

Display(mode): Wave

Keyboard lock: On

Auto power-off time: 3 minutes Auto(power-off): on

Note: After changing the batteries, the settings may get back to the default settings.

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 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 abnormity, 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 housing.
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.

Please note during operation:

Should take out probe and take good care of it after operating monitor If not used for long time please take out battery.

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_2 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_2 & Pulse Rate Measurement Value Verification

a). Connect SpO_2 Probe to the SpO_2 connector on the oximeter.

b). Insert the operator's finger into the finger probe, the SpO_2 measured value of healthy person should be from 95% to 99%, and the pulse rate is same as heart rate,

c). If SpO_2 Simulator is available, verify the accuracy of Oxygen Saturation Value with probes as follows:

Oxygen Saturation	Tolerance
96%	±2%
86%	±2%
70%	±3%

7.3.4 SpO_2 & Pulse Rate Alarm Verification

a). Connect SpO_2 Probe to the SpO_2 connector on the oximeter.

b). Insert the operator's finger into the finger probe, the SpO_2 measured value of healthy person should be more than 96%.

c). Set the SpO_2 high limit as 90, low limit as 80.

d). Verify the SpO_2 visual and auditory alarms, the backgroud color of the SpO_2 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 force majeure. 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_2, 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

Notices:

- Specifications may be changed without prior notice.
- The circuit diagrams, the list of components, the illustration of diagrams, and the detailed rules of calibration, are provided exclusively to professional personnel authorized by our company.

Specifications:

Display:

Data: SpO_2%, PR, pulse column
Others: connection status of probe and other alarm information.
Data update time: less than 5 seconds

Alarm:

Alarm: SpO_2% and pulse rate value, probe off, battery exhausted

Alarm mode: audible alarm, visual alarm and information
Alarm limits range: SpO_2 70%-100%, PR 30-235 bpm
Default limits: SpO_2 High 100%, low 90%; PR High 100 bpm; low 60 bpm

SpO_2

Display range: 0%~100%

Measurement range: 70%~100%

Resolution: 1%

Accuracy: 70%-100% : ±3 Digit;
＜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）

Environment Requirements

Operation temperature: 5～40 centigrade
Operation humidity: ≤80%,no condensation
Storage temperature: -20～55 centigrade
Storage humidity: ≤93%, no condensation
Power supply: Three AA alkaline/NI-MH batteries or adapter
Working time: work for 16 hours continuously at most

AC adapter：

Input Voltage： AC 100~240V

Input Frequency: 47~63Hz

Output Voltage：DC 5V±5%

Output Current：2A MAX

Store and replay

Store and replay 72 hours SpO_2% and Pulse rate value, the time interval is 4 seconds.

Classification

According to the type of protection against electric shock:
Internal powered equipment and class II equipment
According to the degree of protection against ingress of water：

IPX1

Outline of product
Dimension: 125mmX60mmX30mm
Weight: 195g (excluding the batteries)

Accessories:

- **Standard accessories:**

1. Three AA alkaline batteries.
2. One instruction manual
3. One adult finger probe:
   Model：M-50E.
4. The key for screwing the screw.
5. Bluetooth adapter
6. Software CD
7. USB Cable

- **Optional accessories:**

1. Binding sensor for pediatric, infant and neonatal:
   (Pediatric 15-45 Kg, Infant 3-15 Kg).
   Model： M-50C
2. Fingertip sensor for pediatric
   Model： M-50B
3. Soft sensor for pediatric
   (Pediatric 15-45 Kg, Infant 3-15 Kg).
   Model：M-50H
4. Soft sensor for adult
   Model：M-50G
5. Charger Stand (with adapter and USB Cable)

Beijing Choice Electronic Technology Co.,Ltd.
BailangyuanB1127-1128,Fuxing R,A36
100039 Beijing
PEOPLE'S REPUBLIC OF CHINA

EC REP Eiffestraße 80,20537
Hamburg GERMANY

Shanghai International
Holding Corp.GmbH(Europe)

CE 0123

FCC ID: WWIMD300M122

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.