Vital Sign Monitor

Mode: MD2000C

Version:1.0

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CHAPTER 1 INTRODUCTION

1.1 About the Manual

Before using the MD2000C vital sign monitor, the user must carefully read this manual so that the user can operate the monitor properly and make it reach the specific safety standard and performance index.

This manual explains how to set up and use the monitor. Important safety information relating to general use of the monitor appears after this introduction. Other important safety information is located throughout the text where appropriate.

Note: There requires no routine calibration, safety maintenance or in-service during the monitor's life.

1.2 Contraindications

- Active patients.
- Intravascular dyes such as indocyanine green or methylene blue.
- Significant levels of dysfunctional hemoglobins (such as carbonxy-hemoglobin or methemoglobin).
- The presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
- Venous pulsations may cause erroneous low readings(e.g. tricuspid value regurgitation)
- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should be not below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor)
- Avoid placing the sensor on any extremity with an arterial catheter, intravascular line or blood pressure cuff.
- Exercise caution with poorly perfuse patients; skin erosion and/or pressure necrosis may occur.
- Do not use the monitor when the patient in cardiac arrest or in defibrillation.

1.3 Safety Information

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

Cautions: alert the user to exercise care necessary for the safe and

effective use of the monitor.

Notes: contain important information that may be overlooked or missed.

Warnings!

- Before use, carefully read the manual.
- Operation of the equipment may be affected by the use of an electrosurgical unit (ESU) or high-frequency interference.
- Do not use the equipment in an MRI or CT environment.
- Do not use the equipment in an explosive flammable or anesthesia atmosphere.
- Do not use the equipment on the airplane.
- Do not use the equipment with defibrillator, pacemaker or hearing-aid.
- The equipment is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
- Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
- Only the qualified physician can use the equipment, the patient should follow the physician's advice use the equipment.
- Only use the accessories approved by our company. Other accessories may affect the equipment performance. The accessories contain battery, external power supply line, cuff, SpO_2 sensor and temperature sensor.
- Avoid extremes in temperature and humidity. Do not use this device in locations subject too high or too low temperature or humidity.
- Avoid to store in the place that has chemicals or gas leakage dangerous.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Portable and mobile RF communications equipment can affect

medical electrical equipment.

- Chemicals from a broken panel are toxic when ingested. Use caution when the monitor has a broken display screen.
- Defibrillation protection only implement on the ECG cable which has the defibrillation function.
- When using defibrillation, it needs to remove other non-defibrillation applied parts from patients.
- The use of the device is restricted to one patient at a time.
- Use a defibrillator on a patient, the device requires special protection when the discharge of a defibrillator affects the device.
- Please use the accessories that approved by the manufacturer.
- If the device has the battery, it still working after interruption of the supply mains exceeding 30s. Or else it power off.
- PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter ALARM SIGNALS.
- To avoid the risk of leakage on the patients, the cable is isolated by high voltage and adopted the insulation material. In order to improve the service life of the cable, we use the high quality cables.
- These materials that contact with the patient's skin are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
- Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This equipment should be installed and operated with a minimum distance 20cm between the radiator and your body.

Cautions!

- Check whether the equipment in the correct status or not.
- Check all the leads connection; make sure all of them connect well.
- Check the quantity and status of the battery.
- Make sure the safety of the patient, if it needs cut off the power supply, take out the leads or sensor.
- Do drop the fire goods, medal or liquid into the equipment. If these

things drop into the equipment, please cut off the power supply and stop working.

- Please remove the battery, when the equipment will not be used for a long time.
- Pull out the leads and other accessories lightly.
- All the components of this equipment, the user can be maintenance.
- This equipment don't need to calibration.

1.4 Intended Use

Vital Signs Monitor MD2000C is a portable device indicated for measuring physiological parameter, such as NIBP, SpO_2, PR, PI and PR waveform of adult and pediatric patients in hospitals, community hospitals and medical facilities.

1.5 Electromagnetic Interference

Under the normal measuring, the equipment is not interference the surrounding people, unit and environment. During the process of sending data, the device interference the surrounding people, unit and environment. If the equipment in the high-frequency electromagnetic environment, it will do harm to the equipment, and the intended function will failure. During the operation, you should prevent, identify and solve the adverse electromagnetic effect. Make sure the functions of the equipment are normal.

The reasons of the interference and solutions

- From the RF wireless module electromagnetic interference

If the interference from the RF wireless module, please replace the equipment location.

- Direct or indirect ESD

Before use the equipment, make sure the user and the patient without the direct or indirect ESD. The damp room can alleviate problems.

- From the radio receiver (radio or television) interference

Keep away from the interference source. If the above proposals cannot solve the problems, please contact the consumer service center.

1.6 Symbols Definition

Symbol	Definition	Symbol	Definition

⚠	Caution		Follow operating instruction
IP22	the degree of protection against dust and water	SN	Serial number
	Storage temperature and humidity		Manufacturer's information
	Data of manufacture		Quantity of the battery

1.7 Product Properties

- Portable to carry, convenient to operate and easy to measure.
- 7' TFT display screen, it can display physiology parameter, NIBP, SpO_2, PR, PI and PR waveform.
- Rechargeable Lithium battery
- Support external AC-adapter

CHAPTER 2 GENERAL DESCRIPTIONS

2.1 understanding the monitor

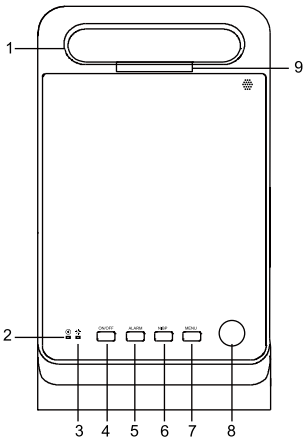
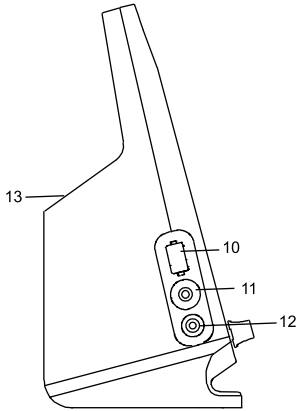
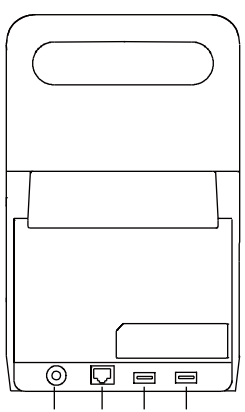


Fig.2.1

1.Integrated carry handle.
2. Power indicator light: use the AC power adapter, the light on.
3. Indicator light: turn on the device, the light on.
4. Power button: press and hold this button for 3S to power on and 4S to turn off.
5. Alarm silence button: press the button to silence the audible alarm for one minute.
6. Shortcut button of NIBP measuring.
7. Menu button: Press menu button enter into the setting menu.
8. Rotary Knob
The operator uses the rotary knob to select the menu item and modify the setup. It can be rotated clockwise or counter-clockwise and pressed like other buttons.
9. Alarm indicator light.



10. SpO_2 interface: connect the SpO_2 sensor.
11. $ETCO_2$ interface
12. NIBP interface: connect the extended BP wires and cuff.
13. Storage space: place the accessories.



14. Power adapter socket.

15. Wire LAN socket.
16. USB socket.
17. USB socket.

2.2 Power supply

External AC adapter: AC-input 100-240V, 50/60Hz, 0.8A Max; DC-output 9.0V, 3.0A

Internal battery: one piece of lithium battery, rated voltage is 7.4V, 2600mAh

The capacity of the battery will be display on the screen. It will take about 3 hours to complete charging, and then you can use about 3.5 hours.

Use the AC power supply, make sure put the device in the safety and proper place and convenient to power off.

2.3 Charging the device

Plug the power adapter into a wall adapter, press the other end of the power adapter into the charging port located on the back of the device, then it becomes to charge the device. When the battery reaches 100%, the battery indicator become fullfilled. Unplug the power adapter after finish charging.

The battery is new and fully charged; the minimum operating time of the device is 3.5h.

The battery charge time from depletion to 90 % charge is 2.5h.

The battery charge time from depletion to 100 % charge is 3h.

2.4 Check the proper function of the device and accessories

The device: press and hold the power button for 3s, the device turn to the normal interface, and press and hold the power button for 4s to power off the device. It means the device in good condition.

SpO_2 probe: SpO_2 probe is not wear out. Rightly insert the SpO_2 probe with the device, the red light of the SpO_2 probe flash. Open the clamp, the red light is on. After insert the finger into the SpO_2 probe, the measurements display in the device, it means the SpO_2 probe in good condition.

Thermometer: Through Bluetooth to pair the thermometer with the device, the device displays the ear temperature. It means the thermometer in good condition.

BP cuff: the BP cuff is not wear out. During the measurement, the device

Continuous inflation without leakage, and the measurements display in the device, it means the BP cuff in good condition.

Power adapter: Rightly insert the power adapter with the device, the power indication light is on in green, it means the power adapter in good condition.

2.5 Power off

After measurement, please take off your finger and press and hold the power button to turn off the device.

CHAPTER 3 Setting

First time use the device, you should setup the following parameters after turn on the device.

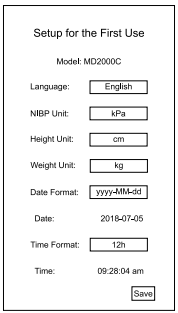


Fig.3.1

Language: English

NIBP unit: mmHg, kPa

Height unit: cm, in

Weight unit: kg,lb

Date format: yyy-MM-dd, yyy/MM/dd, dd-MM-yyy

Time format: 12h, 24h

Under the measuring screen, press the menu button enter into the setting screen.

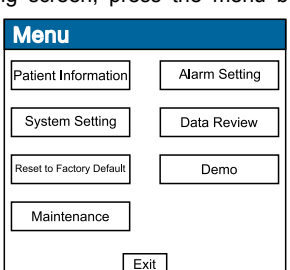


Fig.3.2

Rotary knob is just like the cursor of computer. Operator rotates the knob

on the icon where the operation is wanted. Then pressing the knob, operator will open the setup menu of the corresponding parameter so as to set up the menu.

How to set up the parameters?

1. Rotate the knob to choose the item.
2. Press the knob into the submenu.
3. Rotate the knob to choose the item, press the knob to confirm.
4. Rotate the knob to adjust the item, press the knob to confirm.

Patient information

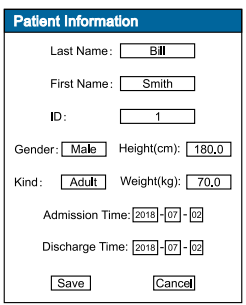


Fig.3.3

In this submenu, fullfill in the patient information.

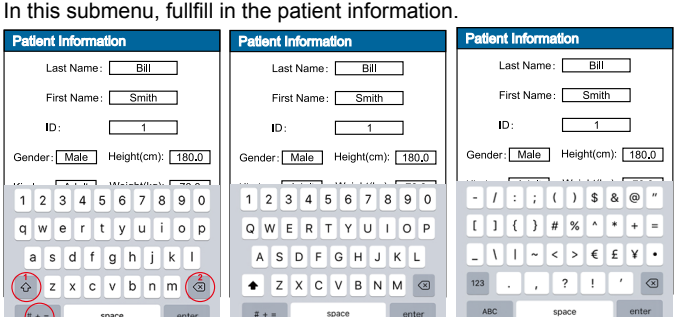


Fig.3.4

Note:

1. Popup the keyboard when input the last name, first name and ID.

Rotate the knob to input them.

2. Rotate the knob to the shift icon (red cycle 1) then press to change case, rotate the knob to the delete icon (red cycle 2) then press to delete letter or number, rotate the knob to the symbol icon (red cycle 2) then press to the symbol keyboard.

3. About the kind, adult and Pediatric .

Alarm setting

Before setting, please enter password (2222) to set the parameter.

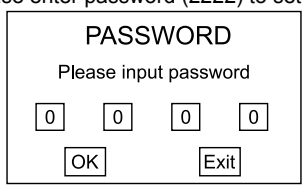


Fig.3.5

How do you input passwords?

1. Rotate the knob to choose the item.
2. Press the knob to confirm.
3. Rotate the knob to adjust the number 2.
4. Press the knob to confirm.
5. Repeat the step one.

Note: Every time enter into the Alarm Setting you should input the password.

Volume

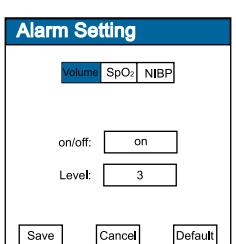


Fig.3. 6

1. turn on or off the alarm.

2. Adjust the value of alarm volume, there are 5 levels, and the default level is 3.

SpO_2

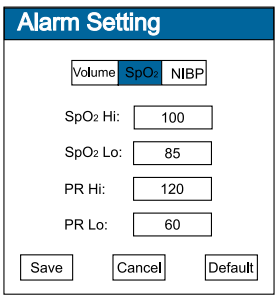


Fig.3. 7

High limit SpO_2 range is71mmHg ~100mmHg

Low Limit SpO_2 range is 70mmHg ~99mmHg

High Limit PR range is 31mmHg ~350mmHg

Low Limit PR range is 30mmHg ~349mmHg

Note: the low limit should less than the high limit.

NIBP

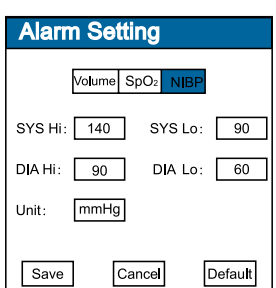


Fig.3.8

High limit SYS range is 16mmHg ~ 295mmHg
Low Limit SYS range is 15mmHg ~ 294mmHg
High limit DIA range is 11mmHg ~ 285mmHg
Low Limit DIA range is 10mmHg ~ 284mmHg
Unit: mmHg / kPa

System setting

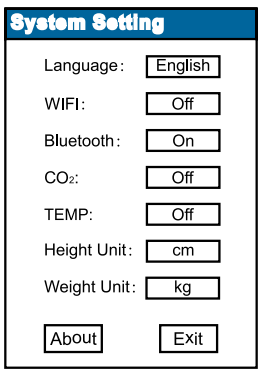


Fig.3.10

Language: English
WIFI: on / off
Bluetooth: on / off
CO_2: on / off
TEMP: on / off
Height Unit: cm/in
Weight Unit: kg/lb

About This Device

Under the system setting, rotate and press the knob on about to check the device.

Fig.3.11

Data review

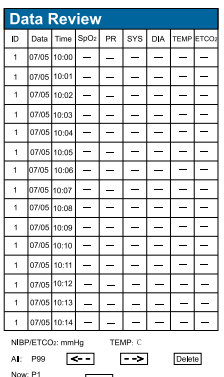


Fig.3.12

Rotate the knob on the arrow that on the bottom of the screen, press the knob to review the records page by page.

The device can record the alarming parameter marked with red color.

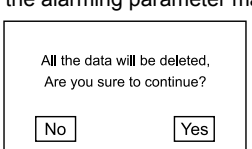


Fig.3.13

Rotate the knob on the delete that on the bottom of the screen, press the knob to delete data.

Please take caution to the deletion of data; you will never get the data back once deleted.

Reset to factory default

Note: All the setting will be reset to factory defaults. Please be careful.

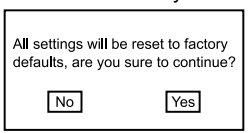


Fig.3.14

Demo

Rotate the konb on the demo, press the knob enter into the demo screen. Under the demo interface， press the knob return to the menu screen.

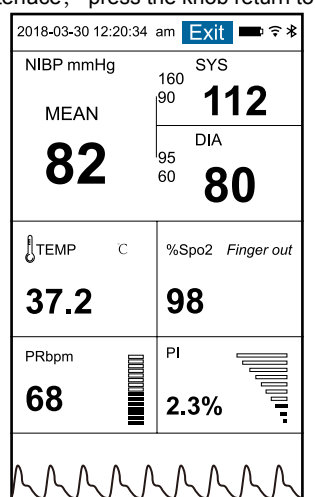


Fig.3.15

CHAPTER 4 Take a measurement

4.1 Preparation

Before measuring, you connect the sensor. Please connect sensors slightly.

Understanding the screen.

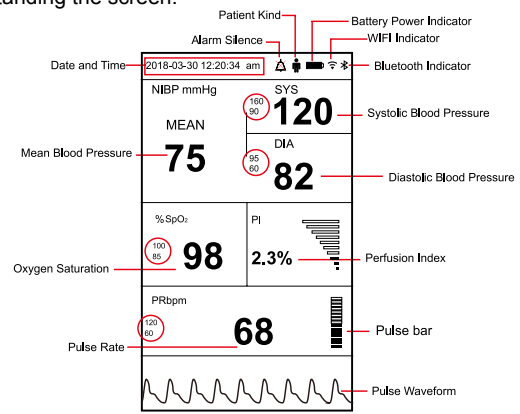


Fig.4.1

Note: In the red circle, In the red circle, there are the high and low limit of the parameter.

Date and time

In the main screen, rotate the konb on the date and time, press the knob enter into the time setting screen.

Under the time setting screen, rotate the konb on the time setup to adjust the date and time.

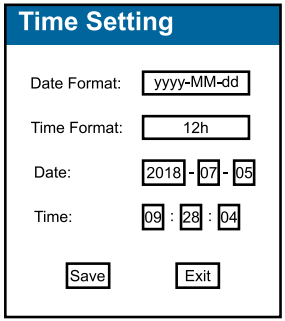


Fig.4.2

4.2 NIBP

Measurement Principle

This device is intended for non-invasive measuring of an adult or pediatric ndividuals' systolic and diastolic blood pressure using the oscillometric method.

NIBP Setting

In the main screen, rotate the konb on the NIBP, press the knob enter into the NIBP setting screen.

You can set the high & low limit and the unit of the NIBP.

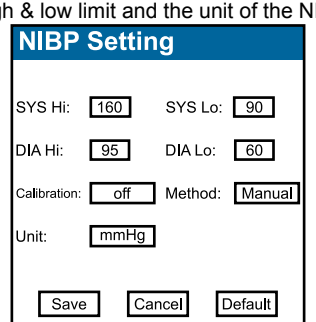


Fig.4.3

Note:

1. Remember to save the settings or you can cancel the settings.

2. Press default, all settings will be reset to factory defaults, please be carefully.

3. Measuring method: manual or auto (1mins, 3mins, 5mins, 10mins, 20mins, 30mins, 60mins).

Warnings!

- Before starting a measurement, verify that you have selected a setting appropriate for your patient.
- Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
- Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
- Plug in the air hose and switch on the system.
- Too frequent measurements can cause injury to the patient due to blood flow interference.
- Do not apply the cuff over a wound, as this can cause further injury.
- Don't apply the cuff and its pressurization on the arm on the side of a mastectomy.
- Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring device on the same limb.
- Check the operation of the Automated sphygmomanometer does not result in prolonged impairment of the circulation of the blood of the patient.
- Any blood pressure reading can be affected by the measurement site, the position of the patient (standing, sitting, lying down), exercise, or the patient's physiologic condition.
- The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
- Apply the blood pressure cuff to the patient's arm as shown in Fig.4.4

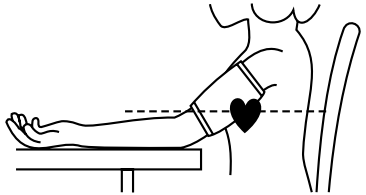


Fig. 4.4

Notes:

- Ensure that the cuff is completely deflated.
- Apply the appropriate size cuff to the patient, and make sure that the symbol “Φ” is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.
- The width of the cuff should be either 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50~80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, then use a larger cuff.
- Make sure that the cuff edge falls within the range of mark <->. If it does not, use a larger or smaller cuff that fits better.
- Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient’s heart. If this is not possible you should apply the following corrections to the measured values.
- If the cuff is placed higher than the heart level, add 0.9 mmHg (0.10kPa) for each inch of different.
- If it is placed lower than the heart level, deduct 0.9 mmHg (0.10kPa) for each inch of different.
- The rated range of cuff pressure: 0mmhg~380mmhg.

Measuring

Press the shortcut button(NIBP) the user feel the cuff inflation. After that, the device will automatically deflate. Finally, the screen will display the results: Systolic Blood Pressure and Diastolic Blood Pressure. The interface is as shown in Fig.4.5

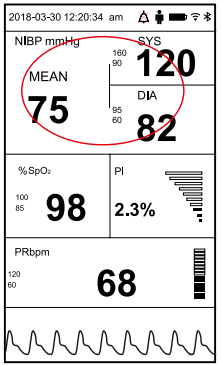


Fig. 4.5

WARNINGS!

- If any abnormality is observed, stop the blood pressure measurements.
- If you suspect the accuracy of the value, please adopt other method to further check.
- If the liquid splashes on the device or accessories, especially liquid enter into the device, please connect the local service center.
- Inaccurate measurements may result from such causes:

a. Limb’s twitch and tremble will cause inaccuracy or prolonged the cycling of measurement; serious tremble will lead to the failure of measure.

b. Placing the cuff too loosely or tightly on the patient.

c. Leaky cuff or hose

d. Insure the NIBP and pulse rate within the range of this monitor.

e. Excessive patient motion will cause the inaccuracy, patient should be relax and avoid movement.

f. Arrhythmia lead to irregular heart beat

g. Use the artificial heart-lung machine

h. The patient is in shock or low temperature.

Pressure Safety Protection

- Automatic deflation will be activated when the cuff pressure exceed 280 mmHg under the adult mode.
- Automatic deflation will be activated when the continuous inflation last more than 30 seconds.
- If there is no value when measurement time exceeds 120 seconds under the adult mode, the measurement will be canceled.
- You can press the START (NIBP) button to cancel a NIBP measurement when necessary.

Maintenance and Cleaning

WARNINGS!

- Do not squeeze the hose of cuff.
- Do not allow liquid to enter the connector socket when cleaning the monitor.
- Do not wipe the inner part of the connector socket when cleaning the monitor.
- When the reusable cuff is not connected with the monitor, or being cleaned, always place the cover on the rubber tube to avoid liquid permeation.

NIBP cuff disinfection

The cuff can be sterilized by means of conventional autoclaving, gas, or radiation sterilization in hot air ovens or disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use this method. The cuff should not be dry-cleaned.

The cuff can also be machine-washed or hand-washed; the latter method may prolong the service life of the cuff. Before washing, remove the latex rubber bag, and for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing, and then reinsert the rubber bag.

To obtain accurate routine resting BLOOD PRESSURE measurements for the condition hypertension including;

– adjustment of the pressure reduction rate, if applicable,

– patient position in normal use, including

1) comfortably seated

2) legs uncrossed

3) feet flat on the floor

4) back and arm supported

5) middle of the cuff at the level of the right atrium of the heart

– a recommendation that the patient relax as much as possible and not talk during the measurement procedure,
– a recommendation that 5 min should elapse before the first reading is taken;
– operator position in normal use

4.3 SpO_2, PR and PI

What is SpO_2 Monitoring?

SpO_2 plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO_2 oxygen saturation of 97%. The SpO_2 numeric on the monitor will read 97%. The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

SpO_2 Setting

In the main screen, rotate the konb on the SpO_2, press the knob enter into the SpO_2 setting screen.

You can set the high & low limit and the unit of the SpO_2.

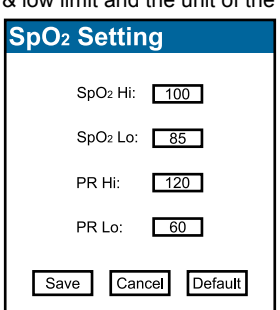


Fig.4.6

Note:

1. Remember to save the settings or you can cancel the settings.

2. Press default, all settings will be reset to factory defaults, please be carefully.

Measurement principle

Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 905nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

Measuring

a.Power on the device

b.Before starting a measurement, verify that you have selected a suitable size sensor for the patient.

c.Connect the end of sensor to the device, the other end to the patient measured finger, as shown in Fig.4.7

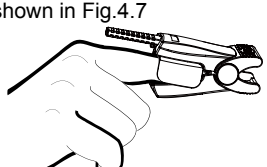


Fig.4.7

Place the measured finger into the probe. Several minutes later, the result will display on the screen as shown in Fug.4.8

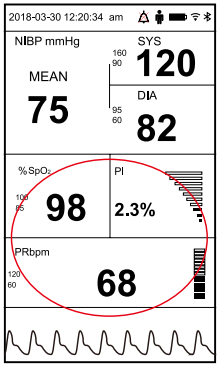


Fig.4.8

Inaccurate measurements may be caused by

- Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin);
- Intravascular dyes such as indocyanine green or methylene blue;
- High ambient light. Shield the sensor area if necessary;
- Excessive patient movement;
- High-frequency electrosurgical interference and defibrillators;
- Venous pulsations;
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
- The patient is in cardiac arrest or is in shock;
- Fingernail polish or false fingernails;
- Weak pulse quality (low perfusion);
- Low hemoglobin;

Maintenance and Cleaning

WARNINGS!

- Disconnect the AC power before cleaning the monitor or sensor.

- Do not immerse sensor completely in water, solvents, or cleaning solutions because the sensor and connector are not waterproof.
- Do not sterilize SpO_2 sensors by irradiation, steam, or ethylene oxide.
- Do not soak the sensor in the detergent liquid; if any abnormity of the sensor or cable is detected, stop using it immediately.

Cleaning:

Moisten the soft cloth or gauze with alcohol and use it to wipe the surface of sensor, and then use the clean cloth to dry it. The same method can be used to clean the light source and photo detector.

Cables can be disinfected by 3% of hydrogen-peroxide or 7% of isopropyl alcohol. Do not immerse the connector into the liquid.

Probe LED Specifications

	Wavelength	Radiant Power
RED	660±3nm	3.2mw
IR	905±10nm	2.4mw

Note:

1. The pulse oximeter equpment is calibrated to display functional oxygen saturation.

2. Pulse oximeter monitor, the pulse oximeter probe and probe cable extender have been validated and tested for compliance with this international standard.

3. Please use the probe and cable that provided by our company.

4. Please Verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result.

5. All the waveforms have been uniformed.

6. Functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.

7.Alarm condition without delay, alarm signal delay, data averaging and other signal processing have no effect of SpO_2 and PR.

Equipment data update period

As shown in the following figure. Data update period of slower average is 8s.

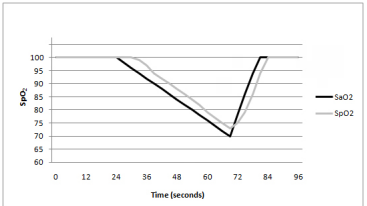


Fig.4.9

CHAPTER 5 MAINTENANCE

5.1 Examination

Before use the device, please check the following things

- Whether the device has mechanic damage
- Check all the cables and accessories
- Check the device functions

Do not use the damage device, or it will injure the patient. Please connect the local consumer service center. The device needs to repair by the professional man.

5.2 Cleaning and Disinfection

Customer should responsible for periodic maintaining of the device and its accessories. Be sure to disconnect power line to the device before cleaning and inspecting.

Warnings!

- Do not use the strong solvents. Such as acetone.
- Do not sterilize the device using autoclaving, ethylene oxide sterilizing.
- Before using the detergent, please follow the manufacturer's instructions to dilute the detergent.
- Do not use the material easy to wear. Such as steel wool and silver polishing agent.
- Do not spray water or cleaning liquor over the product, neither allows any liquid to flow into power switch, connector or other intake.
- Do not leave any detergent in the surface of the device.
- The following detergent can be used:
- Ammonia (diluted)
- Sodium hypochlorite bleacher (diluted)
- Isopropyl alcohol

5.3 Troubleshooting

- No display after power on

Check the power connections, the power adapter.

- No SpO_2 wave and pulse rate display when monitoring

Check the probe connection and the finger temperature

- Cuff inflation lacked when measuring blood pressure.

Cuff too loose or leak, Check the connections of tube.

- When measuring the BP, inflation unfinished but begin to deflate.

Check the battery quantity, if the battery quantity less than 30%, please replace the battery. If still have this problem, please check the BP cable whether it be pressed.

5.4 Warranty and Repair

5.4.1 Warranty and repair content

- Repair response time: AM9:00 to PM17: 30 on Monday to Friday except legal holiday.
- Repair time: AM9:00 to PM17: 30 on Monday to Friday except legal holiday.
- Repair service: Including telephone support, field inspecting, fittings replacement.
- Telephone support: we can give guidance to customer's engineer to inspecting the instrument when you dial our service line. Professional repair engineer online provides technical support.
- Field inspecting: we will send engineers to repair the instrument if necessary. Certified engineers of our company or local repair team trained by our company provide this service.
- Fittings replacement: if necessary, we will replace the damaged fittings according to contract. The damaged fittings should be returned to us expect for special reason.
- Spare machine for repair: it is used to replace the damaged machine for customer using, customer should send the damaged machine to us to repair.
- Repair for sponsoring and contributing machine: customer should send the machine to us to repair.
- Updating software is free.

5.4.2 Exemption and restriction:

- Warranty does not apply to the damage or loss sustained due to well-known act of god, such as fire, earthquake, flood, thunder, cyclone, hail, electrical storm, blast, building collapse, commotion,

etc.

- Non-service items:

a. The cost and insurance of dismantling and testing, overhauling, reinstall, transfer, moving the instrument or parts.

b. Damage or loss sustained due to inspected or repaired by other institute that is not certified

c. Damage or alteration by anyone other than our company authorized service personnel.

- The damage or lose sustained due to connection to peripheral equipment (such as printer, computer etc.), that are not provided by our company are not covered by the warranty.
- Obligation restriction: In the duration of warranty, if the operators use other fittings that are not provided by us, we reserve the right to cancel warranty.

5.4.3 Customer guarantees:

- Read the user manual in details before operation.
- Operation and maintenance according to the user manual, and guarantee the requests of power and environment.

5.4.4 Non-warranty and Non-replacement Policy

- The work environment is not eligible. For example, if the relative humidity exceeds 70%, circuit boards of the instrument may be damaged due to condensate.
- If voltage of power supply is fluctuant and exceeds 240VAC, the power adapter may be damaged.
- There is smear or marks that are not belong to the instrument and cannot be removed from the outside surface of the instrument.
- The instrument or its fittings are mechanically damaged.
- The circuit is short and damaged due to liquor or other stuff flow in the instrument or its fittings.
- All probe and its accessories are not free replacement.
- Leakage of air cell of blood pressure sleeve due to improper storage or operation is not free replacement.
- The malfunction with result from improper repair by anyone other than our company authorized service personnel.
- The malfunction with result from improper use.

- If any code label of parts is damaged or missing, this warranty shall become null and void. For example of code label.

5.4.5 Customer special warranty period

Due to we stipulate the warranty period according to the relevant electronic regulation of country, which we stipulate is on year, accessory is three months. When customer requires to extending the warranty period, you should consider whether it is reasonable. Because electronic product quickly replace, as to the warranty period over three years, purchased accessories may be out of stock. In this case, we will adopt to entirely upgrade or replace the old, you should pay the minimum acceptable cost of renewed device.

5.4.6 Repackaging

Remove all the detectors, leads and accessories and put them into the plastic bag.

Try to use the original packaging case and materials. Any damage due to the improper packaging during the transportation shall be responsible by the user.
If you are still within the period of warranty, please present the warranty card and one copy of the invoice or receipt.

Please present a written note detailing all the troubles when repairing the instrument.

5.4.7 Storage and Transportation

Storage: Temperature: -20℃～55℃, Humidity: ≤93%

Transportation: Transportation: via road, rail or aviation after properly insured and packaged.

CHAPTER 6 SPECIFICATIONS

NOTES:

- 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 personal authorized by our company.
- The illustrations used in this manual may differ slightly from the appearance of the actual device.
- The maximum application time for each type of probe at a single site is 4h.
- The equipment has been calibrated, users do not to calibrate. In order to ensure the accuracy of the probe, please change the probe once a year. Make sure that the type of probe need to be specified.
- The equipment is guaranteed for 5 years from the date of purchase.
- Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Display

The screen dimension: 7inch

The screen resolution: 800×480

The device dimension: 292mm ×168mm × 148mm (±5mm)

Displayed parameters: Patient information, NIBP (systolic and diastolic), TEMP, %SpO_2, PR, PI and PR waveform.

NIBP

Measuring range：

Systolic 60mmHg ~ 255mmHg

Diastolic 30mmHg ~ 195mmHg

Resolution：1mmHg

Accuracy: Max.±3 mmHg

Maximum standard deviation: 8 mmHg

Measuring mode: manual / auto (1 minutes, 3 minutes, 5 minutes, 10 minutes, 20 minutes, 30 minutes, 60 minutes)

SPO_2

Measurement range：70~100%

Resolution：1%

Accuracy：

Classification		Accuracy
no motion	Adults	±2%
	Pediatrics	±2%
motion	Adults	±3%
	Pediatrics	±3%
Low Perfusion	Adults	±2%
	Pediatrics	±2%
	Neonates	±3%

PR

Measurement range： 30bpm～250bpm

Resolution：1bpm；

Accuracy：±2bpm or ±2% (no motion), ±3bpm(motion/ Low PI)

Alarm

Blood Pressure	
Systolic/default	upper limit:160 mmHg，lower limit:90mmHg
Diastolic/default	upper limit:95 mmHg，lower limit:60mmHg
Systolic: upper limit:16mmHg~295mmHg, lower limit:15mmHg~294mmHg Diastolic:upper limit:11mmHg~285mmHg, lower limit:10mmHg ~284mmHg	
PR Default: upper limit:120bpm,lower limit:50bpm upper limit:11bpm~235bpm lower limit: 10bpm~234bpm	

SpO_2
Default: upper limit:100%,lower limit:85%
upper limit:86%~100%,continuously adjust, step: 1%
lower limit:85%~99%,continuously adjust, step: 1%

Note: the upper limit must greater than the lower limit.

Alarm level

High(Level 1)	SpO_2 exceeds the limit
Medium(Level 2)	BP exceeds the limit
	HR exceeds the limit
	Systolic exceeds the limit
	Diastolic exceeds the limit
	Mean exceeds the limit
	The battery less than 5%
Low(Level 3)	SpO_2 probe off
	No finger
	error measurement of BP

Environment Requirements

Operation Temperature: 5℃~40℃

Storage/ Transport Temperature: -20℃~+55℃

Ambient Humidity: ≤80% no condensation in operation; ≤93% no condensation in storage/transport

Atmosphere pressure: 86kPa~106kPa

Power supply

DC7.2V/2600mAh, one rechargeable lithium battery

Operating time: 24 hours continuous working

power adapter: MENB1030A0900F02; Output: 9V DC, 3A

Fuse

3A/32V

Classification

According to the type of protection against electric shock: internal powered equipment.

According to the degree of protection against electric shock: type BF applied part

According to the degree of protection against dust and water: IP22

According to the mode of operation: continuous operation

Applied part

SpO_2 probe

Temperature probe

NIBP cuff

Note: All the applied part contains temperature probe, cuff, electrode plate and SpO_2 probe are compliance with the biological compatibility Standard.

List of accessories

Accessories	Mode	Type	Quantity
SpO_2 probe	M-50E013CS09	9 pin(DB9), 0.9m	1 piece
NIBP cuff for adult	RNC0001A-013B	27CM-35CM	1 piece
NIBP cuff for infant	CM1202	18CM-26CM	1 piece
Power adapter	LXCP30-009A	Input: 100 – 240V AC 0.8A; Output: 9V DC, 3A	1 piece
User manual			1 piece

FCC declaration

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.

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

Note: This product 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 product 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 product 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.

CHAPTER 7 Compliance Information for EMC Test

Electromagnetic emission		
Emission test	Compliance	Electromagnetic Environment – guidance
Conducted and radiated RF emissions	Group 11, Group 1, Class B	Home Healthcare environment

Electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ±15kV air	± 8kV contact ±15kV air	Special healthcare environment The relative humidity should be at least 50%.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Home healthcare environment
Power frequency (50/60Hz) magnetic field IEC61000-4-8	30A/m	30A/m	Home healthcare environment

Electromagnetic immunity to RF wireless communications equipment						
Test frequency (MHz)	Band[a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM[c] ±5kHz deviation 1kHz sine	2	0.3	28

710 745 780	704-787	LTE Band 13,17	Pulse modulation[b]) 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b]) 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
2450	2400-2570	Bluetooth, WALN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217Hz	2	0.3	9

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