Product Information

Product Model: M880

Product Name: Patient monitor

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Statement

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Manufacturer's Responsibility

Only under the following circumstances will manufacturer be responsible for the safety, reliability and performance of the instrument:

- All the installation, expansion, readjustment, renovation or repairs are conducted by the personnel certified by manufacturer.
- The storage condition, operation condition and electrical status of the instrument conforms to the product specification.
- The instrument is used in accordance with the user's manual

About this manual

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your product.

Conventions:

- Bold Italic text is used in this manual to quote the referenced chapter or sections.
- [] is used to enclose screen texts.
- → is used to indicate operational procedures.

Signs in this manual:

- 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.

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Chapter 1 General Introduction

1.1 Intended Use

M880 patient monitor is intended for continuously monitoring or spot checking of CO2, RR, SpO2 and PR signals of single adult, pediatric and neonatal patient.

This device can be used in institutions or units with health care capability. For instance, outpatient departments, emergency rooms and departments of internal medicine in hospitals, and ordinary departments in clinics, nursing hospitals and medical institutions for communities

1.2 Main Unit

1.2.1 Front View

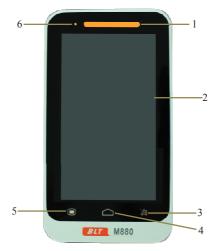


Fig 1-1 Front View of the Monitor

1. Alarm indicating lamp

When an alarm occurs, this lamp will light up as defined below:

- High level alarm: the lamp quickly flashes red.
- Medium level alarm: the lamp slowly flashes yellow.
- Low level alarm: the lamp lights yellow without flashing.

2. Display screen

The device uses resistive touchscreen, using stylus or fingernail will improve sensitivity.

3. Alarm pause button

- It can pause the alarm for 120s when alarm volume is on.
- Pressing it can change the alarm message to prompt message when "Sensor off" alarm happens.

4. Main interface button

- Press this button to return to main interface when it is on menu setting.
- Press this button to shift between different display modes when it is in main interface.

Menu

- Press this button to enter into menu interface when it is on main interface.
- Press this button to return to main interface when it is on menu setting interface.

6. Battery charging indicating lamp

- It is orange when the device is being charged.
- It turns off when the battery is full or device isn't being charged

1.2.2 Rear View



Fig 1-2 Rear View of the Monitor

1.2.3 Side View

Topside:



Downside:



Rightside:



Fig 1-3 Side View of the Monitor

- CO2 connector
- 2. SpO2 probe connector
- 3. Micro USB connector
- Connect with power adapter.
- Export data to computer.
- 4. Shortcut key

Press this button to start or pause the CO2 measurement.

- Power buttom
- Press it about two seconds to turn on when the monitor is on the condition of shutdown.

- Press it about two seconds to turn off when the monitor is on the condition of working.
- Calibration of touch screen
 Press shortcut key firstly and press power button and immediately loose shortcut key, click the center of appearing point on screen. If the calibration passes, it will enter the normall interface, if not, a red fork will appear on screen and continue to calibrate

1.3 Display Views

This device has a function of automatic display rotation (Gravity Activated) which provides for vertical and horizontal positioning to maximizing space utilization and visibility.

1.3.1 Multi-Parameter Display Mode

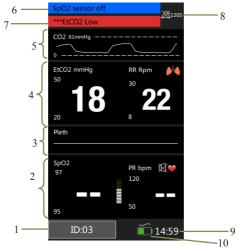


Fig 1-4 Multif-parameter Display Mode

- Patient ID No.: Click and set patient information, its range from 1 to 96.
- SpO2 parameter area: The current SpO2 and its higher and lower alarm limits are shown in the area.
- 3. SpO2 waveform area: The waveform shown in the area is current SpO_2 volume curve.

- CO2 parameter area: The current CO2 and its higher and lower alarm limits are shown in the area
- 5. CO2waveform area: CO2 waveform is shown in the area.
- Physiological alarm area: Current physiological alarm information is shown in the area.
- Technical alarm and prompt information area: Current technical alarm and prompt information are shown in the area.
- Alarm status area: Alarm status symbols are shown in the area
- 9. System time: Current time is shown in the area.
- 10. Battery symbol: The symbol indicates the current quantity of electricity of batteries and whether the device is connecting power source, the alternating-current symbol is above battery symbol when the device is connecting power source.

1.3.2 SpO2 Display mode

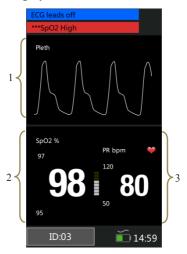


Fig 1-5 SpO2 Display Mode

- SpO2 waveform area: The waveform shown in the area is current SpO₂ volume curve.
- SpO₂ parameter area: The values shown in the area are current SpO₂ value and its higher and lower alarm limits.
- PR parameter area: The values shown in the area are current PR value and its upper and lower alarm limits.

1.3.3 CO2 Waveform Display Mode

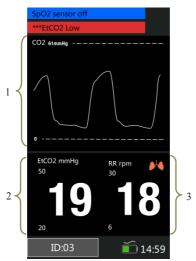


Fig 1-6 CO2 Display Mode

- CO2 waveform display area: Waveform shown in the area is current CO2 waveform 。
- CO2 parameter area: The values shown in the area are current HR value and its higher and lower alarm limits.
- RR parameter area: The values shown in the area are current RR value and its higher and lower alarm limits.

Chapter 2 Safety

2.1 Safety Information



Warning:

- Explosion hazard: Do not use the monitor in the presence of flammable anesthetics mixture with air, oxygen, or hydrogen.
- When the monitor is in use, there should not be any great power appliances as high voltage cables, X-ray machine, ultrasound equipment and electrizer in use nearby.
- Do not open the monitor housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by manufacturer only.
- When the monitor is connecting with high-frequency devices, sensors and cables should avoid touching high-frequency devices, in order to leakage current burns patient.
- Keep the monitor away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.

- Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.
- When the monitor is connecting with high-frequency devices, sensors and cables should avoid touching high-frequency devices, in order to leakage current burns patient.
- The monitor is not designed for the sterilized room.
- The monitor should be handled with care so as to avoid shocks and falls.
- When the monitor is in use, it must be ensured the batteries have sufficient capacity; otherwise there might be such phenomena as starting-up abnormalities or inaccurate measurement data, etc.
- The use of accessories, sensors, and cables other than those specified may result in increased emission, low anti-disturbance and/or create invalid readings of the monitor. It is advised to check it at least once a month.
- The physiological data and alarm messages displayed on the monitor are for reference only and cannot be directly used for diagnostic interpretation.
- Disposable devices are intended for single use only.
 They should not be reused as performance could

degrade or contamination could occur.

- The service life of this monitor is five years. At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of products, please contact manufacturer or its representatives.
- To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patient or personnel.



Caution:

- The monitor does not contain any parts for self-repair by users. The repair of the instrument must be conducted by the technical personnel authorized by manufacturer.
- To ensure patient safety, use only parts and accessories specified in this manual
- When the monitor is connected to AC power, the battery is in a state of being recharged. When it is

unable to be connected to the AC power, the battery can be used to supply power, and at this time it is unnecessary to use the electrical wires, and the instrument can be switched on directly.

- The monitor can only monitor one patient at a time.
- When a defibrillator is applied on a patient, the monitor may have transient disorders in the display of waveforms. If the electrodes are used and placed properly, the display of the monitor will be restored within 10s. During defibrillation, please note to remove the electrode of limb lead to the side of the limb.
- In order to have more accurate measurements results, the monitor should be used in quiet and comfortable environment.
- To guarantee the normal and safe operation of the monitor, a preventive check and maintenance should be conducted for the monitor and its parts every 6 to 12 months (including performance check and safety check) to verify the instrument can work in a safe and proper condition and it is safe to the medical personnel and the patient and has met the accuracy required by clinical use.

 This manual describes all features and options. Your monitor may not have all of them.

2.2 Explanation of Symbols

Symbol	Symbol Note
↓	Type CF applied part, defibrillation protected The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.
(3)	Refer to user's manual.
~	Alternating current
IPX1	Degree of protection against ingress of liquid
Ø	Alarm volume off
A	Alarm paused

Patient Monitor User's Manual

*	Alarm reset
X	QRS volume off
\sim	Date of manufacture
***	Manufacturer
SN	Serial number
ỏ /⊚	Power button
CO2	Short for "Carbon dioxide"
RR	Short for "Respiratory Rate"
SpO ₂	Short for "Pulse Oxygen Saturation"
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.

Chapter 3 Basic Operations

3.1 Unpacking and Checking

Open the package. Parts are as follows in the package .Take out the monitor and its accessories.

Parts	Standard	Optional	Quantity
CO2 nose sampling tube	√		1
CO2 filter	√		1
SpO ₂ probes		√	1
User's manual	√		this manual
QC certificate	√		1
Packing list	√		1
Power adapter	√		1
USB data cable	√		1
Carrying case		√	1
Suction mount		√	1

3.2 Getting Started

Before you start to make measurements, carry out the

following checks on the monitor including all connected modules

- ----Check for any mechanical damage;
- Check for any incorrect connection of all the external cables and accessories



Warning:

- If the monitor is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient. Contact your service personnel.
- To avoid explosion hazard, do not use the monitor in the presence of flammable anesthetics, vapors or liquids.

3.3 Starting the Monitor

Press the button **o**/**o** about two seconds to turn on the monitor. The alarm indicating lamp flashes, and then goes out. The system gives a beep and enters the main screen.

3.4 Screen Brightness Setting

[Menu] → [System], click the right of [Brightness], you can set the screen brightness to a value between 1 to 5, choose the low level brightness to save power.



Caution: If the monitor is used outdoors or the ambient light is strong, set the screen brightness to a higher level.

3.5 Auto-Rotate Setting

[Menu] → [System], click the right of [Auto-rotate] to select [On] or [Off]. If you select [On], the screen can react to the gravity. When the monitor rotates, the screen will rotate the display direction automatically.

3.6 Date & Time Setting

After starting up, you need to set date and time of this monitor. Operations are as follows:

 Select [Menu] → [System] to enter the System menu shown as follows:

- Select 【 Date Format 】 , it can be set to 【 Year/Month/Day 】 、 【 Month/Day/Year 】 or 【Day/Month/Year 】.
- 3. Select [Time Format], it can be set to [24h] or [12h].
- Set the current date and time and select 【OK】 to confirm
 it.

3.7 Patient Information Setting

Please select patient information correctly before measuring, Click 【ID】 on the left bottom of main screen to enter into 【Patient Info.】. You also can select 【Menu】→【System】 → 【Patient Info.】. Setting shown as follow:

- 1. Click the right of **【ID】** to set it values.
- 2. Set [Type] to [Adult], [Pediatric] or [Neonate].
- Caution: The alarm limits of different parameters depend on the patient type. If you set patient type incorrectly, the monitor will judge patient condition by current setting, which might be wrong for your patient.

3.8 Demo Mode Setting

To enter the demo mode:

Select 【Menu】→【System】→【Maintenance】→enter the required password. Click the right of 【Demo】 to turn on.

To exit the demo mode:

Select 【Menu】 → 【System】 → 【Maintenance】 → enter the required password. Click the right of 【Demo】 to turn off.

Ţ

Caution: The Demo mode is for demonstration purpose only. To avoid that the simulated data are mistaken for the monitored patient's data, you should not enter the Demo mode during a patient is being monitored. Otherwise, improper patient monitoring and delayed treatment could result.

3.9 Language Setting

Select 【Menu】→ 【System】→ 【Maintenance】, enter the required password. On 【Factory Mainten.】 interface, you can select 【Language】 and then choose a desired language.

3.10 Checking the Version

Select $[Menu] \rightarrow [System]$ to check the version of the monitor.

3.11 Restoring the Factory Configuration

If you have changed the system's configuration and want to restore the factory configuration, follow this procedure:

- Select 【Menu】 → 【System】.
- Select [Set to Default], popping up a confirming window, select [OK] to restore the factory configuration.

3.12 Shutting off the Monitor

Pressing power button about 2s can turn off the monitor.

- 1. Confirm that the patient monitoring is finished.
- 2. Disconnect all sensors and cables form the monitor.
- 3. Press the power button and hold it for 2s to turn off the monitor If the monitor can't be switched off normally, forced close the monitor by pressing and holding the power switch more than 5s. This may cause some damages to the device.

The device will turn off automatically if any operation or measurement is going on. **Auto power-off setting:** 【Menu】→

【System】→【Maintenance】, enter the required password, click the right of 【Auto power-off setting】, you can select "off", "10min", "30min".

Chapter 4 Alarm

Alarm refers to a prompt that is given by the monitor for medical personnel through visual, audible and other means when a vital sign appears abnormal or the monitor occurs technical problem.

Some Note: The monitor generates all the audible and visual alarms through speaker, alarm lamp and screen. When the monitor powers on, the alarm lamp will be lighted in red and yellow one time and the speaker will give a beep voice, which indicates the alarm system of the monitor is working normally.

4.1 Alarm Categories

By nature, the monitor's alarms can be classified into three categories:

1. Physiological alarms

Physiological alarms are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition. Physiological alarm message are displayed in the physiological alarm area.

Technical alarms

Technical alarms are triggered by a device malfunction or a patient data distortion due to improper operation or system problems. Technical alarm messages are displayed in the technical alarm area.

3. Prompt messages

As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the pulse monitor will show some messages telling the system status. Prompt messages are displayed in the technical alarm area.

4.2 Alarm Levels

- By severity, the monitor's physiological alarms can be classified into three categories: high level alarms, medium level alarms and low level alarms.
 - High level alarms

Indicate that the patient is in a life threatening situation and an emergency treatment is demanded.

■ Medium level alarms

Indicate that the patient's vital signs appear abnormal and an immediate treatment may be required.

Low level alarms

Indicate that the patent's vital signs appear abnormal and an immediate treatment may be required.

By severity, the monitor's technical alarms can be classified into four categories: high level, medium level alarms, low level alarms and prompt message.

Caution:

- The levels of technical alarms are predefined before the monitor leaves the factory and cannot be changed by users.
- The level of technical alarm can't be changed by the user.

4.3 Alarm Indicators

When an alarm occurs, the monitor will raise user's attention by the following indications:

- Alarm tone: According to alarm level, speaker in the monitor gives alarm sound in different tone.
- Alarm lamp: According to alarm level, alarm lamp on monitor flashes in different color speed.
- Alarm message: Alarm message are displayed on the

screen.

- Flashing numeric: The numeric of parameter in alarm flashes.
- Caution: For different alarm levels, the alarm lamp, alarm tone and alarm messages presented are different.

4.3.1. Alarm Tone

The different level alarms are indicated by the system in following different audio ways:

Alarm level	Audible prompt
High	"DO-DO-DODO-DO,DO-DO-DODO-DO"
Medium	"DO-DO-DO"
Low	"DO-"

4.3.2. Alarm Lamp

When an alarm occurs, the alarm levels are indicated in the

following different visual ways:

Alarm level	Visual prompt
High	Alarm lamp flashes in red with 2 Hz.
Medium	Alarm lamp flashes in yellow with 0.5 Hz.
Low	Alarm lamp lights on in yellow without flashing.



- When multiple alarms of different levels occur at the same time, the monitor will select the alarm of highest level give visual and alarm indications.
- When multiple alarms occur at the same time, the alarm message will be displayed in the alarm area in turn.

4.3.3. Alarm Message

When an alarm occurs, the alarm message will be displayed in the alarm area:

The system uses the following symbols to match the alarm level of physiological alarm messages:

High level alarms: ***

Medium level alarms: **

Low level alarms: *

The system uses different background colors for the alarm message to match the alarm level:

High level alarms: red

Medium level alarms: yellow Low level alarms: yellow Prompt message: blue

4.3.4. Flashing Numeric

When a physiological alarm occurs, the numeric of parameter will flash.

4.4 Alarm Status Symbol

To identify the control for alarm paused or to indicate that the alarm system is in the alarm system is in the alarm paused state.

indicates the alarm sound is turned off.

To identify the control for alarm reset.

4.5 Alarm Tone Configuration

1. The minimum alarm volume setting.

Select 【Menu】 → 【System】 → 【Maintenance】, enter the required password, select 【Machine Mainten.】 → 【Alarm Setup】 → 【Min.Alm.Vol.】, you can select "Off, High, Mid, Low".

2. Alarm volume setting

Select 【Menu】 → 【System】 → 【Alarm Volume】, you can select from X to 4. X indicates the minimum alarm volume.

4.6 Pausing Alarms

Press the button \(\otimes \) on the front panel of monitor, you can suspend all alarm indicators of the monitor:

- The visual alarm and audible alarm are all suspended.
- The parameters of physiological alarm stop flashing.
- The alarm message in the physiological alarm area will not be displayed.
- The remaining time and the icon will be shown in the physiological alarm area.

After the alarm paused time, the monitor will automatically cancel the alarm pausing. Press again the button 🖄, the alarm pausing can be cancelled by manual operation.

4.7 Shutting off the Alarm Volume

Set the **[Min.Alm.Vol.]** and **[Alarm Volume]** to **[off]** to shut off the alarm volume. Then there will be a symbol shown in the alarm status area. The alarm lamp and alarm messages are still active after the alarm volume is off. The audible alarm is reactivated automatically when:

- The factory configuration is finished;
- Set the alarm volume to a non-off value.

When a factory configuration is selected, the alarm volume of the monitor may be lower than the minimum alarm volume. In this case the alarm volume is automatically adjusted according to the minimum alarm volume.



Warning:

- When the alarm sound is switched off, the monitor will give no audible alarm tones even if a new alarm occurs.

 Therefore the user should be very carefully about whether to switch off the alarm sound or not.
- Don't rely exclusively on the audible alarm system for patient monitoring. Adjusting alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.

4.8 Alarm Reset

Select 【Menu】→【System】→【Maintenance】→enter the required password, select 【Machine Mainten.】→【Alarm Setup】. You can turn on alarm reset. Alarm reset will be displayed on the interface of system.

Select $[Menu] \rightarrow [System] \rightarrow [Alarm reset]$. After licking alarm reset 2:

- You can reset current alarm system, it will exit alarm pause if it is on the condition of alarm pause.
- It only turns off audible alarm, the visual is going on for the existing alarm.

4.9 When an Alarm Occurs



Note: When an alarm occurs, you should always check the patient's condition first.

Check the alarm message appeared on screen. It is needed to identify the alarm and action appropriately, according to the cause of the alarm.

1. Check the patient's condition.

- 2. Identify alarming parameter and alarm category.
- 3. Identify the cause of the alarm.
- 4. Silence the alarm, if necessary.
- When cause of alarm has been over, check that the alarm system is working properly.

You will find the alarm message for the individual parameter in *Appendix C Alarm message*.

Chapter 5 Measuring CO2

5.1 Introduction

The monitor adopts infrared absorption technology to measure the carbon dioxide (CO₂) concentration in the breathing airway of patient. Because CO₂ molecule can absorb infrared light of special wavelength, and the amount of absorbed infrared light directly relates to the concentration of CO₂, therefore while the infrared light radiated from the infrared light source passing through the gas sample containing CO₂, part of energy will be absorbed by CO₂ in the gas. At another side of infrared light source, a photodetector is used to measure the remaining infrared energy and convert it to electric signal, which will be compared with the energy of infrared light source and adjusted so as to correctly reflect the CO₂ concentration in the gas sample.

Sidestream: Takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with the CO₂ sensor.

5.2 Safety Information



Warning:

■ Do not position the sensor cables or tubing in any

- manner that may cause entanglement or strangulation.
- Performance is not guaranteed if an item labeled as single patient use is reused.
- Monitor the CO₂ waveform (Capnogram). If you see changes or abnormal appearance check the sampling tube. Replace it if needed.
- Monitor the CO₂ waveform (Capnogram) for elevated baseline. Elevated baseline can be caused by sensor or patient problems.
- Do not operate the CO₂ module when it is wet or has exterior condensation.
- Do not use device on patients that cannot tolerate the withdrawal of 50 ml/min±10 ml/min from the airway or patients that cannot tolerate the added dead space to the airway.
- Do not connect the exhaust tube to the ventilator circuit.

5.3 Monitoring Procedure

 The measurement value will be more accurate if the monitor has 2 minutes' warming-up time. To connect the CO2 filter with 3-way joint of the loop of anesthetic machine by sampling tube, or to directly connect patient's nose by the hose.

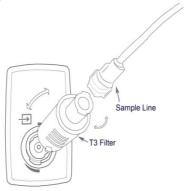


Fig 5-1-1 Connection of Sampling and Filter



Fig 5-1-2 Connection of Sampling with 3-way joint or patient's nose



Note:

- Inserting the sampling tube into the receptacle automatically starts the sampling pump. Removal of the sampling tube turns the sample pump off.
- To remove the CO2 filter from CO2 connector, press and rotate anticlockwise the filter, and then pull out filter.

- Connect CO2 filter into CO2 connector and rotate CO2 filter closewise.
- Connect sampling tube into CO2 filter. If the sampling tube is occluded or damaged, perform a "Check sampling line" on screen..
- Ensure that the CO2 sensor exhaust tube vents gases away from the sensor environment.
- 5. Using the shortcut key on the right of monitor to start or pause CO2 measurement.

Caution:

- Always disconnect the filter from the CO₂ connector when not in use.
- Do not insert the things other than filter into CO2 connector.
- The sampling tubes are disposable. Please keep the sampling tube clean, and prevent the tube from clogging by dust. It is advised to replace the sampling tube every 12h (up to 120h of use with filter tip), the sampling tube leaks or has been damaged and contaminated.

5.4 CO2 Display

CO2 parameter display

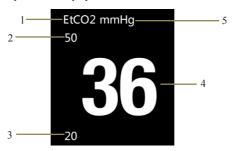


Fig 5-2 CO2 Display

1.CO2 label 2.CO2 high alarm limit

3. CO2 low alarm limit 4. CO2 value

5. CO2 unit

• CO2 waveform display



Fig 5-3 CO2 Waveform Display

5.5 Respiratory Rate

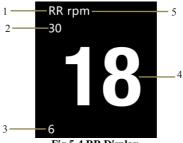


Fig 5-4 RR Display

RR label 1.

- 2. RR higr alarm limit
- 3. RR low alarm limit
- 4. RR value

5. RR unit

5.6 Setting CO2

Select 【Menu】 → 【CO2 Setup】, enter into CO2 setup interface.

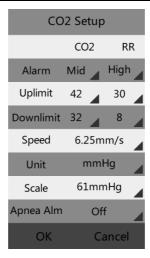


Fig 5-5 CO2 Setup Interface

5.6.1 Setting CO2 and RR Alarm

Click the right of **【Alarm】**, you can set CO2 and RR Alarm, you can select "Mid, High".

5.6.2 Setting CO2 and RR Alarm Limits

Click the right of **[Uplimit]** or **[Downlimit]**, you can set up limit and down limit of CO2 and RR. Attention: The high

alarm limit should greater than the lower one.

5.6.3 Setting CO2 Scan Speed

Select scan speed of CO2 waveform. Click the right of **[Speed]**, you can select "6.25 mm/s, 12.5mm/s, 25 mm/s".

5.6.4 Setting CO2 Unit

Click the right of [CO2 Unit], you can select "mmHg, %, kPa"

5.6.5 Setting Scale

You can adjust the position of wave scale manually, and the waveform amplitude will vary along with it. Click the right of **[Scale]**, you can select "61mmHg、76mmHg、91 mmHg、106 mmHg".

5.6.6 Setting Apnea Alarm

You can select the apnea time as required in the options. The monitor indicates an alarm when a pre-adjusted time has elapsed since the last detected breath. Click the right 【Apnea Alm】, you can select "Off, 5s, 10s, 20s, 40s, 60s, 80s, 100s, 120s".

5.7 CO2 Zero

While zeroing is recommended the first time the monitor is connected to the filter, it is only absolutely necessary when the message "Zero Required" is displayed.

Follow these steps:

- Ensure that the sampling tube is not connected to the patient or close to any source of CO2 (including the patient's, your own, exhaled breath and ventilator exhaust valves).
- Select [Menu] → [System] → [Maintenance], enter password.
- 3) Select 【Machine Mainten.】→【CO2 Setup】→【CO2 Zero】, The unit zeroes the module and displays the Zero In Progress message for approximately 15-20 seconds. The message disappears upon completion of the zeroing.

Caution:

- Always ensure that the filter is properly connected to the CO2 connector before zeroing.
- Do not attempt zeroing for 20 seconds after removing the sampling tube from the patient's airway. This time

- allows any CO2 remaining in the sampling tube to dissipate before zeroing.
- Do not attempt to zero the monitor while the sampling tube is in the patient's airway.
- Do not attempt zeroing if the temperature is not stable.
- Zeroing with CO2 in sampling tube can lead to inaccurate measurements or other error conditions. If you attempt zeroing while CO2 remains in sampling tube, the time required to zero the monitor may be increased.

5.8 Calibration

The monitor has already been calibrated before leaving factory. User can directly apply it to measuring in normal conditions, to the exclusion of the below conditions.

For Sidestream CO₂ module, please carry out gain calibration and manual offset calibration, when the following conditions happened:

- The module has been used for between half a year and one year.
- —The accuracy of CO₂ reading has been doubted by clinical physician.

- ——After the latest calibration, atmospheric pressure or height above sea level varies evidently.
- Caution: User may only calibrate the device under the instruction of the technical personnel authorized by manufacturer. Moreover, incorrect calibrating procedure may result in incorrect reading.

5.9 Removing Exhaust Gases from the System

Warning: When using the Sidestream CO2 measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, or to the anesthesia machine/ventilator, to avoid exposing medical staff to anesthetics.

This monitor removes exhaust gas to outside directly.

Chapter 6 Measuring SpO2

6.1 Introduction

The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, usually shortened as SpO_2) adopts the principles of light spectra and volume tracing. The LED emits lights with two specific wavelengths, which are selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin. The optical receptor measures the changes in the light intensity after the light passes the capillary network and estimates the ratio of oxygenated hemoglobin and the total hemoglobin.

Wavelengths of the light emitted by the pulse oximeter probe are nominally 660nm for red LED and 940nm for infrared LED.

6.2 Safety Information



Warning:

- Use only SpO2 sensors specified in this manual. Follow the SpO2 sensor's instructions for use and adhere to all warnings and cautions.
- When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's conditions.
- Do not use the monitor and the SpO2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.
- Prolonged continuous monitoring may increase the risk of unexpected changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
- Measurements and pulse signals can be affected by certain environmental conditions, sensor application

errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.

- Check the SpO2 sensor and its package for any sign of damage before use. Do not use the sensor if any damage is detected.
- When disposing the disposable SpO2 probe or useless SpO2 probe, please observe all local, state, and federal regulations that relate to the disposal of this products or similar products.
- Caution: In case it is necessary to add a clip to fix the fingertip sensor, the cable instead of the sensor itself should be clipped. Please note that the cable of sensor should not be pulled with force.

Note:

- The pleth wave is not equal to the intensity of PR signal.
- The monitor does not provide automatic

self-examination alarm signal and the operator has to use SpO_2 simulator for self-examination.

6.3 Monitoring Procedure

1. Selecting SpO₂ Sensor

Depending on the patient category, weight and application site, you can select the SpO₂ sensor as required.

2. Connecting SpO2 Sensor

Plug the SpO₂ sensor cable into the SpO₂ connector on the measurement module.

3. Applying SpO2 Sensor

Clean the application site, such as colored nail polish, and apply the sensor to the patient



Warning:

- Do not use the SpO2 sensor on a limb where the NIBP cuff is applied. This may result in inaccurate SpO2 reading due to blocked blood flow during cuff inflation.
- Do not conduct SpO2 measurement on the finger smeared with nail polish, otherwise unreliable

measurement results might be produced.

When using finger sensor, make sure the nail faces to the light window.

6.4 SpO2 Display

• Parameter Display

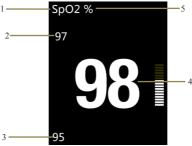


Fig 6-1 SpO₂ Parameter

1. SpO₂ label

- 2. High alarm limit of SpO₂
- 3. Low alarm limit of SpO₂
- 4. SpO₂ value

 $5. \; SpO_2 \; unit$

Waveform Display

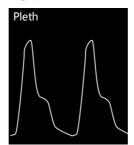


Fig 6-2 SpO₂ Volume Curve

6.5 PR Display

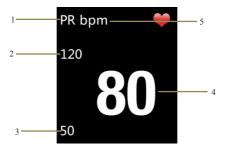


Fig 6-3 PR Display

1. PR label

- 2. High alarm limit of PR
- 3. Low alarm limit of PR
- 4. PR value
- 5. PR unit

Caution: During the monitoring of HR and PR, displaying of HR has priority. That is PR will be displayed only when there isn't HR monitoring.

6.6 Setting SpO2

Select 【Menu】→【SpO2 Setup】, enter into SpO2 Setup interface.



Fig 6-4 SpO2 Setup

6.6.1 Setting SpO2 Alarm

Click the right of **【Alarm】**, you can set alarm level of SpO₂ and PR, you can select "**Mid, High**"

6.6.2 Setting SpO2 Alarm Limits

Click the right of **[Uplimit]** or **[Downlimit]**, you can set the SpO2 uplimit and downlimit. Attention: The high alarm limit should greater than the lower one.

6.6.3 Setting Scan Speed

Click the right of **[Speed]**, you can select "6.25 mm/s, 12.5mm/s, 25 mm/s".

6.6.4 Setting Average Time

Click the right of [Avg Time], you can select "4s, 8s, 16s".

6.6.5 Setting QRS Volume

Click the right of **[QRS Vol.]**, you can select "Off, High, Mid, Low".

6.7 Setting Desat Limit

SpO₂ desat means when SpO₂ measuring value is lower than

the desat limit, a high physiological alarm will be trigged. Its setting is as follows.

- Select [Menu] → [System] → [Maintenance], enter the required password.
- Select 【Machine Mainten】 → 【SpO2 Setup】 → 【Desat limit】, click the right of 【Desat limit】 to set its value.

Chapter 7 Trend Review

7.1 Introduction

Select 【Menu】 → 【Trend】 to enter trend reviewing window. In the window, you can review CO2, RR, SpO₂ and PR data stored before

7.2 Review Interface

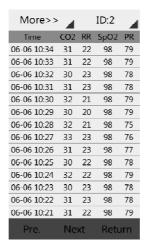


Fig 7-1 Review Interface

If the trend date is not only one page, you can turn pages by the next/return button.

7.3 Review Setup

Click the right of **[ID]** to select patient's ID, you can review patient's trend review by selecting different ID.



Fig 7-2 ID Review Interface

Click the right of **[More]** on the top of review interface, the drop-down window shown as following:

More>>		ID:2			
Save Time		RR	SpO2	PR	
Delete		22	98	79	
		22	98	79	
Delete All .		23	98	78	
		23	98	78	
Transmission ¹		21	98	79	
06-06 10:29	30	20	98	79	
06-06 10:28	32	21	98	75	
06-06 10:27	33	23	98	76	
06-06 10:26	31	23	98	77	
06-06 10:25	30	22	98	78	
06-06 10:24	32	22	98	79	
06-06 10:23	30	23	98	78	
06-06 10:22	31	23	98	78	
06-06 10:21	31	22	98	79	
Pre. I	Next		Retu	Return	

Fig 7-3 The drop-down Window of "More"

You can set [Save time], [Delete], [Delete all],

[Transmission] in this interface.

- Save time: To adjust recording time, you can select"10s, 30s, 1min, 2 min, 5min, 10min".
- **Delete**: To delete trend data of the selected ID No.
- **Delete all**: To delete trend data of all patients.
- **Transmission**: To send trend. Before the operation, "review system of monitoring data" provided by manufacturer must be opened, and connect computer and

monitor with the USB connector. After sending all the trend data, you can check them in the computer.

Chapter 8 Battery

8.1 Introduction

A rechargeable and maintenance-free battery is designed for Patient Monitor, which enables continuous working when AC power off.

When r a lithium ion battery is used, the battery icon indicates the battery status as follows:

- 1. Indicates that the power of the battery is full;
- 2. Indicates that the power of the battery is 3 grids left;
- 3. Indicates that the power of the battery is 2 grids left;
- 4. Indicates that the power of the battery is 1 grid left;
- 5. Indicates that the battery is almost depleted.

Battery power supply can only last for a period of time. If the voltage of batteries is too low, an alarm of "Battery Low" will be triggered. Please insert the monitor to battery charger to charge the battery. The monitor will be switched off automatically 10 minutes after the first "Battery Low" alarm is given.

8.2 Charging the Battery

To charge the battery:

- 1. Connect the Micro USB in power adapter,
- Connect the other connector of Micro USB in the monitor, and plug the adapter into the AC mains,
- The indicating lamp on the monitor is on to indicate that the battery is in charge,
- When the battery charging indicating lamp on the monitor turns off, the battery is fully charged.

8.3 Optimizing Battery Performance

A battery needs at least two optimizing cycles when it is put into use for the first time. A battery cycle is one complete, uninterrupted charge of the battery, followed by a complete, uninterrupted discharge of the battery. A battery should be conditioned regularly to maintain its useful life. Condition a battery once when it is used or stored for two months, or when its run time becomes noticeably shorter.

To optimize a battery, follow this procedure:

 Disconnect the monitor from the patient and stop all monitoring and measuring procedures.

- Place the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 4 hours.
- Remove the AC mains and allow the monitor to run from the battery until it shuts off.
- Replace the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 4 hours.
- 5. The optimizing of the battery is over.

8.4 Checking the Lithium Battery

The performance of a battery may deteriorate over time. To check the performance of a battery, follow this procedure:

- Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
- Place the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 4 hours
- Disconnect AC mains and allow the monitor to run on the battery until it shuts off.
- The operating time of a battery reflects its performance directly.

8.5 Disposing of the Batteries

Batteries that are damaged or depleted should be replaced and discarded properly. Dispose of used batteries according to local regulations.



Warning: Do not disassemble batteries, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, or leak, causing personal injury.

Chapter 9 Maintenance and Cleaning

9.1 Introduction

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.
- 2. Do not immerse part of the equipment in the liquid.
- 3. Do not pour liquid onto the equipment or accessories.
- 4. 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).



Warning:

- Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the equipment.
- For optimal performance, product service should be performed only by qualified service personnel



Caution: If you spill liquid into the equipment of accessories, connect you service personal or us.

9.2 Seasonal Safety Checking



Note: To ensure the performance and safety of equipment, it must be checked after using 1 year.

When check the equipment, please contact professional technology engineers.

Please clean the plug of power cord at least once a year. Too much dust on plug may cause the fire.

The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the following tests, the device has to be repaired.

- ① Inspect the equipment and accessories for mechanical and functional damage.
- ② Inspect the safety relevant labels for legibility.
- 3 Verify that the device functions properly as described in the

instructions for use.

4 Test the earth leakage current according IEC 60601-1 Limit:

NC 500μA, SFC: 1000μA.

⑤ Test the enclosure leakage current according to IEC 60601-1:

Limit: NC 100µA, SFC: 500µA.

⑥ Test the patient leakage current (normal operation) according IEC 60601-1

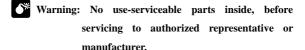
Limit: type CF: for a.c.: 10μA, for d.c.: 10μA.

 $\ensuremath{\overline{\bigcirc}}$ Test the patient leakage current under single fault condition according IEC 60601-1

Limit: type CF: for a.c.: 50μA, for d.c.: 50μA.

® Test the patient leakage current Mains voltage on applied part: According IEC 60601-1:

Limit: type CF: for a.c.: 50uA.



9.3 Cleaning the Monitor

- Common detergent and non-corrosive disinfectant used in hospital can be applied to clean monitor, however you must be aware that many kinds of detergents must be diluted prior to utilization, and please use it according to the instruction of detergent manufacturer.
- 2. Avoid the use of alcohols, amino or acetonyl detergent.
- 3. The enclosure and screen of monitor shall be free of dust, and they can be wiped with lint-free soft cloth or sponge soaked in detergent. While cleaning, be careful and do not spill liquid onto the instrument and keep any liquid out of it. When wiping the side panel of monitor, you must be especially careful to keep water out of all kinds of cable and outlet on the panel.
- Do not use abrasive material including wire brush or metal brightener during cleaning because this material will damage the panel and monitor screen.
- 5. Do not submerge the monitor in liquid.
- 6. While cable or plug of attachment accidentally gets wet, please rinse it with distilled water or deionized water and dry it in the environment of temperature 40°C to 80°C for at least one hour.

9.4 Cleaning SpO2 Sensor

- The casing of the sensor and light tube can be cleaned with swab or non-velvet soft cloth dipped with medical alcohol.
- The sensor cable can be cleaned or sterilized with Hydrogen Peroxide 3% or isopropyl alcohol 70%.
- It is forbidden to put the monitor in high-pressure containers and put the sensor directly in liquid.



Warning: Do not reuse or disinfect the disposable SpO2 sensor.

9.5 Disposal

Dispose of the monitor in accordance with local environment and waste disposal laws and regulations. For the disposal of SpO2 sensor and ECG cable, follow local regulations regarding disposal of hospital waste.

Chapter 10 Accessories



Warning:

- Use only accessories specified in this manual. Using other accessories may cause damage to the monitor.
- Disposable accessories are designed for single-patient use only. Reuse of them may cause a risk of contamination and affect the measurement accuracy.
- Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.

Туре	Mode	PN
	CO2 Filter	15-100-0184
	CO2 Tube	15-100-0035
CO2	3-Way Joint	15-100-0037
	Adult/ pediatric nose sampling tube	15-100-0187
SpO ₂ sensor	usable, adult	15-100-0013
	usable, pediatric	15-100-0014
	usable, neonatal	15-100-0015

Appendix A Product Specifications

A.1 Safety Specifications

CFDA classification	II
CE classification	IIb
Type of protection against electric shock	II, with internal power or external power device
Degree of protection against electric shock	CF
Degree of protection against hazards of explosion	Ordinary equipment, without protection against hazards of explosion
Degree of protection against ingress of liquid	IPX1
Equipment type	Handheld
Mode of operation	Continuous

A.2 Physical Specifications

Mainframe weight	500g(full configuration, including the
	batteries)
Mainframe size	142mm(W)×78mm(H)×36mm(D)

A.3 Environmental Specifications

	Operating: 5° C to $+40^{\circ}$ C;	
Temperature	Storage: -20° C to $+55^{\circ}$ C;	
Atmospheric	Operating: 860hPa to 1060hPa;	
pressure	Storage: 500hPa to 1060hPa;	
Humidity	Operating: 15% to 85%(non condensing)	
	Storage: 10% to 93%(non condensing)	

A.4 Charging Specifications

A4.1 Charger

Micro USB	Charge, Data export
Power adapter	Input: AC 100~240 V
	Output: DC 5V/2A

A4.2 Battery Requirement

Type	Built-in lithium battery
Voltage	3.7V
capacity	4800mAH
Charging time	3~4h
Run time	>18h

A.5 Hardware Specifications

A.5.1 Display

Size	4.3inch
Resolution	480*272
Touch	Resistive touch
Autorotation	four direction
Direction	

A.5.2 Indicating Lamp

Alarm indicating	1(Yellow/Red), on the top of screen
Battery charging	1 (orange)
indicating lamp	When charged, it lights orange.
	When fully charged or not charged, it
	doesn't light

A.5.3 Audio Indicating

Speaker	Gives audible alarm, button tone and
	QRS tone
	Supports Pitch Tone and multi-level
	volume;
	Alarm tones meet the requirement of IEC

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	60601-1-8.
Alarm pressure	45 dB to 85 dB, Testing place is 1 meter
	from the tone.

A.5.4 Buttons

Power button	Turn on/off
	Start/Pause CO2 measurement
Shortcut key	Short press to achieve the above function,
	long press + power button to achieve
	calibration of LCD

A.6 Data Storage

The changing trends of physiological parameters will be shown in the monitor, you can select optionally PC software, to upload trend review to computer by USB.

Patient ID	1~96
Display way	Trend tabular
SpO2 trend	10s 、 30s 、 1min 、 2min 、 5min 、
interval	10min
Storage	Save when power down

Capacity	500 groups/patient can be stored (only
Capacity	data, no waveform).

A.7 Measurement Specifications

A.7.1 CO2 Specifications

CO2 (Sidestr	eam)
Measureme	Infrared spectrum
nt Way	
Measureme	0—19.7%(0-150mmHg or 0-20.0kPa)
nt Range	
CO2	0%-5.3%(0mmHg-40mmHg), ± 0.3 %(± 2 mm
Accuracy	Hg);
	5.4% - 9.2% (41 mmHg- 70 mmHg), $\pm 5\%$ of
	reading;
	9.3%-13.2%(71mmHg-100mmHg); ±8% of
	reading;
	13.3%-19.7%(101mmHg-150mmHg), ±10%
	of reading.
CO2	0.1mmHg
Resolution	
Gas Flow	60~80ml/min
Rate	

Unit	%, mmHg, kPa
Measureme	3~150 rpm
nt Range of	
awRR	
Measuring	$\pm 1\%$ or ± 1 rpm, whichever is greater
accuracy of	
RR	
Response	<3s
Time	
Calibration	Offset calibration, auto/ manual; gain
	calibration
CO2 Alarm	0—19.7%(0-150mmHg or 0-20.0kPa)
Range	high/low limit can be adjusted continuously
Alarm	Blinking display of the data and parameters,
Indication	text prompts, Three levels of alarming:
	sound-light alarming, alarming with blinked
	data and parameters, and that with text
	prompts.

A.7.2 BLT-SpO2

SpO ₂		
Measurement	0~100%	

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range			
Resolution	1%		
Accuracy	70~100%: ± 2%		
Alarm	Select the high and low alarm limit of		
	SpO_2		
Sensor	Pulse oximetry sensors contain LEDs		
	that emit red light at a wavelength of		
	approximately 660 nm and infrared light		
	at a wavelength of approximately 905		
	nm.		
	The total optical output power of the		
	sensor LEDs is less than 15 mW.		
	This information may be useful to		
	clinicians, such as those performing		
	photodynamic therapy.		
Data update	13s		
period			
Anti-interference	Anti-motion interference		
	Anti-electrotome interference		
Resisting low	With powerful ability of resisting low		
perfusion ability	perfusion, PR amplitude can reach to		
	0.2% with value of SpO2 displaying.		

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Pitch Tone	with
PR	
Measurement	25 bpm ~250 bpm
range	
resolution	1 bpm
accuracy	$\pm 1\%$ or ± 1 bpm, whichever is greater
Alarm	Select the high and low alarm limit of PR

Appendix B Factory Defaults

This section lists the most important factory default settings. These settings can be adjusted and you can load the factory defaults if you need.

B.1 Alarm Setup

Alarm Setup	Factory Default
Alarm volume	Medium
Minimum alarm volume	Low
SpO ₂ Alarm Level	Medium
CO2 Alarm Level	Medium

B.2 System Setup

System setup	Factory Default
QRS volume	medium
Brightness	3
Scan speed	12.5mm/s

B.3 CO2 Setup

CO2 setup	Adult	Pediatric	Neonate
EtCO2 High Limit	50	50	45
EtCO2 Low Limit	20	20	30
RR	Adult	Pediatric	Neonate
RR High Limit	30	30	100
RR Low Limit	8	8	30

B.4 SpO2 Setup

SpO ₂ Setup	Adult	Pediatric	Neonate
SpO2 High Limit	100	100	95
SpO2 Low Limit	90	90	85
PR Setup	Adult	Pediatric	Neonate
PR High Limit	120	160	200
PR Low Limit	50	75	90

B.5 Trend Setup

Trend Setup	Factory Default
Interval	30s

Appendix C Alarm Message

This section lists some important alarm message. In the tables below, "*" means the alarm level is user-adjustable.

C.1 Physiological Alarm

SpO2	Cause	Level
Alarm Messages		
SpO2 Too High *		High、
	A measurement has risen	Medium
SpO2 Too Low *	above the high alarm limit	High、
	or fallen below the low	Medium
PR Too High *	alarm limit	High
		Medium
PR Too Low *		High、
		Medium
SpO ₂ Desat	SpO ₂ measurement has	High
	fallen below the SpO ₂ desat	
	limit.	
No Pulse	The pulse signal was too	High

	weak to be analyzed.	
CO2	Cause	Level
Alarm Messages		
EtCO2 Too High *	A measurement has risen above the high alarm limit	High、 Medium
EtCO2 Too Low *	or fallen below the low alarm limit.	High,
RR Too High		High \ Medium
RR Too Low		High \
Apnea	Resp can't be detected on preset-time.	High

C.2 Technical Alarm

Message	Cause	Level
SpO ₂ Sensor Off	The SpO ₂ sensor detached	T
	the patient or the monitor.	Low

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CO ₂ Sensor Off	The CO ₂ sensor detached the patient or the monitor.		
Communication Error	Communication error or test model error.	Low	
Battery Low	The battery power is low.	Medium	
SpO ₂ Low Perf	The signal detected is weak.	Medium	
CO ₂ measurement over range	CO2 measurement Over range, need verify zero		
CO ₂ sensor error	CO ₂ sensor error.	Low	
CO ₂ sensor Over Temp	Temperature of the sensor is over the normal working temperature.	High	
Check CO ₂ Sampling Line	Sampling line is occluded or damaged. Sampling tube is kinked or pinched. Exhaust tube is blocked.		
Zero Required	The sensor needs verify zero.	High	
CO ₂ sensor no initialized	CO ₂ sensor no initialized	Low	

C.3 Prompt Message

Message	Cause	Level
searching	Searching pulse	
SpO ₂ sensor off	SpO ₂ sensor may be	
	disconnected from the	
	patient or the monitor.	Prompt
Zero in Progress	Zeroing is in progress.	Message
CO ₂ sensor off	Sensor dose not connect	
	with monitor when the	
	monitor is running.	
	After confirming alarm	
	message of sensor off, the	
	alarm message will become	
	prompt message.	

Appendix D EMC

Appendix E Warranty Registration Card

Thank you for purchasing products of BLT!

Please complete this card and mail back to BLT Service Center in ZHUHAI within one week. If you need any support or the defects occur, please feel free to contact us by telephone or fax. Warranty will apply with no charge in the warranty period (exclude accident, misuse, abuse or misapplication). You are also and always welcome to our service center, when you need any special service after warranty. Do not repair the product by any person who is not authorized or trained by BLT.

Product	Model
Serial No.	Contract
Date Installed	Warranty
Name	
Address	
Contact	Tele/fax
Person	

Product name: Patient Monitor

Product type: M880

Manufacturer: Guangdong Biolight Meditech Co., Ltd.

Address: No.2 Innovation First Road, Technical Innovation

Coast, Hi-tech Zone, Zhuhai, P.R.China

Postcode: 519085

PN: 22-067-0006