Product Information

- Product Model: M880
- Product Name: Patient monitor
- Manufacturer: Guangdong Biolight Meditech Co., Ltd.
- After Service Contact Information:

Address: No.2 Innovation First Road, Technical Innovation Coast, Hi-tech Zone, Zhuhai, P.R. China

Fax: +86-756-3399919

Postcode: 519085

Toll-free consultation hot line: +86-400-8818-233

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

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EC Representative Name:

Shanghai International Holding Corp. GmbH (Europe)

EC Representative Address:

Eiffestraβe 80, 20537 Hamburg Germany

Statement

Manufacturer holds the copyright of this manual, and we are also entitled to deal with this manual as confidential files. This manual is only used for operation, maintenance and service of product, someone else can not publish the manual.

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The contents contained in this manual are subject to amendments without notification.

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 conform 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.

Contents

Chapter 1 General Introduction

1.1 Intended Use

M880 patient monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including CO2, RR, SpO2 and PR.

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.

Warning: The monitor is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operations on it.

1.2 Main Unit

1.2.1 Front View

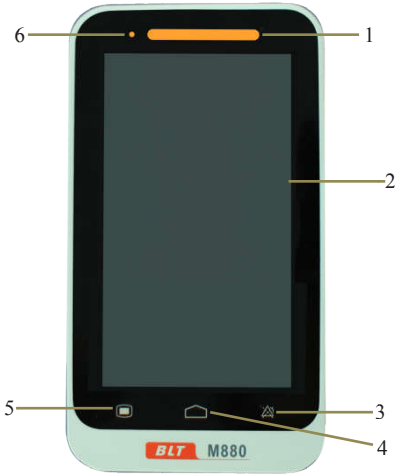

Fig 1-1 Front View of the Monitor

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.
5. 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

1. CO2 connector
2. SpO2 probe connector

3. Micro USB connector

- Connect with power adapter.

Caution：Use only power adapters specified in this manual. Using other power adapters may cause damage, and the power adapter is a part of the product.

- Export data to computer.

Warning:

- **The equipment connected to monitor shall meets requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department or your local representative.**
- **Operator shall be responsible for safe of system after monitor connected to computer.**
- **Don't touch the patient when operating the USB connector, if not, it will generate risk of electric shock.**

4. Shortcut key

   Press this button to start or pause the CO2 measurement.

5. 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 normal 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 maximize space utilization and visibility.

1.3.1 Multi-Parameter Display Mode

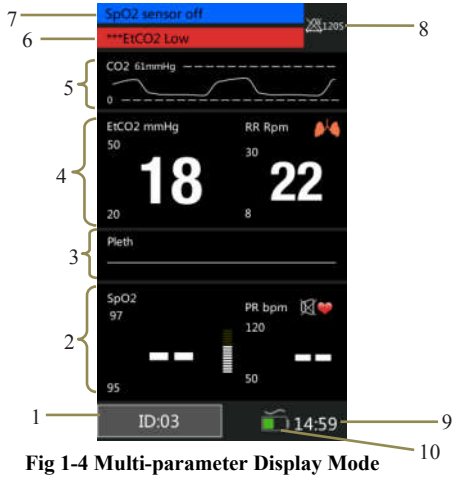

Fig 1-4 Multi-parameter Display Mode

1. Patient ID No.: Click and set patient information, its range from 1 to 96.
2. 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.
4. 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.
6. Physiological alarm area: Current physiological alarm information is shown in the area.
7. Technical alarm and prompt information area: Current technical alarm and prompt information are shown in the area.
8. 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

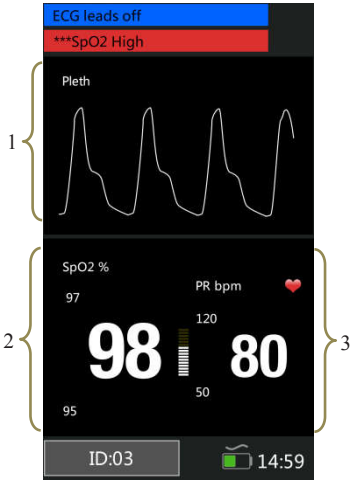

Fig 1-5 SpO2 Display Mode

1. SpO2 waveform area: The waveform shown in the area is current SpO_2 volume curve.
2. SpO_2 parameter area: The values shown in the area are current SpO_2 value and its higher and lower alarm limits.
3. 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

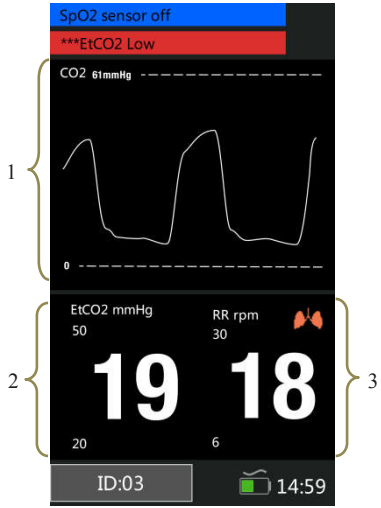

Fig 1-6 CO2 Display Mode

1. CO2 waveform display area: Waveform shown in the area is current CO2 waveform.
2. CO2 parameter area: The values shown in the area are current CO2 value and its higher and lower alarm limits.
3. 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。**
- **The adapter plug is intended to be used as isolation device from the supply mains. Please always make it easily to operate.**

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.**
- **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.
	Refer to user's manual.
	Alternating current
IPX1	Degree of protection against ingress of liquid
	Alarm volume off
	Alarm paused
	Alarm reset
	QRS volume off

	Date of manufacture
	Manufacturer
SN	Serial number
	Power button
CO2	Short for "Carbon dioxide"
RR	Short for "Respiratory Rate"
SpO_2	Short for "Pulse Oxygen Saturation"
PR	Short for "Pulse Rate"
	Contents of the distribution packages are fragile therefore it shall be handled with care.
	This is the correct upright position of the distribution packages for the transport and/or storage.

	Distribution packages shall be kept away from rain and be kept in dry conditions.
	Maximum number of identical transport packages/items which may be stacked on the bottom package, where "6" is the limiting number.
	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 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 ⏻/◉ 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 1to 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:

1. Select **【Menu】→【System】** to enter the System menu shown as follows:
2. Select **【Use 24-hour format】**, it can be set to **【24h】** or **【12h】**.
3. Select **【Date format】**, it can be set to**【YYYY/MM/DD】**、

【MM/DD/YYYY】or【DD/MM/YYYY】.

4. 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 its 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.

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**】→【**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:

1. Select【**Menu**】→【**System**】.
2. Select【**Set to Default**】, popping up a confirming window, select【**OK**】to restore the factory configuration.

Caution: The factory configuration only can be set by manual.

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.

Warning:

- **Setting alarm limits to extreme values that can render the alarm system useless.**
- **Alarm settings are restored automatically after power is interrupted for ≤30s, the alarm setting will lose if the power is interrupted for ＞30s.**

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.

2. 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

1. 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.

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

Caution:

- **The levels of technical alarms are predefined before the monitor leaves the factory and cannot be changed by users.**

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-DO------DO-DO,DO-DO-DO------DO-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.

Caution:

- **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 "**off**, **High**, **Mid**, **Low**".

 **Warning: Auditory alarm signal sound pressure levels, which are less than ambient levels, can impede operator recognition of alarm conditions.**

4.6 Pausing Alarms

Press the button  on the front panel of monitor, you can

suspend all alarm indicators of the monitor about 60s:

- 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.
- The technical alarm message will still be shown in the technical alarm area.
- The alarm of lead-off/sensor-off turns into a prompt message.
- The alarm of lead-off/sensor-off turns into a prompt message.

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 Adjust the Alarm Volume to Zero

Set the **【Min.Alm.Vol.】**and**【Alarm Volume】**to **【0】** to adjust the alarm volume to 0. 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 set to 0. The

audible alarm is reactivated automatically when:

- The factory configuration is finished;
- Set the alarm volume to a nonzero 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:

- **Potential hazard can exist if different alarm pre-sets are used for the same of similar equipment in any single area.**
- **When the alarm sound is adjusted to 0, the monitor will give no audible alarm tones even if a new alarm occurs. Therefore the user should be very carefully about whether to adjust the alarm volume to 0 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】→【Alarm reset】.

Press alarm reset , you can reset 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.
- The audible alarm will be restored when a new alarm occurs.
- The parameters of physiological alarm keep on flashing.
- The alarm of lead-off/sensor-off turns into a prompt message.

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.
5. 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 (CO_2) concentration in the breathing airway of patient. Because CO_2 molecule can absorb infrared light of special wavelength, and the amount of absorbed infrared light directly relates to the concentration of CO_2, therefore while the infrared light radiated from the infrared light source passing through the gas sample containing CO_2, part of energy will be absorbed by CO_2 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 CO_2 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 CO_2 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 CO_2 waveform (Capnogram). If you see changes or abnormal appearance check the sampling tube. Replace it if needed.**
- **Monitor the CO_2 waveform (Capnogram) for elevated baseline. Elevated baseline can be caused by sensor or patient problems.**
- **Do not operate the CO_2 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

1. 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.

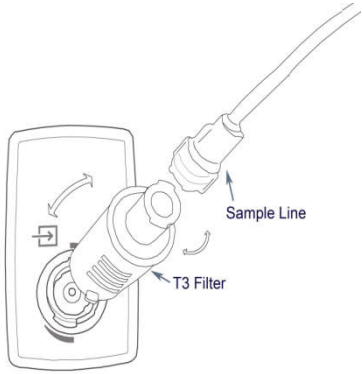

Fig 5-1-1 Connection of Sampling and Filter

Fig 5-1-2 Connection of Sampling with CO2 3-way Stopcock 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.**

2. Connect CO2 filter into CO2 connector and rotate CO2 filter closewise.
3. Connect sampling tube into CO2 filter. If the sampling tube is occluded or damaged, perform a "Check sampling line" on screen..
4. Ensure that the CO2 sensor exhaust tube vents gases away from the sensor environment.
5. Using the shortcut key CO_2 on the right of monitor to start or pause CO2 measurement.

Caution:

- **Always disconnect the filter from the CO_2 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

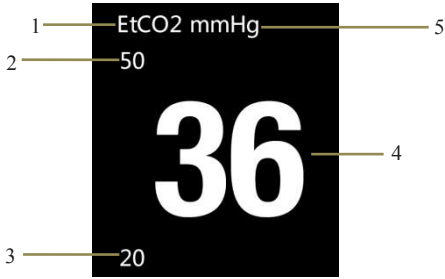

Fig 5-2 CO2 Display

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

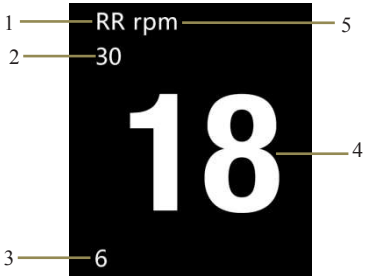

Fig 5-4 RR Display

1. RR label
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 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.

$$\text{SpO2 \%} = \frac{\text{oxygenated hemoglobin}}{\text{oxyhemoglobin + deoxyhemoglobin}} \times 100\%$$

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.

- **A functional tester cannot be used to assess the accuracy of SpO2 of the monitor.**

6.3 Monitoring Procedure

1. Selecting SpO_2 Sensor

Depending on the patient category, weight and application site, you can select the SpO_2 sensor as required.

2. Connecting SpO2 Sensor

Plug the SpO_2 sensor cable into the SpO_2 connector on the measurement module.

3. Applying SpO2 Sensor

Clean the application site, such as colored nail polish, and apply the sensor to the finger of 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**

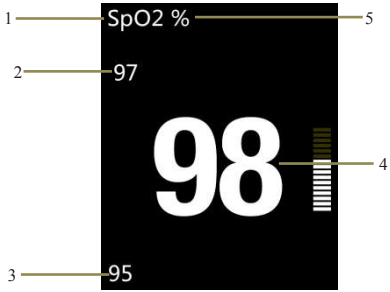

Fig 6-1 SpO_2 Parameter

1. SpO_2 label
2. High alarm limit of SpO_2
3. Low alarm limit of SpO_2
4. SpO_2 value
5. SpO_2 unit

- **Waveform Display**

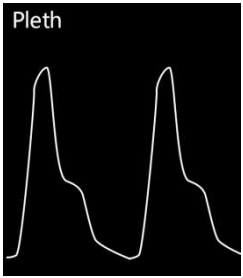

Fig 6-2 SpO_2 Volume Curve

6.5 PR Display

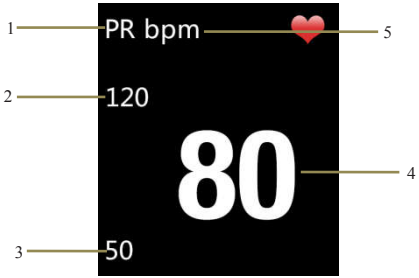

Fig 6-3 PR Display

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

6.6 Setting SpO2

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

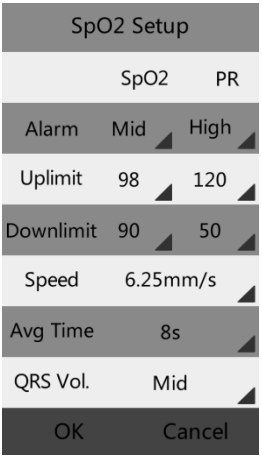

Fig 6-4 SpO2 Setup

6.6.1 Setting SpO2 Alarm

Click the right of 【**Alarm**】, you can set alarm level of SpO_2 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 and PR uplimit and downlimit. Attention: The high alarm limit should greater than the lower one. The downlimit for SpO2 should higher than desat limit.

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

Select the average time for SpO2. The shorter the averaging time is, the quicker the monitor responds to the change in the patient's oxygen saturation level. 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

SpO_2 desat means when SpO_2 measuring value is lower than the desat limit, a high physiological alarm will be trigged. Its

setting is as follows.

1、 Select【**Menu**】→【**System**】→【**Maintenance**】, enter the required password.

2、 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, SpO_2 and PR data stored before.

7.2 Review Interface

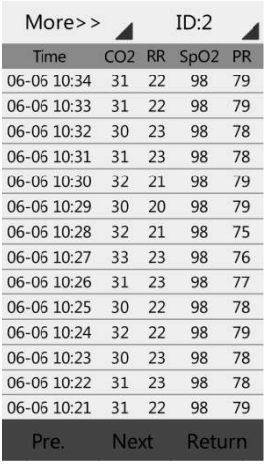

Fig 7-1 Review Interface

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.

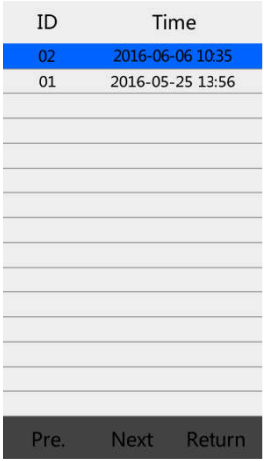

Fig 7-2 ID Review Interface

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

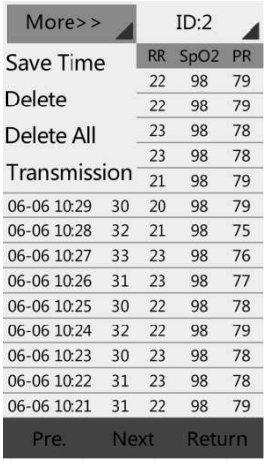

Fig 7-3 The drop-down Window of "More"

You can set 【**Save time**】, 【**Delete**】, 【**Delete all**】, 【**Transmission**】in this interface.

- **Save time**: To adjust recording time, you can select"1**0s, 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.

Warning：The replacement and maintenance of battery shall only be conducted by the manufacture. Please contact to the manufacturer or its representatives.

When 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,
2. Connect the other connector of Micro USB in the monitor, and plug the adapter into the AC mains,
3. The indicating lamp on the monitor is on to indicate that the battery is in charge,
4. 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:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 4 hours.
3. Remove the AC mains and allow the monitor to run from the battery until it shuts off.
4. 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:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for

above 4 hours.

3. Disconnect AC mains and allow the monitor to run on the battery until it shuts off.
4. 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:

1. 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.
5. 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.

⑦ Test the patient leakage current under single fault condition according IEC 60601-1

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

⑧ Test the patient leakage current Mains voltage on applied part: According IEC 60601-1:

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

Warning: No use-serviceable parts inside, before servicing to authorized representative or manufacturer.

9.3 Cleaning the Monitor

1. 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.
4. 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℃ to 80℃ for at least one hour.

9.4 Cleaning SpO2 Sensor

1. The casing of the sensor and light tube can be cleaned with swab or non-velvet soft cloth dipped with medical alcohol.
2. The sensor cable can be cleaned or sterilized with Hydrogen Peroxide 3% or isopropyl alcohol 70%.
3. 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 CO2 accessories, 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.**

Type	Mode	PN/Model
CO2	CO2 Filter	15-100-0184
	CO2 sampling Tube	15-100-0035
	CO2 3-Way Stopcock	15-100-0074
	CO2 nasal cannula，adult ,pediatric	15-100-0187
	CO2 nasal cannula，infant	15-100-0188
BLT-SpO_2 sensor	usable，adult	15-100-0013
	usable，pediatric	15-100-0014
	usable，neonatal	15-100-0015
Power adapter	LXCP12-005	15-048-0020

Appendix A Product Specifications

A.1 Safety Specifications

Classification	Class IIb (Rule 10 of Annex IX of the MDD 93/42/EEC)
Type of protection against electric shock	II, with internal power or external power device
Degree of protection against electric shock	Type CF applied part, defibrillation protected (CO2, SpO2)
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
EMC	Group 1, class A

A.2 Physical Specifications

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

A.3 Environmental Specifications

Temperature	Operating: 5℃ to +40℃；
	Storage: -20℃ to +55℃；
Atmospheric pressure	Operating: 860hPa to 1060hPa；
	Storage: 500hPa to 1060hPa；
Humidity	Operating: 15% to 85%(non condensing)
	Storage: less than 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 hours to 90% 4 hours to 100%
Run time	>18h

A.5 Hardware Specifications

A.5.1 Display

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

A.5.2 Indicating Lamp

Alarm indicating	1(Yellow/Red), on the top of screen
Battery charging indicating lamp	1（orange） 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 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
Shortcut key	Start/Pause CO2 measurement 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 interval	10s 、 30s 、 1min 、 2min 、 5min 、 10min
Storage	Save when power down
Capacity	500 groups/patient can be stored (only data, no waveform).

A.7 Measurement Specifications

A.7.1 CO2 Specifications

CO2 (Sidestream)	
Measurement Way	Infrared spectrum
Measurement Range	0—19.7%(0-150mmHg or 0-20.0kPa)
CO2 Accuracy	0%-5.3%(0mmHg-40mmHg),±0.3%(±2 mmHg)； 5.4%-9.2%(41mmHg-70mmHg), ±5% of reading； 9.3%-13.2%(71mmHg-100mmHg);±8% of reading； 13.3%-19.7%(101mmHg-150mmHg),

	±10% of reading.
CO2 Resolution	0.1mmHg
Gas Flow Rate	60~80ml/min
Unit	%, mmHg, kPa
Measurement Range of awRR	3~150 rpm
Measuring accuracy of RR	±1% or ± 1 rpm, whichever is greater
Response Time	＜3s
CO2 Alarm Range	0—19.7%(0-150mmHg or 0-20.0kPa) high/low limit can be adjusted continuously
Alarm Indication	Blinking display of the data and parameters, text prompts, Three levels of alarming: sound-light alarming, alarming with blinked data and parameters, and that with text prompts.
Recovery time of equipment after defibrillation	5s

A.7.2 BLT-SpO2

SpO_2	
Measurement range	0~100%
Resolution	1%
Accuracy	70~100%：± 2% 0~69%：unspecified
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 period	13s
Anti-interference	Anti-motion interference Anti-electrotome interference

Recovery time of equipment after defibrillation	5s
Resisting low perfusion ability	With powerful ability of resisting low perfusion, PR amplitude can reach to 0.2% with value of SpO2 displaying.
Pitch Tone	with
PR	
Measurement range	25 bpm ~250 bpm
resolution	1 bpm
accuracy	±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 mmHg	50 mmHg	45 mmHg
EtCO2 Low Limit	20 mmHg	20 mmHg	30 mmHg
RR	Adult	Pediatric	Neonate
RR High Limit	30 rpm	30 rpm	100 rpm
RR Low Limit	8 rpm	8 rpm	30 rpm

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 bpm	160 bpm	200 bpm
PR Low Limit	50 bpm	75 bpm	90 bpm

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 Alarm Messages	**Cause**	**Level**
SpO2 Too High *	A measurement has risen above the high alarm limit or fallen below the low alarm limit	High、Medium
SpO2 Too Low *		High、Medium
PR Too High *		High、Medium
PR Too Low *		High、Medium
SpO_2 Desat	SpO_2 measurement has fallen below the SpO_2 desat limit.	High
No Pulse	The pulse signal was too weak to be analyzed.	High

CO2 Alarm Messages	Cause	Level
EtCO2 Too High *	A measurement has risen above the high alarm limit or fallen below the low alarm limit.	High、Medium
EtCO2 Too Low *		High、Medium
RR Too High		High、Medium
RR Too Low		High、Medium
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 the patient or the monitor.	Low
CO_2 Sensor Off	The CO_2 sensor detached the patient or the monitor.	Low

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.	Low
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.	Low
CO_2 sensor no initialized	CO_2 sensor no initialized	Low

C.3 Prompt Message

Message	Cause	Level
searching	Searching pulse	Prompt Message
SpO_2 sensor off	SpO_2 sensor disconnected from the patient or the monitor after starting monitor, resetting alarm, pausing alarm or resetting alarm.	
CO_2 sensor off	Sensor does 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 Guidance and Manufacturer's Declaration of EMC

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

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such and environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission CISPR 11</td><td>Class A</td><td rowspan="3">The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

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

Guidance and manufacture's declaration – electromagnetic immunity			
The *monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of *monitor* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

			Make sure there is not impulse interference >1kV in use environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *monitor* requires continued operation during power mains interruptions, it is recommended that the *monitor* be powered from an uninterruptible power supply or a battery.

Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	If image distortion occurs, it may be necessary to position the *monitor* further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

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

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

			

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *monitor* is used exceeds the applicable RF compliance level above, the *monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *monitor*

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *monitor*

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

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 Person		Tele/fax	

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: 22-067-0009