Product Information

- Product Model: M850
- 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.

- Document No.: J/M850-I-002
- Revision number: V1.0
- Release time: Oct.2016

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.

This manual contains exclusive information protected by copyright laws and we reserve its copyright. Without written approval of manufacturer no parts of this manual shall be photocopied, xeroxed or translated into other languages.

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 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.

Contents

Chapter 1 General Introduction

1.1 Intended Use

M850 Patient monitor is intended for continuously monitoring or spot checking of SpO_2, PR, ECG, HR and RR 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

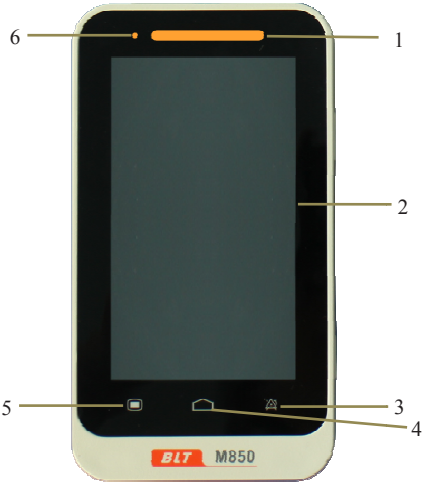


Fig 1-1 Front View of the Monitor

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 "Lead off" or "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

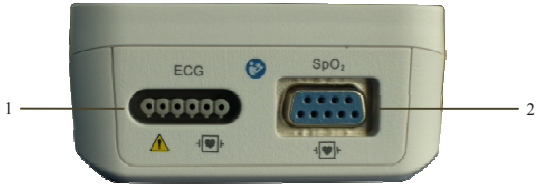
- It is orange when the device is being charged.
- It turns off when the battery is full or device isn't being charged.

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. ECG cable connector
2. SpO2 probe connector
3. Micro USB connector

- Connect with power adapter.
- Export data to computer.

4. Shortcut key

   Press this button to freeze or unfreeze the ECG waveform

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 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

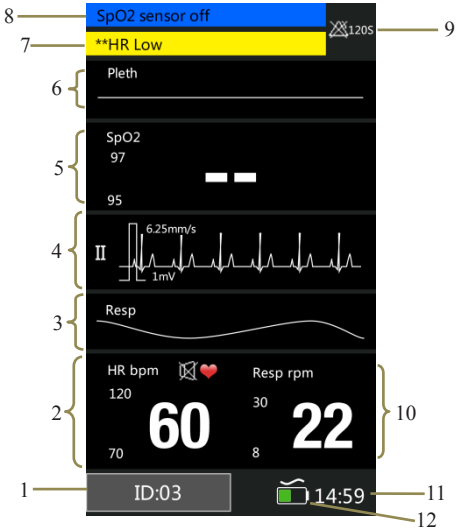


Fig 1-4 Multi-Parameter Display Mode

1. Patient ID No.: Click and then set patient information, its range from 1 to 96.
2. HR parameter area: The current HR parameter and its high and low alarm limits are shown in the area.
3. Resp waveform area: Resp waveform is shown in the area.
4. ECG waveform area: ECG waveform is shown in the

area.

5. SpO2 parameter area: The current SpO2 and its high and low alarm limits are shown in the area.
6. SpO2 waveform area: The waveform shown in the area is current SpO_2 volume curve.
7. Physiological alarm area: Current physiological alarm information is shown in the area.
8. Technical alarm and prompt information area: Current technical alarm and prompt information are shown in the area.
9. Alarm status area: Alarm status symbols are shown in the area.
10. Resp parameter area: The current Resp and its high and low alarm limits are shown in the area.
11. System time: Current time is shown in the area.
12. 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

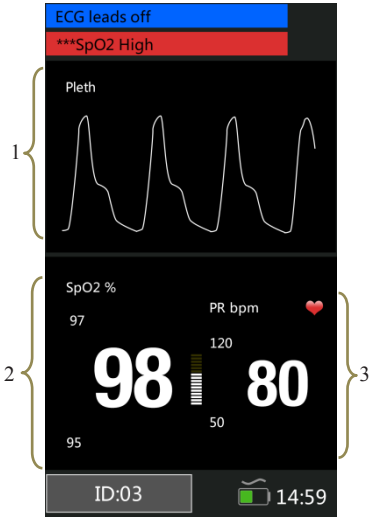


Fig 1-5 SpO2 Display Mode

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 upper 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 ECG Waveform Display Mode

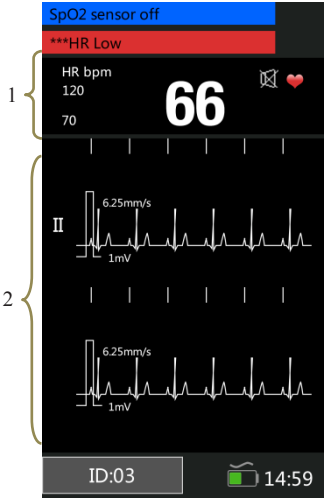


Fig 1-6 ECG Display Mode

1. HR parameter area: The values shown in the area are current HR value and its higher and lower alarm limits.
2. ECG waveform display area: Waveform shown in the area is current ECG waveform.

1.3.4 ECG Waveform Display Mode with RESP

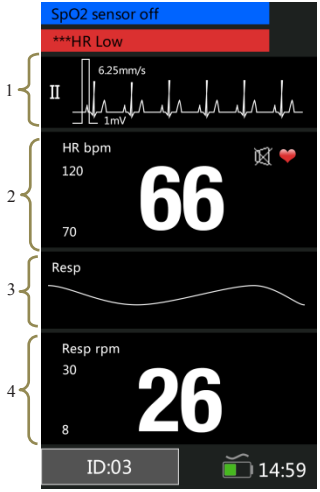


Fig 1-7 ECG Display Mode with RESP

1. ECG waveform display area: Waveform shown in the area is current ECG waveform.
2. HR parameter area: The values shown in the area are current HR value and its upper and lower alarm limits.
3. Resp waveform area: Resp waveform is shown in the area.
4. Resp parameter area: The current Resp and its high and low alarm limits are shown in the area.

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.**
- **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.**
- **For pacemaker patients, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance.**
- **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.
	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
ECG	Short for "Electrocardiogram"
SpO_2	Short for "Pulse Oxygen Saturation"
	Warning：the protection against the effects of the discharge of a cardiac defibrillator is dependent upon the appropriated cable
	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
3-lead/5-lead ECG cable	√		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:

- **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 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:

1. Select**【Menu】→【System】**to enter the System menu shown as follows:
2. 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】** .
4. Set the current date and time and select **【OK】** to confirm it.

3.7 Patient Information Setting

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.

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**】.
3. Select 【**Pace**】to 【**Yes**】when patient with pacemaker.

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 software.

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.

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.

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 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-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 X to 4. X indicates the minimum alarm volume.

4.6 Pausing Alarms

Press the button  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】→【System】→【Alarm reset】**. After licking alarm reset :

- 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.
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 ECG

5.1 Introduction

Before the mechanical contraction, the heart will firstly produce electrization and biological current, which will be conducted to body surface through tissue and humors; the current will present difference in potential in different locations of the body, forming potential difference ECG, also known as body surface ECG or regular ECG, is obtained by recording this changing potential difference to form a dynamic curve. Monitor measures the changes in the body surface potentials caused by the heart of the patient, observe the cardioelectric activities, record the cardioelectric waveforms and calculate the HR through the multiple electrodes connected to ECG cable.

5.2 Safety Information

Warning:

- **It is imperative to only use the ECG electrodes and cables provided by manufacturer or specified in this manual. Users shall use the electrode which has little polarization voltage and little contact resistance.**

- **When conducting defibrillation, it is imperative to only use the ECG electrodes and cables specified by manufacturer.**
- **Check the ECG cable and its package for any sign of damage before use. Do not use the cable if any damage is detected.**
- **Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.**
- **When the electrode polarized voltage is too high, the monitor will indicate the abnormal state by alarm system.**
- **The monitor is protected against defibrillation effect. When applying defibrillator to the patient, the monitor will experience transient disorderly waveforms. If the electrodes are used and placed correctly, the display of the monitor will be restored within 10s. During defibrillation, the chest leads such as V1~V6 should be removed and such limb electrodes as RA, LA, RL, LL should be moved to the side of the limbs.**
- **When you are connecting the electrodes or the patient**

cable, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, make sure that all of the ECG electrodes are attached to the patient, to prevent them from contacting conductive parts or earth.

- **Please check the skin where the electrodes are placed, replace the electrodes or relocate the electrodes in case of skin allergy occurs.**
- **Interference from instruments near the patient and ESU interference can cause problems with the ECG wave.**
- **The monitor cannot be directly applied to heart and cannot be used for the measurement of endocardio ECG.**
- **Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarm, at this time, you should unplug power adapter and supply power by lithium battery.**

5.3 Monitoring Procedure

5.3.1 Skin Preparation for Electrode Placement

Good electrode-to-skin contact is important for a good ECG signal, as the skin is a poor conductor of electricity. It is necessary to deal with the skin properly before placing the electrodes. The steps are shown as follows:

1. Select sites with intact skin, without impairment of any kind.
2. Clip or shave hair from sites as necessary.
3. Gently abrade the skin to remove dead skin cells to improve the conductivity of the electrode site.
4. Wash sites thoroughly with soap and water, leaving no soap residue.(We do not recommend using ether or pure alcohol, because this dries the skin and increases the resistance.)
5. Dry skin thoroughly.

5.3.2 Placing Electrode

1. Preparation before electrode placement

1) Skin preparation (refers to Chapter 5.3.1).
2) Check if the buttons on the electrodes are clean and free of damage.
3) Place the electrodes on the body of patient. Before attaching, smear some conducting cream on the electrodes

if the electrodes are not electrolyte self-supplied.

4) Connect the cable leads to the electrodes through the buttons of the electrodes.

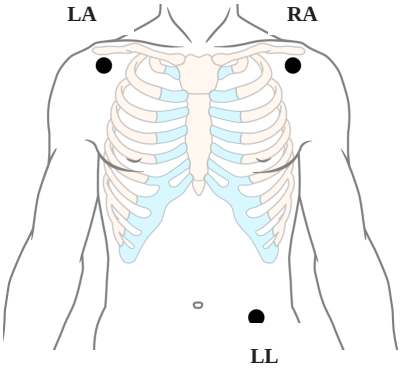
Note:

- **For patients who tremble a lot or patients with especially weak ECG signals, it might be difficult to extract the ECG signals, and it is even more difficult to conduct HR calculation. For severely burnt patients, it may be impossible to stick the electrodes on and it may be necessary to use the special pin-shape electrodes. In case of bad signals, care should be taken to place the electrodes on the soft portions of the muscle.**
- **Check the irritation caused by each electrode to the skin, and in case of any inflammations or allergies, the electrodes should be replaced and the user should relocate the electrodes every 24 hours or at a shorter interval.**
- **When the amplifier is saturated or overloaded, the input signal is medical meaningless, then the equipment gives an indication on the screen.**

2. Electrode Placement

■ **3-Lead**

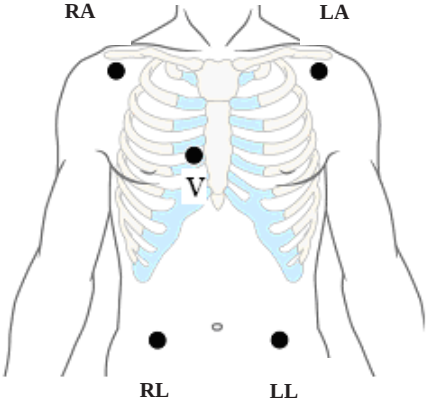
Take the AHA standard as an example, when conducting 3-lead ECG monitoring, use 3-lead ECG cable. The three limb-leads of RA, LA and LL as shown in below figure, will be placed on the relevant locations. This connection can establish the lead of I, II, III.



■ **5-Lead**

Take the AHA standard for example, when conducting 7-lead ECG monitoring, use 5-lead ECG cable. The four limb-leads of RA, LA, RL and LL as shown in below figure, will

be placed on the relevant locations. This connection can establish the lead of I, II, III, aVR, aVL, aVF; according to actual needs, chest lead V can be placed on any of the locations between V_1~V_6, respectively making one lead of V_1~V_6 established.



Warning:

- **To avoid burning, when the electrotome operation is performed, the electrodes should be placed near the middle between ESU grounding pad and electrotome**

and the electrotome should be applied as far as possible from all other electrodes, a distance of at least 15 cm/6 in is recommended.

- **When using the ESU device, avoid placing the electrodes near the ESU grounding pad, otherwise, grate deal interference will influence the ECG signals. The monitor should be placed far from the operating table. Power wires and the ECG cables should be partitioned and should not be in parallel.**

5.3.3 Connecting ECG Cable

Plug the ECG cable into the ECG connector. An ECG waveform and numeric appears on the monitor display. Using the shortcut key ⋈ on the right of monitor to start or pause ECG measurement.

5.3.4 Selecting leads

Depending on the patient to be monitored, you shall select the proper leads. Enter into **【ECG Setup】**to select**【Lead Type】**.

5.4 Checking Paced Status

It is important to set the paced status correctly when you start monitoring ECG.

If the【**Pace**】status has been set to【**Yes**】, If the system detects paced signal, the symbol " | " will be marked on the ECG wave.

To change the paced status, you can review ***3.7 Patient Information Setting.***

Warning:

- **For paced patients, you must set 【Paced】to【Yes】. If it is incorrectly set to【No】, the monitor could mistake pace pulses for regular QRS complexes and fail to alarm during asystole.**
- **Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Keep pacemaker patients under close observation.**
- **For non-paced patients, you must set【Paced】to【No】, otherwise, the system cannot detect the arrhythmia**

related to Ventricular Premature (including PVCs count), and will not conduct ST analysis.

5.5 ECG Display

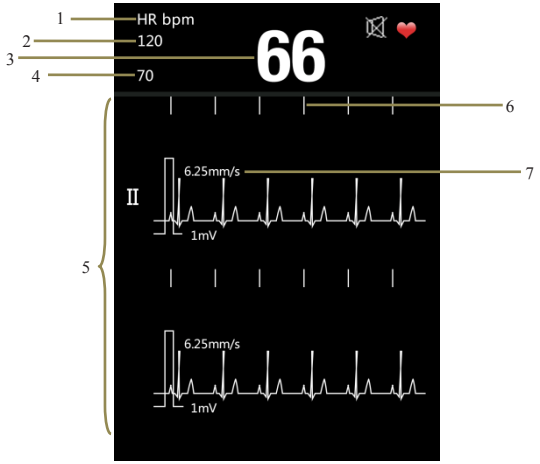


Fig 5-1 ECG Display

1.HR label 2.HR high alarm limit 3.HR value

4.HR low alarm limit 5. ECG waveform

6.Pacemake pulse symbol 7.Scan speed

5.6 Setting ECG

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

Fig 5-2 ECG Setup Interface

5.6.1 Setting HR Alarm

Click the right of 【**HR Alm**】, you can select "**Mid**, **High**".

5.6.2 Setting HR Alarm Limits

Click the right of【**HR Uplimit**】or【**HR Downlimit**】, you

can set the HR uplimit and downlimit. Attention: The high alarm should greater than the low one.

5.6.3 Setting ECG Scan Speed

Select scan speed of ECG waveform. Click the right of **【Speed】**, you can select "**6.25 mm/s、12.5mm/s, 25 mm/s**".

5.6.4 Setting ECG Gain

Select the gain item of ECG waveform. Click the right of **【ECG Gain】**, you can select "**2.5 mm/mV、5 mm/mV、10 mm/mV**".

5.6.5 Setting Lead Type

Select the lead type of ECG input.

- If the monitor only has 3 lead, you can select "**3 lead**" as lead type.
- If the monitor has 3 lead and 5 lead, you can select "**3 lead**" or "**5 lead**" as lead type.

5.6.6 Setting Primary Lead

Select the ECG waveform, and this lead is the key monitoring lead。

- If lead type is 3 lead, you can select "**I，II，III**".
- If lead type is 5 lead, you can select" **I，II，III，aVR，aVL，aVF，Vx**".

5.6.7 Setting Lead Layout

- If lead type is 3 lead, you can select "**Primary Lead**".
- If lead type is 5 lead, you can select" **Primary Lead, 7-Lead**".

5.6.8 Setting QRS Volume

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

Chapter 6 Measuring RESP

6.1 Principle of Measuring

Monitor measures RESP with the method of impedance. When a patient exhales and inhales, changes will take place in the size and shape of the thoracic cavity, causing consequent changes in the impedance between the two electrodes installed at the patient's chest. Based on the cycle of impedance changes, the respiration rate can be calculated. The measuring range of respiration rate is from 0/minute to 150/minutes.

6.2 Preparatory Steps of Measurement

1）Plug the 5-lead ECG cable into the ECG socket of the monitor.

2）Place the various pads of the electrodes onto the body of patient and connect them to the relevant lead cables. At this moment, the screen will show Resp waves and the RESP rate will be calculated.

3）Set the parameters relevant to Resp monitoring.

To measure Resp parameters, it is unnecessary to use other cables and it is only necessary to use the two RA and LL leads in

the 5-lead ECG cable. So please plug the 5-lead ECG cable into the ECG socket and refer to ***5.3 Monitoring Procedure*** to place the RA and LL leads onto the body of patient.

Warning: For the sake of safety, all the leads on the 5-lead ECG cable must be connected to the body of patient.

Caution:

- **In order to get the best Resp waveforms, when selecting lead Ⅱ for measuring Resp, it is advised to place RA and LL electrodes cornerways.**
- **For reducing the influence of rhythmic blood flow on Resp electrode pickup impedance changes, avoid the liver area and ventricles of heart in the line between RA and LL electrodes. This is particularly important for neonates.**
- **The measurement of RESP is not applicable for patient with excessive motion, otherwise it may cause the mistake of RESP alarm.**

6.3 Resp Display

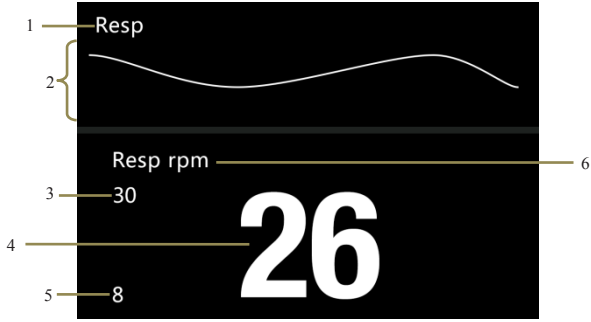


Fig 6-1 Resp Display

1. Resp label
2.Resp waveform
3. Resp uplimit value
4. Resp value
5. Resp downlimit value
6. Resp unit

6.4 Resp Setup

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

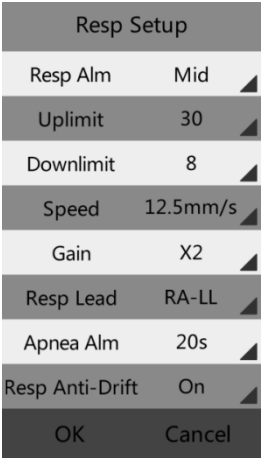


Fig 6-2 Resp Setup Interface

6.4.1 Resp Alarm Setup

Click the right of【**Resp Alm**】, you can select "**Mid**, **High**".

6.4.2 Resp Alarm Limits Setup

Click the right of 【**Uplimit**】or 【**Downlimit**】, you can set the Resp uplimit and downlimit. Attention: The high alarm limit should greater than the low one.

6.4.3 Resp Scan Speed Setup

Select scan speed of Resp waveform. Click the right of **【Speed】**, you can select "**6.25 mm/s,12.5mm/s, 25 mm/s**".

6.4.4 Gain Setup

Select gain of Resp waveform. Click the right of **【Gain】**, you can select "**x0.25 ,x1,x2**".

6.4.5 Resp Lead Setup

Select computing method of Resp lead. Click the right of **【Resp Lead】**, you can select "**RA-LA，RA-LL**".

6.4.6 Apnea Alarm Setup

Suffocation alarm occurs when the time of zero Resp rate has reached this time scale. Click the right of **【Apnea Alarm】**, you can select "Off, 5s, 10s, 20s, 40s, 60s, 80s, 100s, 120s".

6.4.7 Resp Anti-Drift Setup

Click the right of **【Resp Anti-Drift】**, you can turn on or turn off this function.

Chapter 7 Measuring SpO2

7.1 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.

$$SpO_2\ \% = \frac{\text{oxygenated hemoglobin}}{\text{oxyhemoglobin + deoxyhemoglobin}} \times 100\%$$

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

7.2 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.**

7.3 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 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**

7.4 SpO2 Display

- **Parameter Display**

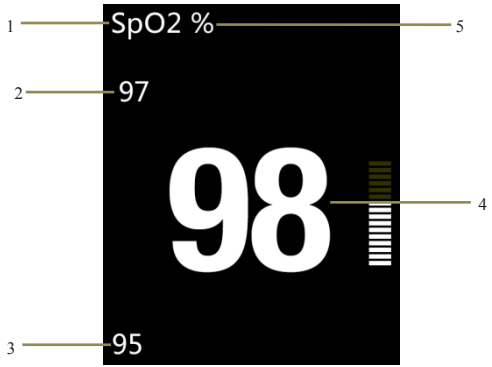


Fig 7-1 SpO_2 Parameter

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**

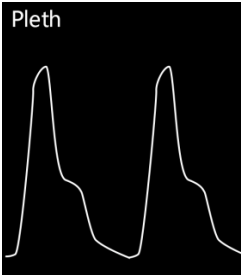


Fig 7-2 SpO_2 Volume Curve

7.5 PR Display

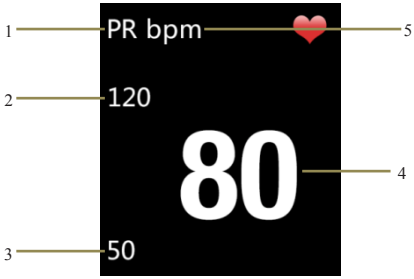


Fig 7-3 PR Display

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.

7.6 SpO2 Setup

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

Fig 7-4 SpO2 Setup

7.6.1 SpO2 Alarm Setup

Click the right of【**Alarm**】, you can set alarm level of SpO_2 and PR, you can select "**Mid, High**"

7.6.2 SpO2 Alarm Limits Setup

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

7.6.3 Scan Speed Setup

Click the right of 【**Speed**】, you can select "**6.25 mm/s、12.5mm/s, 25 mm/s**".

7.6.4 Average Time Setup

Click the right of【**Avg Time**】, you can select "**4s, 8s, 16s**".

7.6.5 QRS Volume Setup

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

7.7 Desat limit Setup

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 8 Trend Review

8.1 Introduction

Select【**Menu**】→【**Trend**】to enter trend reviewing window. In the window, you can review ECG, Reap, SpO_2 and PR data stored before.

8.2 Review Interface

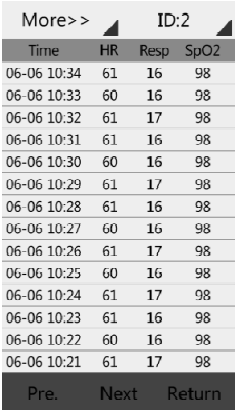


Fig 8-1 Review Interface

If the trend date is not only one page, you can turn pages by

clicking the【**next**】or【**Pre.**】.

8.3 Review Setup

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

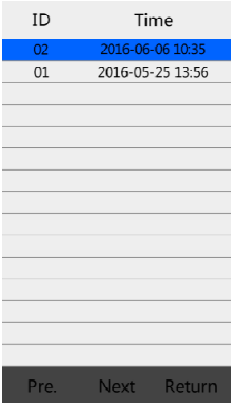


Fig 8-2 ID Review Interface

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

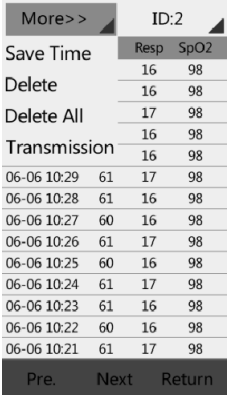


Fig 8-3 The drop-down Window of "More"

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

- **Save time**: To adjust recording time, you can select1**"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 9 Battery

9.1 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.

9.2 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.

9.3 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.

9.4 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.

9.5 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 10 Maintenance and Cleaning

10.1 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.

10.2 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.

10.3 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.

10.4 Cleaning ECG Cable

The recommended disinfectors include glutaric dialdehyde solution and 10% decolourant solution.

a) Please clean cable prior to sterilization.
b) Clean the cable surface with soft cloth bedewed with some fresh water or neutral soapy water.
c) Scrub cable with soft cloth bedewed with some disinfector.
d) Wipe off the disinfector remaining on cable by soft cloth bedewed with fresh water.
e) Put cable in a shady and cool environment for airing.

Attention:

- Do not sterilize lead wire with high-pressure, radioactive or steam device.
- Do not directly submerge lead wire in liquid.
- To avoid long-time harm to cable, it is suggested that sterilization to the product be conducted only when necessary according to the regulation of your hospital.
- Do not clean and reuse disposable electrode.

10.5 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.

10.6 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 11 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	Model	PN
ECG Electrode	Adult	15-100-0008
	Pediatric/Neonatal	15-100-0009
ECG Cable	3 lead, IEC	15-048-0002
	3 lead, AHA	15-048-0001

Type	Model	PN
	5 lead, IEC	15-048-0004
	5 lead, AHA	15-048-0003
SpO2 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
EMC	Group 1, class B

A.2 Physical Specifications

Mainframe weight	350g(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: 10% to 93%(non condensing)

A.4 Charging Specifications

A4.1 Power Adapter

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	>28h

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	Freeze/Unfreeze ECG waveform. 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
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 ECG Specifications

ECG	
Lead type	3-lead：I,II,III 5-lead：I, II, III, aVR, aVL, aVF, Vx
Lead standard	AHA、IEC
ECG input rang	±6mV
Gain	2.5mm/mV, 5mm/mV, 10mm/mV
Input impedance	≥5.0MΩ
Leakage Current	＜10 uA

GMRR	≥89dB
Frequency response	0.5－40Hz
Electrode offset potential	±500mV d.c.
Standardizing signal	1mV ±5%
Protection	Electric isolation voltage is 4000V at 50/60Hz 60s. Anti-high-frequency interference of electrotome. defibrillator-proof.
Electrode off indicating	with(except RL)
Scan speed	6.25 mm/s,12.5 mm/s, 25 mm/s
Pacemaker pulse symbol	With pacemaker detection，meet the requirement of IEC60601-2-27: 2005 50.102.12，the pace pulse meet the following requirements ,the pace symbol (≥2mm) will be shown on screen： Pulse amplitude：±2mV~±700mV

	Pulse width：0.1~2.0ms Rise time：10~100us
Electrosurgery protection (electrotome protection)	Cut power :300W Coagulation power :100W Change of heart rate : ≤10％ Recover time : ≤10s Comply with the requirement of clause 4.2.9.14 in ANSI/AAMI EC 13:2002
Tall T-Wave rejection capability	Minimum recommended 1.2 mV T-Wave amplitude. Comply with requirement of clause 4.1.2 c in ANSI/AAMI EC 13:2002.)
Heart rate averaging	≤ 50 bpm, once every two beats; 50 bpm to 120 bpm, once every four beats; > 120 bpm, once every six beats.
Heart rate meter accuracy and response to irregular rhythm	Ventricular bigeminy : 80bpm Slow alternating ventricular bigeminy : 60bpm Rapid alternating ventricular bigeminy : 120bpm Bidirectional systoles : 90bpm
Response time	HR changes from 80bpm to 120bpm: less than

of HR meter to change in HR	6s to 10s. HR changes from 80bpm to 40bpm: less than 6s to 10s.
Time to alarm for Tachycardia	Vent Tachycardia 1mVp-p, 206bpm: Gain 0.5, Range 6.5 to 8.4 seconds, Average 7.2 seconds Gain 1.0 Range 6.1 to 6.9 seconds, Average 6.5 seconds.
HR	
Measurement range	Adult: 15 bpm to 300 bpm Pediatric and Neonatal: 15 bpm to 350 bpm
Resolution	1 bpm
Accuracy	±1% or ±1 bpm, whichever is greater
Detecting sensitivity (II lead)	≥0.20mVpp
Response time of HR meter to change in HR	<12s

Response of HR to QRS amplitude is 1mVp-p, width is 10ms	Adult: without response
Alarm range	0 bpm to 300 bpm, high/low limit can be adjusted continuously.

A.7.2 RESP Specifications

RESP	
Method	Impedance
Measuring lead	Lead I(RA-LA)、 II(RA-LL)optional， II(default)
Excitation frequency	64.8 kHz sine wave
Excitation voltage	≤0.3mA@64.8 kHz
Measuring impedance range	0.2 ~3 Ω
Base line impedance range	500~2000 Ω (using defibrillation cable with 1 Ω)
Gain	X0.25、X1、X2

Resp bandwidth(BW)	0.25~2.0Hz(-3dB)
Measurement range	0~150 rpm The high/low limit can be adjusted continuously
Resolution	1 rpm
Accuracy	±2 rpm or ±2%

A.7.3 BLT-SpO2

SpO_2	
Measurement range	0~100%
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 period	13s
Anti-interference	Anti-motion interference Anti-electrotome interference
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
HR Alarm Level	Medium
RESP Alarm Level	Medium

B.2 System Setup

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

B.3 ECG Setup

HR setup	Adult	Pediatric	Neonate
HR High Limit	120	160	200
HR Low Limit	50	75	90
RESP	Adult	Pediatric	Neonate
Resp High Limit	30	30	100
Resp 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 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
ECG Alarm Messages	**Cause**	**Level**
HR Too High *	A measurement has risen above the high alarm limit or fallen below the low alarm limit	High、Medium
HR Too Low *		High、Medium
Asystole	No QRS is detected for 4 consecutive seconds.	High
RESP Too High	A measurement has risen above the high alarm limit or fallen below the low alarm limit	High、Medium
RESP 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
ECG Sensor Off	The ECG 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
I Polarized	ECG electrode polarized	Low
II Polarized	ECG electrode polarized	Low
V Polarized	ECG electrode polarized	Low

C.3 Prompt Message

Message	Cause	Level
searching	Searching pulse	Prompt Message
SpO_2 sensor	SpO_2 sensor may be	Prompt

off	disconnected from the patient or the monitor	Message
ECG sensor off	ECG sensor may be disconnected from the patient or the monitor	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 Person		Tele/fax	

Product name: Patient Monitor

Product type: M850

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: 22-067-0002