M800 Handheld Monitor
User's Manual

Guangdong Biolight Meditech Co., Ltd.

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Product Information

- Product Model: M800
- Product Name: Handheld monitor
- Manufacturer: GuangdongBiolightMeditech Co.,Ltd.
- After Service Contact Information:

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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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Statement

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

M800 handheld monitor is intended for continuously monitoring or spot checking of SpO_2, PR, ECG and HR 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 as well as home care.

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.

1.2 Main Unit

1.2.1 Front View

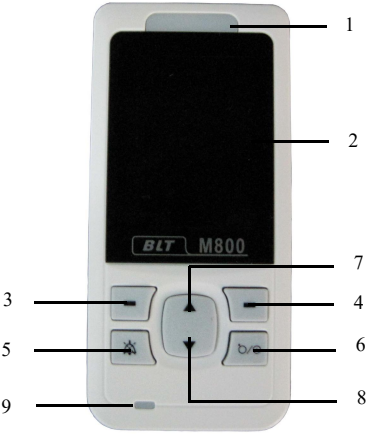

Fig 1-1 Front view of the monitor

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
3. Left button

Press this button to:

- Enter the main menu under the monitoring screen.
- Select the highlighted menu item under the menu screen.
- Freeze/Unfreeze the ECG waveform under the ECG waveform display screen.

4. Right button

Press this button to:

- Change the screen display among Big Numerics mode, SpO_2 waveform mode and ECG waveform mode under the monitoring screen.
- Exit current menu under the menu screen.

5. Alarm pause button

- It's invalid to press this button when the alarm volume is off.
- It can pause the alarm for 120s when the alarm volume is on.

- It can change the alarm message to prompt message when "Lead off" or "Sensor off" alarm happens.

6. Power button

   After the batteries are installed:

   - Press this button to turn on the monitor.
   - Press and hold it for 2 seconds to turn the monitor off.

7. Up button

   Press this button to:

   - Raise the beat volume under the monitoring screen.
   - Move the cursor upwards or increase the value of selected menu item under the menu screen.

8. Down button

   Press this button to:

   - Lower the beat volume under the monitoring screen.
   - Move the cursor downwards or decrease the value of selected menu item.

9. Battery charging indicating lamp

   - Lights orange when the battery is being charged.

- Is shut off when the battery is fully charged or not being charged.

1.2.2 Rear View

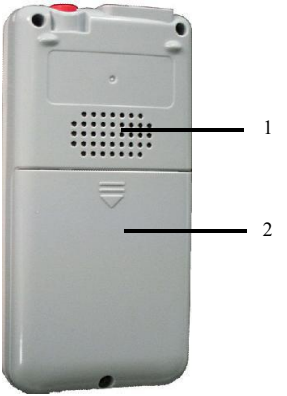

Fig 1-2 Rear view of the monitor

1. Speaker
2. Battery door

1.2.3 Side View

Topside: Downside: Leftside:

Fig 1-3 Side view of the monitor

1. SpO_2 probe / Communication connector
2. ECG cable connector
3. Cord hold
4. Power supply connector

   It is used to connect the charger stand.

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 Big Numerics Display Mode

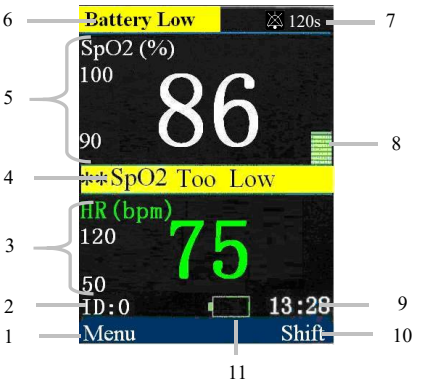

Fig 1-4 Big numerics display mode

1. Menu: After startup, 【**Menu**】 shown here is functions of the left button. At the time, press the left button to enter 【**Menu**】.

2. Patient ID No.: When 【**Continuous**】 is selected for work mode, the value is 0 at all times; when 【**Spot-Check**】 is selected, the value is between 1 and 99.
3. HR/PR parameter area: HR/PR parameter and its high and low alarm limits are shown in the area.
4. Physiological alarm area: Current physiological alarm information is shown in the area.
5. SpO_2 parameter area: Current SpO_2 value and its high and low alarm limits are shown in the area.
6. Technical alarm and prompt information area: Current technical alarm and prompt information are shown in the area.
7. Alarm status area: Alarm status symbols and alarm pause time are shown in the area.
8. Pleth bar: Pulse intensity is denoted by the quantity of blocks.
9. System time: Current time is shown in the area.
10. Shift: After startup, 【**Shift**】shown here is functions of the right button. At the time, press the right button to shift between different display modes.

11. Battery symbol: The symbol indicates the current quantity of electricity of batteries.

Caution: Under the ECG waveform Display Mode, function indicating button【Menu】will be changed into【Freeze】or【Unfreeze】.

1.3.2 SpO_2 Waveform Display Mode

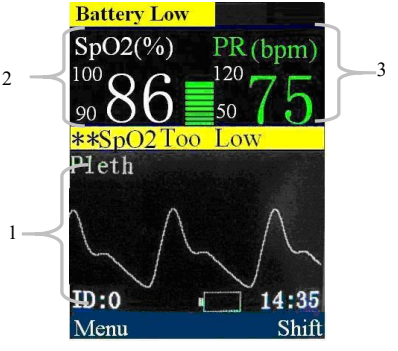

Fig 1-5 SpO_2 waveform display mode

1. SpO_2 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

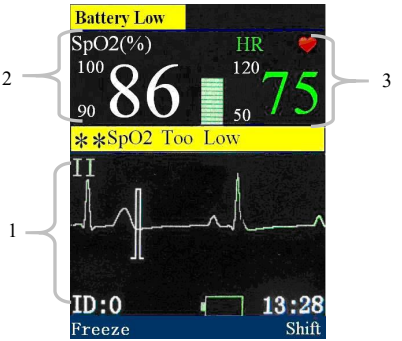

Fig 1-6 ECG Waveform Display Mode

1. ECG waveform display area: Waveform shown in the area is current ECG waveform.
2. SpO_2 parameter area: The values shown in the area are current SpO_2 value and its upper and lower alarm limits.
3. HR parameter area: The values shown in the area are current HR value and its upper 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.**
- **Keep the monitor away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.**
- **The monitor is not designed for the sterilized room.**
- **The monitor should be handled with care so as to avoid shocks and falls.**

Warning:

- **Do not use this device during defibrillation.**
- **Do not use this device to monitor a paced patient.**
- **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.**
- **Do not conduct SpO_2 measurement on the finger smeared with nail polish; otherwise this will lead to unreliable measurement results.**
- **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.**
- **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.**

Caution:

- **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.**

2.2 Explanation of Symbols

Symbol	Symbol Note
	Type CF applied part without defibrillation-proof
	Attention: Consult accompanying documents (this manual).
	Direct Current（DC）
IPX1	Degree of protection against ingress of liquid
	Alarm volume off
	Alarm volume pause
	parameter alarm off
	Beep volume off
	Power supply connector
	Left/right button
	Up button

Symbol	Symbol Note
	Down button
	Date of manufacture
	Manufacturer
	CE mark
SN	Serial number
	Power button
ECG	Short for "Electrocardiogram"
SpO_2	Short for "Pulse Oxygen Saturation"
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.

Chapter 3 Basic Operations

3.1 Unpacking and Checking

Open the package. In the package are parts as follows. Take out the monitor and its accessories.

Parts	Standard	Optional	Quantity
SpO_2 probes (DB9 plugs)	√		1
3-lead ECG cable		√	1
AA battery	√		3
User's manual	√		this manual
QC certificate	√		1
Packing list	√		1
Lithium battery		√	1
AC-DC adapter		√	1
USB to DB9 connector		√	1
Battery charger		√	1
Protective cover		√	1
Carrying case		√	1

3.2 Getting Started

1. 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.

2. Put batteries into the battery compartment. Make sure that the battery has sufficient power for monitoring. When you use a lithium battery for the first time, you must charge it, following the instructions given in ***Battery*** chapter.

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 ⏻/◉ to turn on the monitor. The alarm indicating lamp flashes, and then goes out. The system gives a beep and enter the main screen. For you to use the monitor more conveniently, after starting the monitor you can make the following setting as shown in ***section 3.4*** first.

3.4 General Setup

Press the Left button to enter【**Menu**】, then select【**General Setup**】to enter the general setup menu shown as follows. You can set the following parameters' values.

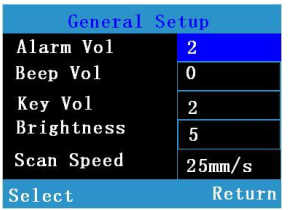

Fig 3-1 General setup window

3.4.1 Beep Volume Setup

Press the Left button to select the item, then set its value through the Up or Down button. You can select from 0 to 4. A sign of 🔇 will be shown at the bottom of the monitoring screen.

3.4.2 Key Volume Setup

Press the Left button to select the item, then set its value through the Up or Down button. You can select from 0 to 4.

3.4.3 Adjust the Screen Brightness

Press the Left button to select the item, then set its value through the Up or Down button. You can select from 1 to 5. Selecting the minimum brightness can save power.

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

3.4.4 Scan Speed Setup

Press the Left button to select the item, then set its value through the Up or Down button. You can select from 12.5mm/s to 25mm/s.

3.5 Date and Time Setup

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:

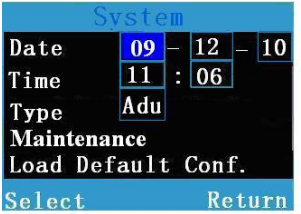

Fig 3-2 System setup window

2. Select the year, month and day on the right of 【**Date**】, and set them to the current date.
3. Select the hour and minute on the right of 【**Time**】, and set them to the current time.

3.6 Selecting the Work Mode

The monitor is designed to operate in the continuous monitoring and spot-checking mode. Its work mode is shown in the technical alarm area. You can set the monitor's work mode as following steps:

1. Select【**System**】→【**Maintenance**】, a password entering window will pop up, input the password and select【**OK**】to enter the maintenance window shown as follows:

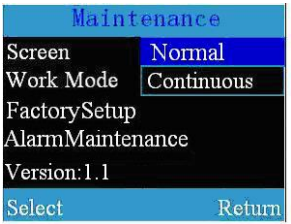

Fig 3-3 Maintenance window

2. Select【**Work Mode**】, you can set the monitor's wok mode to【**Continuous**】or【**Spot-Check**】.

3.6.1 Continuous Monitoring Mode

The continuous monitoring mode is intended for long-term monitoring. This mode is normally selected when the patient is in hospital or under transport. At the time, the patient ID defaulted by the system is 0. When the memory reaches the above limit, the data stored primarily will be cleared.

3.6.2 Spot-checking Mode

Spot-checking mode is intended for short-term on-site measurement. This mode is normally selected to check outpatient when doctors make rounds of the wards. The patient ID will automatically increase from 1 to 99 according to the connecting of SpO_2 sensor or ECG electrode. Details are as follows:

Apply the SpO_2 sensor or ECG electrode to the patient. After valid signals are detected,

1. The patient ID flashes and automatically increases by 1 after 8 seconds to admit a new patient.
2. Press the Left button when the current patient ID is flashing, the patient ID will stop flashing and remain unchanged. The patient will not be admitted and new measurements will be stored under the current patient ID.
3. When the storage of patient measuring data reaches its limit, the newly measuring data will cover for the primary one.

Caution: Only when the monitor isn't monitoring any patient, connecting its SpO2 sensor or ECG electrode to a patient, the patient ID will add 1 automatically.

3.7 Selecting Patient Type

To select the patient type,

1. Select【**Menu**】→【**System**】→【**Type**】.
2. Set【**Type**】to【**Adu**】,【**Ped**】or【**Neo**】.

3.8 Entering/Exiting the Demo Mode

To enter the demo mode:

1. Select【**Menu**】→【**System**】→【**Maintenance**】→enter the required password.
2. Set【**Screen**】to【**Demo**】and the message【**Demo Mode**】is shown in the technical alarm area.

To exit the demo mode:

1. Select【**Menu**】→【**System**】→【**Maintenance**】→enter the required password.
2. Set【**Screen**】to【**Normal**】.

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 Changing the Language

Select【**Menu**】→【**System**】→【**Maintenance**】, enter the required password. Select 【 **Factory Setup** 】 to set 【**Language**】.

3.10 Checking the Version

Select【**Menu**】→【**System**】→【**Maintenance**】, enter the required password. Select【**Factory Setup**】to check the version of the monitor.

3.11 Selecting the Screen Maintenance

Select【**Menu**】→【**System**】→【**Maintenance**】,enter the required password. Select【**Factory Setup**】→【**Screen**

Maintenance】, set【**DspSwitch**】to【**On**】or【**Off**】. If you select【**On**】, the screen can react to the gravity. When the monitor rotates, the screen will rotates the display direction automatically.

3.12 Wifi Maintenance

Select【**Menu**】→【**System**】→【**Maintenance**】,enter the required password. Select【**Factory Setup**】,then select【**Wifi Maintenance**】to set the SSID, Mac No., IP address. The default number of SSID is"bltcnswif1".The Mac No. is the same with the bedside unit's number displays by central software. The default gateway is 50. After setting, you should restart the monitor. When you want to use the Wifi, you should set the Wifi routers according to the Central Monitoring System Installation Instruction, otherwise, it will be disconnected.

3.13 Selecting Wifi

Select【**Menu**】→【**System**】, set【**Wifi**】to【**On**】or【**Off**】. If you select【**on**】, the device will connect the

router automatically. The symbol  will display on the upper right of the screen after connecting successfully. The display icon may change according to the intensity of signal.

3.14 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【**Load Default Conf.**】, popping up a confirming window, select【**OK**】to restore the factory configuration.

3.15 Shutting off the Monitor

Please follow the below steps to shut off the monitor:

1. Confirm that the patient monitoring is finished.
2. Disconnect the SpO_2 sensors form the monitor.
3. Press the power button and hold it for 2s to turn off the monitor.

Caution: Under the Spot-check mode, if the monitor is not in use and there is no button operation for more than 5 minutes, the monitor will shut down automatically.

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.

4.1 Alarm Categories

By nature, the pulse 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 pulse 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 is required.

- Low level alarms

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

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

Caution: The level of technical alarm can't be changed by the user.

4.3 Alarm Indicators

When an alarm occurs, the pulse monitor will indicate it through 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 and speed.
- Alarm message: Alarm messages 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 the highest level and give visual and audible 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

4.3.4 Flashing Numeric

When a physiological alarm occurs, the numeric of parameter flashes.

4.4 Alarm Status Symbol

 indicates the alarm sound is turned off.

 indicates the alarm sound is paused.

 indicates individual measurement alarms are turned off.

4.5 Alarm Tone Configuration

4.5.1 Setting the minimum Alarm Volume

1. Select【**Menu**】→【**System**】→【**Maintenance**】→ enter the required password.
2. Select【**Min.Alm.Vol.**】and then select a value between 0 and 4.

4.5.2 Changing the Alarm Volume

1. Select【**Menu**】→【**General Setup**】.
2. Select【**Alarm Vol.**】and then select a value between X and 4. X is the minimum volume which depends on the setting of the minimum alarm volume.

4.6 Pausing the Alarm Tones

Press the alarm pause button  to keep the alarm paused for 120 seconds. And there will be alarm paused symbol and paused time shown in the alarm status.

- The audible alarm is paused, but the alarm lamp remains lit and the alarm message remains displayed;
- The remaining alarm pause time is displayed in the alarm status area;

- The symbol  is displayed in the alarm status area.

Audible alarm starts again automatically after the alarm pause period expires. You can also press the  key to restart the audible alarm.

4.7 Setting the alarm silence

Press the alarm pause button  for 2 seconds to make the alarm silence. You can restart the audible alarm by pressing this button again. During the alarm silence, if there is a new alarm occurs, the monitor will restart the audible alarm. This symbol  will be displayed on the screen upright the monitor.

4.8 Shutting off the Alarm Volume

Set the【**Min.Alm.Vol.**】and【**Alarm Vol.**】to 0 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 loaded;
- 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:

- **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 weather 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.**

4.9 When an Alarm Occurs

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

Check the alarm message appeared on the 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 messages for the individual parameter in ***Appendix D Alarm message***.

Chapter 5 Measuring SpO_2

5.1 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.

5.2 Safety Information

Warning:

- **Use only SpO_2 sensors specified in this manual. Follow the SpO_2 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 SpO_2 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.**

Warning:

- **Check the SpO_2 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 SpO_2 probe or useless SpO_2 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.**

5.3 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 SpO_2 Sensor

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

3. Applying SpO_2 Sensor

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

Warning:

- **Do not use the SpO_2 sensor on a limb where the NIBP cuff is applied. This may result in inaccurate SpO_2 reading due to blocked blood flow during cuff inflation.**
- **Do not conduct SpO_2 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.**

5.4 SpO_2 Display

- **Parameter Display**

Fig 5-1 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**

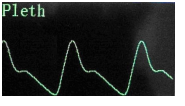

Fig 5-2 SpO2 waveform

5.5 PR Display

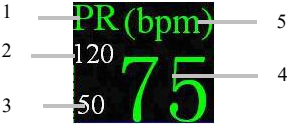

Fig 5-3 PR parameter

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.

5.6 SpO_2 Alarm Setup

5.6.1 Switching On/Off SpO_2 Alarm

1. Select【**Menu**】→【**Alarm Setup**】.
2. Set the【**Alarm**】of SpO_2 to【**Off**】to shut off SpO_2 alarm. When the alarm of SpO_2 is off, there is a sign of in the SpO_2 parameter display area.

5.6.2 Setting Alarm Level

1. Select【**Menu**】→【**Alarm Setup**】.
2. Set the【**Alarm**】of SpO_2 to【**Med**】or【**High**】.

5.6.3 Adjusting the Alarm Limit

1. Select【**Menu**】→【**Alarm Setup**】.
2. Adjust【**High**】:If the SpO_2 measurement is higher than the high alarm limit, the "SpO2 Too High" alarm will be triggered.

3. Adjust【**Low**】:If the SpO_2 measurement is lower than the low alarm limit, the "SpO2 Too Low" alarm will be triggered.

5.6.4 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**】, then pops up a password entering window.
2. Input the password and select 【 **OK** 】 to enter the maintenance window. Select 【**Desat Limit**】, Then set its value through the Up and Down button.

Chapter 6 Measuring ECG

6.1 Introduction

Before mechanical systole, the heart firstly produces electrical excitement, which results in biological current, and conducts the current to the body surface through tissue and humour. Different potential changes take place at various parts of the body, thus body-surface potential differences are formed. Record the changing potential differences to form the dynamic curve, i.e. ECG, also called body-surface ECG or regular ECG.

Through many electrodes connected with ECG cables, the monitor examines the changes of body-surface potential caused by the heart of patient, observes the ECG activities, records the ECG waveform, and calculates the HR. The monitor can achieve 3-lead monitoring.

6.2 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.**
- **Check the ECG cable and its package for any sign of damage before use. Do not use the cable if any damage is detected.**
- **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.**

Warning:

- **Do not use this device during defibrillation.**
- **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.**
- **During the measurement of ECG, when interference from the mains causes distortion of the ECG waveform, please disconnect the AC adapter and use the battery to be the power supply.**

6.3 Monitoring Procedure

6.3.1 Skin Preparation

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.

6.3.2 Placing Electrode

1. Preparation before placement

1) Skin preparation (refers to ***Chapter 6.3.1***);
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 count. 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 24h or at a shorter interval.**

2. Electrode Placement

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.

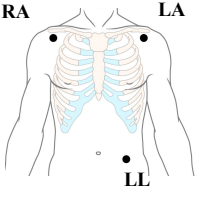

Fig 6-1 Electrode placement

3. The following table shows the ECG electrode label to identify each electrode and its associated color of AHA and IEC standards.

Electrode labels (IEC)	Electrode colors (IEC)	Electrode labels (AHA)	Electrode colors (AHA)	Placement
R	Red	RA	White	Directly below the clavicle and near the right shoulder
L	Yellow	LA	Black	Directly below the clavicle and near the left shoulder
F	Green	LL	Red	On the left lower abdomen

6.4 ECG Display

- ECG Parameter

Fig 6-2 ECG Parameter

1. HR label 2. HR high alarm limit 3. HR low alarm limit
4. HR value 5. Heartbeat icon

- ECG Waveform

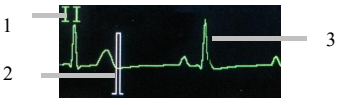

Fig 6-3 ECG waveform

1. Lead label 2. ECG scale 3. ECG waveform

6.5 ECG Setup

Select【**Menu**】→【**ECG Setup**】, Press the up and down button to set【**Lead**】,【**ECG Gain**】and【**ECG Drift**】.

Lead： Select an ECG lead as required. You can select【Ⅰ】,【Ⅱ】or【Ⅲ】.

ECG Gain： Select an ECG gain as required. You can select【×**0.25**】,【×**0.5**】or【×**1.0**】.

6.6 Drift filter Setup

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

2. Select【**Factory Setup**】→【**ECG Maintenance**】→【**ECG Drift**】, set【**ECG Drift** 】to【**On**】or【**Off**】.

6.7 Hum filter Setup

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

2. Select【**Factory Setup**】→【**ECG Maintenance**】→【**Hum**】, Set its value to the local main power frequency.

6.8 HR Alarm Setup

6.8.1 Alarm Switch Setup

Select【**Menu**】→【**Alarm Setup**】, Set【**Alarm**】of HR to【**Off**】to shut off HR alarm. There is a sign of shown in the left corner of HR display area. Or the HR alarm is on.

6.8.2 Alarm Level Setup

Select【**Menu**】→【**Alarm Setup**】, Set【**Alarm**】of HR to【**Low**】,【**Med**】or【**High**】.

6.8.3 Alarm Limit Setup

Select 【**Menu**】→【**Alarm Setup**】, set the high/low alarm limit of HR to a value as required. The high alarm limit should greater than the low one.

Chapter 7 Reviewing

7.1 Introduction

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

7.2 Reviewing Screen

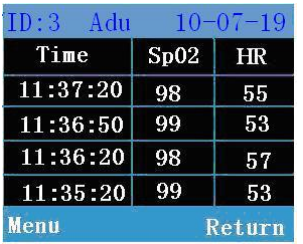

Fig 7-1 SpO_2/HR reviewing window

The above is SpO_2/HR reviewing window. In the window, you can review SpO_2/HR value measured in different time. When SpO_2 or HR is over the setting alarm limit, their values are red. If the trend date is not only one page, you can turn pages by the up/down button. When the monitor is

monitoring ECG, the line of【**HR**】displays the values of HR. While there is no ECG monitoring, the line of【**HR**】displays the values of PR.

7.3 Reviewing Setup

After entering the reviewing window, press the left button to enter 【 **Trend Setup** 】 window shown as the following:

Fig 7-2 Trend Setup

In the window you can set【**Interval**】,【**Select ID**】,【**Delete Selected**】,【**Delete All**】and【**Export Trend**】:

- Interval：To adjust recording time interval within the range from 2 seconds to 30 minutes.
- Select ID：To select patient ID No. The user may

change ID No. to browse trend data of related patients.

- Delete Selected： To delete trend data of the selected ID No.
- Delete All：To delete trend data of all patients.
- Export Trend：To send trend data of the selected ID No. Before the operation, related computer software must be opened, and connect computer and monitor with the USB to DB9 connector. After sending all the trend data, you can check them in the computer.(With Wifi, it is not suitable)

Chapter 8 Battery

8.1 Introduction

The handheld monitor is designed to operate on three 1.5V alkaline AA batteries or a rechargeable lithium ion battery. Under normal circumstances, no special maintenance is needed.

When alkaline batteries or 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. If alkaline AA batteries are used, please change them timely; if a rechargeable battery is used, please insert the monitor to battery charger and connect the charger with commercial power to charge the battery. The monitor will be switched off automatically 10 minutes after the first "Battery Low" alarm is given.

Caution: Remove the batteries prior to shipping or if the monitor is not likely to be used for an extended period of time.

Warning:

- **Use only batteries specified in this manual.**
- **Keep the batteries out of children's reach.**
- **When the monitor is not in use for a long time, the battery should be removed from it. Dispose of battery in accordance with local ordinances and regulations.**

8.2 Installing Batteries

Battery compartment is at the back of the device, please follow the following steps to install or change batteries.

8.2.1 Opening the Battery Door

1. Turn the monitor off first.
2. Use the screw driver to loose the screw that secures the battery door to the monitor.

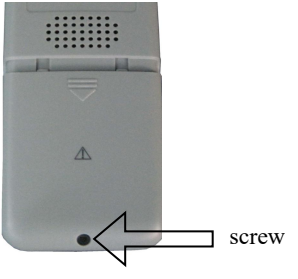

Fig 8-1 Loose the screw

3. Press the battery door, push it downwards and remove the battery door.

Fig 8-2 Push the battery door

8.2.2 Installing the Alkaline Battery

1. Insert the AA alkaline batteries in the battery compartment, aligning the + on each battery with the + shown inside the battery compartment.
2. Close the battery door and push it upwards.
3. Tighten the screw that secures the battery door to the pulse monitor.

Caution: Check the batteries periodically for corrosion. Replace batteries if corrosion is present, otherwise damage to the monitor may occur.

Caution: Do not run the pulse monitor using alkaline batteries of different types or capacities at the same time.

8.2.3 Installing the Lithium Ion Battery

1. Insert the lithium ion battery in the battery compartment, following shown as follows:

Press the battery in

Fig 8-3 Install the battery

2. Close the battery door and push it upwards.

3. Tighten the screw that secures the battery door to the pulse monitor.

Warning:

- **Do not use the charger stand when the alkaline batteries is depleted or no battery is installed.**
- **Disconnect the monitor from the patient and stop monitoring before charge the battery.**
- **When connect the running monitor to the AC-DC adapter to charge its battery, there will be a message displayed on the screen, and the monitor will shut down after 10 seconds.**

8.3 Charging the Lithium Ion Battery

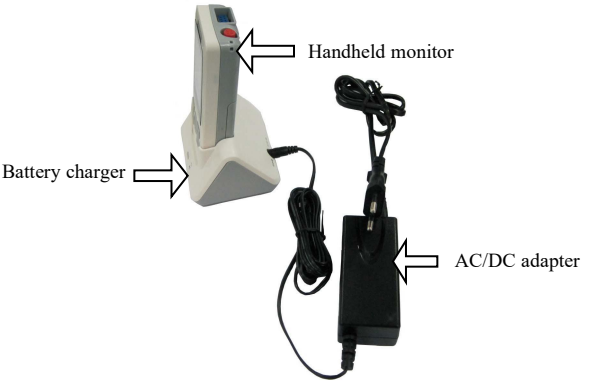

Fig 8-4 Charging device

To charge the lithium ion battery:

1. Place the pulse monitor in the charger stand.
2. Connect the AC-DC adapter and plug the adapter into the AC mains.
3. The indicating lamp on the battery charger and the indicating lamp on the monitor are 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.

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

8.5 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.

Caution:

- **The service life of battery depends on the service time and frequency. This lithium battery can be charged and discharged for 300 times generally.**
- **The operating time of a battery depends on the configuration and operation of the pulse monitor.**

8.6 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.

Warning: For optimal performance, product service should be performed only by qualified service personnel.

Caution: If you spill liquid onto the equipment or accessories, contact your service personnel 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 60601-1:1988 + A1:1991 + A2:1995: Limit: NC 500μA, SFC: 1000μA.

⑤ Test the enclosure leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: NC 100μA, SFC: 500μA.

⑥ Test the patient leakage current (normal operation) according IEC 60601-1:1988 + A1:1991 + A2:1995:

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

⑦ Test the patient leakage current under single fault condition according IEC 60601-1:1988 + A1:1991 + A2:1995:

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

⑧ Test the patient leakage current Mains voltage on applied part: According IEC 60601-1:1988 + A1:1991 + A2:1995: 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 SpO_2 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 SpO_2 sensor.

9.5 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.

9.6 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 10 Accessories

10.1 SpO_2

Nellcor SpO_2 sensor

Type	Model	Patient Category
Disposable	MAX-A	Adult finger (patient size>30kg)
	MAX-P	Pediatric foot/hand (patient size 10-50kg)
	MAX-I	Neonatal foot/hand (patient size 3-20kg)
	MAX-N	Adult finger or neonatal foot/hand (patient size >40 kg or <3 kg)
Reusable	DS-100A	Adult
	OXI-A/N	Adult / neonatal
	OXI-P/I	Pediatric / neonatal

BLT SpO_2 sensor

Type	Patient Category	PN
Reusable	Adult	15-100-0013
	Pediatric	15-100-0014
	Neonatal	15-100-0015

10.2 ECG

ECG Electrode

Type	Patient category	PN
Disposable	Adult	15-100-0008
	Pediatric/ Neonatal	15-100-0009

ECG Cable

Type	Description	Standard	PN
Snap	3-lead	IEC	15-033-0001
Snap	3-lead	AHA	15-033-0002

Appendix A Product Specifications

A.1 Safety Specifications

SFDA classification	II
CE classification	IIb
Type of protection against electric shock	II, with internal 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

A.2 Physical Specifications

Mainframe weight	＜400g(full configuration, including the batteries)
Mainframe size	58.5mm(W)×123mm(H)×28mm(D)

Charger weight	＜100g
Charger size	96mm(W)×66mm(H)×78mm(D)
AC-DC adapter weight	＜200g
AC-DC adapter size	41.5mm(W)×90mm(H)×32mm(D)

A.3 Environmental Specifications

Temperature	Operating: 5℃ to +40℃；
	Storage: -20℃ to +55℃；
Atmospheric pressure	Operating: 700hPa to 1060hPa；
	Storage: 500hPa to 1060hPa；
Humidity	Operating: 15% to 85%(non condensing)
	Storage: 10% to 93%(non condensing)

A.4 Charging Specifications

A.4.1 AC-DC Adapter (Optional)

Input	100～240VAC, 50/60Hz , 0.5A
Output	5V,1.5A

A.4.2 Battery Specification

Standard	
Type	1.5V, AA alkaline battery

Capacity	2000mAh
Voltage	1.5V DC
Quantity	3
Indication of battery capability	There are five status including empty ,1,2,3 and full.
Run time	>14 hours With ECG, SpO_2 monitored continuously, Wifi off, Audio indicators off and backlight brightness set to minimum and using new, full power batteries at ambient temperature 25℃.
Shutdown delay	10 min(After the first "low battery" alarm)
Optional	
Type	Lithium ion rechargeable battery
Size	50mm×46.5 mm×13.5mm
Weight	50g
Quantity	1
Rated voltage	3.7 VDC
Capacity	1600 mAh
Run time	＞14 hours With ECG, SpO_2 monitored continuously, Wifi off, Audio indicators off and backlight brightness set to minimum and using new, full power batteries at ambient temperature 25℃.
Charge time	3 hours to 90%

	4 hours to 100%
Shutdown delay	10min（After the first "low battery" alarm）
Indication of battery capability	There are five status including empty ,1,2,3 and full.
Type	AA NI-MH battery
Capacity	2100 mAh
Voltage	1.2 VDC
Quantity	3

A.5 Hardware Specifications

A.5.1 Display

Type	TFT
Size（diagonal）	2.4 inch
Resolution	320×240 pixels

A.5.2 indicating LED

Mainframe LED	
Alarm indicating lamp	1 (Yellow/Red）
Battery charging indicating lamp	1 (Orange) When charged, it lights orange. When fully charged or not charged, it doesn't light.

Charger LED	
AC power indicating lamp	1(Green) When connecting to the AC-DC adapter, it lights green; When disconnecting from the AC-DC adapter, it doesn't light.

A.5.3 Audio indicating

Speaker	Gives audible alarm, button tone and beep 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

Quantity	6
Functions	Power button, Up button, Down button, Left button, Right button, and Alarm pause button.

A.5.5 Sensors

Wavelength	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.

A.6 Data Storage

The changing trends of SpO_2 and PR data will be shown in the monitor:

Displaying way	Trend tabular
Trend interval	30 seconds to 30 minutes
Trend parameter	HR, SpO_2
Storage	Save when power down
Trend data	Spot-check: ID from 1 to 99, 300 groups (200 groups with wifi) can be stored for each ID. Continuous: ID is 0, 60000 groups (20000 groups with wifi) can be stored.

A.7 USB Communication

USB to DB9 connector	In compliance with IEC 62680
Steady communication distance	1.0 meters

A.8 Measurement Specifications

A.8. 1 SpO_2 Specifications

Fulfill the requirement	ISO 9919
Measurement technique	Digital SpO_2 technique
SpO_2 alarm range and error	50%～100%，the high and low limit is adjustable，alarm error is ±1%
PR alarm range and error	0bpm ～ 250bpm， the high and low limit is adjustable， alarm error is ±1bpm

- **BLT Digital SpO_2**

SpO_2	
Technic	Digital SpO_2 technic

Range	0~100%
Resolution	1%
Accuracy	70% to 100%: ±2% 0% to 69%: unspecified
Alarm	Select the high and low alarm limit of SpO_2
Refreshing rate	<13 seconds
Pitch Tone	with
PR	
Range	25 bpm to 250 bpm
Resolution	1 bpm
Accuracy	±1% or ±1bpm , whichever is the greater
Refreshing rate	<13 seconds

- **Nellcor SpO_2**

SpO_2	
Range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2%（adult/pediatric）

	70% to 100%: ±3%（neonate） 70% to 100%: ±2%（low perfusion） 0% to 69%, unspecified
Refreshing rate	7s
Pitch Tone	with
PR	
Range	20bpm to 300bpm
Resolution	1bpm
Accuracy	20bpm～250bpm: ± 3bpm 251bpm～300bpm: unspecified
Refreshing rate	7s

A.8.2 ECG

Standard	Comply with EN 60601-2-27 / IEC 60601-2-27、ANSI/AAMI EC 13:2002
Lead type	Standard: 3 lead (RA, LA, LL or R, L, F)
Lead	I, II, III
Lead standard	AHA ,IEC
Gain	2.5mm/mV(×0.25), 5mm/mV(×0.5), 10mm/mV(×1)
Input impedance	≥5.0MΩ

Input current	<0.1 uA
Baseline recovery	≤ 3 s
Electrode offset potential	±300 mV d.c.
ECG signal input range	-6.0mV to +6.0mV
Leakage current	＜10 uA
CMRR	≥90dB
Bandwidth (-3d B)	0.5Hz to 40Hz
Noise	≤30μVp p RTI
Standardizing signal	1mV ±5%
Electrode off indicating	with
HR range	10 bpm ~300 bpm
HR Resolution	1 bpm
HR Accuracy	±1% or ±1 bpm, whichever is the greater
Alarm range and error	0bpm ～ 250bpm, the high and low limit is adjustable，alarm error is ±1bpm
HR Detecting	≥0.20mVpp

sensitivity	
Scan speed	12.5mm/s，25 mm/s
Protection	Electric isolation voltage is 4000V at 50Hz/60Hz., defibrillator-proof.
Defibrillator-proof	Recovering time for defibrillator-proof ≤5s
Recovering time of electrode polarization after defibrillation	ECG waveform will recover to the baseline within 10 seconds.
Pacemaker pulse rejection amplitudes and widths	Without
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 of HR meter to change in HR	HR changes from 80bpm to 120bpm: less than 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

	Vent Tachycardia 2mVp-p, 195bpm: Gain 0.5, Range 5.4 to 6.2 seconds, Average 5.8 seconds Gain 1.0, Range 5.7 to 6.5 seconds, Average 6.1 seconds

A.8.3 Alarm limit specifications

Alarm limits	**Range(%)**	**Step(%)**
SpO2 high limit	(low limit +1) to 100	1
SpO2 low limit	Desat to (high limit -1)	
Alarm limits	**Range(bpm)**	**Step(bpm)**
PR high limit	(low limit +1) to 250	1
PR low limit	0 to (high limit -1)	
HR high limit	(low limit +1) to 250	1
HR low limit	0 to (high limit -1)	

Appendix B EMC

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

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The M800 HANDHELD MONITOR is intended for use in the electromagnetic environment specified below. The customer of the user of the M800 HANDHELD 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 M800 HANDHELD 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 B</td><td rowspan="3">The M800 HANDHELD MONITOR is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings 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 manufacture's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *M800 HANDHELD MONITOR* is intended for use in the electromagnetic environment specified below. The customer or the user of *M800 HANDHELD 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%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for signal line	±0.5 kV for power supply lines ±0.5 kV for signal line	Mains power quality should be that of a typical commercial or hospital 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	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.

	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	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	
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields Should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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 manufacturer's declaration – electromagnetic immunity
The *M800 HANDHELD MONITOR* is intended for use in the electromagnetic environment specified below. The customer or the user of *M800 HANDHELD 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	1 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the *M800 HANDHELD MONITOR*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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 *M800 HANDHELD MONITOR* is used exceeds the applicable RF compliance level above, the *M800 HANDHELD MONITOR* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *M800 HANDHELD 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 *M800 HANDHELD MONITOR*

The *M800 HANDHELD MONITOR* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *M800 HANDHELD MONITOR* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *M800 HANDHELD 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	0.35	0.12	0.23
0.1	1.11	0.37	0.74
1	3.5	1.17	2.33
10	11.1	3.69	7.38
100	35	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 C 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.

C.1 Alarm Setup

Alarm Setup	Factory Default
Alarm Vol	2
SpO_2 Alarm Level	Med
PR Alarm Level	Med
HR Alarm Level	Med

C.2 System Setup

System Setup	Factory Default
Beep Vol	2
Key Vol	2
Brightness	3
Scan Speed	25mm/s

C.3 SpO2 Setup

SpO_2 Setup	Adult	Pediatric	Neonate
SpO2 High Limit	100	100	95
SpO2 Low Limit	90	90	90
PR Setup	Adult	Pediatric	Neonate
PR High Limit	120	160	200
PR Low Limit	50	75	100

C.4 ECG Setup

ECG Setup	Adult	Pediatric	Neonate
HR High Limit	120	160	200
HR Low Limit	50	75	100
Lead	Ⅱ		
ECG Gain	×1.0		
ECG Drift	ON		

C.5 Trend Setup

Trend Setup	Factory Default
Interval	30s

Appendix D Alarm Message

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

D.1 Physiological alarm

Messages	Cause	Level
SpO_2 Too High*	A measurement has risen above the high alarm limit or fallen below the low alarm limit.	Medium
SpO_2 Too Low*		
SpO_2 Desat	SpO_2 measurement has fallen below the SpO_2 desat limit.	High
PR Too High*	A measurement has risen above the high alarm limit or fallen below the low alarm limit.	Medium
PR Too Low*		
HR Too High*		
HR Too Low*		
No Pulse	The pulse signal was too weak to be analyzed.	High
Asystole	No QRS is detected for 4 consecutive seconds.	

D.2 Technical alarm

Messages	Cause	Level
Sensor Off	The SpO_2 sensor detached the patient or the monitor.	Medium
Lead Off	The ECG leads were disconnected	
ECG Polarized	ECG electrode polarized	
Battery Low	The battery power is low.	
SpO_2 Low Perf	The signal detected is weak.	

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: Handheld Monitor

Product type: M800

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：22-033-0001