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Foreword

Description

Welcome to use our Multi-parameter Monitor (hereinafter referred to as the "Monitor")! This manual describes the product performance, operating methods and other safety information in detail. Please read and comprehend the contents of this manual carefully before using the product in order to ensure proper use and normal operation under the appropriate safety standards.

This manual describes the product in its most complete configuration, so some of the contents may not apply to the product you purchased. If you have any questions, please contact us.

Applicable objects

This manual is intended for professional clinical staff.

Illustration

All illustrations provided in this manual are for reference only, and the settings or data in the illustrations may not exactly match the actual display seen on your product.

Scope of application

The multi-parameter monitor is suitable for monitoring and measuring vital signs such as ECG, respiration rate, SPO₂, heart rate/pulse rate, non-invasive blood pressure, and body temperature in medical institutions. The monitoring information can be displayed, reviewed and stored.

Disclaimer

Zhuhai Linte Medical Instrument Co., Ltd(Hereinafter referred to as "Lintemed" does not make any form of guarantee for the user's self-installation or wrong operation of the product, and does not assume any legal responsibility for accidental or inevitable damage.

The content contained in this manual is protected by copyright law. Without the prior written permission of the company, no part of this manual may be reproduced, photographed, copied or translated into another language.

Lintemed is only responsible for the reliability, safety and effectiveness of the instrument under the following circumstances: assembly operation, expansion, readjustment, performance improvement and maintenance are carried out by personnel or organizations recognized by our company; The supporting electrical equipment complies with relevant national standards; The instrument is operated in accordance with the instructions in this manual.

The contents of this manual are subject to change without notice.

The company shall not assume any legal responsibility for any consequences arising from failure to operate in accordance with the instructions of this manual

Chapter 1. Safety

1.1 Electrical Safety Specifications

The monitor is designed to comply with international safety requirements for medical electrical equipment such as IEC 60601, IEC 80601, etc.

Classified according to the risk level of medical equipment, it is Class IIb active (non-implanted) medical equipment.

Classification according to the requirements of the medical electrical equipment safety standard IEC60601-1:

Classified according to the type of protection against electric shock: a) Equipment using external power supply: class I equipment; b) equipment with internal power supply;

Classified according to the degree of protection against electric shock: BF and CF type application part with anti-defibrillation and BF type application part without anti-defibrillation, of which the ECG detection, invasive blood pressure and CO2 part is anti-defibrillation CF type, non-invasive blood pressure part is anti-defibrillation BF type, pulse SPO₂ and body temperature detection part is BF type without anti-defibrillation;

Shell protection grade: IP22;

Rated voltage and frequency of the equipment: AC 100-240V, 50/60Hz;

Input power of the equipment: 250AV;

1.2 Safety Information



Prompt for potentially dangerous or unsafe operations. Failure to comply may result in serious personal injury, property damage or death



Information that you should know in order to avoid damage to your equipment.



Important information for relative operation and usage that should be emphasized.

1.2.1 Warning

- 1. The equipment can be used by only one patient at a time.
- 2. Before use, the user must check the equipment, cables and accessories to ensure that they work properly and safely.
- 3. Do not use this equipment in an environment where flammable or explosive materials such as anesthesia are placed in order to prevent fire and explosion.
- 4. In order to reduce the risk of electric shock, do not open the equipment. If necessary, please ask qualified personnel to repair.
- 5. In order to use the equipment safely and continuously, please follow the instructions listed. The instructions listed in this manual are not a substitute for medical procedures already in progress.
- 6. Do not rely on the audible alarm system to monitor the patient. If the volume is set too small or completely shut down when monitoring the patient, it may cause disaster to the patient. It is important to remember that a reliable patient monitoring method combines the proper use of monitoring equipment with close personal monitoring of the patient.

- 7. When using a defibrillator, make sure that the patient is not exposed to metal or other conductors or equipment. Avoid contacting with the patient, operating table or equipment when using the defibrillator, as this may result in serious injury or death.
- 8. The physiological waveforms, physiological parameters and alarm information displayed by the equipment are only used for medical reference and can't be directly used as the basis for clinical treatment.
- 9. Carefully place the power cord and accessory cables to prevent the patient from being entangled or suffocated, the cables entangled, or subject to electrical interference.
- 10. This equipment may interfere with the ultrasound imaging system and behave as an interference signal on the ultrasound display. Keep the distance between the two instruments as far as possible.
- 11. Exposure of electrical contacts or attachments to normal saline or other liquids and conductive adhesives is dangerous. Electrical contacts and connections such as cable connectors, power supplies, parameter module plug connectors and rack connectors must be kept clean and dry. Dry thoroughly if they are contaminated with liquids. If further decontamination is needed, please contact biomedical department or our company.
- 12. This is not a treatment unit.
- 13. Failure to implement a satisfactory maintenance plan by hospitals or medical institutions that are responsible for the use of this instrument may result in instrument failure and may endanger personal health.
- 14. This equipment can only be connected to a power outlet with protective ground. This equipment is a Class I equipment that can be connected to the power grid or operated by internal power supply (batteries). If the external protective conductor has problem in installation or the integrity of its wiring, the equipment should be operated by the internal power supply.
- 15. All sensor interfaces of this equipment can only be connected to the sensors specified by our company.
- 16. Regularly check whether the alarm function of the monitor is valid.
- 17. Do not use wires with exposed conductors on both ends. Check the wires and connectors before using the lead wires. If damage is found, please replace it immediately.
- 18. When the patient uses several devices at the same time, the leakage current will increase injury to the patient. Consult a professional to check the leakage current before use to ensure that the leakage current is within the safe range.
- 19. When using electrosurgical equipment, the patient lead cables should be kept away from the operating table to reduce the risk of burns due to improper connection.
- 20. The operator should not touch the signal input or output terminal of the patient and the monitor.
- 21. Before replacing the patient, make sure that all previous monitoring data has been cleared to prevent confusion.

1.2.2 Caution 1.2.2

- 1. To ensure patient safety and product performance, please use the accessories specified in this manual.
- 2. When the equipment and its accessories are about to exceed their service life, they must be disposed of in accordance with relevant local regulations or the hospital's system.
- 3. The electromagnetic field will affect the performance of this equipment. Therefore, other equipment used in the vicinity of this equipment must comply with the EMC requirements

of the latest edition of IEC60601-1-2. Mobile phones, X-ray or MRI equipment are all possible sources of interference because they emit high-intensity electromagnetic radiation.

- 4. Before turning on the equipment, please confirm that the voltage and frequency of the power supply meet the requirements of the equipment label or the requirements specified in this manual.
- 5. Please install or carry the equipment properly to prevent it from damage caused by falling, colliding, strong vibration or other mechanical force.

1.2.3 Note

- 1. This instrument can't be used at home.
- 2. Install the equipment in a location that is easy to observe, operate, and maintain.
- 3. This manual describes the product in the most complete configuration. The product you purchased may not have some configuration or function.
- 4. The accessories must comply with the IEC60601 standard.
- 5. The batteries will discharge even if they are not used, so check the battery level once a month.
- 6. Data lost. When equipment data is accidentally lost, pay close attention to the patient until the equipment returns to normal.
- 7. The back of the equipment must not be blocked in order to dissipate heat.
- 8. If the liquid spills into the casing of the equipment, immediately disconnect the power supply and contact the maintenance personnel.
- 9. Plastic bags and other packaging materials and used batteries should be kept away from children or properly disposed of according to relevant regulations.

1.3 Patient Safety

1.3.1 Environment

Follow the instructions below to ensure absolute safety in electrical installation. The environment in which the monitor is used should be reasonably protected from vibration, dust, corrosive or explosive gases, extreme temperatures, humidity, and the like. When installed in the instrument cabinet, there must be enough space in front to facilitate operation. With the door open, there must be enough space behind for easy maintenance. The circulation of air in the cabinet should be guaranteed.

About 15 minutes after the power is turned on, the monitor can meet the technical specifications working in the ambient temperature range of 5~45°C. Ambient temperatures outside this range may affect the accuracy of the instrument and cause damage to components and wiring. Allow at least 2 inches (5 cm) of space around the instrument to ensure air circulation.

1.3.2 Power Requirements

The operating power of the monitor is: AC 100-240V, 50/60Hz.

To protect patients and medical staff, the monitor's outer casing must be grounded. Therefore, the monitor is equipped with a detachable three-wire power cable that grounds the instrument through the ground wire (protective ground) in the power cord, when plugged into a matching three-wire outlet. If you do not have a three-wire outlet, please contact the electrical management staff of the hospital.

Do not connect the three-wire cable of this instrument to the two-wire plug.

If it is not clear from the instrument specifications whether a particular combination of instruments is dangerous, for example, due to the accumulation of leakage current, you should consult the manufacturer or experts in this area to ensure that the necessary safety of

all the instruments is not compromised by the proposed combination.



1.3.3 Condensation

During operation, ensure that the instrument is not condensed and condensation may form as the instrument moves from one room to another. This is because the instrument is exposed to moist air and different temperatures.

1.3.4 Description of Symbols or Icons on the Monitor

Table 1-1

	Table 1-1	
Symbol	Description	
<u>.</u>	Off/on (power)	
~	AC power supply	
	DC power supply	
為	Alarm silent or restore alarm	
×	frozen or unfrozen waveform	
\	Start or stop non-invasive blood pressure measurement	
5	Start or stop print	
ð	Menu	
\$	Potential equalizer terminal	
	Anti-defibrillation CF type application part	
	BF type application part	
⊣	Anti-defibrillation BF type application part	
- 	Standard RJ45 interface, connect to the central monitoring system via internet	
•	USB interface	
\longrightarrow	Signal output	
\triangle	Note! Please check the attached file of this monitor(this manual)!	
	Refer to the manual	
	Disposal of waste electrical and electronic equipment separately, (Follow local government regulations and recycling instructions for batteries)	
(€	Comply with the Medical Device Directive 93/42/EEC, the European Commission Medical Device Directive	
SN	Serial number	
IPX1	Shell protection grade	

((·•))	Non-ionizing radiation	
	Date of manufacture	
···l	Manufacturer	
	Lifespan	

1.4 Electromagnetic Compatibility



Caution:

- The monitor complies with the electromagnetic compatibility requirements of the latest version of the IEC 60601-1-2 standard.
- You should install and use according to the electromagnetic compatibility information in the provided document.
- Portable and mobile RF communication equipment may affect the performance of the monitor, so please avoid strong electromagnetic interference when use, such as mobile phone and microwave oven.
- The guidance and manufacturer declaration are detailed in the attachment.



Warning:

- The monitor should not be used close to or stacked with other equipment. If necessary, observe and make sure that it can operate normally under the configuration it uses;
- Class A equipment is intended for use in industrial environments where electromagnetic compatibility may be potentially difficult in other environments due to conducted disturbances and radiated disturbances from the monitor;
- In addition to the cables sold by the manufacturer of the monitor as spare parts for internal components, using accessories and cables outside the specified regulations may result in increased monitor emissions or reduced immunity.
- Operating the device lower than the minimum or minimum value as specified in the instructions may result in inaccurate consequences. The minimum amplitude or minimum value of the patient's physiological signal is: heart rate 20bpm, SPO2: 70%, pulse rate: 25bpm, diastolic blood pressure: 10mmHg, systolic blood pressure during adult monitoring: 30mmHg.

No	Cable name	Cable length (m)	Whether to block
1	Power cable	1.8	Yes
2	Equipotential cable	1.2	No
3	ECG lead cable	2.9	Yes
4	Blood oxygen probe cable	2.9	Yes
5	Temp probe cable	2.8	Yes

Attachment:

Guidelines and manufacturer's statement - electromagnetic emission

The instrument is intended to be used in the electromagnetic environment specified below, and the purchaser or user of the instrument should guarantee that it is used in this electromagnetic environment:

Conformity	Flectromagnetic environment-guidelines		
	Electromagnetic environment-guidelines		
Group 1	The instrument uses RF power only for its internal functions. Therefore, its RF emission is low and the possibility of interference to nearby electronic devices is minimal.		
Class A			
N/A	The instrument is suitable for use in all facilities, including		
N/A	household facilities and public low-voltage power supply networks directly connected to household homes.		
	Class A N/A		

Guidelines and manufacturer's statement - Electromagnetic immunity

The instrument is intended to be used in the electromagnetic environment specified below, and the purchaser or user of the instrument should guarantee that it is used in this electromagnetic environment:

Immunity test	IEC60601 test levels	Applicability levels	Electromagnetic environment-guidelines
electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The ground should be wood, concrete or ceramic tile, if the ground is covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transients/bur sts IEC 61000-4-4	±2kV 100KHz repetition frequency	±2kV	The network power supply should have the quality used in a typical commercial or hospital environment.
Surges IEC 61000-4-5	±1 kV Line-to-line ±2 kV Line-to-ground	±1 kV Line-to-line ±2 kV Line-to-ground	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0%U _T ;0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°	0%U _T ;0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°	The network power supply should have the quality used in a typical commercial or

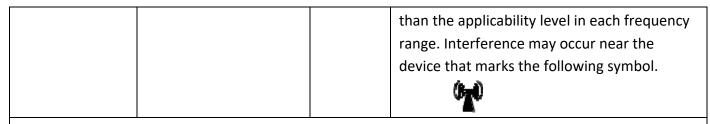
	0%U _T ;1 cycle and 70%U _T ; 25/30 cycles	$0\%U_T$; 1 cycle and $70\%U_T$; 25/30 cycles	hospital environment. If the user of the device needs to run
	Single phase: at 0°	Single phase: at 0°	continuously during a power
Voltage interruptions IEC 61000-4-11	0%U _⊤ ;250/300 cycle	0%U⊤;250/300 cycle	outage, it is recommended that the device be powered by an uninterruptible power supply or battery.
RATED power frequency magnetic fields IEC 61000-4-8	30A/m	30A/m, 50/60Hz	The power frequency magnetic field should have a power frequency magnetic field level characteristic typical of a typical commercial or hospital environment.

Note: U_T refers to the voltage of the AC network before the test voltage is applied.

Guidelines and manufacturer's statement-Electromagnetic immunity

The instrument is intended to be used in the electromagnetic environment specified below, and the purchaser or user of the instrument should guarantee that it is used in this electromagnetic environment:

Immunity test	IEC60601 test levels	Applicabil ity levels	Electromagnetic environment-guidelines	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz 80% AM at 1 kHz	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should not be used closer to any part of the instrument than recommended isolation distances, including cables. The distance shall be calculated by a formula corresponding to the frequency. Recommended isolation distance d= 124P	
Radiated RF EM fields IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3V/m	d= 1.2 80MHz to 800MHz d= 2.3 800MHz to 2.7GHz In the formula: p-According to the maximum rated output of transmitters provided by transmitter manufacturers, Watt (W) is the unit; d -The recommended isolation distance, Meter(m) is the unit. The field strength of a stationary RF transmitter is determined by surveying (c) the electromagnetic site, and (d) should be lower	



Note1: In the frequency of 80MHz and 800MHz, the higher frequency formula is adopted.

Note2: These guidelines may not be suitable for all situations, where electromagnetic transmission is affected by the absorption and reflection of buildings, objects and bodies.

- a. Stationary transmitter, such as base stations for wireless (cellular/cordless) telephones and ground-based mobile radios, amateur radios, AM and FM radio broadcasts and television broadcasting, are theoretically predicted accurately in the field strength. In order to evaluate the electromagnetic environment of the Stationary RF transmitter, the investigation of the electromagnetic field should be considered. If the measured field strength is higher than the applicable RF conformance level, the instrument should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as re-adjusting the orientation or position of the instrument.
- b. In the whole frequency range from 150KHz to 80MHz, the field strength should be less than 3 V/m.

Recommended isolation distance between portable and mobile RF communication devices and instruments

The instrument is expected to be used in the electromagnetic environment controlled by radio frequency radiation disturbance. Depending on the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio frequency communication equipment (transmitter) and the instrument as recommended below.

the instrument as recommended below.				
Rated maximum output	Isolation distance for different frequencies of the transmitter/m			
power of the transmitter/w	150kHz~80MHz d= I.2√P	80MHz~800MHz d= 1.2√P	800MHz~2.7GHz d= 2.3√P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For the rated maximum output power of the transmitter not listed in the table above, the recommended isolation distanced, in meters(m),can be determined by the formula in the corresponding transmitter frequency bar, where p is the transmitter manufacturer's maximum output power rating, in Watts (W) units.

Note1: In the frequency of 80MHz and 800MHz, the higher frequency formula is adopted.

Note2: These guidelines may not be suitable for all situations, where electromagnetic transmission is

affected by the absorption and reflection of buildings, objects and bodies.

Chapter 2. Overview

- > A comprehensive understanding of the monitor
- > Get the information displayed on the screen
- Comprehend the location of interfaces
- Comprehend general operation methods

Warning: The monitor is intended for clinical patient monitoring and only trained personnel such as doctors and nurses are allowed to use the monitor. Anyone who is not authorized or who is not trained may not perform any operations.

Marning: Do not open the case of the instrument in order to avoid possible electric shock.

Any repairs and upgrades to the monitor must be performed by a service personnel trained and authorized by our company.

2.1 Introduction to Multi-parameter Monitor

This monitor is designed to meet the diverse needs of today's healthcare organizations. It adopts miniaturized design, small size, light weight, AC/DC operation, which is convenient for clinical and emergency needs. Its characteristics are as follows:

Complete measurement parameters

Display simultaneous five-lead ECG, respiration, SPO₂, heart rate/pulse, non-invasive blood pressure, body temperature, invasive blood pressure(optional), CO2(optional) at the same time. The monitoring information is displayed, reviewed, stored and printed(optional).

Flexible and convenient

Small size, light weight, easy to carry, and long battery life.

With trend data display, ECG playback function

Optional built-in rechargeable, maintenance-free, high-capacity battery for operation during power outages and when transporting patients

Scope of application: Suitable for assembly in operating rooms, ICU wards, CCU wards and other places where patients need to be monitored. It can display ECG waveforms, respiratory waveforms(CO2 waveform) and blood oxygen waveforms in real time. It is mainly used in the monitoring and measurement occasions such as intraoperative monitoring, postoperative monitoring, and continuous hospitalization of critically ill patients.

2.2 Description of Instrument and External Interfaces

The front view of the monitor, as shown in Fig. 2-1:

Display window: Displays various measurement parameters, waveforms, menus, alarms, and status quantities.

Power switch: Press and hold this button for at least 3 seconds to turn the monitor on/off.

AC indicator: When the instrument is connected to AC, the green indicator light is always on.

Battery indicator: When only the internal battery is used for power supply, the green light is always on after the power is turned on, and the battery level icon is displayed in the upper right corner of the display; Install the battery and use AC power. When turned on, the green light is always on, and the battery charging icon is displayed at the upper right corner of the display.

Alarm light: The alarm light flashes when any parameter exceeds the set alarm limit.

Rotation button: The rotation button can be rotated clockwise or counterclockwise or pressed. You can rotate the button to select a menu item and press the button to execute a menu item. In the main menu, select each submenu by turning the button left/right, and press the button

to enter the selected submenu. In the main interface, use the button to select the text and the highlighted text selected; press the button to enter the corresponding menu or interface.

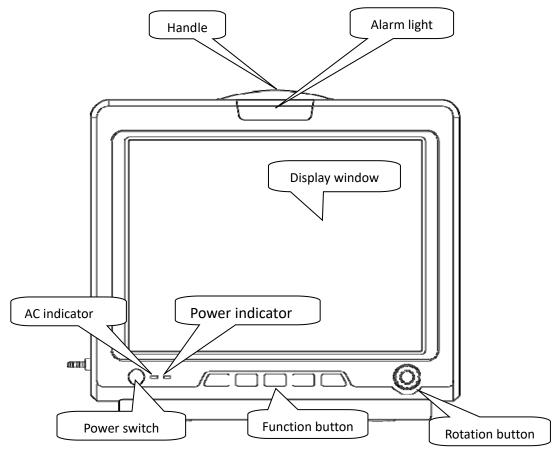


Fig. 2-1 Front View

Function buttons: from left to right: [SILENCE], [FREEZE], [NIBP], [PRINT], [MENU].

- (1) SILENCE: Press this button to switch between mute for 2 minutes and normal alarm.
- (2) FREEZE: In normal monitoring mode, press this button to freeze all waveforms of the display window. Press this button again in the frozen state to exit the frozen state.

Caution: If you press this button during test in continuous measurement mode, not only the measurement is abandoned, but also the continuous measurement process is stopped.

- (3) NIBP: Press this button to inflate the cuff in the non-blood pressure measurement state and start a blood pressure measurement. If you want to give up the measurement in the measurement state, press this button to stop the measurement and deflate immediately.
- (4) PRINT: After this button is pressed, print according to the information actually set by the machine.
- (5) MENU: Main menu button. Press this button to enter the system main menu, through which you can enter the setup menu for each measurement parameter. Press this button again to hide the menu.

The rear view of the monitor, as shown in Fig. 2-2:

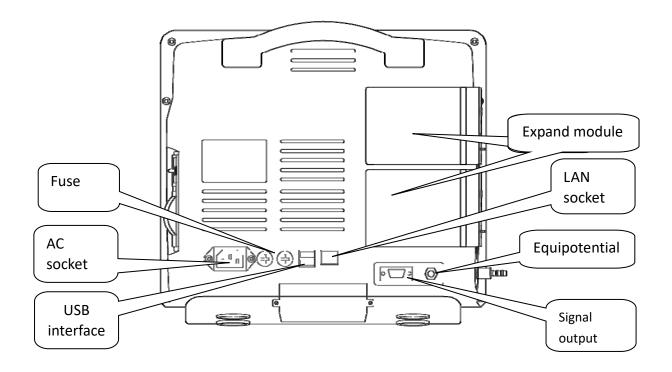


Fig. 2-2 Rear view

Marning: When other equipment is used together with the monitor, it should be connected to the equipotential terminal of the monitor by wires to eliminate the ground potential difference between different them and ensure the safety.

The side view of the monitor (and the sensor interface diagram), as shown in Fig. 2-3:

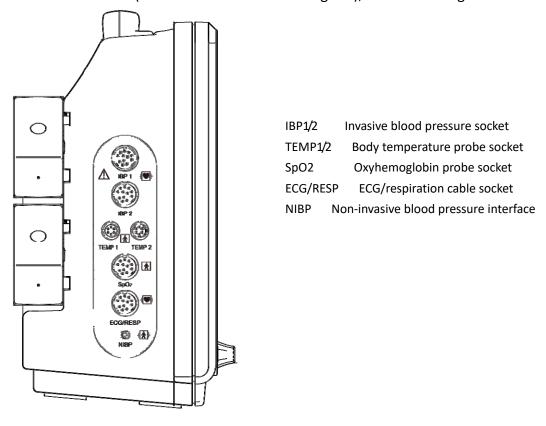


Fig. 2 - 3 Side View

⚠ Warning: All signal output and signal input parts of this equipment can only be connected with the equipment specified by our company!

△Warning: The functions of the USB interface,RJ 45 and VGA interfaces are not open to users and are only used for internal maintenance and debugging in the factory.

2.3 Abbreviation Definition

Name	Definition & abbreviation	
ECG	Electrocardiogram abbreviation, represent ECG parameter	
RESP	Respiration abbreviation, represent respiration parameter	
TEMP	Temperature abbreviation, represent body temperature parameter	
NIBP	Non-invasive blood pressure abbreviation, represent NIBP parameter	
SPO ₂	Pulse Oxygen Saturation abbreviation, represent SpO2	
HR	Heart rate	
RR	Respiratory rate	
PR	Pulse rate	
IBP	Invasive Blood Pressure abbreviation, represent IBP parameter	
CO2	Carbon dioxide abbreviation, represent CO2 parameter	

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Chapter 3. Installation of the Monitor

Caution: To ensure proper operation of the monitor, please read this chapter and Chapter

1, Section 3 - Patient Safety before use and install as required.

3.1 Unpacking and Inspection

Carefully take out the monitor and accessories from the box and keep the packing materials properly for later shipping or storage. Check the accessories according to the packing list.

Check for any mechanical damage.

Check all exposed wires, inserts and accessories.

If you have any questions, please contact us or the agent immediately.

3.2 Installation and Connection

Make sure the AC power supply meets the following specifications: 100-240V, 50/60Hz.

Keep the air circulation in the place where the monitor is placed. Prevent the vents of the instrument from being blocked (such as other instruments, walls or blankets); ensure that the surrounding environment indicators meet the specifications of the instrument at all times.

Use the power cord that comes with the instrument. Plug the power cord into an AC outlet on the rear panel of the instrument and plug the other end of the power cord into a grounded electrical outlet.

Turn on the instrument by pressing the power switch for more than 3 seconds, and the green indicator light is on, indicating that the instrument has started working.

 $\hat{m{\Gamma}}$ Caution: Connect the power cord of the monitor to the dedicated outlet in the hospital.

3.3 Turning On

⚠ Warning: If you find evidence of damage to the monitor or an error message, do not use the monitor to perform any monitoring procedures on the patient. Contact biomedical engineer of your hospital or our service engineer.

Press the power switch (located on the front panel, as shown in Fig. 2-1) to turn on the machine. After about 1 minute, the monitor passes the self-test and enters the main display interface for normal monitoring. For specific operation methods and how to configure parameters according to the monitoring requirements, please refer to the relevant chapters.

3.4 Patient Sensor Connection

Connect the required patient sensor to the monitor and the monitoring position of the patient.

Caution: Please refer to Chapter 2 for the correct connection method and related requirements for various sensors.

Chapter 4. How to Use

4.1 Display Interface Introduction Standard layout

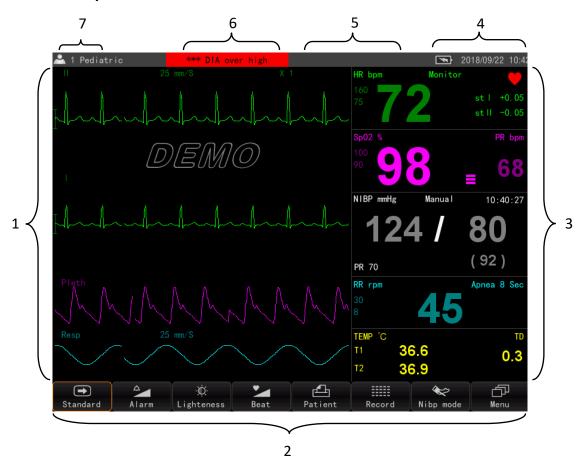


Fig. 4-1

No.	Name	No.	Name
1	Waveform area	5	Technical alarm area
2	Shortcut button area	6	Physiological alarm area
3	Parameter area	7	Patient info area
4	Status bar		

The above is the demo mode interface, which displays 2-channel ECG waveform, respiratory waveform, SPO₂ waveform and various measurement parameters. Description of each area of the screen:

1. Waveform area:

Lead I, lead II, SPO₂ waveform and respiratory waveform can be displayed in the main interface. As shown in Fig. 4-1.

I 25.0mm/s ×1

The text at the top left of each ECG channel indicates the lead displayed on this channel.

"x1" indicates the gain of the waveform and can be set by selecting the text.

"25.0 mm/s" indicates the waveform scanning speed, which is set by selecting the text.

PLETH indicates the SPO₂ waveform, which is adjustable in the SPO₂ setting menu.

RESP6.25mm/s indicates the respiratory waveform scan speed, which is adjustable in respiratory settings menu.

2. Shortcut button area:

There is a row of shortcut buttons at the bottom of each interface. You can select it on the shortcut bar by turning the knob. After pressing the knob, you can enter the relevant interface to set it. The shortcut bar is shown in Fig. 4-11:



Fig. 4-11

From left to right:

- (1) Interface switching button: The name of the current interface is displayed on the button. When the button is pressed, the display interface of the monitor and the interface name on the button will be switched accordingly.
- (2) Alarm tone: Adjust the alarm volume of the monitor at the time of alarm. Ten levels are available. After entering the volume adjustment interface (as shown in Fig. 4-12), you can see three buttons, which from left to right are: lower alarm volume, increase alarm volume, and exit setting window;



Fig. 4-12

(3) Lighteness: Adjust the brightness of the monitor display. Three levels are available. After entering the brightness setting interface (as shown in Fig. 4-13), the method of adjusting the brightness is similar to the volume adjustment. The three buttons from left to right are: reduce display brightness, increase display brightness, and exit the settings window;



Fig. 4-13

(4) Beat sound: Adjust the volume of the pulse sound emitted by the monitor through measurement. After entering the beat volume adjustment interface (as shown in Fig. 4-14), the method of adjusting the beat volume is similar to the volume adjustment. The three buttons from left to right are: reduce the beat volume, increase the beat volume, and exit settings window;

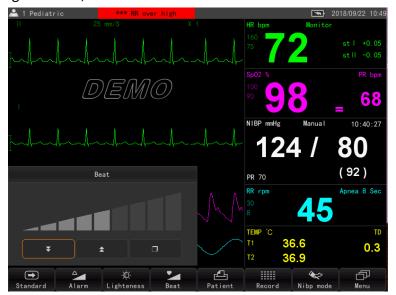


Fig. 4-14

(5) Patient info setting: Set information about the patient monitored by the monitor. After entering the patient info setting interface (as shown in Fig. 4-15), use the knob to select the information to be set, and press the knob to set the information. After pressing the knob, the input button for input information will pop up;



Fig. 4-15

The information available for setup includes:

- ① Medical record number: Maximum length: 12, consisting of characters or numbers;
- ② Name: Maximum length: 12, consisting of characters or numbers;
- ③ Department: Maximum length: 12, consisting of characters or numbers;
- Patient type: Adult, Pediatric, Neonate;
- ⑤ Bed number: Optional range: 0~999;
- 6 Gender: Male or female;
- Age: According to the patient type, the optional range is: adults 18~120 years; children 2~17 years;

8 Height: Optional range: 50~300cm;9 Weight: Optional range: 10~200kg;

Some patient information needs to be entered with characters or numbers. The monitor provides the corresponding input keyboard, as shown in Fig. 4-16:

The input keyboard of English uppercase letters is displayed. The rotary button can be used to move the selection cursor. When the rotary button is pressed, the button at the cursor position can be selected. The area indicated by the arrow in the figure will display the information input by the user for preview; when the input is completed, click the

button [Enter] to complete the input or modification of the selected patient information;

[] is the back button, which can delete the last entered character; [Space] is the space

button, which enters a space when being clicked; [so] is the exit button. When this button is clicked, the current input window will be exited, and the original information will not be changed. You can switch the input keyboard to lowercase English, numeric and

Chinese Pinyin by clicking the [abc], [123] and [19].

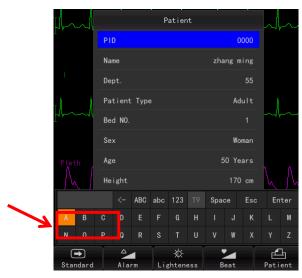


Fig. 4-16

It should be noted that when the bed number in a certain patient info is modified and the setting window is exited, a window for prompting [whether to save new patient info and accepting a new patient] is displayed, that is, whether to create new patient file. If the information other than the bed number is modified, when the setting window is exited, the prompt message [The patient info has been modified. Whether to save?] will pop up, that is, whether to save the modified patient file.

(6) History: You can view information such as test records and alarm records related to monitoring. The history interface is shown in Fig. 4-17.

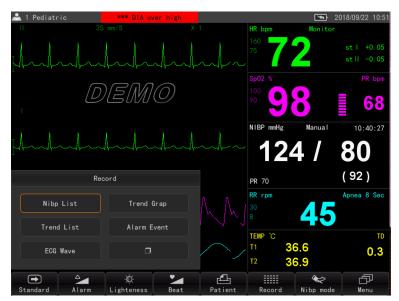


Fig. 4-17

The contents that can be viewed in the history include: blood pressure list, trend chart, trend list, alarm event, and waveform playback;

A) Blood pressure list:

Record the results of each NIBP measurement, including: record number, bed number, systolic pressure, diastolic pressure, mean pressure, date and time of measurement; page

turning operation can be performed by pressing the [and [a

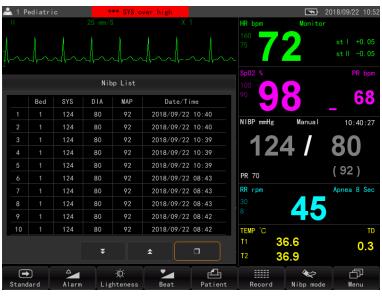


Fig. 4-18

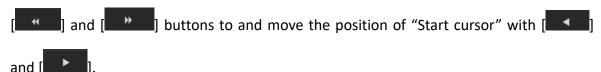
B) Trend chart:

Record each parameter value and display it as a trend chart. You can select the parameters to view, including heart rate, body temperature, SPO₂, respiration rate, S-T parameters, blood pressure parameters, pulse rate and TD parameters. As shown in Fig. 4-19, the first curve corresponds to the parameter "HR", the second curve corresponds to the parameter "SpO2", and the third curve corresponds to "RR". You can rotate the knob to select the button of the parameter name that needs to be replaced, and click the knob to switch the displayed parameter.

The sampling interval of the trend chart includes 1 minute, 5 minutes, 10 minutes, 30

minutes, and 60 minutes, which can be switched by [1 Min]. The current sampling interval will be displayed on the button. The monitor can save up to 720 hours of measurement data; "Trend waveform area" shows the trend chart of each measurement parameter, and the left scale shows the measurement data range.

"Move cursor" is used to query the measurement data of each point in the trend chart. When displayed in the interface, it is a purple vertical line. Move the waveform with the



The "Trend data area" shows the measurement data at the moment of "Move cursor", which is displayed in the "Trend data" box.

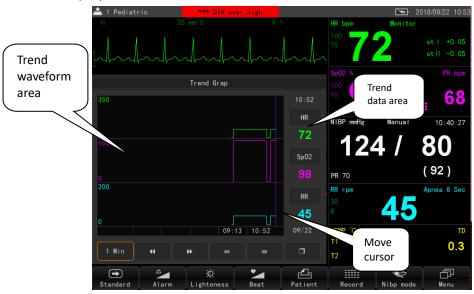


Fig. 4-19

C) Trend list:

Each parameter value is recorded and displayed in the form of a trend list, as shown in Fig. 4-20. The recorded parameters include: date and time, heart rate, SPO2, blood pressure parameters, respiratory rate, pulse rate, ST parameters, body temperature and TD parameters; the sampling interval of the trend list includes 1 minute, 5 minutes, 10

minutes, 30 minutes, and 60 minutes, which can be switched by [1 Min]. The current sampling interval will be displayed on the button;

Turn page up/down with [and [buttons to view more record data;

Turn page left/right with [and [buttons to view more parameter data;

The monitor can store up to 720 hours of measurement data.

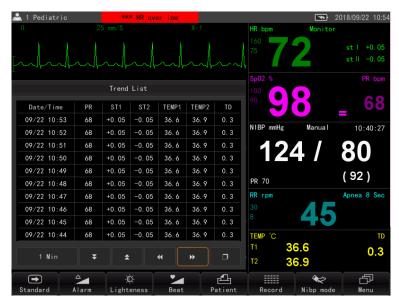


Fig. 4-20

D) Alarm event:

The playback of alarm events is shown in Fig. 4-21. You can view the relevant vital signs of the measured object and the cause of the alarm when the alarm is generated. The parameter values of each record are displayed at the top of the alarm event window, including: heart rate, SPO2, pulse rate, respiration, blood pressure, and body temperature; below is the waveform data of lead II and lead I;

Use the [] and [] buttons to view the alarm events, and use the [] and

[buttons to move the waveform;

The monitor can store up to 1000 alarm data;



Fig. 4-21

E) Waveform playback:

Play back the ECG waveform, as shown in Fig. 4-22. The waveform playback window displays three ECG waveforms. From top to bottom, the first and second waveforms are lead I ECG waveform and lead II ECG waveform, which are fixed and can't be switched. The third ECG waveform can be switched to display lead III, aVR, aVL, aVF, or V. Below the third waveform is the waveform record corresponding to it. The record includes: the

number of the bed being measured, and the start and end time of the recorded data.

Use the [] and [] buttons to select and view records, use the [] and

[buttons to move the waveform; the monitor can store up to 720 waveform data.

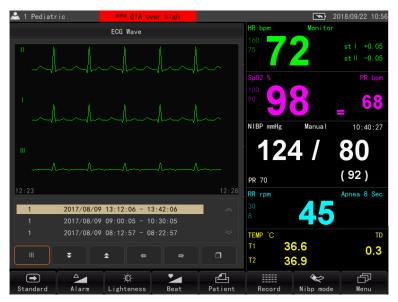


Fig. 4-22

(7) Blood pressure mode:

It is used for quickly switching blood pressure measurement. When clicking the [Blood pressure mode] button, the setting window shown in Fig. 4-23 will pop up; the options in blood pressure mode include: Auto 1 min, Auto 2 min, Auto 5 min, Auto 10 min, Auto 15 min, Auto 20 min, Auto 30 min, Auto 1 H, Auto 2 H, and manual;



Fig. 4-23

(8) Main menu:

The main menu is the setting of a specific measurement parameter or system parameter, including: ECG, SPO₂, blood pressure, respiration, body temperature, and alarm settings, as shown in Fig. 4-24:

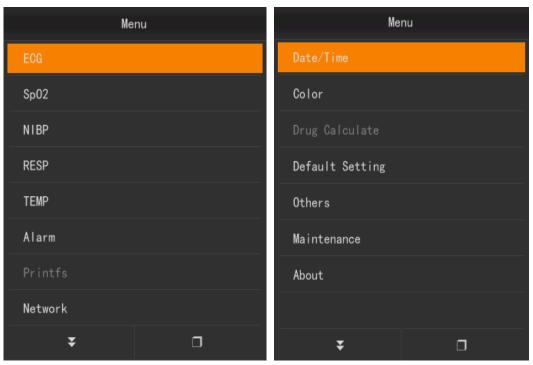


Fig. 4-24

3. Parameter area:

This area shows real-time measurements. Measurement parameters are displayed in a fixed position. The text marked in the upper left corner of each parameter indicates the name of the parameter.

The NIBP area shows systolic blood pressure and diastolic blood pressure, and mean pressure is shown below the two. The top of the area shows patient (adult or child) and measurement mode (cycle, manual or continuous).

The ECG area shows the heart rate value.

SPO2 area shows SPO2 value and pulse rate. There is a pulse column on the right side that indicates the SPO2 signal intensity.

RESP shows the respiration rate.

TEMP1 and TEMP2 show the temperature value.

The above texts can be selected by rotating buttons to enter respective menu interfaces.

4. Status bar:

The status bar includes battery level indicator, charging indicator, sound status or sound pause countdown.

- ① Alarm sound status: (The alarm sound is off, and the number 120 is the remaining time (unit: second) when the alarm sound is off; when the time is zero, the alarm sound will be turned on)
- ② Battery level: Indicates the current battery level when using battery power only.

 Please pay attention to the remaining battery power of the monitor and charge it in time to prevent the monitor from automatically shutting down.
- ③ When the monitor is connected to AC power, the charging symbol is displayed in the upper right corner of the monitor, indicating that AC power is connected and the internal power supply is being charged.
- 4 The current date and time is displayed in the upper right corner of the monitor. The

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format is year-month-day hour: minute: second. The date and time settings can be modified in the date/time menu in the main menu.

5. Technical alarm display area:

Display all technical alarm information. When multiple alarms occur, each alarm is displayed in turn. Technical alarms include: ECG electrode falling off, SpO2 probe falling off, etc.

6. Physiological alarm display area:

Display all physiological alarm information. When multiple alarms occur, each alarm is displayed in turn.

7. Patient information area:

Display the bed number and type of the patient being monitored.

Large font layout

Display the ECG waveform of the key monitoring lead in large font interface with heart rate, SPO₂, blood pressure, respiration rate, and body temperature values amplified, as shown in Fig. 4-2.

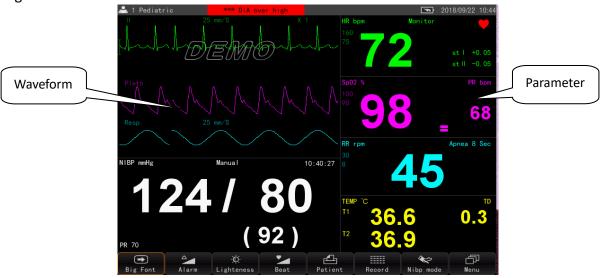


Fig. 4-2

Seven-lead ECG interface

Display the ECG waveforms of I, II, III, aVR, aVL, aVF, and V (chest lead) in the 7-lead interface, with ECG waveform highlighted; as shown in Fig. 4-3.

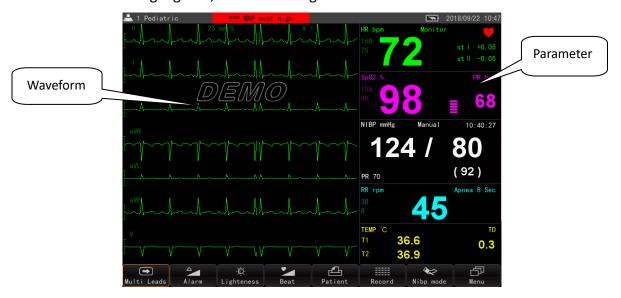


Fig. 4-3

Oxygenation diagram interface

The interface with respiratory oxygenation diagram shows a graph consisting of heart rate, SPO₂, and respiration, as shown in Fig. 4-4. There are three curves in the respiratory oxygenation diagram; the far left of each curve indicates the parameter source of the curve, and the rightmost is the display range of the curve;

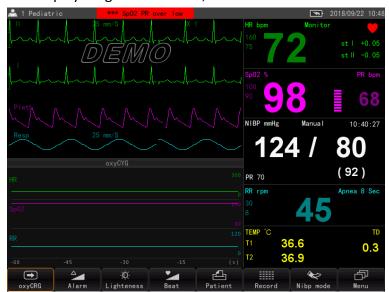


Fig. 4-4

Blood pressure list interface

The interface of the blood pressure list, as shown in Fig. 4-5, shows the records of systolic blood pressure, diastolic blood pressure and mean pressure measured at different times through the blood pressure list. The content of blood pressure list includes: SYS (systolic pressure), DIA (diastolic pressure), MAP (mean pressure), PR (pulse rate), and TIME (measurement time). This feature makes it easy to view diagnostic records.

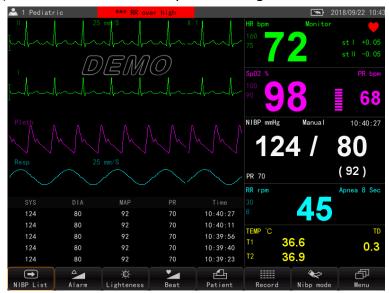


Fig. 4-5 Interface of Blood Pressure List

4.2 Operation and Auxiliary Information

Network settings

The network setting is to set the IP address when the monitor is connected to the central unit. The window of the network setting is shown in Fig. 4-6.

Steps to enter the menu: Shortcut button area -> Main menu -> Network settings.



Fig. 4-6

Date and time

In the date/time menu, you can set the date and time displayed by the monitor. The date/time menu is shown in Fig. 4-7. The options that can be set include: year, month, day, hour, minute and date format; after setting, click [Set to modified date and time], and the status bar in the upper right corner of the monitor interface will modify the time according to the set information.

To enter the menu: Shortcut button bar -> Main menu (second page) -> Date and time;



Fig. 4-7

Custom color

In custom color menu, you can set the relevant parameters and the color of the waveform in the display interface. The parameters that can be selected include: ECG, SPO₂, blood pressure, respiration, and body temperature; each parameter has 7 colors optional: green, light blue, red, purple, yellow, white, and blue; once set, the color of each waveform or value associated with the parameter will become the same as the selected color.

To enter the menu: Shortcut button bar -> Main menu (second page) -> Custom color The custom color menu is shown in Fig. 4-8:



Fig. 4-8

Other settings

Set the display language of the monitor: Simplified Chinese and English.

ECG grid: Set whether to show grid line in the ECG waveform area. When it is turned on, it will display the grid background with the interval of 0.5cm in the ECG waveform area.

Demo mode: Entering the correct password to turn on the demo mode (password: 1122)

Key tone: Set the key tone of the monitor. If it is set to on, you can hear the key tone when you press any key.

To enter the menu: Shortcut button bar -> Main menu (second page) -> Other settings; The menu for other settings is shown in Fig. 4-9:



Fig. 4-9

System info

Display the software and hardware version currently in use.

To enter the menu: Shortcut button bar -> Main menu (second page) -> System info; The menu of system information is shown in Fig. 4-10:



Fig. 4-10

Chapter 5. Alarm

The alarm refers to the prompt made to medical staff through sound, light and other means when the patient under monitoring has abnormal vital signs change or the monitor itself fails to monitor the patient smoothly.

5.1 Alarm Type

According to the nature, the alarms can be divided into physiological alarm, technical alarm and prompt information.

1. Physiological alarm

The physiological alarm is usually caused by a certain physiological parameter of the patient exceeding the set upper and lower limits of the alarm or a physiological abnormality of the patient. Physiological alarm information is displayed in the physiological alarm area.

2. Technical alarm

Technical alarms, also known as system error messages, are alarms that are triggered when a certain monitoring function fails to function properly or the monitoring result is distorted due to improper operation or system failure. Technical alarm information is displayed in each parameter display area.

3. Prompt information

Strictly speaking, the prompt information is not alarm. It means that in addition to the physiological alarm and the technical alarm, the monitor also displays some information related to the system state, which generally does not involve the vital signs of the patient. The prompt information is generally displayed in each parameter display area or information prompt area.

5.2 Alarm Level

According to the severity, the physiological alarms can be divided into high level alarm, medium level alarm and low level alarm; the technical alarms can be divided into medium level alarm and low level alarm.

1. High level alarm

The patient is in a critical state and may be in danger of life and should be rescued immediately.

Medium level alarm

The patient's physiological signs are abnormal, appropriate measures or treatment should be taken immediately.

3. Low level alarm

The patient's physiological signs are abnormal and may require appropriate measures or treatment.

The physiological alarms have been set before the monitor is shipped from the factory and can't be changed by the user.

5.3 Alarm Method

When an alarm occurs, the monitor will prompt the user with the following audible or visible alarms:

- Flashing light
- Sound response
- Text prompt

Among them, the flashing light, sound response and text prompts distinguish the level of the alarm in different ways.

5.3.1 Flashing Light

When a physiological alarm occurs, the alarm indicator prompts different levels of alarms with flashing in different colors.

■ High level alarm: Red, flashing.

■ Medium level alarm: Yellow, flashing.■ Low level alarm: Yellow, normally on.

5.3.2 Sound Response

The sound response means that the monitor uses different sound characteristics to alert different levels of alarms when an alarm occurs.

■ High level alarm: Short three beeps and two beeps

■ Medium level alarm: Three slow beeps

■ Low level alarm: One beep

△Caution: When multiple alarms of different levels occur at the same time, the monitor will visually and audibly alert in the highest level of all current alarms.

5.3.3 Text Prompt

The system uses different character colors to distinguish the level of physiological alarms:

■ High level alarm: Red

■ Medium level alarm: Yellow

■ Low level alarm: Yellow

When a physiological parameter of the patient has alarm, the parameter in the parameter area flashes at a frequency of once per second.

5.3.4 Alarm Status Icon

In addition to the above alarm methods, the following alarm icons will appear on the screen to indicate the different status of the alarm.

Table 5-1

lcon	Description
×	All sounds off
💢 119	Alarm mute countdown

5.4 Setting Alarm Volume



Fig. 5-1 Alarm Volume Settings

Menu position: Shortcut button area —> Alarm tone;

The "button is used to lower the alarm volume and the "button is used to increase the alarm volume.



- 1. When the sound is turned off, the monitor will emit a sound when a new alarm is triggered. Therefore, you must carefully choose whether to turn off the sound.
- 2. Do not rely on the audible alarm system to monitor the patient. If the volume is set too small, the patient's risk may be ignored. The actual clinical condition of the patient should be closely monitored.
- 5.5 Setting Parameter Alarm
- 5.5.1 Setting Alarm Level

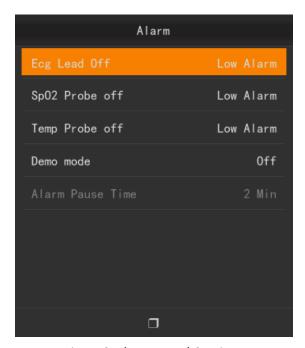


Fig. 5-2 Alarm Level Settings

Menu position: Shortcut button area —> Main menu —> Alarm settings

The ECG electrode off, the blood oxygen probe off, and the body temperature probe off. The optional values are: low alarm, medium alarm, do not shut down.

5.5.2 Setting Alarm Limit (ECG as example)

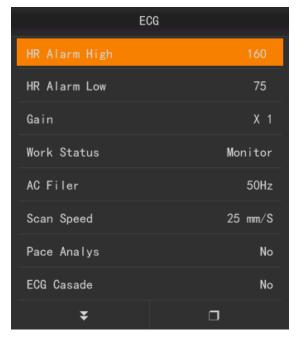


Fig. 5-3 ECG Related Alarm Limit Settings

5.5.3 Alarm Log

The alarm log is displayed as an alarm event on this monitor and up to 1000 alarm messages can be stored. When the messages exceed 1000, the earlier messages are automatically overwritten. The alarm list is not saved when the monitor is shut down or the system power is cut off.

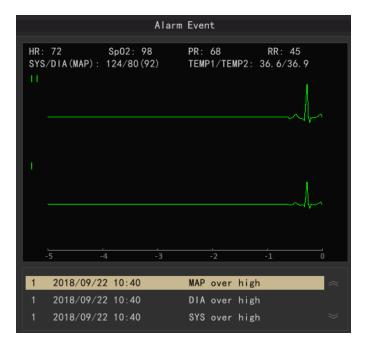


Fig. 5-4 List of Alarm Events

5.6 Sound Pause

Press "SILENCE" to temporarily turn off all sound prompts from the monitor:

■ All alarm sounds are suspended, but light and text alarm messages are still displayed.Icon



- The generated alarm parameters will remain flashing.
- The countdown icon will be displayed in the sound icon area.

5.7 Latched Alarm

This monitor uses non-latched alarm.

5.8 Alarm Response Measures

When the monitor has an alarm, please refer to the following steps to take the appropriate action:

- 1. Check the condition of the patient.
- 2. Confirm the parameter being alarmed or alarm type.
- 3. Identify the cause of the alarm.
- 4. Remove the cause of the alarm.
- 5. Check if the alarm is eliminated.

For details on how to handle each alarm, see Chapter 15 Alarm Information.

Caution: 1. Do not turn off the alarm for the parameters that need to be alarmed during use.

2. When the power is off, the alarm settings before power loss can be automatically restored.

⚠Warning: 1. It is forbidden to turn off the alarm sound of ECG, respiration and blood pressure unless the medical staff ensures that the parameters measured by the monitor can be observed at any time.

2. There are potential hazards associated with using different alarm presets for the same or similar devices used in any separate area, such as intensive care units or cardiac operating rooms. The operator must confirm whether the alarm preset meets the current use situation!

5.9 Verification of Alarm System

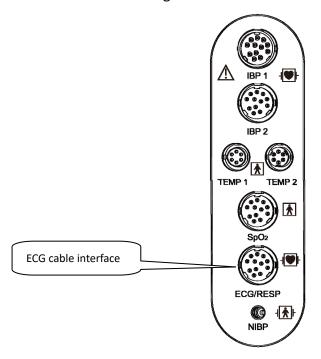
When the alarm system is suspected to be invalid, the equipment can no longer be used. Contact the maintenance engineer immediately. The effectiveness of the alarm system must be checked by a professional maintenance engineer.

Chapter 6. ECG/Respiration

6.1 Overview

The electrocardiogram (ECG) measures the electrical activity of the heart and displays the ECG waveform and parameter values on the screen.

The ECG module and the connecting wires have anti-defibrillator discharge effect.





Respiratory measurements use the thoracic impedance method to measure the impedance change between two ECG electrodes on the patient's chest and display the Resp waveform on the screen. The monitor calculates the respiration rate (PR) based on the waveform period.

6.2 Safety Information

\triangle Warning:

- Be sure to use the ECG lead wire and ECG electrode specified by the company.
- ECG electrodes are disposable items that are only used for one patient at a time.
- It is strictly forbidden to use electrode sheets of different metal materials, or else it may cause over-polarization or accelerated polarization to the electrodes.
- The ECG lead wire socket is only used to connect ECG wires. Do not connect with other signal sources. Pay attention to the color marking of the ECG lead wire.
- When placing the electrode or connecting the ECG lead wire, make sure that it does not touch other conductive parts or ground. In particular, ensure that all ECG electrodes are attached to the patient.
- Regularly check the skin where the electrode is placed. If there is any indication of allergies, replace the electrode or change the placement position.
- When defibrillation is required for the patient, do not use non-defibrillation ECG lead wire. When the patient respiration is monitored, do not use anti-ESU type ECG lead wire.
- With the correct electrode and the electrode placed according to the manufacturer's instructions, the display will return to normal display within 10 seconds after defibrillation.
- This monitor cannot be used simultaneously with high-frequency electrosurgical equipment when measuring ECG.

- Interference from ungrounded instruments near the patient and ESU interference may cause distortion of the ECG waveform.
- The transient effect of the grid power isolation monitor may be similar to the actual ECG waveform, thus suppressing the SPO₂ alarm. The ECG lead wire must not be entangled with the power cord or other cables.
- The waveform can return to normal display within 5s after defibrillation.

6.3 Publication of ECG Performance Parameters

6.3.1 Respiration, Lead-off Detection and Active Noise Suppression

This monitor has no current applied to the patient.

6.3.2 Response Time to Heart Rate Changes

When heart rate is increased from 80bpm to 120bpm or reduced from 80bpm to 40bpm, the maximum response time (including device refresh time) required by the monitor to indicate new heart rate is less than 10s.

6.3.3 Start Time of Tachycardia Alarm

When the upper limit of the alarm is set to 100bpm and the lower limit is 60bpm, the alarm should be started within no longer than 10s if the SPO₂ is changed from 80bpm to 120bpm.

6.3.4 Suppression of Pacing Pulse Detector on Fast ECG Signals

When the pacemaker switch is turned on, the pacing pulse detector suppresses the fast ECG signal at a minimum input slew rate of 1 V/s RTI.

The ECG pacing test must be turned on and the pacing signal can't be detected when turned off.

6.3.5 High T wave suppression ability

+1.0 mV.

6.3.6 Effective time base and screen aspect ratio.

The height/width ratio of the monitor screen is not adjustable, the aspect ratio is 4:3, and the screen pixels are: 800×600 .

The time base adjustable range is: 6.25mm/s, 12.5mm/s, 25.0mm/s, 50mm/s.

6.4 Measuring ECG

The monitor generates a continuous waveform and heart rate of the patient's ECG activity to accurately assess the current physiological state of the patient. In order to get the correct measurement data, sufficient precautions must be given.

6.4.1 Precautions

The quality of the ECG signal depends on the signal acquired from the electrode sheets. In order to obtain a reliable signal, the skin must be cleaned before the electrode sheets are attached. It is recommended to:

Scrape the hair in the position to attach the electrode.

Gently scrub to remove the stratum corneum.

Wash your skin with alcohol or nourishing soap.

Wait until the skin is completely dry and then stick the electrode sheet.

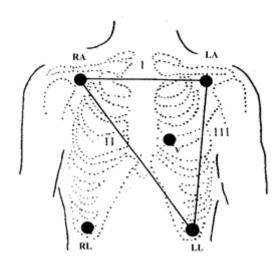
6.4.2 Lead Wire and Electrode Sheet Precautions

Pay attention to the following points when setting up ECG/respiration monitoring:

Check the wires and cables for wear or breakage and replace if necessary;

First connect the lead wire to the electrode sheet, and then attach the electrode sheet to the patient as shown in the figure below;

(1) Attach the electrode to the cleaned skin. The positions where the sheets are attached are as follows: RA(R), LA(L), RL(N), LL(F) and V(C).



(2) Connect the ECG lead wire to the electrode and monitor. Make sure the lead wire is placed in the correct position. The part of ECG lead wire connecting to patient should be colored and coded as specified. Please refer to the following table:

Electrode marking Position Color First intercostal space of the midline of White(Red) RA(R) the clavicle on the right sternum LA(L) First intercostal space of the midline of Black(Yellow) the clavicle on the left sternum Right clavicle midline rib Green(Black) RL(N) Left clavicle midline rib Red(Green) LL(F) V(C) Fourth intercostal space on the left Brown(White) sternal border

ECG 5-lead Electrode Identification

- (3) Insert the ECG cable into the ECG jack on the side panel of the monitor.
- (4) Make sure that the 5 lead marks are correct.
- (5) Adjust the ECG settings when necessary; Refer to section 6.5 ECG Parameter Settings for the setting method.

The parameters to be set for ECG measurement are: Scan speed of waveform, ECG gain, monitoring mode, etc.

The mark beside ECG socket indicates that the input signal is highly insulated and protected from defibrillation, which guarantees the patient safety and avoids damage to the monitor during defibrillation and electrosurgery.

6.4.3 Mounting the Electrodes

Five lead electrode installation:

The electrodes are mainly applied in four locations:

First intercostal space of the midline of the clavicle on the right sternum RA(R)

First intercostal space of the midline of the clavicle on the left sternum LA(L)

Right clavicle midline rib RL(N)

Left clavicle midline rib LL(F)

Conventional ECG Lead Position

Lead	I	II	III	aVR	aVL	aVF	
Positive	Positive electrode						
	LA(L)	LL(F)	LL(F)	RA (R)	LA(L)	LL(F)	
Negativ	Negative electrode						
	RA(R)	RA(R)	LA(L)	LA(L)+LL(F)	RA(R)+LL(F)	RA(R)+LA(L)	

V(C) lead is the chest lead, the fourth intercostal space on the left sternal border

Installing electrodes for surgical patients

When installing electrodes for surgical patients, the type of surgery performed should be considered. For example, for thoracotomy, the chest electrode can be placed on the side or back of the chest. In addition, when using a surgical electrosurgical device, in order to reduce the influence of artifacts on the ECG waveform, the electrodes can be placed on the left and right shoulders, close to the left and right sides of the abdomen, and the chest lead can be placed on the left side of the chest. Avoid placing the electrode on the upper arm or the ECG waveform will become very small.

△Warning:

- When using electrosurgical unit (ESU), place the ECG electrode in the middle between the ESU ground plate and the electrosurgical blade to avoid burns, and the ESU cable can't be entangled with the ECG cable.
- When using electrosurgical unit (ESU), do not place the electrodes on the grounding plate close to the ESU, or else there will be a lot of interference on the ECG signal.

6.4.4 Checking Pacing Status

It is very important to correctly set the patient's pacing state before starting ECG monitoring.

When [Pacing] is [On], the icon is displayed. When the system detects a pacing signal, the "I" symbol will be marked above the ECG waveform.

This setting will open [Main Menu]; enter [ECG] and set [Pacing] to [On] or [Off].

⚠Warning:

- For pacing patients, [Pacing] must be set to [On], or else the pacing pulse will be treated as a regular QRS complex, and when the ECG signal is too weak, the system can't detect and alarm.
- For non-pacing patients, [Pacing] must be set to [Off], or else the system can't detect arrhythmia related to ventricular premature beats.

6.4.5 Indication of Abnormal Working Status of ECG Monitoring Equipment

When the monitor is not in normal operation due to signal overload or any part of the amplifier saturated, the monitor ECG waveform channel will prompt "signal saturation".

\triangle Warning:

When the message "signal saturation" is prompted, the monitor ECG function is in an inactive state.

6.4.6 ECG Display

The following figure shows the ECG monitoring interface. It is for reference only. The graphics displayed on your monitor may be slightly different.

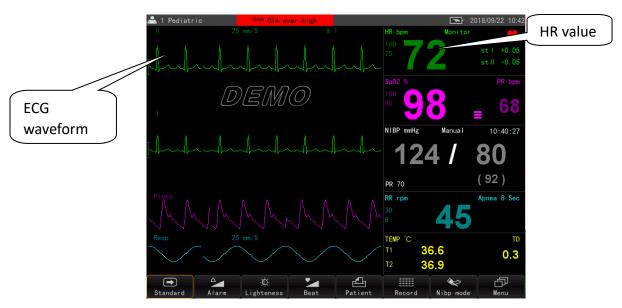


Fig. 6-1 ECG Display

6.5 Setting ECG

To enter the ECG menu: Shortcut button bar -> Main menu -> ECG

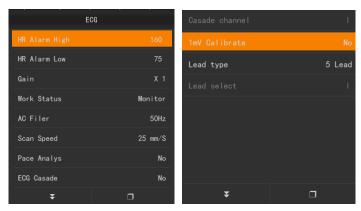


Fig. 6- 2 ECG Menu Settings

Monitoring ob	ject: Adult	Monitoring object: Child		
Parameter	Range	Parameter	Range	
name		name		
HR alarm	1~300	HR alarm	1~300	
upper limit		upper limit		
HR alarm	0~299	HR alarm	0~299	
lower limit		lower limit		

HR alarm upper/lower limit: The upper or lower limit values of the HR alarm. When the heart rate of the measured object is higher than the upper limit or lower than the lower limit of the HR alarm, the alarm will be started; The minimum value of the HR alarm upper limit can't be lower than the lower limit of the current HR alarm, and the maximum value of the HR alarm lower limit can't be higher than the upper limit of the current HR alarm;

Gain: Adjust the height of the ECG waveform display according to the gain setting. The gain value of the current ECG waveform is displayed above the first ECG waveform on the display interface. Options: $\times 1/4$, $\times 1/2$, $\times 1$, $\times 2$, $\times 4$.

Working mode: Select the ECG filtering status. Options: Monitor, surgery, expand.

Power frequency notch: 50Hz, 60Hz, off. After the ECG simulator inputs the 50Hz or 60Hz power frequency ECG signal, set the notch to 50Hz or 60Hz. The ECG waveform displayed on the screen should be smooth with no obvious burrs; when the notch is set to OFF, it means

that the power frequency interference signal is not filtered.

Waveform speed: Set the waveform speed. Adjust the wave distance of the waveform according to the speed setting, and display the speed of the wave above the first ECG waveform on the display interface. The options for waveform speed: 6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s.

Pacemaker: Turn the pacemaker detection on/off. When the function is turned on, the

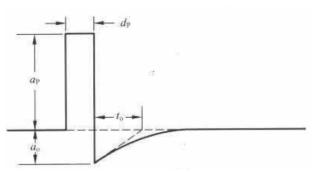
pacemaker marker "••" is displayed in the upper left corner of the display interface, indicating that pacing detection is turned on. If the ECG waveform is superimposed with a pacing signal, the position of the pacing signal on the ECG waveform will display a purple vertical line to indicate that this is a pacing signal. By default, pacemaker detection is turned off.

The suppression ability of pacemaker pulse includes the suppression of pacemaker pulse without overshoot and the suppression of pacemaker pulse with overshoot.

The suppression ability range of pacemaker pulse without overshoot: ± 2 mV to ± 700 mV, 0.1ms to 2.0ms width, overshoot less than 0.05ap [Fig. 5a], stabilization time less than 5 μ s. The start, rise and fall time of the pulse did not exceed 100 μ s; The initial time of the pulse is 40ms or less before the initial time of QRS. The above pacing pulse is preceded by an identical pulse with a time lead of 150ms to 250ms.

The overshoot (charge) time constant is between 4ms and 100ms, and the other parameters are the same as the pacing pulse suppression capability above. The overshoot is defined by Method A, which should be in the range of 0.025ap to 0.25ap, independent of the choice of time constant, but not greater than 2mv.

When the pacing pulse signal is greater than 1mV, 2ms or 2mV, 1ms, the pacing pulse detector can work normally.



Waveform polar: Option: Yes/No.

Polar channel: Option: I, II, III, aVR, aVL, aVF, V.

1mV calibration: The output of the calibration ECG module is 10mm/mV. When 1mV calibration is turned on, the module internally outputs a standard model of 10mm/mV. The actual measurement error is $\pm 10\%$; when 1mV calibration is turned off, the actual measurement error is $\pm 10\%$ when 1mV signal is input from the outside. Compare the two measurement results and determine the impedance in the module and the lead according to the difference. By default, 1mV calibration is off.

Description of working mode:

Monitor: Use under normal measurement conditions.

Expand: Use when an enlarged waveform is required. At this moment, the unfiltered ECG waveform is displayed, and you can see the changes in the waveform, such as the notch of the R wave, the discrete rise or depression of the ST segment.

Surgery: Use when the signal is subject to high or low frequency interference. High frequency interference usually causes high amplitude spikes that cause the ECG signal to appear irregular.

Low frequency interference usually causes the baseline to drift or become thicker. In the operating room, the choice of "Surgery" approach can reduce artifacts and interference from electrosurgical equipment. In normal measurement situations, selecting this method may suppress the QRS complex and cause ECG analysis to be disturbed.

△Caution: The "Monitor" or "Surgery" mode will cause some distortion of the ECG waveform. The "Surgery" mode may affect the results of the VPC analysis. Therefore, it is recommended to monitor the patient in an "expand" mode when the interference is small. Average heart rate:

Normally, the heart rate is calculated by averaging the 12 most recent RR intervals.

For consecutive PVC, take up to 8 RR intervals to average the heart rate at most.

If each of the three consecutive RR intervals is greater than 1200 ms (which means that the heart rate is below 50 bpm), then the most recent four RR intervals are averaged to calculate the heart rate.

Heart rate calculate accuracy and response to arrhythmia:

Ventricular dual law: 80bpm; slow interaction ventricular dual law: 60bpm; fast interaction. ventricular dual law: 120bpm; bidirectional systolic pressure: 90bpm.

6.6 Measuring Respiration

6.6.1 Principle of Respiration Measurement

The monitor measures the respiration from the value of the thoracic impedance between the two electrodes, and the impedance change between the two electrodes (due to the activity of the thorax) results in a waveform of the respiration.

There is no need for additional electrodes for respiration monitoring, and the same RA(R) and LA(L) electrodes for ECG monitoring are used.

For the operation method of the respiration monitoring setting parameters, please refer to Fig. 6-4.

Caution: Respiration monitoring isn't recommended for patients with a high degree of monitoring activity, as this may result in calculation error.

6.6.2 RESP Display

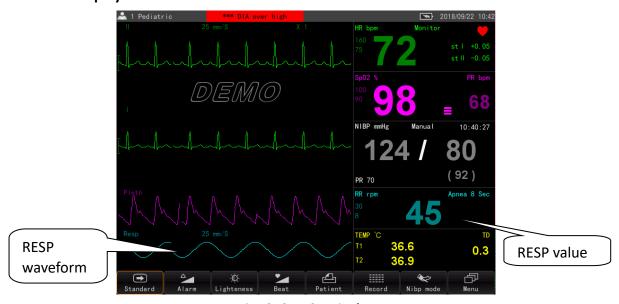


Fig. 6-3 RESP Display

6.6.3 Respiration Parameter Setting Menu

To enter the Respiration menu: Shortcut menu bar -> Main menu -> Respiration

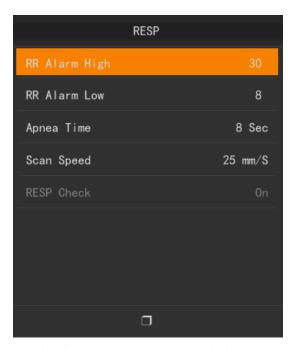


Fig. 6- 4 Respiration Parameter Settings

Monitoring obj	ect: Adult	Monitoring object: Child	
Parameter name Range		Parameter name	Range
Respiration rate	1~150	Respiration rate	1~150
alarm upper limit		alarm upper limit	
Respiration rate	0~149	Respiration rate	0~149
alarm lower limit		alarm lower limit	

Respiration rate alarm upper/lower limits: The upper or lower limit of the respiration rate alarm. When the respiration rate of the measured object is higher than the upper limit or lower than the lower limit of the respiration rate alarm, the alarm will be started; The minimum value of the upper limit of the respiration rate alarm can't be lower than the lower limit of the current respiration rate alarm, and the maximum value of the lower limit of the respiration rate alarm can't be higher than the upper limit of the current respiration rate alarm;

Suffocation time: Range 5~80s; select the time for the sound and light alarm after the respiration stops, or choose to turn off the suffocation alarm.

Waveform speed: Select the respiration waveform scan speed. Option: 6.25, 12.5, 25.0mm/s. **Respiration detection**: Option: On, off.

6.7 ECG Monitoring Precautions

ECG monitoring relies on the continuous waveform of the patient's ECG activity to accurately assess the current physiological state of the patient. For this reason, a good connection of the ECG cable should be ensured in order to obtain good expected results.

For patients with severe burns, electrodes may not be attached and special needle electrodes are required.

The skin is a poor conductor, so the skin assessment of the patient is very important to get good contact between the electrodes and the skin.

If a disposable electrode that meets industry standards and has not expired is used, generally no special handling is required. If the signal quality is poor, the electrode should be placed in the soft part of the muscle as much as possible. When placing it, first wipe off the oily sweat on the skin with alcohol. If necessary, wear off the keratinized layer on the patient's skin, wipe it off with alcohol, and attach the electrode.

Check the skin irritation caused by the ECG electrode every day. When any signs of inflammation appear, replace the electrode and reposition it every 24 hours or less.

When performing electrosurgery, the ECG mode of the monitor ECG module should be set to the surgery mode. Place the electrode on the circumference centered on the operating area and twist the ECG lead wires as much as possible. The monitor should be farther away from the operating bed. The power cable and the ECG lead cable should be separated as far as possible, and the direction should not be parallel.

The cable of the electrosurgical device can't be entangled with the ECG cable.

Note: When connecting the electrode or patient cable, make sure that it is not in contact with any other conductive parts or ground. In particular, make sure that all ECG electrodes, including neutral electrodes, are attached to the patient to prevent them from coming into contact with conductive parts or ground.

⚠ Warning: For patients with pacemakers, the heart rate monitor may count the pacemaker pulse during cardiac arrest or arrhythmia. Do not rely solely on the heart rate monitor at this moment.

 $ilde{\Delta}$ Warning: Overload of the electrosurgical device will damage this instrument.



Precautions:

1. What is the danger of using it with a pacemaker?

When the monitor is used with a pacemaker, the pulse of the pacemaker is mistaken for the QRS wave by the monitor, and some pacemakers may cause inaccurate respiration impedance, which may cause artifacts, result in false respiration detection and affect the diagnosis of medical staff. The medical staff should closely monitor patients who use pacemakers and make correct diagnosis in a timely manner.

2. What are the circumstances that the monitor may have misdetection?

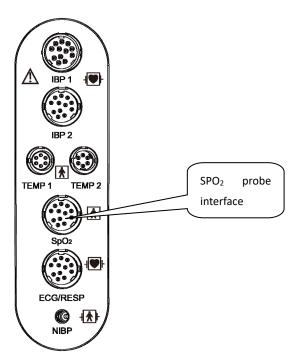
When the monitor is used in the same patient as the pacemaker or other electrical generator, or the patient has an arrhythmia, it may cause the monitor to be misdetected, and the monitor may still have ECG signals when the patient is dead. The medical staff should closely monitor the patient and make a correct diagnosis in a timely manner.

Chapter 7. SPO₂

7.1 Measuring SPO2 Saturation

7.1.1 Measurement Content

SPO₂ refers to the measurement of arterial oxygen saturation, which is the percentage of oxyhemoglobin to the total number of hemoglobin. The value of SPO₂ shows the percentage of oxygen-carrying hemoglobin molecules that form oxyhemoglobin. The SPO₂ plethysmographic parameters also provide pulse rate signals and plethysmographic waveforms.



7.1.2 SPO₂ Display

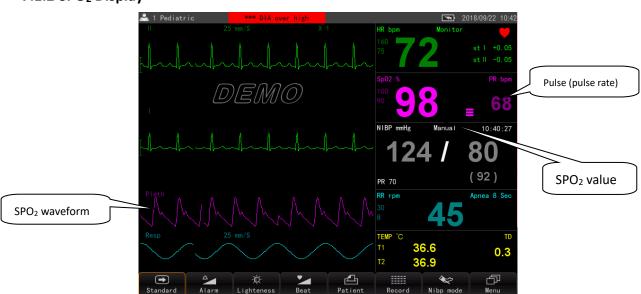


Fig. 7-1 SPO₂ Display

7.1.3 Measurement Principle

Oxygen saturation is measured by pulsating oximetry. This is a continuous, non-invasive method for measuring hemoglobin oxygen saturation. It measures how much light emitted from one side of the sensor source passes through the patient's tissue to the receiver on the

other side. The amount of light that passes through depends on a number of factors, most of which are constant. However, one of these factors is that arterial blood flow changes over time. By measuring the light absorbed during the pulsation, it is possible to obtain the oxygen saturation of the arterial blood. The detection of the pulsation itself gives a "plethysmographic" waveform and pulse rate signal.

7.1.4 Limitations of Measurement

- 1. Arterial blood flow may be reduced to levels that can't be measured under the following conditions:
- *Shock
- *Low temperature
- * Vasoactive drugs applied
- *Anemia
- 2. Measurement also depends on the absorption of light at specific wavelengths by oxyhemoglobin and reduced hemoglobin. If other substances that absorb the same wavelength exist, they will cause a false SPO₂ value to be measured.

For example:

When carboxyhemoglobin >3%, SPO₂ determination may be high; when bilirubin >200mg/L, SPO₂ determination may be low; when methemoglobin >5%, SPO₂ may be fixed at 85%; in addition, if there is dye (such as methylene blue, indigo carmine and fluorescein, etc.) in the blood, the SPO₂ value may be greatly reduced.

3. The strong light of surrounding environment will also affect the measurement. Covering the sensor with a suitable opaque substance improves the quality of the measurement.

7.2 Safety Information



Use only the SPO₂ sensor specified by our company. It is the responsibility of the operator to check the compatibility of the SPO₂ probe and the cable with the monitor before use. Incompatible accessories may cause degradation of the instrument performance.

When the patient has a tendency to lack oxygen, a blood gas analyzer should be used to analyze the blood sample to properly comprehend the patient's condition.

Avoid using the monitor and blood oxygen sensor when using MRI equipment, as induced currents can cause severe burns to patients.

7.3 Publication of SPO2 Performance

7.3.1 Emitted Light Power Statement of SPO₂ Probe

Probe peak wavelength: Red light 660nm, infrared light 880nm, maximum light output power ≤150mW.

Low power light in this wavelength range is safe for the human body.

7.3.2 SPO₂ Compliance Statement of the Monitor

The SPO2 accuracy of this monitor complies with the requirements of IEC 80601-2-61.

7.3.3 Approved SPO₂ Probe and SPO₂ Probe Extension Cable

The SPO2 probes and cables used with this monitor must comply with the requirements of the IEC 80601-2-61 standard.

The recommended blood oxygen probe models are: S200A, T200A.

7.3.4 Maximum Use Time of SPO₂ Probe in Single Position

For continuous long-term monitoring of the patient, check the position where the SPO₂ probe attached every 2 hours (the continuous monitoring on the same position should not exceed 4 hours), and move appropriately when the skin changes. Check the measurement points



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regularly during use to ensure that the patient's skin at the measurement position is not injured. Some patients may require more frequent examinations, such as patients with perfusion disorder or skin sensitivity, because prolonged monitoring can increase unpredictable skin changes such as skin irritation, redness, blistering or oppressive necrosis.

7.3.5 Known Interferences that Affect the Function and Accuracy of Pulse SPO₂ Measurement

Interference can be caused by excessive ambient light, electromagnetic interference, excessive or enormous patient movement, low filtration testing, weak perfusion, electrosurgical unit, diseased hemoglobin, presence of certain dyes, and improper wearing position of pulse SPO₂ probe.

7.3.6 SPO₂ Measurement Function Statement

The verification of the SPO₂ accuracy is obtained by a clinical test in invasive contrast with the blood gas analyzer.

7.3.7 Characteristics of Clinical Research Population

- a) Adult males or females between the ages of 18 and 45;
- b) No history of smoking / smoking addiction;
- c) No history of cardiopulmonary disease;
- d) Volunteers have the capacity to act autonomously, agree to participate in the test, and sign an informed consent form;
- e) Volunteers must be in a good mood when participating in clinical validation;
- f) Blood pressure values of volunteers: Systolic pressure 90-140mmHg, diastolic pressure 60-90mmHg;
- g) SPO₂ value of volunteers: 60-100 bpm;
- h) First arterial blood gas analysis of volunteers under breathing air:

SaO2 > 95%;

COHb < 3%, MetHb < 2%, ctHb > 10g/dl;

- i) Good compliance and able to cooperate to complete the entire test.
- j) The samples should meet the expected requirements of the clinical test:

Subjects should include both men and women;

Adult volunteers should be able to withstand the minimum risk of a controlled blood oxygenation test in the agreement.

7.3.8 Description of the Material of SPO₂ Probe in Contact with Patients

The material of the SPO₂ probe used in this monitor in contact with the patient meets the following standards:

ISO 10993-5:2009 Biological evaluation of medical devices-Part5: Tests for invitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices-Part10: Tests for irritation and skin sensitization

7.3.9 Specific Instructions for Use of SPO₂ Probe

Applicable people and application parts:

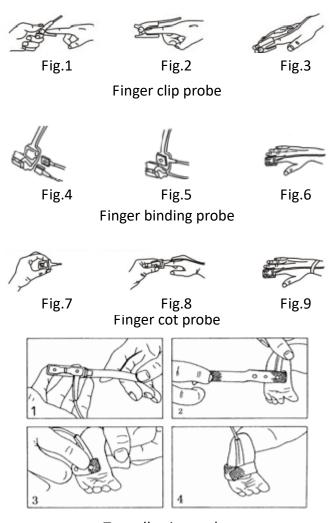
Adult, older than 12 years, on fingers

Children, 29 days to 12 years, on fingers or toes

7.3.10 Description after Power off and Restart

When the device switch is turned to "ON", the grid power supply is interrupted and restored after more than 30 seconds, the SPO₂ function will automatically restore the state before the power on.

7.4 Use of Common SPO2 Probes



Toe-adhesive probe

Note: Do not clamp the sensor housing of the probe with a clip. If the probe sensor needs to be fixed, fix the cable next to the probe.

7.5 SPO₂ Parameter Setting Menu

To enter the SPO₂ menu: Shortcut menu bar -> Main menu -> SPO₂

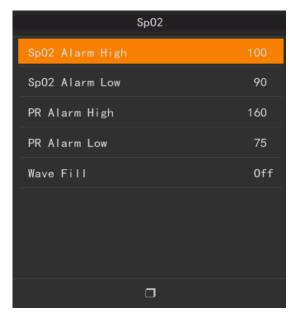


Fig. 7-2 SPO₂ Parameter Settings

Monitoring object: A	dult	Monitoring object: Child		
Parameter name	Range	Parameter name Ran		
SPO ₂ alarm upper limit	86~100	SPO ₂ alarm upper limit	86~100	
SPO ₂ alarm lower limit	85~99	SPO ₂ alarm lower limit	85~99	
Pulse rate alarm upper limit	21~300	Pulse rate alarm upper limit	21~300	
Pulse rate alarm lower limit	20~299	Pulse rate alarm lower limit	20~299	

The minimum value of the upper limit of each parameter alarm mustn't be lower than the current lower limit of the alarm, and the maximum value of the lower limit of each parameter alarm mustn't be higher than the current upper limit of the alarm;

SPO₂ alarm upper/lower limit: The upper or lower limit values of the SPO₂ alarm. When the SPO₂ of the measured object is higher than the upper limit or lower than the lower limit of the SPO₂ alarm, the alarm will be started;

Pulse rate alarm upper/lower limit: The upper or lower limit values of the pulse rate alarm. When the pulse rate of the measured object is higher than the upper limit or lower than the lower limit of the pulse rate alarm, the alarm will be started;

Waveform fill: When the waveform fill is turned on, the SPO₂ waveform displayed on the interface becomes filled. The effect after turning on is shown in Fig. 7-3:

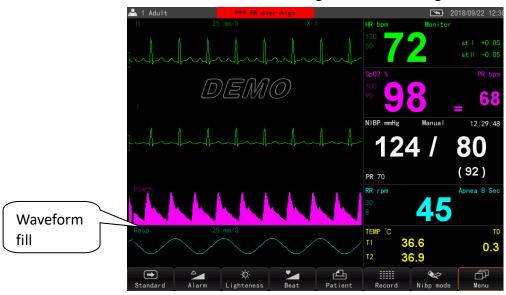


Fig. 7-3

7.6 Precautions for SPO₂ Measurement

When measure blood pressure and SPO₂ at the same time, do not place the SPO₂ probe and the blood pressure cuff on the same extremity, because blood pressure will block the blood flow and affect the SPO₂ measurement.

When the blood oxygen signal is out of the measurement range, an alarm [low blood oxygen signal] is generated.

When the blood oxygen probe fault, the alarm of the blood oxygen probe off or fault will be prompted.

7.7 Incompleteness of SPO₂ Signal

This monitor uses a normalized waveform, which does not meet the requirements of IEC 80601-2-61.

7.8 The functional tester cannot be used to evaluate the accuracy of the pulse oximetry probe and pulse oximetry monitor.

Chapter 8. Non-invasive Blood Pressure

8.1 Overview

This monitor measures non-invasive blood pressure (NIBP) using the oscillation method, which is suitable for adults and children.

To understand how the oscillation method works, you can compare it to auscultation method. Auscultation: The doctor listens to blood pressure through a stethoscope and obtains systolic and diastolic blood pressure. As long as the arterial pressure curve is normal, the mean pressure can be calculated from systolic and diastolic blood pressure.

Oscillation: The monitor can't listen to blood pressure; it measures the amplitude of the cuff pressure vibration. The change in blood pressure causes the cuff to vibrate. The cuff pressure when the amplitude is the maximum is the mean pressure. After the mean pressure is measured, the diastolic pressure and the systolic blood pressure can be calculated.

Briefly, the auscultation method measures systolic and diastolic blood pressure and calculates the mean pressure. The oscillation method measures the mean pressure and calculates the systolic pressure and the diastolic pressure.

NIBP measurements can be applied during electrosurgery and defibrillator discharge according to IEC 80601-2-30.

8.2 Measuring Non-invasive Blood Pressure

Measurement targets: adults, children; Measurement method: Manual, cycle. Manual: Take one measurement only.

Cycle: Automatically measure at set intervals.

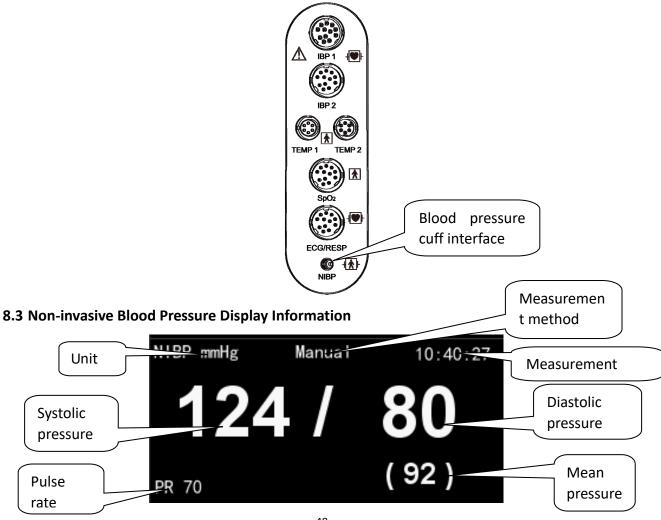


Fig. 8- 1 NIBP Display

Measurement of non-invasive blood pressure can obtain the blood pressure (systolic, diastoli and mean) and pulse rate.

8.4 Safety Information



The patient type must be confirmed before measurement. Incorrect settings can jeopardize patient safety because higher adult settings are not applicable to children.

NIBP should not be measured in patients with sickle cell disease, who have developed or are expected to have skin damage.

For patients with severe emboli disease, it is necessary to decide whether to perform an automatic blood pressure measurement based on the clinical situation, because the cuff is attached to the limb and tissue damage may be caused around the catheter when the infusion slows down or blocks up during inflation of the cuff.

If you have doubts about the accuracy of the measurement, first check the patient's vital signs with other methods, and then check if the monitor is functioning properly.

If the time of the cycle measurement is set too long and the balloon is over-inflated, the limb rubbing against the cuff may be accompanied by cyanosis, ischemia, and nerve injury. When monitoring a patient, check the color, warmth and sensitivity of the distal part of the limb regularly. Once you have observed any abnormalities, place the cuff in another location or stop measuring immediately.

For patients with severe coagulopathy, it is necessary to determine whether continuous blood pressure is measured based on clinical evaluation, because there is a risk of hematoma due to friction between the limb and the cuff.

The air pipe of blood pressure cuff must be kept smooth and not bendable or squeezed to block the pressure transmission, or else the blood circulation of the tissue may be blocked. Repeated use of short-term automatic measurement mode can cause tissue blood circulation to be blocked, so please observe the color of the distal part of the limb.

8.5 Measurement Limits

Depending on the patient's condition, there are certain limitations in the measurement of the oscillation method. This method is to look for regular arterial pressure pulsations. In the case where the patient's condition is difficult to use this method, the measured value becomes unreliable and the time for measuring the pressure increases. The following conditions can interfere with the measurement:

- * Patient movement: If the patient is moving, shaking or convulsing, the measurement will be unreliable or even impossible, as this may interfere with the detection of arterial pressure pulsation and the measurement time will be prolonged.
- * Cardiopulmonary machine: If the patient is connected with cardiopulmonary machine, measurement will not be possible.
- * Pressure change: If the arterial pressure pulsation is being analyzed to obtain a measured value for a certain period of time, and the patient's blood pressure changes rapidly at this time, the measurement will be unreliable or even impossible.
- * Severe shock: If the patient is in severe shock or hypothermia, the measurement will be unreliable, as a decrease in blood flow to the periphery will result in a decrease in arterial pulsation.
- * Ultimate heart rate: Measurements can't be made when the heart rate is below 40 bpm or above 280 bpm.
- *Patients with arrhythmia.

Acaution: About the cycle measurement mode: After setting the cycle measurement mode, the blood pressure measurement should be started. It will enter the cycle measurement mode only after the measurement is successful.

8.6 Measurement Range and Accuracy

Range:

Adult: Systolic pressure 30~260mmHg
Mean pressure 20~235mmHg
Diastolic pressure 10~215mmHg
Child: Systolic pressure 40~220mmHg

Mean pressure 20~165mmHg

Diastolic pressure 10~150mmHg

Blood pressure accuracy: The error of blood pressure measurement is ± 8 mmHg (± 1.07 kPa)

8.7 Overvoltage Protection (Maximum Pressure Value)

Adult: 295mmHg Child: 250mmHg

8.8 Blood Pressure Parameter Setting Menu

To enter the blood pressure menu: Shortcut button bar -> Main menu -> Blood pressure

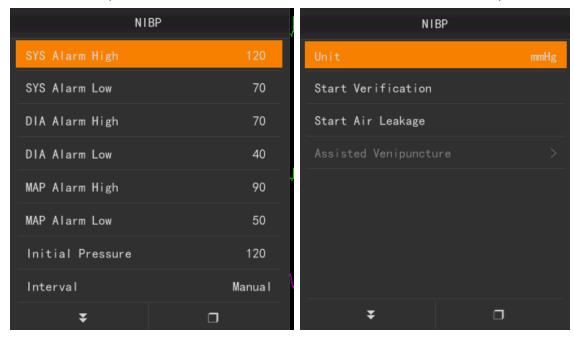


Fig. 8- 2 Blood Pressure Parameter Setting

Monitoring object: A	dult	Monitoring object: Child	
Parameter name	Range	Parameter name	Range
Systolic pressure alarm upper limit	1~300	Systolic pressure alarm upper limit	1~300
Systolic pressure alarm lower limit	0~299	Systolic pressure alarm lower limit	0~299
Diastolic pressure alarm upper limit	1~300	Diastolic pressure alarm upper limit	1~300
Diastolic pressure alarm lower limit	0~299	Diastolic pressure alarm lower limit	0~299
Mean pressure alarm upper limit	1~300	Mean pressure alarm upper limit	1~300

Mean pressure alarm lower limit	0~299	Mean pressure alarm lower limit	0~299	
Initial pressure	120~280	Initial pressure	80~170	
The unit of the above values is: mmHg				

The minimum value of the upper limit of each parameter alarm mustn't be lower than the current lower limit of the alarm, and the maximum value of the lower limit of each parameter alarm mustn't be higher than the current upper limit of the alarm;

Measurement interval: You can select the interval for manual measurement or automatic measurement; options: Manual, Auto 1 min, Auto 2 min, Auto 5 min, Auto 10 min, Auto 15 min, Auto 30 min, Auto 60 min, Auto 120 min.

Unit: Select display unit of blood pressure: mmHg, kPa.

Start calibration: After the module closes the air valve, it allows inflating manually. Compare the real time cuff pressure with the pressure displayed by the blood pressure simulator (or mercury sphygmomanometer) to determine whether the pressure sensor value of the current module exceeds the nominal error range pressure value.

Start leak detection: After the leakage detection is clicked, the word "leakage detection" and the pressure value of the inflation will be displayed at the lower left corner of the parameter area of the blood pressure measurement; After the leakage detection is completed and the pressure is stable, a 60s countdown is displayed; After the timer is over, the 60 second leakage value will be displayed.

8.9 Approved Blood Pressure Cuff

The blood pressure cuff (including the extension tube) used with this monitor must meet the ANSI/AAMI SP-10 standard.

8.10 Use of Blood Pressure Cuff

Please install the blood pressure cuff correctly as shown below:

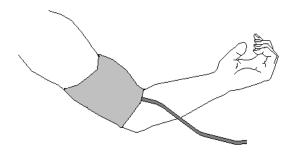


Fig. 8- 3 Schematic Diagram of Using Blood Pressure Cuff

Choose the right cuff according to the patient's arm size, as this has a large impact on blood pressure measurement accuracy. The cuff width should be 40% of the upper circumference of the arm or 2/3 of the upper length of the arm. The length of the inflated portion of the cuff should be sufficient to wrap 50%~80% of the limb, and an unsuitable cuff can produce erroneous readings.

For patients with too thin upper limbs (e.g., children) or those who have injury and can't tie cuff on the upper limbs, the cuff can be tied to the patient's thigh.

The limb used for pressure measurement should be at the same level as the patient's heart, or else there will be deviation.

Make sure that the hose does not kink after coming out of the cuff.

8.11 NIBP Pressure Verification

The NIBP pressure verification should be performed at least every two years, or when you think the reading is not accurate. If you can't calibrate the NIBP, please contact a qualified service technician.

Before verification, prepare the following materials:

T connector

Air duct

Precision mercury sphygmomanometer: Calibrated, accuracy higher than 1mmHg

Verification method: Connect one end of the T-connector to the monitor, and the other end to the cuff, and connect the middle to the mercury sphygmomanometer.

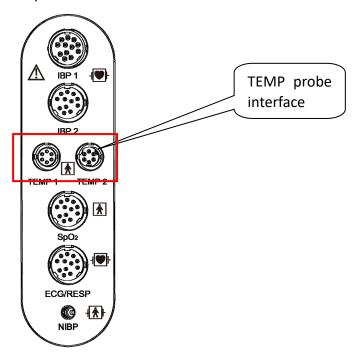
After connecting, inflate by activating the blood pressure of the monitor, and compare the reading of the monitor with the reading of the sphygmomanometer. The error should be within the error range stated by the monitor specifications.

Chapter 9. Body Temperature

9.1 Measuring Body Temperature

This monitor measures the temperature of the body surface (underarm, forehead, fingers and toes) or body cavity (oral cavity, rectum and nasopharynx).

The body temperature probe of the monitor uses a high-precision thermistor. After the body temperature probe is fully in contact with the patient and fixed, wait for about 3 minutes to get the actual body temperature data of the patient.



9.2 Body Temperature Parameter Setting Menu

To enter the body temperature menu: Shortcut button bar -> Main menu -> Body temperature

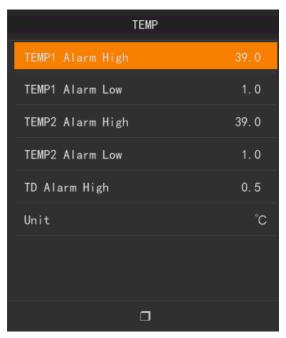


Fig. 9-1 Body Temperature Parameter Setting

Monitoring object	t: Adult	Monitoring object: Child		
Parameter name	Range	Parameter name	Range	
Temp 1 alarm upper	0.1~49.0	Temp 1 alarm upper	0.1~49.0	
limit		limit		
Temp 1 alarm lower	0.0~48.9	Temp 1 alarm lower	0.0~48.9	
limit		limit		
Temp 2 alarm upper	0.1~49.0	Temp 2 alarm upper	0.1~49.0	
limit		limit		
Temp 2 alarm lower	0.0~48.9	Temp 2 alarm lower	0.0~48.9	
limit		limit		
Temperature difference	0.2~7.0	Temperature difference	0.2~7.0	
alarm upper limit		alarm upper limit		
The unit of the above value is $^{\circ}\mathrm{C}$				

Unit: Select the body temperature display unit: "°C" or "°F".

9.3 Troubleshooting

When the temperature is not measured or the temperature value is seriously deviated, replace the probe.

9.4 Temp Display



Fig. 9- 2 Body Temperature Display

T1 represents the temperature measured by the probe 1; T2 represents the temperature measured by the probe 2. TD represents the temperature difference between T1 and T2.

9.5 Approved Body Temperature Probe

The temperature probe used with this monitor must comply with the requirements of IEC 80601-2-56.

9.6 Precautions

Handle the temperature probe and cable gently. When not in use, wind the probe and cable into a loose ring shape.

Calibrate the temperature measurement at least every two years, either externally or according to hospital procedures.



Chapter 10. Invasive Blood Pressure (IBP)(Optional)

10.1 Overview

The invasive blood pressure measurement is mainly applied to pressure sensor by arterial or venous blood pressure through liquid coupling, so as to obtain a continuous blood pressure curve.

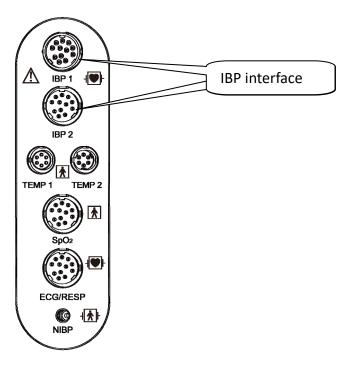


Fig. 10 - 1 IBP Interface

The display interface of IBP is as shown below:

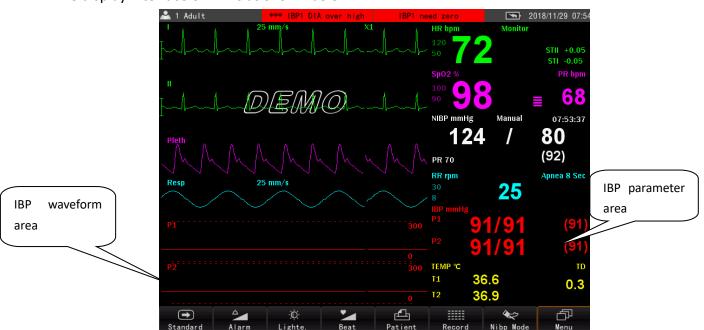


Fig. 10-2 IBP Display Interface

IBP settings interface:

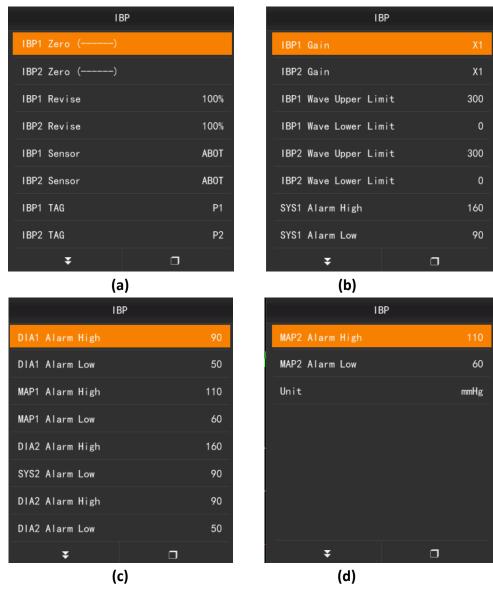


Fig. 10 - 3 IBP Settings Interface

Related parameters:

- 1. **IBP Zero**: IBP must be zeroed every time after the sensor connected and then the measurement can be made. After the zeroing is completed, the zeroing time will be displayed on the option button;
- 2. **IBP Revise**: Revise the parameters of the sensor after zeroing; optional range: 80%~120%;
- 3. **IBP Sensor:** Set the type of sensor used for measurement; options: ABOT, BIOSENSOR;
- 4. **IBP TAG:** Select the part measured by IBP; options: P1, P2, ART, PA, CVP, RAP, LAP, ICP (see below for explanation);
- 5. **IBP Gain:** The gain amplitude of the waveform measured by IBP. In auto mode, the upper and lower limits of the IBP waveform can't be adjusted; options: ×1, auto
- 6. **IBP Wave Upper Limit:** The upper limit displayed by IBP waveform; It can't be adjusted when the IBP gain is in auto mode. It can be adjusted only when the IBP gain is ×1. Optional range: 120 ~320;
- 7. **IBP Wave Lower Limit:** The lower limit displayed by IBP waveform; similarly, it can't be adjusted when the IBP gain is in auto mode, and can only be adjusted when the IBP gain is ×1;
- 8. SYS Alarm High: Set the upper limit of the systolic pressure alarm measured by IBP;
- 9. **SYS Alarm Low**: Set the lower limit of the systolic pressure alarm measured by IBP;

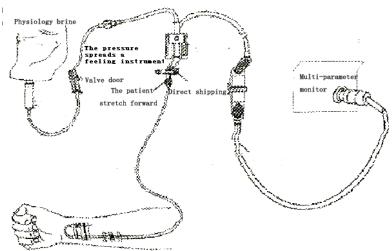
- 10. DIA Alarm High: Set the upper limit of the diastolic pressure alarm measured by IBP;
- 11. **DIA Alarm Low**: Set the lower limit of the diastolic pressure alarm measured by IBP;
- 12. MAP Alarm High: Set the upper limit of the mean blood pressure alarm measured by IBP;
- 13. MAP Alarm Low: Set the lower limit of the mean blood pressure alarm measured by IBP;
- 14. Unit: Select the unit for the results of IBP measurement; Options: mmHg, kPa;

Optional range of related parameters (in mmHg):

Para	Parameter name		Optional range	Parameter	Optional range
				name	
IBP1 Limit	Wave	Upper	120~300	SYS1 Alarm High	1~300
IBP1 Limit	Wave	Lower	0~80	SYS1 Alarm Low	0~299
IBP2 Limit	Wave	Upper	120~300	SYS2 Alarm High	1~300
IBP2 Limit	Wave	Lower	0~80	SYS2 Alarm Low	0~299

Parameter name	Optional range	Parameter	Optional range
		name	
MAP1 Alarm High	1~300	DIA1 Alarm High	1~300
MAP1 Alarm Low	0~299	DIA1 Alarm Low	0~299
MAP2 Alarm High	1~300	DIA2 Alarm High	1~300
MAP2 Alarm Low	0~299	DIA2 Alarm Low	0~299

10.2 How to connect the sensor to the monitor



10.3 Recommended sensor types

The invasive blood pressure sensor used with this monitor must comply with the requirements of the IEC 60601-2-34 standard.

10.4 Setting the pressure measurement

- 1. Insert the pressure cable.
- 2. Prepare the rinse solution.
- 3. Rinse the system to remove all air from the piping and ensure that there are no air bubbles in the sensor and valve.

- 4. Connect the pressure tube to the patient catheter.
- 5. If the pressure tube is used together with an infusion pressure cuff, replenish the fluid to be infused into the pressure cuff. Inflate the cuff according to standard hospital regulations and then start the injection.
- 6. Adjust the sensor position so that it is at the same level as the heart, about the same as the midaxillary line.

⚠WARNING: If the patient is undergoing intracranial pressure measurements (ICP, IC1 or IC2), level the sensor with the top of the patient's ear. Incorrect levels will result in erroneous measurements.

10.5 Select monitoring pressure

Inform the monitor which pressure is to be monitored by selecting the pressure tag name for the monitoring. This tag name is a unique identifier for each type of pressure. Once the tag name is selected, the monitor will use the storage settings for that tag name, such as color, waveform scale, and alarm settings. The tag name also determines which algorithm is used to process the pressure signal, so incorrect tag name will result in incorrect pressure values.

- 1. Select the tag name in the Setup <Pressure> menu.
- 2. Select the appropriate tag name from the list.

Tag name	Description
ART	Arterial blood pressure
PA	Pulmonary artery pressure
CVP	Central venous pressure
RAP	Right atrial pressure
LAP	Left atrial pressure
ICP	Intracranial pressure

10.6 Expanded pressure tag name set

If the tag name group is set to be sufficient, the following additional tag names can be used as well. This setting can only be changed in "Configuration Mode".

Note: If the monitor is connected to an Information Center, the additional tag names in the expanded tag name set may not display correctly.

Tag name	Description	
BAP	Brachial artery pressure	
FAP	Femoral artery pressure	
IC1、IC2	Alternative intracranial pressure	
P1、P2	Alternative non-specific pressure tag	
	name	

Precautions during IBP monitoring:

△ WARNING:

- 1. The parts used must meet the medical device safety requirements. When connecting or using accessories, do not touch the metal parts that are connected to the appliance.
- 2. When the monitor is used with HF surgical equipment, do not allow the sensor and cable to connect with the HF surgical equipment to prevent leakage current from burning the patient.
- 3. Do not reuse disposable sensors.
- 4. The sensor has electric shock protection function (especially prevent leakage current)

and prevent the effects of cardiac defibrillator. It can be used for surgery. When the patient is in defibrillation, the pressure wave may be temporarily disturbed, and the monitor will work normally after defibrillation. The operating mode and user configuration of the monitor will not be affected.

- 5. Check if the sensor cable is normal before monitoring. Unplug the sensor of channel 1 from the socket, the error message "IBP1 sensor is off" will appear on the screen and alarm sound. The same for other channels.
- 6. If liquid (not the solution used to prime the pressure tube and sensor) is spilled on the device or accessory, especially if liquid is likely to enter into the sensor or monitor, contact your hospital's service department.
- 7. The sensor must be zeroed before measuring blood pressure.
- 8. Make sure to drain the air inside the catheter before zeroing.
- 9. During zeroing, the catheter mustn't be connected to the patient, that is, the three-way valve 2 should be closed.
- 10. During the measurement, the catheter should be flushed periodically with heparin saline.

Chapter 11. Carbon Dioxide (CO₂)(Optional)

11.1 Overview

Carbon dioxide is an optional item for the monitor that primarily detects end-tidal CO₂ and respiration rate (Resp Rate).

The measurement principle of CO_2 is mainly based on the fact that CO_2 molecules can absorb infrared rays. The measurement method is that CO_2 is sent to the measurement chamber in the module through the airway system, and then the side of the cavity is irradiated with 4.26 um of infrared rays, and the degree of infrared attenuation received by the other side is measured by the sensor.

The degree of attenuation of infrared rays is corresponding with the concentration of CO_2 . The measured CO_2 concentration can be converted to a partial pressure display at the same temperature and pressure.

The relationship between the partial pressure of CO₂ and the percentage of CO₂ concentration is as follows:

 CO_2 partial pressure (mmHg) = percentage of CO_2 (%) × Pamp (ambient pressure mmHg) / 100; CO_2 partial pressure (kPa) = CO_2 partial pressure (mmHg) / 7.5.

11.2 Operation

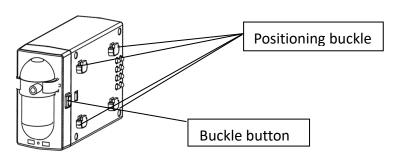


Figure 11-1 CO₂ Module Diagram

At the back of the CO₂ module, there are four positioning buckles and a buckle button;

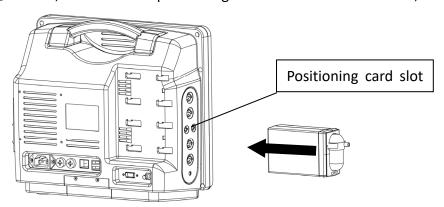


Figure 11-2 CO2 Module Installation Diagram

When installing the CO2 module, first press and hold the buckle button, and align the positioning buckle on the module with the positioning card slot at the installation position on the monitor and install it according to the method shown in the above figure; (This CO₂ module can be installed at any installation location of the monitor.)

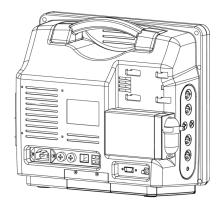


Figure 11-3 Diagram after the Completion of CO₂ Module Installation

After the installation of the CO₂ module, the waveform area and parameter area of the CO₂ will be displayed on the interface (to replace the original respiratory waveform area and respiratory parameter area).

Note:To remove the CO₂ module, simply pull it out in the opposite direction of the installation while pressing the buckle button.

Usage

- 1. After the [Standby Mode] of EtCO2 is set to [Off], measurement can be performed. (The method to [turn off] the [Standby mode] is: select the parameter area of EtCO₂ by the knob or select the CO₂ menu in the main menu, and switch [Standby mode] to [Off].)
- 2. Connect the CO2 measuring window sensor connector to the ventilator line near the artificial airway side.
- 3. Install the CO2 sensor on the measurement window in the direction indicated by the arrow.
- 4. Observe the changes in the end-tidal CO₂ waveform to observe the accuracy of the values.

CO₂ Display Interface

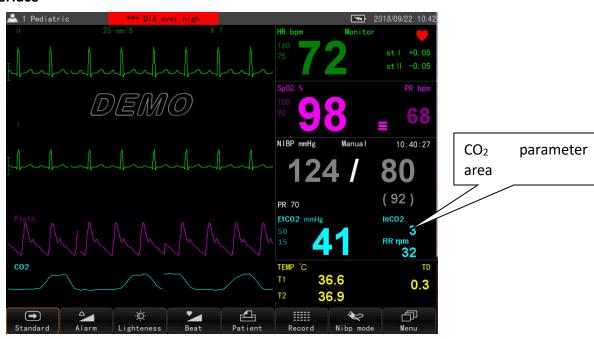


Figure 11-4 CO₂ Display Interface

The waveform area of CO₂ will replace the original respiratory waveform area, and the parameter area of CO₂ will replace the original breathing parameter area.

CO₂ Set Interface

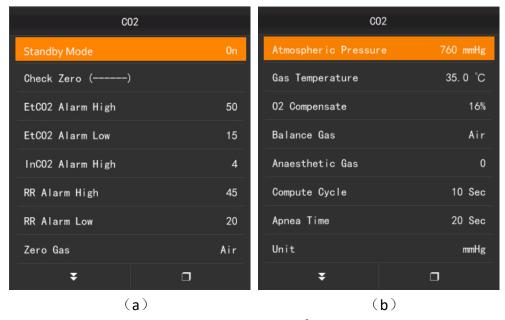


Figure 11-5 CO₂ Set Interface

CO₂ Set Interface

- Standby mode: Set whether the module is in working state. When it is on, the module enters the standby state and does not work; When it is off, the module starts working; work options: on, off;
- 2. Zero calibration: Conduct zero calibration to the module, and the zero-calibration time will be displayed;
- 3. Upper and lower limit of EtCO₂ alarm: set the upper and lower limit of EtCO₂ alarm;
- 4. Upper limit of InCO₂ alarm: set the upper and lower limit of InCO₂ alarm;
- 5. Upper and lower limit of RR alarm: set the upper and lower limit of RR alarm;
- 6. Zero calibration gas: set the zero-calibration gas type used when setting the zero calibration EtCO₂ module; optional: air, N₂
- 7. Atmospheric pressure: set the atmospheric pressure value under normal use and measurement environment; optional range (unit: mmHg): 450 ~ 850;
- 8. Gas temperature: set the temperature of the gas to be measured under normal use and measurement environment; optional range (unit: $^{\circ}$ C): 0 $^{\sim}$ 50.0;
- 9. 02 Compensation: Set the percentage of O_2 contained in the gas to be measured under normal use and measurement environment; optional range: $0 \sim 100\%$;
- 10. Balancing gas: set the type of balancing gas in normal use and measurement environment; optional: air, N2O, Helium;
- 11. Anesthetic gas: set the percentage of anesthetic gas in normal use and measurement environment; optional: $0 \sim 100\%$;
- 12. Calculation cycle: Set the frequency for the EtCO2 module to perform calculations; optional: 10 seconds, 20 seconds, 1 respiratory wave;
- 13. Choking time: set the detection time of measuring suffocation, optional range: 10~60 (seconds);
- 14. Unit: Set the unit of data displayed after the EtCO₂ module is measured. Available options: mmHg, KPa, %

Alarm Parameter Setting

	Parameter Name	Available Range	Parameter Name	Available Range
	Upper limit of EtCO ₂ alarm	9 ~ 100	Upper limit of RR alarm	9 ~ 300
ĺ	Lower limit of EtCO ₂ alarm	8 ~ 99	Lower limit of RR alarm	8 ~ 299
ĺ	Upper limit of InCO₂ alarm	1~15		

EtCO₂ Alarm and Reminder Information

Alarm or Reminder Name	Alarm Grade	Information Description
CO2 work temperature is too low.	Lower alarm	
CO2 work temperature is too high.	Lower alarm	
CO2 work temperature is unstable.	Lower alarm	
CO ₂ air pump is closed.	Lower alarm	
CO ₂ is dormant.	Lower alarm	
Check adapter	Intermediate alarm	The adapter is not connected properly, or a negative value has occurred in the CO2 concentration calculation and an error has occurred in the measurement. At this point, the adapter should be checked for moisture interference and zero calibration.
CO ₂ requires zero calibration.	Intermediate alarm	Measurement has a negative value or the measurement environment changes.
CO2 nasal tube's internal pressure is too low.	Intermediate alarm	Maybe the nasal tube is blocked.
CO ₂ module temperature is too high.	Intermediate alarm	
CO ₂ sink falls off.	Intermediate alarm	
CO ₂ zero calibration error	Intermediate alarm	It may have detected breathing in the past 20 seconds or the air pump has not started.
CO ₂ sensor hardware error	High alarm	
CO ₂ module failure	High alarm	
CO ₂ calculation value exceeds the upper limit.	High alarm	
CO ₂ module hardware error	High alarm	There is something wrong with the module components.
CO ₂ zero calibration in progress	No alarm	
CO ₂ module is pre-heated.	No alarm	Being charged and pre-heated.

⚠ Warning:

- 1. It is recommended that zero calibration is conducted to EtCO₂ before each measurement.
- 2. Collision and vibration should be avoided when measuring CO₂.
- 3. The CO₂ module is only suitable for measuring children and adults and not for newborns.
- 4. Excessive concentrations (>0.5%) in the environment may result in inaccurate

measurements.

- 5. Do not use the device in a flammable anesthetic atmosphere. This device may only be operated by personnel who are professionally trained and familiar with this manual; if the package or internal accessories are damaged, do not use the accessory and return it to the supplier.
- 6. It indicates that the sensor is starting and pre-heated. When the temperature is rising, the module can measure CO₂, which is not a standard measurement. When the information disappears from the screen, standard measurements can be performed.
- 7. Side-stream sampling tubes are disposable consumables and cannot be reused for different patient disinfection and use.
- 8. The trap is used to collect water droplets that have condensed in the sample airway to prevent water droplets from entering the module. When the water collected in the trap reaches a certain amount, the water should be drained to avoid blocking the air passage.
- 9. In long-term use, dust or other impurities will reduce the air permeability of filter material in the trap and block the airway. In this case, the trap must be replaced.



Chapter 12. Recorder(Optional, NOT available for LT-M10)

12.1 Overview

The monitor uses a thermal array printer with a printing width of 50mm. The installation position of the printer is shown in the figure below. When printing is required, press the print shortcut button on the monitor panel (as shown in the figure, the icon is) to print relevant information;

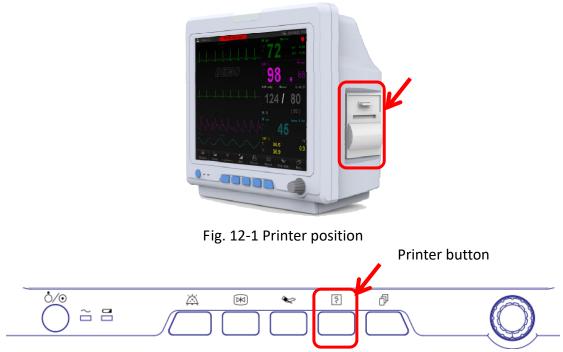


Fig.12-2 The position of the print button on the front panel

12.2 Print setup interface

Enter into the print setup interface method: Press the main menu button on the front panel of the monitor or enter the main menu in the shortcut menu bar through the knob, then select [Printer] to enter into the print setup interface. The setup interface is shown in the following figure.



Fig.12-3 Print setup in the main menu

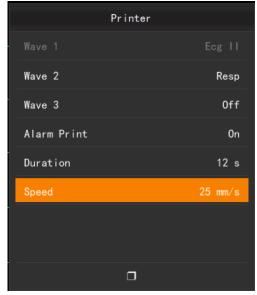


Fig. 12-4 Print setup menu

12.3 Print setup

- (1) Waveform 1: The first printed waveform; Fix print ECG II waveform;
- (2) Waveform 2: The second printed waveform; Optional: ECG I, Pleth, Resp, Off;
- (3) Waveform 3: The third printed waveform; Optional: Pleth, Resp, Off; (Waveform 2 and waveform 3 will not show repeated measurement waveform. When waveform 2 and waveform 3 are selected the same measurement parameter waveform, only waveform 2 will be retained and waveform 3 will be automatically closed);
- (4) Alarm print: Whether to print alarm record; Can be set on or off;
- (5) Print time length: Set the length of the printing record, such as how long the record is printed; Options: 8s, 12s, 16s, 20s;
- (6) Paper speed: Set the speed of paper output when printing; Optional: 25mm/s, 50mm/s

12.4 Print information

(1) General printing: When monitoring on any display interface, press the print shortcut key [] on the monitor panel, and the monitor recorder will print relevant information. The printed content is the parameters set in the print setup. (the printing effect is shown as below:)

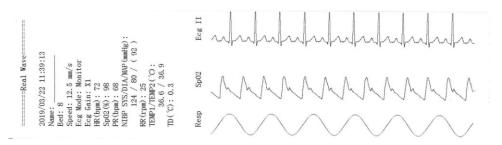


Fig. 12-5 General printing

(2) Blood pressure list printing: When displaying the blood pressure list, press the shortcut key [] on the monitor panel, the monitor recorder will print the current displayed blood pressure list information. The printed content is the bed number, systolic blood pressure, diastolic blood pressure, average pressure, and date/time;

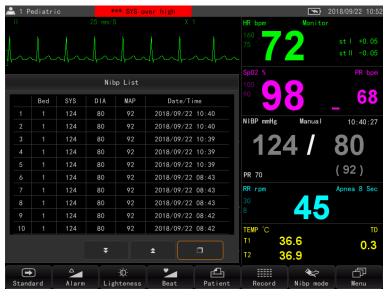


Fig. 12-6 Blood pressure list

(3) Trend chart and trend list printing: When displaying the trend chart or trend list, press the shortcut key [] on the monitor panel, the monitor recorder will print the information of the current trend chart or trend list. When printing the trend chart, it can choose to print HR, SPO2, SYS, DIA, MAP, RR, PR, ST, TEMP, TD and date/time. The trend list can be printed for Date/time, HR, SPO2, SYS, DIA, MAP, RR, PR, ST, TEMP, TD;

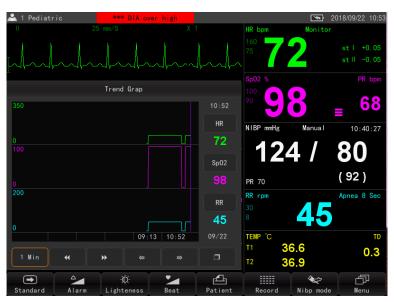


Fig. 12-7 Trend chart

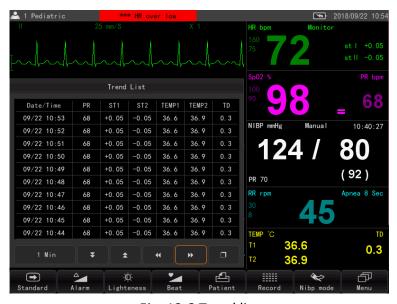


Fig. 12-8 Trend list

(4) Alarm event printing: When displaying the alarm event, press the shortcut key [] on the monitor panel, the monitor recorder will print out the alarm event information currently displayed. The contents printed by the alarm event are the parameter values, ECG II and ECG I waveforms, alarm time and alarm event contents at the time of alarm;



Fig. 12-9 Alarm event

(5) Waveform replay printing: When displaying waveform reply, press the shortcut button [on the monitor panel, the monitor recorder will print the currently displayed waveform replay information. The printed content of waveform replay is the selected replay waveform ECG I, ECG II and ECG III, aVR, aVL, aVF, V, replay interval;

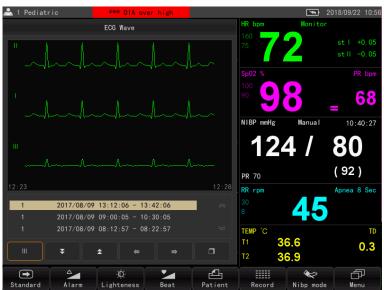


Fig. 12-10 Waveform replay

(6) Screen frozen printing: Press the freeze button [] on the monitor panel, the monitor display enters into frozen state, and show the "frozen waveform review" window, press the print shortcut button [] on monitor panel, the monitor recorder will print out the frozen waveform review information which currently displayed. Frozen waveform review print content is the selected frozen waveform review of ECG I, ECG II, ECG III, aVR, aVL, aVF, V, replay interval;

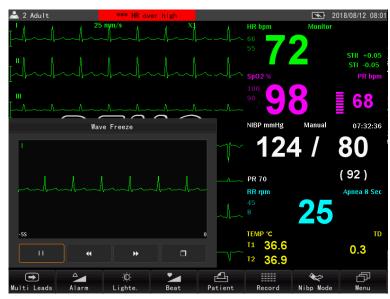


Fig. 12-11 Display interface when freezing

12.5 Precautions

After the recorder installed correctly, the green power indicator light will be on the front of the recorder, it can work normally. If there is any abnormal state of the recorder, such as: the cover plate of the recorder is not covered well, lack of printing paper, etc., the recorder will light up red error indicator. Please check the recorder at this time.

Error indicator



Fig 12-12 Recorder front side

Chapter 13. Battery

13.1 Overview

The monitor can be equipped with a rechargeable battery to ensure that the monitor can still be used normally in the event of power outage. When the monitor is connected to AC power, the battery can be charged whether it is turned on or not. In the event of a sudden power outage, the system will automatically use the battery to power the monitor without causing a sudden interruption in monitoring.

The battery icon on the screen indicates the status of the battery:



With a single battery, new and fully charged, the minimum working time with all external accessories connected is 120 minutes.

The charging time for the battery to charge to 90% in the depleted state is about 4 hours.

When the battery-loaded monitor uses AC power and charges simultaneously, the charging icon displays.

The charging state of the battery does not cause any degradation in performance.

Battery power can only maintain for a while. Too low battery voltage will triggers an advanced technical alarm of [Battery Low], at this point the monitor can operate for at least 5 minutes while releasing the cuff pressure to 2 kPa (15 mm Hg) (adult), and cancel the pressure display and do not allow blood pressure measurement.

Caution: Remove the batteries before transporting the monitor or when the monitor is not in use for a long time.

⚠Warning:

Keep the batteries out of the reach of children.

Use only the batteries specified by the company.

13.2 Optimizing Battery Performance

When using the batteries for the first time, ensure at least two complete optimization cycles. A complete optimization cycle: intermittent charging, then discharge until the monitor is turned off. During battery use, it should be optimized periodically to maintain its service life. It is recommended to optimize the battery once every two months of use or storage, or when the battery runtime is significantly reduced.

When optimizing, please refer to the following steps:

- Disconnect the monitor from the patient and stop all monitoring and measurement.
- 2. Load the batteries that need to be optimized into the battery compartment of the monitor.
- 3. Connect the monitor to AC power and charge the batteries for more than 6 hours continuously.
- 4. Disconnect the AC power and use the batteries to power the monitor until the monitor is turned off.

- 5. Re-connect the monitor to AC power and charge the batteries for more than 6 hours continuously.
- 6. The batteries are optimized.

13.3 Checking Battery Performance

Battery performance may decrease over time. When checking battery performance, please refer to the following steps:

- 1. Disconnect the monitor from the patient and stop all monitoring and measurement.
- 2. Connect the monitor to AC power and charge the batteries for more than 6 hours continuously.
- 3. Disconnect the AC power and use the batteries to power the monitor until the monitor is turned off.
- 4. The length of the battery power supply reflects the performance of the batteries.

If the battery duration is significantly less than stated in the specifications, replace the batteries or contact a maintenance person.

Caution:

The battery life depends on the frequency and time of use. If the battery is properly maintained and stored, the battery life is approximately 3 years. If the battery is used improperly, its life may be shortened. We recommend replacing the battery every 3 years.

The battery's power-on time depends on the device configuration and operation. For example, frequent NIBP measurements can shorten the battery's power-on time.

13.4 Installing Batteries

- 1. Turn off the power to the monitor and disconnect the power cord and other cables.
- 2. Open the battery door.
- 3. Remove the old batteries and insert the new batteries into the battery compartment according to the polarity.
- 4. Close the battery door.

13.5 Battery Recycling

If the batteries are significantly damaged or exhausted, replace and recycle properly. When disposing of used batteries, follow the corresponding regulations.

⚠ Warning:

Do not disassemble the batteries, throw them into fire or short circuit. Burning, exploding or leaking batteries can cause personal injury.

Chapter 14. Troubleshooting

14.1 No display

Symptom: When the instrument is turned on, the screen has no display and the indicator is off.

Inspection method:

- 1 Check if the rechargeable batteries are exhausted or damaged when the instrument is not connected to AC power.
- (2) When the instrument is connected to AC power, check if the power socket and the socket connected to the instrument are in good contact, if the power cable has open circuit, and if there is AC output.

Solution: Connect all the connection parts reliably, and connect the AC power to charge the instrument.

14.2 No ECG waveform

Symptom: There is no ECG waveform when the lead wire is connected. The display shows "electrode falling off" or no waveform scan display in the waveform area.

Inspection method: Check if the electrode piece is in poor contact with the human body and if the lead wire has open circuit.

Solution:

- 1) Check all external parts of the ECG lead (the three/five extension cords that are in contact with the human body should be connected the three/five pins on the ECG socket. If it is infinite, the lead wire is broken and should be replaced).
- 2) When three-lead ECG lead is used, check whether ECG is set to three-lead mode; ECG waveform can't be measured if it is in five-lead mode.
- 3) If there is no waveform scan display in the waveform area, it means that there is a problem in the communication between ECG measurement module and the main unit. If the prompt still appears after turning off the power, please contact the supplier.

14.3 ECG baseline drift

Symptom: The ECG scan baseline can't be stabilized on the display and sometimes drifts. Inspection method:

- 1) Check whether the environment of the instrument is damp and whether the inside of the instrument is damp;
- 2) Check the quality of the electrode sheet and whether the body part that contacts the electrode sheet is clean.

Solution:

- 1) Turn on the instrument continuously for 24 hours, and eliminate the moisture.
- 2) Replace the electrode sheet and clean the body part that contacts the electrode sheet.

14.4 ECG waveform messy

Symptom: The ECG waveform is too large to show the entire waveform.

Inspection method: Check if the ECG amplitude in the ECG setting is too large to overflow the ECG waveform.

Solution: Adjust the ECG amplitude to the appropriate value in order to observe the entire waveform.

14.5 No SPO₂ waveforms and values

Symptom: No SPO2 waveform and value during the monitoring process.

Inspection method: Check whether the finger probe has red flashing light, whether the

subject's arm is pressed, and whether the temperature in the monitoring room is too low.

Solution: If there is no red light flashing in the finger probe, the wire interface may be in poor contact; check the extension cable and the socket interface. In areas with cold temperatures, try not to expose the patient's arm to avoid affecting the test results. Blood pressure measurement and SPO2 measurement can't be performed on the same side of the arm to prevent the arm from being pressed and affecting the measurement.

If there is no waveform scanning display in the waveform area of the SPO2 display waveform channel, it means that there is a problem with the communication between the SPO2 module and the main unit. Please turn it off and then turn it on. If the prompt still appears, replace the SPO2 plate.

14.6 Respiration signal is weak

Symptom: The respiration signal is weak and difficult to observe.

Inspection method: Check the electrode position, electrode quality and check whether the skin at the electrode is clean.

Solution: Clean the skin, reattach the electrode, or replace it with a new one.

14.7 SPO₂ value intermittent

Symptom: The SPO2 value is intermittent when measuring human blood SPO2. Inspection methods:

- 1) During long-term monitoring and surgery, check if the patient's arm moves frequently, which will cause SPO2 values to be intermittent.
- 2) Check if the SPO2 extension line is broken.

Solution: Try to keep the patient stable. Once the SPO₂ value is lost due to the movement of the hand, it can be considered normal. If the SPO₂ extension line is broken, replace it.

14.8 Blood pressure measurement abnormal

Symptom: The measured blood pressure value has large deviation.

Inspection method: Check if the blood pressure cuff leaks and if the pipe connection connected with blood pressure leaks.

Solution: Replace with good cuff or connector.

14.9 Insufficient blood pressure inflation

Symptom: When measuring the blood pressure, the inflation pressure can't be increased (lower than 150mmHg) and measured.

Inspection method: Check if the blood pressure cuff and its extension tube are broken.

Solution: Replace with blood pressure cuff of good quality.

Chapter 15. Cleaning and Disinfection

The monitor should be kept clean and free of dust.

The surface of the monitor and its accessories can be cleaned and disinfected, and equipment or accessories must not be removed for cleaning.

Cleaning and disinfection methods are limited to wiping. Do not drench or pour liquid on the equipment or immerse it in liquid.

In order to avoid long-term damage to the product, we recommend disinfecting the product only if it is deemed necessary by the hospital's procedures; the disinfected product should be cleaned first.

15.1 Cleaning

Wipe with a soft cloth soaked in clean water, mild soapy water or diluted non-corrosive detergent (most detergents must be diluted according to the detergent instructions before use), and then dry with a soft cloth or dry naturally.

15.2 Disinfection

The following products can be used as disinfectants:

- 1) 75% ethanol
- 2) Dilute ammonia
- 3) Diluted sodium hypochlorite (bleaching powder for washing). Note: The sodium hypochlorite of concentration range about 500ppm (1:100 diluted household bleach) to 5000ppm (1:10) is very effective, and the amount depends on how many organic matters (blood, animal and plant mucus) exists on the cleaned and disinfected surface.
- 4) Hydrogen peroxide solution (3%)
- 5) Isopropyl alcohol solution

⚠ Warning:

- 1) Turn off the power and disconnect the AC power before cleaning and disinfecting.
- 2) Do not disinfect the instrument with gas (EtO) or formaldehyde.
- 3) Do not use strong solvents such as acetone.
- 4) Never use abrasive materials (such as steel wool or silver polish).
- 5) When cleaning and disinfecting, place the cap on the rubber tube of the blood pressure cuff to prevent the liquid from entering the rubber tube and being sucked into the blood pressure module.

! Caution:

We are not responsible for the effectiveness of the above disinfectant or disinfection method as a means of infection control. Please discuss with the hospital's infection control leader or epidemiologist.



Chapter 16. Maintenance and Repair

16.1 Maintenance



Hospitals or medical institutions that use this equipment should establish a comprehensive maintenance plan, or else it may cause equipment failure and unpredictable consequences, and may endanger personal safety.

All safety inspections or repairs that require disassembly of equipment should be performed by qualified service personnel. Operation by non-professionals may result in equipment failure and may endanger personal safety.

If you find something wrong with your equipment, contact your service representative or our company.

16.1.1 Inspection

Before the monitor is used, continuous use for 6~12 months, after maintenance or upgrade, a comprehensive inspection should be carried out by professional maintenance personnel to ensure the normal operation and work of the monitor.

The items to be inspected should include:

- Environment and power supply meet the requirements.
- Equipment and accessories have no mechanical damage.
- The power cord has no wear and has good insulation performance.
- Use specified accessories.
- The function of the alarm system is normal.
- Battery performance.
- Monitoring functions are in good condition.
- Grounding impedance and leakage current meet the requirements.

If any damage or abnormality is found, do not use the monitor and immediately contact the medical engineer of the hospital or our maintenance personnel.

16.1.2 Maintenance Plan

The following tasks can only be completed by professional maintenance personnel approved by the company. Please contact us if you need to perform the following maintenance. Equipment must be cleaned and disinfected prior to testing or repair.

Inspection/maintenance item	Frequency
Safety inspection according to IEC 60601-1	At least once every two years. It is also necessary when the power supply is replaced or the monitor is dropped.
Check all monitoring or measurement functions not listed below	At least once every two years, or when you suspect that the measurements are inaccurate.
NIBP leak detection	At least once every two years, or as prescribed by the hospital.
NIBP pressure check	At least once every two years, or as prescribed by the hospital.
NIBP calibration	At least once every two years, or as prescribed by the

haspital
hospital.

Marning:

The demo function is primarily used to demonstrate machine performance and to train users. In actual clinical use, the demo function should be prohibited, so as to prevent the medical staff from mistaking the monitor displays as the waveforms and parameters of the patient being monitored, thereby affecting patient monitoring and delaying the diagnosis and treatment of the disease.

16.2 Authorized Service Representative

Name: Shenzhen Lintemed Medical Instrument Co., Ltd.

Address: Room 205, Sub-building R2-A, Virtual Campus Park, High-tech Nanqi Avenue, Yuehai

Street, Nanshan District, Shenzhen, Guangdong 518057, P.R. China

Tel:+86 755-26608473 Fax:+86 755-26602490

16.3 Qualified Maintenance Facilities

The ECG simulator, NIBP simulator, SPO₂ simulator, ECG tester, constant temperature water tank, dielectric strength tester, leakage current tester, grounding impedance tester, multimeter, and oscilloscope calibrated by the metrology department can be used as qualified maintenance and testing devices.

16.4 Maintenance Training

The maintenance representative authorized by the company can go to the company to participate in equipment maintenance training, and can take the job only when pass be training.

Chapter 17. Default Manufacturer Settings (patient type is adult)

17.1 Alarm Settings

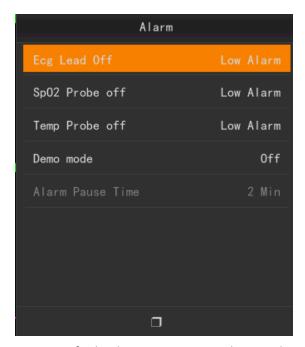


Fig. 17-1 Default Alarm Settings as Shown Above

17.2 ECG

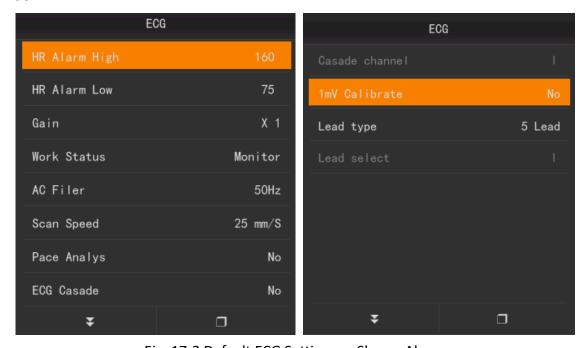


Fig. 17-2 Default ECG Settings as Shown Above

17.3 SPO₂

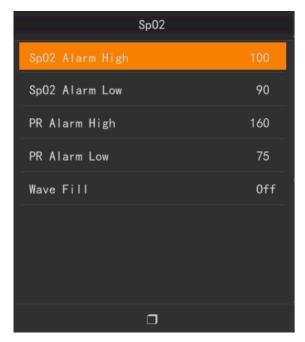


Fig. 17-3 Default SPO₂ Settings as Shown Above

17.4 NIBP

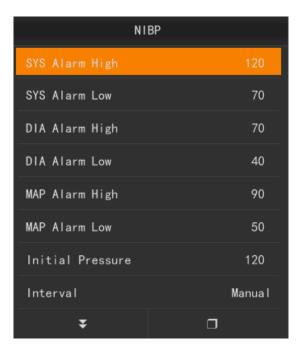


Fig. 17-4 Default Blood Pressure Settings as Shown Above

17.5 RESP

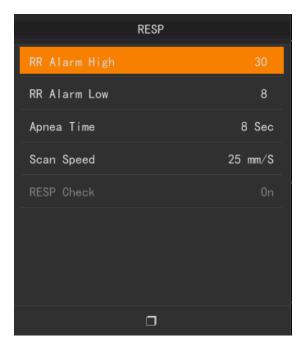


Fig. 17-5 Default Respiration Settings as Shown Above

17.6 TEMP

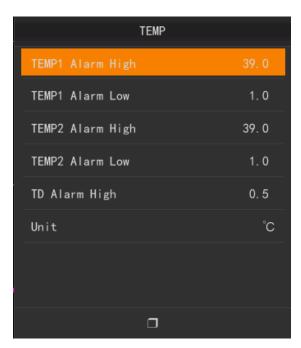


Fig. 17-6 Default Temperature Settings as Shown Above

Chapter 18. Alarm Information

This chapter lists some of the most important physiological and technical alarm messages, some of which are not necessarily listed.

Note that in this chapter:

Alarm levels: H indicates high, M indicates medium, and L indicates low.

XX represents a physiological parameter such as ECG, NIBP, HR, PR, RR, SPO2, and TEMP.

For each alarm message, the corresponding countermeasures are listed. If the problem persists after taking the measures, please contact the service personnel.

18.1 Physiological Alarm Information

Source	Alarm information	Alarm	Causes and countermeasures				
		level					
XX	XX overrun	н	XX value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, confirm the patient type and check whether the alarm limit setting is suitable for the patient.				
ECG	No SPO ₂ detected	Н	If no SPO ₂ is detected, check the patient's condition. If it is confirmed that there is no SPO ₂ , take rescue measures immediately.				
RESP	Suffocation	Ι	The patient's respiration signal is too weak for the system to analyze. Check the patient's condition, electrodes, cables and lead wires.				
NIBP	Pressure difference too low	н	The difference between the patient's systolic and diastolic blood pressure is less than the set value; check the patient's condition to see if there is any danger.				

18.2 Technical alarm information

Source	Alarm information	Alarm level	Causes and countermeasures				
ECG	Electrode falling off	L/M	The electrode sheet or the lead wire falls o check the electrode sheet and the lead wire.				
SPO ₂	Probe falling off	L/M	SPO ₂ probe is detached or installed incorrectly check the probe.				
NIBP	Measurement error	L/M	Cuff leak or installation error; check cuff				
System	Battery symbol flashing	Н	The battery level is low; please connect the AC power for charging				

Chapter 19. Parameter Setting Fast Index

19.1 Restore default settings

Restore all parameters of the monitor to their default values.

To enter the menu: Shortcut button bar -> Main menu (second page) -> Reset;

The menu to restore the default settings is shown in Fig. 19-1:



Fig. 19-1

19.2 Parameter setting options

Function selection: ECG parameters, SPO₂ parameters, non-invasive blood pressure parameters, respiration parameters, body temperature parameters, alarm settings, print settings, network settings, date and time, custom colors, drug concentration calculations, restore default settings, other settings, maintenance, system information.

Record mode: Manual single time.

Pulse sound: Adjustment of Grade 0-9.

Alarm tone: Adjustment of Grade 1-10, Alarm sound (45 ~ 85dB)

Key monitoring leads: I, II, III, aVR, aVL, aVF, V

Scanning speed: 6.25 mm/s, 12.5 mm/s, 25.0 mm/s, 50.0 mm/s.

ECG gain: $\times 1/4$, $\times 1/2$, $\times 1$, $\times 2$, $\times 4$.

Monitoring mode: Extended mode, monitoring mode, surgery mode.

Lead mode: 3/5 leads.

Blood pressure measurement mode: Adult, child.

Blood pressure measurement method: Manual, cycle.

Blood pressure unit: mmHg, kPa.

Blood pressure cycle measurement interval: 1, 2, 5, 10, 15, 20, 30, 60, 120 minutes.

Correct measurement parameters:

Systolic pressure (SYS): -3~+3. Diastolic pressure (DIA): -3~+3.

Mean pressure (MAP): -3~+3.

Chapter 20. Product Specifications

20.1 Monitor Type

Class I anti-shock device, connected to external power supply; integrated with internal power supply

Protection against electric shock:

ECG (RESP) is anti-defibrillation CF

TEMP, SPO2 is BF

NIBP is anti-defibrillation BF

Operating method: Continuous

Waterproof grade: IP22

20.2 Specifications of the Monitor

20.2.1 Dimensions and Weight of the Monitor

LT-M10:Dimensions (length × width × height): $266 \times 126 \times 226$ mm LT-M12:Dimensions (length × width × height): $308 \times 288 \times 148$ mm

Net weight: See outer packing

20.2.2 Operating and Storage Environment

Temperature range:

Operating +5~+40°C

Transportation and storage -20~+55°C

Humidity range:

Operating ≤80%

Transportation and storage ≤90%

Altitude range:

Operating 70kpa~106kpa

Transportation and storage 50kpa~106kpa

Electrical specifications:

AC 100-240V, 50/60Hz

DC 7.2V

I 0.59A~1.4A

Fuse: T1.6AL.250VAC

20.2.3 ECG Specifications

Heart rate measurement / alarm range: 0~300bpm

Alarm limit range: Upper limit (1~300bpm); lower limit (0~299bpm)

Accuracy: ±1 bpm or ±1% (whichever is greater)

Adult: 20~300bpm Paediatric: 15~300bpm Neonate: 15~350bpm

20.2.4 Respiration Specifications

Measuring range: 0~150 rpm

Accuracy: ±2 rpm

20.2.5 Blood Pressure Specifications

Measuring range:

Adult:

Systolic pressure 30~260mmHg Mean pressure 20~235mmHg Diastolic pressure 10~215mmHg

Children:

Systolic pressure 40~230mmHg Mean pressure 20~165mmHg Diastolic pressure 10~150mmHg

Neonate:

Systolic pressure 30~135mmHg Mean pressure 20~110mmHg Diastolic pressure 10~100mmHg

Accuracy: Maximum error ±5mmHg (±0.67kPa)

Static pressure Range:
Adult: 0~290mmHg
Paediatric: 0~250mmHg
Nonate: 0-160mmHg

20.2.6 SPO₂ Specifications

Nominal measurement range: 35%~100%

Resolution: 1%

Accuracy: In the range of 70%~100%, the measurement error is ≤2%, and other ranges are not

defined;

When the pulse SPO₂ is lower than 70%, the monitor still works normally, but accuracy is not

guaranteed.

Update time: About 1 second Alarm delay: 10 seconds

ELD Transmitting power: less than 90mW

ELD red light(600nm~700nm)

ELD Near infrared light(800nm~900nm)

Pulse rate:

Measuring range 20~300 bpm

Resolution 1 bpm

Accuracy ±2 bpm or ±2% (whichever is greater)

Alarm delay 10 seconds

20.2.7 TEMP Specifications

Measuring range: 0.0°C ~ 50.0°C

Accuracy: ±0.1°C Alarm limit range:

Upper limit: 0.1°C ~ 50.0°C Lower limit: 0.0°C ~ 49.9°C

The above specifications are subject to change without notice.

20.3 Appendix List

NAME	NUMBE	UNIT	Specificatio	Specificatio	Name of	Address of supplier	Material
	R		n and model	n	supplier		code
ECG Cable	1	Article	ES:	3 meters	Shenzhen	A2-4th floor of	16. CKL-MT

			CK-SMD-980A1	long, 5-lead\	Changke	Xiang dali	YXDDL-12-
			-05IR2	buttontype\a	Connect	Technology Park	HUI-01
				nti	Electronics	No.87 of HengPing	
				defibrillati	Co., Ltd.	Road, Henggang	
				on	,	Longgang istrict,	
						Shenzhen, CN	
	1		M5304	Bandage	Xuzhou	NO.75 Jianguo	16. MK-MTY
				material:	Maicuff	West Road, B-1106	XYXD-00-L
				Nylon cloth	Technology	Fortune Plaza,	AN-01
				Internal	Co., 1td.	Xuzhou City, China	
Adult blood				capsule	,		
pressure		Article		material: TPU			
cuff		01010		26-35.5 cm			
				Airway			
				material:			
				medical PVC,			
				3M long			
	1	Article	M5303	Bandage	Xuzhou	NO.75 Jianguo	16. M
	-	01010		material:	Maicuff	West Road, B-1106	K-MTYXYX
				Nylon cloth	Technology	Fortune Plaza,	D-00-LAN
				Internal	Co., 1td.	Xuzhou City, China	-02
Paediatric				capsule	001,1041	Raznoa orty, onrha	02
blood				material: TPU			
pressure				21-27 cm			
cuff				Airway			
				material:			
				medical PVC,			
				3M long			
Blood oxygen	1	Article	T200A	Adult /	Shenzhen	4/F, Building 1,	16. S
probe	1	MI CICIC	120011	Pediatric	Soleri	Zhongjian	LR-MTYXY
prose				Soft-finger	Medical	Industrial	TT-06-HU
				3. Om	Technology	Building, 18	I-01
				0. o.m	Co. LTD	Yanshan Road,	1 11
					00. EID	Nanshan District,	
						Shenzhen, China	
Body	1	Article	W0001A	10ft(3.0m),	Shenzhen	4th floor and 5th	16. M
temperature	1	01010	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	round, 4pin	Med-link	floor, No. 2	DL-MTYTW
probe				plug > 12	Electronics	Hualian	TT-02-HU
r=				plate	Tech Co.,	Industrial Zone,	I-01
				F	Ltd	Xinshi Community,	= 32
						Dalang Street,	
						Longhua District,	
						Shenzhen	
Power supply	1	Article	ES :	3*0.75mm2, PV	Dongguan	2/F, Building A,	11. Y
cord			YG102	C 300/500V	Yingji	Zhenhua	G-M12DYD
				250V, 10A	Electric	Industrial Zone,	L-03-HEI
					Industry	Jishi Town,	-01

					Co., LTD	Dongguan city	
Power supply	1	Article	US: QP3	16AWG,	NINGOBO	Xiaoxia	11.Y
cord				3*0.82mm2,	QIAOPU	Industrial Park,	G-M12DYD
				PVC	ELECTRIC CO	Simen Town, Yuyao	L-03-HEI
				105℃, 300V,	LTD	City, Zhejiang	-02
						Province, China	
Protective	1	Article	F002 1.2m	80° C,600V,	ZHONGSHAN	Area A, 2-A, No.	11. K
earth wire			long	18AWG, yellow	FUYUANTONG	3, Guiyuan	NT-M12DX
			ø1.0mm2)	green colour	WIRE & CABLE	Street, Yudan	-01-HLS-
					CO LTD	Village, Shenwan	01
						Town, Zhongshan	
						city	
Mains fuse	1	Article	6*30	6 x 32mm	XC	Building 11,	08. T
				1.6A, 250V,	Electronics	Jinyuan ndustrial	B-KS-1A6
				Fusing speed:	ShenZhen)Co	Zone, Henggang	-250
				T	rp,.Ltd	Town, Longgang	
						istrict, shenzhen	
						,Guangdong, China	

Chapter 21. Important Information

21.1 Manufacturer Information



Zhuhai Linte Medical Instrument Co., Ltd 4th Floor, Building 1, No.66, Yongda Road, Hongqi Town, Jinwan District, 519090 Zhuhai, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Tel: +86 756-2133994 Fax: +86 756-2133237



Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany

21.2 Product Information

Name: Multi-parameter Monitor

Model: LT-M12 / LT-M10 Service life: See product label

Production date: See product label (as shown below: the production date is October 2018)





Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany





21.3 Manual Information

Insrtuction document number: IFU-M12-01

Vesion number: A/2

Date of preparation: 2018.10

Revision date: 2022.03

21.4 Disposal Information

Dispose of the monitor and accessories according to local regulations or the hospital's waste disposal system.