KC Series
Multi parameter module
Patient Monitor
Instruction for Use

MDKMed Medical Technology Co., Ltd.

Table of Contents

Product Information

The registered trademark used on the product is: GRASEBY 佳士比医疗

Product name: Multi parameter Patient Monitor

Specifications and models: This manual is the KC series product manual, applicable to the following models:

KC series: KC16 KC19, KC22.

Registered address: 502A, Building 7, No. 22, Xinyan Road, Donghu Street, Linping District, Hangzhou City, Zhejiang Province, P. R China 311323

Production address: No.22, Cangling Rd, Huzhen Town, Jinyun County, Lishui City.Zhejiang Province, P. R. China 321404

Production date/expiration date: as per label

KC16 structure: The product consists of KC16 main unit, power cord, standard KC7 subunit, optional parameter modules and accessories.

KC19/KC22 structure: The product consists of KC19/KC22 main unit, power cord, standard KC7 subunit, optional parameter modules and accessories, plug-in module, and DP communication cable.

Accessories include ECG lead wires, temperature sensors, blood oxygen probes, optional parameter modules and blood pressure cuffs, etc.

The company has passed ISO13485 product quality system certification.

Statement

This manual applies to our company's patient monitors, and the content may not be changed without our consent. Our company reserves the right to improve products in terms of technology, parts, software and hardware. If you need further information about the product, please contact our company or your dealer.

Copyright

Manufacturer's Responsibilities

Our Company considers itself responsible for the safety, reliability and performance of our products only under the following circumstances, namely:

(1) Assembly operations, expansion, readjustment, improvements and repairs are all performed by personnel approved by our company;

(2) Relevant electrical equipment complies with national standards;

(3) The product should be used according to the operating instructions.

Our company does not make any form of guarantee for errors in this manual, installation errors, or operation errors, and does not assume any legal responsibility for incidental or inevitable damage.

⚠**Notice**

●This product is not for home use.

●This product is restricted to one patient at a time.

●According to YY 9706.261-2023 requires that claims of blood oxygen saturation accuracy be supported by clinical research measurements covering the entire range, and functional testers cannot be used to evaluate the accuracy of pulse oximeter probes and pulse oximeter monitors.

●Expired products or batteries should be disposed of in accordance with local electronic product scrapping regulations or returned to the manufacturer for recycling.

⚠**Warning**

●For safe and continuous use of this equipment, please follow the instructions below. The instructions listed in this manual do not replace medical procedures already being performed.

●You cannot rely solely on audible alarm systems to monitor patients. When monitoring a patient, if the volume is set too low or is completely turned off, the safety of the patient may be endangered. The most reliable method of patient monitoring combines the proper use of monitoring equipment with close personal monitoring of the patient.

●This device is intended for use in healthcare facilities by trained caregivers only.

●To reduce the risk of electric shock, do not disassemble the equipment. If necessary, ask professionals to perform repairs.

●This device may interfere with the ultrasound imaging system, such as interference signals appearing on the ultrasound display. Place the two devices as far apart as possible.

●Exposing electrical contacts or connecting devices to saline or other liquids and conductive glue is extremely dangerous. Electrical contacts and other connecting devices such as cable connectors, power supplies, parameter module plug-in connectors, rack connectors, etc. must be kept clean and dry. If devices are contaminated with liquid, they must be dried thoroughly. If further decontamination is required, please contact your medical equipment department or our company.

●KC monitors can not be used in ambulances.

⚠**Warning**

●This product is not a therapeutic device.
●If hospitals or medical institutions responsible for maintaining this product fail to maintain this product as planned, it may cause the product to fail and ultimately endanger the patient's health.

Quality Assurance

Free service scope:

All equipment that meets the scope of our company's warranty service regulations can enjoy free service.

Paid service scope:

(1) For equipment that exceeds the scope of the company's warranty service regulations, the company will provide paid services;

(2) Even within the warranty period, the product needs repair due to the following reasons: man-made damage; the network power supply voltage exceeds the rated range of the equipment; irresistible natural disasters.

The company is not responsible for direct, indirect or final damages and delays caused by the following situations (including but not limited to):

Components are disassembled, stretched, and re-adjusted;

Replace accessories not approved by our company or have the machine repaired by personnel not authorized by our company.

Goods Return

If you need to return a product, please follow these steps:

(1) Obtain the right to return goods. Contact our company's customer service department and inform them of the product series number. If the series number is not clearly legible, returns will not be accepted. Please indicate the product model and serial number, and briefly describe the reason for return.

(2) Freight: When the product is shipped to our company for repair, the user must bear the freight (including customs fees).

After-Sales Service

When you need product technical service support, please contact agents and dealers, or contact the nearest office of our company. Also, you could contact our company's service department,please see the last page of this manual for detailed information.

Please make sure to record the following information before you make a call:

1. Product model and factory number;
2. Production date;
3. Product validity period;
4. Malfunction details

Introduction

This manual introduces the performance, operation methods and other safety information of the monitor in detail. Reading this manual is the first step for you to familiarize yourself with and make full use of this device, ensuring proper use and ensuring patient and operator safety.

The following symbols indicate certain important reminders that the you should pay attention to:

⚠ **Danger:** Indicates an imminent hazard which, if not avoided, may result in death, serious personal injury or property damage.

⚠ **Warning:** Indicates a potentially hazardous or unsafe operation that, if not avoided, may result in death or serious personal injury or property damage.

⚠ **Careful:** Indicates potentially dangerous or unsafe operations which, if not avoided, may result in minor personal injury or product failure, damage or property loss.

⚠ **Notice:** Highlight important precautions, provide instructions or explanations for better use of this product.

This manual is intended for people who are familiar with various measurements and need to use monitoring equipment.

This monitor is a multi parameter patient monitor that can be used in situations such as surgery, surgical/anesthesia recovery, emergency rooms, etc. to monitor the vital signs of adults and children.

This monitor can be powered by the built-in battery or AC power. Easy to carry and transport.

Scope of application

This monitor is used to measure and monitor the patient's ECG, respiration, non-invasive blood pressure, pulse oximeter, pulse rate, body temperature, end-tidal carbon dioxide, invasive blood pressure, and other parameters.

Intended users

Patients who need to monitor parameters such as ECG, respiration, non-invasive blood pressure, pulse oxygen saturation, pulse rate, end of breath carbon dioxide, body temperature, invasive blood pressure, and EEG bispectral index. This device is not suitable for newborns.

Contraindications

Patients with sickle cell disease and anyone with skin lesions or expected lesions;

For patients with severe coagulation disorders or severe thrombosis;

Patients with intravenous fluids or catheters in their limbs;

Patients with perfusion disorders or skin sensitivities.

⚠Danger

●Do not use this device in an environment rich in oxygen or containing flammable or explosive items such as anesthetics to prevent fire or explosion. At the same time, this device and surrounding areas should be kept clean and dry.

●Do not touch the patient during defibrillation, or keep a sufficient distance from metal objects connected to the patient. Failure to do so may result in serious injury or death.

⚠Warning

●Product only plays a supporting role in diagnosis, doctors made diagnosis in conjuctions with patient's clinical situations.

●If this device is not secured properly, it may fall, resulting in personal injury or device damage. To prevent personal injury or device damage, install the device in a fixed location.

●Before use, you must check the device, connecting cables and supporting accessories to ensure that they can work normally and safely. The device should self-check normally when it is turned on.

●This device cannot be used in the presence of magnetic resonance (MR) device, otherwise the induced current may cause burns to the patient.

●This device cannot be used in places with excessive electromagnetic radiation or EMC device, otherwise the measurement accuracy will be affected.

●To avoid personal injury, the device cannot be repaired by anyone except professional technicians.

●Do not replace the power cord of this device. Do not connect the three-core power cord of this device to a two-core or multi-hole socket without protective grounding. If the reliability of the grounding cannot be confirmed, please use the internal battery for power supply.

⚠Notice

●Before use, calibration should be correctly verified and this device should be ensured to function properly.

●Please ensure that the battery has been charged so that the device can still work normally when the network power is cut off for more than 30 seconds.

●Pay attention to the placement of power cords, conduits, and all electrical cables so that they do not strangle the patient or trip others.

●The back of this device must not be blocked to facilitate heat dissipation.

●If liquid is spilled into the casing of this equipment, please disconnect the power supply immediately and contact service personnel.

●The product should be kept at a temperature (5℃～40℃) and humidity (15%～85%, no condensation) and atmospheric pressure (700-1060hPa). If the product has been stored for more than one year, it must be re-tested according to the factory inspection procedures before it can be used again. For related accessories with storage life requirements (such as ECG electrodes, batteries, etc.), follow their respective instructions.

●To avoid contaminating or infecting people, the environment, or other equipment, equipment and accessories that have reached the end of their useful life must be disposed of in accordance with relevant local regulations or hospital policies.

●Equipment should be installed in a location that is easy to observe, operate and maintain.

⚠**Warning**

●The multi parameter patient monitor is used for clinical patient monitoring. Only doctors and nurses are allowed to use this monitor.

●Do not open the product's casing to avoid possible electric shock hazard. Any repairs and upgrades to the monitor must be performed by trained service personnel and authorized by our company.

●Do not use this product where flammable items such as anesthetics are placed to prevent an explosion.

●Before use, you should check whether this product and its accessories can work properly and safely.

●To prevent delays in treatment, set adequate alarm settings for each patient. At the same time, it should be ensured that the alarm sound can be made when alarming.

●Do not use mobile phones near the monitor. Mobile phones can produce excessively strong radiation fields that can interfere with monitor functionality.

●During defibrillation, keep away from the patient, table, and the device.

●The equipment interconnected with the monitor should form an equipotential body (effective connection to the protective ground).

●When the monitor is shared with electrosurgical equipment, the user (doctor or nurse) should pay attention to ensuring the safety of the patient being monitored.

●Packaging must be disposed of in accordance with current waste control practices and kept out of the reach of children.

●For patients with a pacemaker, the heart rate monitor may include pacemaker pulses in the heart rate value during cardiac arrest or arrhythmia. Don't rely entirely on heart rate monitor alarms. Patients with pacemakers should be closely monitored and the device's ability to

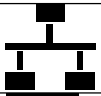
suppress pacing pulses should be discussed elsewhere in this manual.

⚠**Careful**

●When the products described in this manual are about to expire, they must be disposed of in accordance with the relevant product handling regulations. If you would like further information, please contact our company or our agents.

●When you have doubts about the completeness and arrangement of the external grounding of the monitor, you must use device's internal battery for operation.

Description of equipment symbols

	Warning		Alternating current		ECG
	Battery		Protective ground (earth)		Equipotential
	NIBP		computer network		Lead selection
	Unlock		graph recorder		Input /Output
	gas output		USB interface		gas input
	Temperature limit		Manufacturing date		Serial number
	Non-ionizing radiation		Dangerous electric shock		Video output
	Manufacturing measuring instrument license mark		Humidity limits		Air pressure limit
	Power on and off		The application part of defibrillation prevention CF type		The application part of defibrillation prevention BF type
	Alarm off		Alarm pause		Alarm reset
	Alarm SILENCE		Follow the operating instructions		Universal warning symbols (safety symbols)
	Signal incompletenes s indicator				

Chapter 1 Safety Information

This system has floating input anti-defibrillation and surgical electrosurgical protection. If the correct electrodes are used (see the ECG and Respiratory section) and placed according to the manufacturer's instructions, the screen display will resume within 5 seconds of defibrillation.

⚠**WARNING: Do not touch the patient, bed, or product during defibrillation.**

1.1 Environment:

1. Please follow the following guidelines to ensure absolute safety in electrical installation. The environment in which the monitoring system is used must be reasonably protected from vibration, dust, corrosive or explosive gases, extreme temperatures, moisture, etc. When installed in a product cabinet, there must be sufficient space in front of the device for easy operation. With the cabinet door open, there should be enough space behind it to facilitate maintenance. The air circulation inside the cabinet should be ensured.

2. The monitoring system can meet the technical specifications when the ambient temperature is below 5℃~40℃. Ambient temperatures outside this range may affect the accuracy of the product and cause damage to components and circuits. Leave at least 2 inches (5 cm) of space around the product to allow air circulation.

Please refer to the product specifications section for power requirements.

1.2 Condensation:

During operation, ensure that the product does not condensate. Condensation may form when product is moved from one room to another. This is because the product is exposed to moist air and varying temperatures.

⚠ **WARNING: If this device is used in the presence of flammable anesthetics, there is a risk of explosion.**

Please see the introduction part for descriptions of other safety matters.

Chapter 2 Product Overview

- For your fully understanding of this monitor, please read this overview.
- For an introduction to the various information displayed on the screen, read Introduction to Display Interface
- To master the operation method, please read the monitor button functions and basic operations.
- To learn the location of the various interfaces, please read Monitor External Interfaces
- To learn about the precautions for using the monitor on battery power, read Built-in Rechargeable Battery

2.1 Basic information introduction

Structural features and working principles:

The multi parameter patient monitor controls multiple parameter function modules through a CPU, and forms a monitoring system with physiological parameter measurement modules such as ECG, RESP, NIBP, SPO_2, TEMP, PR,and CO_2,. It can monitor physiological parameters such as ECG, RESP, TEMP, NIBP, SPO2, PR,,and CO_2 for adult and pediatric patients. Through serial port communication with the host computer, 7-lead ECG waveform, 1 TEMP waveform, 1 SPO_2 waveform, 1 RESP waveform and 1 CO_2 waveform data can be provided in real time. Through analysis and calculation, this device can provide physiological parameters such as HR, RR, SPO_2, PR, CO_2, NIBP (systolic blood pressure, diastolic blood pressure and mean blood pressure).

KC16 structure: consists of KC16 main unit, power cord, standard KC7 subunit, optional parameter modules and accessories.

KC19/KC22 structure: consists of KC19/KC22 main unit, power cord, DP communication cable, standard KM7 subunit, KX6 plug-in module, optional parameter modules and accessories.

Accessories include ECG lead wires, temperature sensors, blood oxygen probes, and blood pressure cuffs.

Working environment:

Temperature: Working temperature 5 ~ 40 (°C), transportation and storage temperature -20~55(°C);

Humidity: Working humidity 15%~85%, no condensation, transportation and storage humidity ≤93%;

Atmospheric pressure: 700-1060hPa;

Power supply voltage: a.c.100V～a.c.240V 50Hz/60Hz;

Internal battery specifications:14.8V/2.2AH 18650 Battery.

⚠**Notice: Do not use this monitor outside the temperature and humidity range specified by the manufacturer, otherwise it will not meet the performance specifications claimed in Appendix II.**

Abbreviation definition:

Abbreviation	Definition, abbreviation	Name	Definition, abbreviation
ECG	electrocardiogram	HR	heart rate
RESP	respiration	RR	respiratory rate
TEMP	temperature	TD	temperature difference
SPO2	pulse oximetry	SaO2	blood oxygen saturation
Pleth	plethysmography	PI	perfusion index
NIBP	non-invasive blood pressure	SYS	systolic blood pressure
MAP	mean arterial pressure	DIA	diastolic blood pressure
CO2	carbon dioxide	EtCO2	end-tidal carbon dioxide content
FiCO2	Inhaled carbon dioxide content	awRR	Airway respiratory rate (breaths per minute)
INS	Inspiratory air minimum CO2	InsCO2	Minimum amount of carbon dioxide inhaled
RAP	right atrial pressure	CVP	central venous pressure
ICP	intracranial pressure	LAP	left atrial pressure
PA	pulmonary artery pressure	ART	arterial pressure
PR	pulse rate		

2.2 Introduction to Display Interface

The display screen of this monitor is a color touch screen, which can simultaneously display the collected patient parameters, waveform parameters, alarm information, bed number, monitor status, time and other prompt information provided by the monitor.

The main screen is divided into four areas (as shown in Figure 2-2):

Figure 2-2 General interface

Shortcut area button icon:

More	NIBP measurement	NIBP measuring stops
continuous measurement	patient management	review
Interface selection	Alarm pause	alarm reset
Alarm settings	Temporarily screen lock	main menu

Information area introduction:

The information area is located at the top of the screen and displays the current status of the monitor and patient.

Examples of information area content are as follows:

"10001": refers to the medical record number of the patient currently being monitored.

"Bed number": refers to the bed number of the patient currently being monitored.

"Li Ming": refers to the name of the patient currently being monitored.

"2022/12/25 10:32": refers to the current time.

Other prompt messages in the information area appear and disappear at the same time as the reported status, and are divided into:

(1) The monitor prompts information to report the status of the monitor or sensor, and the area in front of the "current time" is fixed;

(2) Monitor alarm information (see the "Alarm" chapter for specific setting methods).

⚠**Notice**

●When the waveform on the screen is frozen, the corresponding words "Screen Freeze" appear above the monitor screen.

●Patient parameter alarm information always appears in the rightmost area.

(3) "———" indicates that the monitored parameters are in an invalid state.

Introduction to waveform/menu area:

The waveform area displays 6 waves, and the order of waveform display can be adjusted. Under the maximum configuration, the system can display 12-lead ECG waves, SPO2 plethysmography waves, respiratory waves, etc. in the waveform area.

The name of the waveform is displayed on the upper right side of each waveform. Through the touch screen function, touch the waveform name to pop up the parameter setting menu;

touch anywhere on the waveform to pop up the "Settings" and "Freeze" buttons, which can be selected to perform related operations.
ECG leads can be selected upon request. The left side of the ECG waveform has the gain of this channel and a 1mV scale. When a menu pops up during screen operation, the menu always occupies a fixed position on the left side of the waveform area, making part of the waveform temporarily invisible. After exiting the menu, the original screen display is restored.
The waveform is refreshed at the set rate. To adjust the refresh rate of each waveform, see the settings of each parameter.

Introduction to parameter area:

The parameter area is located on the right side of the waveform area and is basically placed corresponding to the waveform. The parameters displayed in the parameter area are:
(1) ECG - heart rate or pulse rate (unit: beats/minute)
(2) Body temperature TEMP - temperature (unit: Celsius ℃ or Fahrenheit °F)
(3) Non-invasive blood pressure NIBP - from left to right are systolic blood pressure, mean blood pressure, and diastolic blood pressure (unit: mmHg or kPa)
(4) Blood oxygen saturation SPO2 - blood oxygen saturation SPO2 (unit: %), pulse rate (unit: beats/minute) (when select "simultaneous" as the heart rate source)
(5) Respiratory RESP - respiratory rate (unit: times/minute)
(6) End-tidal carbon dioxide CO2 - carbon dioxide concentration (unit: mmHg or kPa)

Alarm lights and alarm status:

In normal state, the alarm light does not light up. When an alarm occurs, the alarm light flashes or stays on. The color of the light represents a certain alarm level. For details, please refer to the "Alarm" chapter.
For the specific content of alarm information and prompt information, please refer to the relevant descriptions of each parameter in the relevant chapters.

2.3 Front view

KC16A: Power switch"  " is located on the front panel of the monitor, and the alarm light ALARM is located directly above the front screen of the whole machine. The KC7 standard subunit socket is located on the left rear side of the product; the optional parameter module slot is located on the right side of the product. Data transfer and power jacks are located on the rear panel.

KC19A/KC22A: Power switch"  " is located on the left side of the front panel of the plug-in module connected to the display. The alarm light ALARM is located in the center on the right side of the front screen of the display; the plug-in module and the screen are connected through the data transmission interface, and the KC7 standard subunit socket is located on the left side of the plug-in module; The optional parameter module slot is located on the front of the plug-in module. The data transmission jack is on the left panel and the power jack is on the right panel.
When the product is plugged into AC power, the green AC indicator light lights up; when the monitor uses the internal battery to work, the battery indicator light flashes; when the product is equipped with a battery and is in charging state, the charging indicator light stays on; wait for the battery to When fully charged, this light turns off.
This monitor has a user-friendly operation interface. All operations can be completed by touching the display screen after starting up. For details, please refer to the system menu section.

Model KC16A

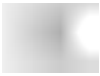
Model KC19A/KC22A

Function description: 1. Alarm indication area 2. Parameter and waveform display area3. Function key area 4. Shortcut function key area

Chapter 3 Monitor Installation

3.1 Key functions and basic operations

Operations on the monitor can be completed through buttons and knobs.

	Press and hold for 2 seconds to power on or off.		Start or stop blood pressure measurement.
	The alarm can be paused for up to 2 minutes ("1 minute" or "2 minutes" are available), and there is "  "Symbol display in the information area.		The "Main Menu" pops up, in which the user can choose to set various system information and perform corresponding operations. Press this key again to return to the main interface.
	Battery status indicator light: The light is always on when charging, off when fully charged, and flashes when the battery is working.		ACIndicator light: Always on when AC power is connected.
	Alarm reset function		
	 Indicates the alarm pause time mark. Indicates that all alarm prompts are temporarily turned off until the alarm pause time ends or the operator manually cancels the alarm pause setting. The system then restores the prompt. The alarm pause time is "1 minute".  Indicates that the alarm volume is off. It means that the alarm sound prompt function has been artificially and permanently turned off until the operator releases the setting of turning off the alarm volume.  Indicates alarm reset.  Indicates that the system is in alarm off state.		

3.2 Monitor external interface

Electrocardiogram (ECG):
ECG lead wire socket
Blood oxygen (SPO2):
blood oxygen probe socket
Non-Invasive Blood Pressure (NIBP):
Cuff Tracheal Socket
Carbon dioxide (CO2):
CO2 module connection socket
Network/RS232 interface: communicate with our company's or other companies' equipment through a standard RJ45 or RS232 serial port plug.
USB interface: used for USB protocol communication between this machine and other devices.

Panel jack description:

Model KC16A	Model KC19A/KC22A		
 The back of the machine	 left side of monitor	 Back of plug-in module	 right side of monitor

(1) AC power supply: network power interface, 100V-240VAC, 50Hz/60Hz AC power input.

(2) NET: Network interface, connected to the company's central monitoring system through a standard RJ45 plug network cable.
(3) Equipotential grounding terminal, grounding can reduce signal interference and improve safety protection.
(4) Fuse: T 1.6AL/250V fuse.
(5) 4 USB interfaces: can be connected to external expansion USB flash drives, mice, keyboards, printers and other devices.
(6) DP interface: The power and communication connection between the main unit and the plug-in module.
(7) COM interface: Function extension interface, not defined yet.
(8) HDMI interface: display expansion interface.

Logger plug-in module:

Information plug-in module installation demonstration diagram

Model KC16A

Model KC19A/KC22A

Optional plug-in modules: built-in side stream CO_2 module, external mainstream CO_2 module, Masimo blood oxygen module, Nellcor blood oxygen module, Suntech blood pressure module, 12-lead ECG module, information plug-in module, recorder module.

⚠**WARNING**

●All analog and digital devices connected to this monitor must be products certified by specified IEC standards (such as IEC 60950 data processing equipment standard and IEC 60601-1 medical equipment standard). And all configurations should comply with the contents of the valid version of the IEC 60601-1-1 system standard. The person responsible for connecting additional equipment to the input/output signal ports configures the medical system and is responsible for the system's compliance with IEC 60601-1-1 standards. If in doubt, please contact the supplier.

3.3 Built-in rechargeable battery

KC16, KC19, KC22 built-in 14.8V/2.2AH, 18650 battery, not removable.

When working on battery power, the monitor will alarm when the battery is low. When the battery is exhausted, the monitor will trigger a high-level alarm, make a continuous "beep..." sound, and prompt "Battery voltage is too low" in the information area. At this time, the DC power supply should be plugged in to charge the battery immediately. If it is still powered by batteries, the monitor will automatically power off before running out of power (about 10 minutes after the alarm).

Battery and AC status light indication: When the network power supply is powered, the AC indicator light is on, the battery light is on during the charging process, and when the battery is fully charged, the battery indicator light is off; when the battery is powering the device, the AC indicator light is off and the battery indicator is flashing.

The warranty period of the battery is 1 year, and it needs to be charged and discharged every 3 months, otherwise the battery life will be seriously shortened. Often due to manufacturer inventory - logistics inventory - dealer inventory - customer inventory, the battery is often damaged or life performance is reduced due to this reason. If the monitor will not be used for a long time, then the battery need to be removed. If not used for a long time > 3 months, the battery should be removed from the monitor.

3.4 Unpack and check

Carefully remove the product from the packaging box. If any damage is found, please contact the shipping company immediately and save the packaging materials for future transportation or storage. Please check the accessories according to the packing list.
(1) Check for any mechanical damage.
(2) Check all exposed wires.
When installing, leave at least 2 inches (5 cm) of space around the monitor to allow air circulation. The environment in which the monitor is used must be reasonably free from vibration, dust, corrosive or explosive gases, extreme temperatures and moisture, etc.
If you have any questions, please contact our sales department or agent immediately.
When equipment is moved from one environment to another, condensation may occur on the equipment due to differences in temperature or humidity. At this time, you must wait for the condensation to disappear before use.

⚠**WARNING**

●Packaging materials may cause pollution to the environment. When disposing of packaging materials, you must comply with relevant local regulations or the hospital's waste disposal system. Please keep packaging materials out of the reach of children.

●The equipment may be contaminated by microorganisms during storage, transportation and use. Please confirm whether the packaging is intact before use, especially single-use accessories. If damage is found, please do not use it.

3.5 Power connection

Steps to connect the DC power cord:

(1) Make sure the AC power supply meets the following specifications: a.c.100-240V, 50/60Hz.
(2) Use the power cord provided by the monitor. Plug the power cord into an electrical outlet. Plug the output end of the power cord into the monitor's power connector.

⚠**Notice**

●The battery must be charged after the product has been transported or stored. If you turn on the product without connecting it to AC power, the product may not work properly due to insufficient battery power. Plug in AC power and charge the battery whether the monitor is turned on or off.
●Please ensure that this equipment works under the specified environmental requirements, otherwise it will not be able to meet the technical specifications claimed in this manual, and may cause equipment damage and other unpredictable consequences.
●When the power supply of this monitor network is cut off for more than 30 seconds, the product switches to the internal battery power supply. All alarm limit settings and other related parameter settings are the values before the power outage.

3.6 Power on and start up

Press and hold the power button for 2 seconds. At this time, the alarm light flashes red once. After 2 seconds of powering on, the company logo or model number will be displayed for about 9 seconds. Enter the monitoring screen. Touch anywhere on the display to pop up the touch screen unlock switch. Touch "Yes" to complete the touch screen unlocking, and the user can perform operations at this time.

⚠**WARNING**

●If you find signs of damage on the monitor function, or if an error self-test prompt appears,

do not use this monitor for patients, and please contact the hospital's medical equipment engineer or our company's maintenance engineer.

⚠**Notice**

●Check all available monitoring functions to make sure them are well functioning.
●Equipped with a battery, the battery must be charged after each use to ensure sufficient power reserve.
●Wait 1 minute after shutting down before turning it on again.

3.7 Connection of plug-in modules, parameter modules and sensors

Connect the required plug-in modules, parameter modules, and sensors to the monitor and the patient's monitoring area.

⚠ **Note: For the correct connection methods and related requirements of various sensors, please refer to the relevant chapters.**

3.8 Start working

1. Confirm which monitoring mode is required.
2. Check whether the patient cable and sensor are correct.
3. Connect the patient cable and sensor.
4. Enter the required working mode and check whether the various settings and alarm parameters meet the current needs.

For other parameters or system settings, please refer to the relevant chapters.

3.9 End work

Press and hold the On/Off button for 2 seconds to turn off the monitor, and unplug the power cord or adapter if used. Before turning off the monitor, perform the following checks:

1. Ensure that patient monitoring has been completed.
2. Disconnect cables and sensors from the patient.
3. Ensure that patient monitoring data is saved or cleared as needed.

3.10 Disconnecting the network power method

To unplug the adapter from the network power supply.

Chapter 4 System Menu

The configuration of this monitor is flexible, and the monitoring content, waveform scanning speed, waveform color, etc. can be configured by the user’s needs. Use the touch screen function to select the "Main Menu" item in the "Shortcut function area", and the menu shown in Figure 4 will pop up. You can perform the following operations:

Figure 4 Main menu

4.1 Patient management

In the "Patient Management" task bar, users can perform the following operations:

4.1.1 Patient management

Select the "Patient Management" item in the "Patient Management" task bar in the "Main Menu", and the window shown in Figure 4-1-1 will pop up.

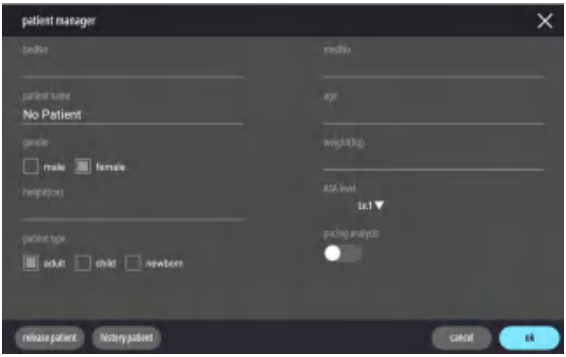


Figure 4-1-1 Patient management

Enter the following patient information according to actual needs:

Bed number; Medical record number;
Patient name; Age;
Gender: male/female; Weight;
Height; ASA level: Level 1-6 optional;
Patient categories (optional): adults, children, neonates; Pacing analysis: on or off.

4.1.2 Cancel the patient

In the "Patient Management" task bar of the "Main Menu" or the lower left corner of the "Patient Management" window, the user can select the "Patient Cancel" item, and the " Patient

Cancel " dialog box will pop up, asking if you are sure to cancel the current patient. As shown in Figure 4-1-2 below:

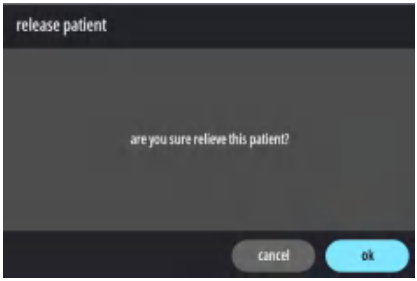


Figure 4-1-2-1 cancel the patient

Figure 4-1-2-2 query patients

Select: "No" to maintain the current patient monitoring status and exit the menu.
Select: "OK" to cancel the current patient's monitoring status and exit the menu.
After confirming to cancel the patient, the monitor will automatically jump to the initial interface, and a dialog box will pop up asking "Do you want to accept new patients?" Select OK to enter new patient information.

⚠**Notice: After confirming that the patient is canceled, all patient data, including patient information, trend data, physiological alarm information, etc., will be stored in historical patients. Technical alarms are reset and monitor settings return to default values.**

4.1.3 Historical patients

In the "Patient Management" task bar of the "Main Menu" or the lower left corner of the "Patient Management" window, the user can click the "Historical Patients" item to enter the "Query Patient" window, as shown in Figure 4-1-3 above. Select the desired patient (you can search by entering the patient's name in the search bar above) and query the data information of patients who have been released from monitoring, including patient information, parameter waveforms, data and physiological alarm information, etc.

⚠**Notice: The currently monitored patient data is not displayed in historical patients.**

4.2 Review

Trends are patient data collected over time, displayed in graphs, tables, or other forms that allow users to understand how a patient's condition is progressing. Users can view trend data in trend tables, trend graphs, alarm events, holographic waveforms, and NIBP reviews.

In the "Review" task bar, users can perform the following operations:

4.2.1 Trend table

Click the "Trend Table" item in the "Review" task bar of the "Main Menu", and the window shown in Figure 4-2-1 will pop up.

Figure 4-2-1 Trend table

The time period corresponding to each set of trend data is displayed in the top row. Listed on the right side of the event are previously marked events, which correspond to the time displayed before the alarm event. Each measured parameter value recorded in the trend table is shown in Figure 4-2-1. You can view more historical parameters by adjusting the slider at the bottom of the page left or right.

Event type: different color blocks correspond to different types of events

■ Red: high priority alarm event

■ Yellow: Medium priority alarm event

■ Blue: low priority alarm event

■ White: Manual event recording

Observe trend data for earlier or later dates:
Adjust the slider at the bottom of the page. Swipe left to observe earlier trend data; slide right to observe later trend data.

Review time: Adjusting the " Review Time" can make the interface jump to the trend data of the specified time period.

Current time: Click the "Current Time" button at the bottom of the page, and the trend table jumps to the trend data corresponding to the current system time.

Yesterday: Click the "Yesterday" button at the bottom of the page, and the trend table will jump to the data of the previous day at the current time.

Since admission: Click the " Since admission " button at the bottom of the page, and the trend table will jump to the first set of trend data recorded since the patient was entered.

Choose trend tables with different resolutions:
Click "Resolution" in the lower right corner of the window, select the required resolution value, and change the trend data time interval. Trend table data can be displayed at the following

resolutions: 1 minute, 5 minutes, 10 minutes, 30 minutes, 60 minutes.

4.2.2 Trend chart

Select the "Trend Chart" item in the "Review" task bar of the "Main Menu", and the window shown in Figure 4-2-2-1 will pop up.

On the trend chart, the ordinate represents the measured value, the abscissa represents the measurement time, "ECG" represents "electrocardiogram", "SPO_2" represents "blood oxygen saturation", and "NIBP" represents "non-invasive blood pressure"… Except for the NIBP value, other trends are shown as continuous curves. On the NIBP trend chart, "SYS" represents systolic blood pressure, "DIA" represents diastolic blood pressure, and "MAP" represents mean arterial pressure.

Figure 4-2-2-1 Trend chart

Observe trends earlier or later:

Adjust the slider at the bottom of the page. Swipe left to observe earlier trend data; slide right to observe later trend data.

Review time: Adjusting the " Review time " can make the interface jump to the trend data of the specified time period.

Current time: Click the "Current Time" button at the bottom of the page, and the trend graph will jump to the trend data corresponding to the current system time.

Yesterday: Click the "Yesterday" button at the bottom of the page, and the trend graph will jump to the trend data of the previous day at the current time.

Since admission: Click the " Since admission " button at the bottom of the page, and the trend graph will jump to the first set of trend data recorded since the patient was admitted.

Choose trend graphs at different resolutions:

Click "Resolution" in the lower right corner of the window, select the required resolution value, and change the trend data time interval. Trend graph data can be displayed in the following resolutions: 1 minute, 5 minutes, 10 minutes, 30 minutes, 60 minutes.

4.2.3 Events

Select the "Event" item in the "Review" task bar of the "Main Menu", and the window shown in Figure 4-2-3-1 will pop up. You can review the alarm parameters and waveforms corresponding to alarm events that occurred in the last month.

Event type: different color blocks correspond to different types of events

■ Red: high priority alarm event

■ Yellow: medium priority alarm event

■ Blue: low priority alarm events

■ White: manual event recording

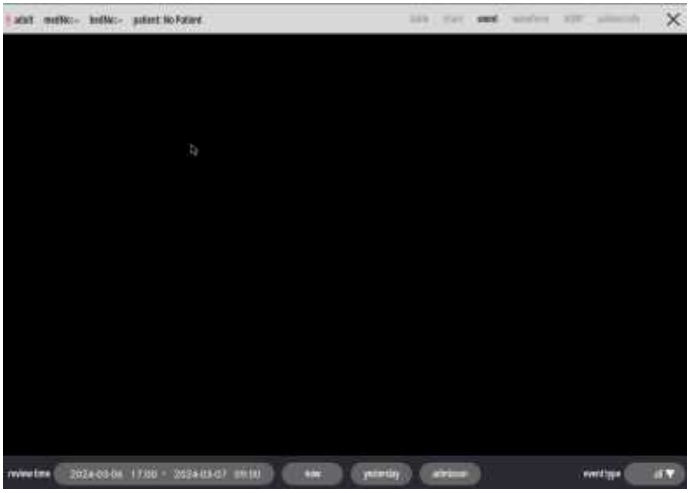


Figure 4-2-3-1 Event

Review time: Adjusting the " Review time " can make the interface jump to alarm events in the specified time period.

Current time: Click the "Current Time" button at the bottom of the page, and the alarm event will jump to the data corresponding to the current system time.

Yesterday: Click the "Yesterday" button at the bottom of the page, and the alarm event will jump to the data of the previous day at the current time.

Since admission: Click the "Since Admission" button at the bottom of the page, and the alarm event will jump to the first set of data recorded since the patient was admitted.

Event type filter

You can click the corresponding option in the "Event Type" in the lower right corner of the window to filter the alarm times you want to view. The "Event Type" options are "All, High Alarm, Medium Alarm, Low Alarm, Manual Recording".

Event Records

Click on the "Shortcut function area" to select the "Event Record" item, and the window shown in Figure 4-2-3-2 will pop up.

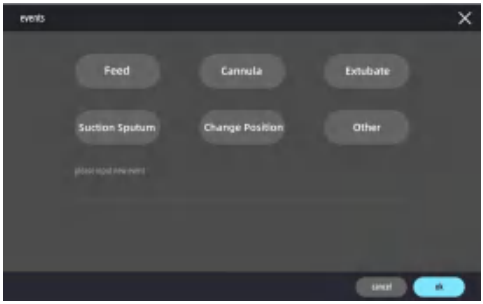


Figure 4-2-3-2 Event record

Users can select the corresponding event in the "Event Records" window or customize the event content in the input box below "Please enter the event name" to manually record the event. The event time defaults to the current time of recording.

4.2.4 Holographic waveform

Select the "Holographic Waveform" item in the "Review" task bar of the "Main Menu", and the window shown in Figure 4-2-4 will pop up. You can review the parameter waveforms of the last month.

Figure 4-2-4 Holographic waveform

Observe holographic waveforms earlier or later in time:

Adjust the slider at the bottom of the page. Swipe left to observe earlier trend data; slide right to observe later trend data.

Review time: Adjusting the " Review time" allows the interface to jump to trend data at a specified time.

4.2.5 NIBP review

Click the "NIBP Review" item in the "Review" task bar of the "Main Menu", and the window shown in Figure 4-2-5 will pop up.

The data is arranged in chronological order from recent to distant. Each screen can display 20 measurement data. You can view measurement results for up to the last month.

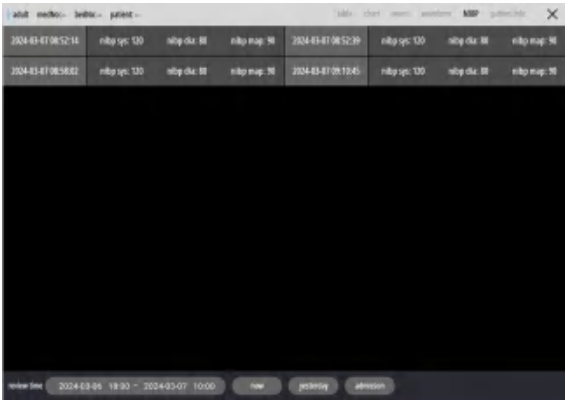


Figure 4-2-5 NIBP review

Review time: Adjusting the " Review time " can make the interface jump to the NIBP data of the specified time period.

Current time: Click the "Current Time" button at the bottom of the page, and the NIBP review will jump to the NIBP data corresponding to the current system time.

Yesterday: Click the "Yesterday" button at the bottom of the page, and the NIBP review jumps to the previous day's data at the current time.

Since admission: Click the " Since admission " button at the bottom of the page, and the NIBP review will jump to the first set of data recorded since the patient was admitted.

4.3 Monitor settings

In the "Monitor Settings" task bar, users can perform the following operations:

4.3.1 Monitor information

Click "Monitor Information" in the "System Management" task bar of the "Main Menu" to view the software version information of the monitor, as shown in Figure 4-3-1.

Figure 4-3-1 Monitor information

4.3.2 Interface selection

Select the "Interface Selection" item in the "Monitor Settings" task bar or "Shortcut Function

Area" of the "Main Menu". A window pops up as shown in Figure 4-3-1, you can see The current option is the regular interface.

Figure 4-3-2 Interface selection

On the left side of the window, select the interface type required for currently monitoring the patient. There are four options: "regular interface, large font interface, respiratory oxygenation interface, and ECG multi-lead interface". Users can configure parameter values, waveforms, and the order in which they are displayed on the screen. Select a corresponding ▼ to a parameter value area or waveform area, then select an element to be displayed in that area from the drop-down menu, and click the "OK" button to complete the interface switch. Parameters and waveforms not selected by the user will not be displayed on the interface.

⚠**Notice: You can also use two fingers to slide left or right on the touch screen to switch interfaces.**

4.3.2.1 General interface

Most commonly used for patient monitoring. For general practice, ICU and CCU, the regular interface is used by default.

4.3.2.2 Large font interface

Display parameter values in large font.

4.3.2.3 Respiratory oxygenation interface

When neonatal mode is selected, the respiratory and oxygenation interface is the default user screen. It displays 6-minute HR/btbHR, SpO_2 and SpO_2b trends, CO_2/Resp compression waveforms, ABD parameters and latest ABD events. OxyCRG functionality is only available for neonatal patients.

4.3.2.4 ECG multi-conductor interface

The waveform area of the interface displays six ECG waveforms. This interface can be selected when focusing on observing ECG trend data.

4.3.3 Parameter color

Select the "Parameter Color" item in the "Monitor Settings" task bar of the "Main Menu", and the "Parameter Color" window as shown in Figure 4-3-3 will pop up, which is used to customize the display color of the parameter waveform on the screen.

Click on ▼ to the right of each "waveform parameter color" in the window and set the corresponding parameter waveform color in the drop-down menu. Each waveform has seven colors to choose from: "green", "blue", "red", "yellow", "white", "blue", and "purple". Click the "OK" button in the bottom right corner to complete the setting.

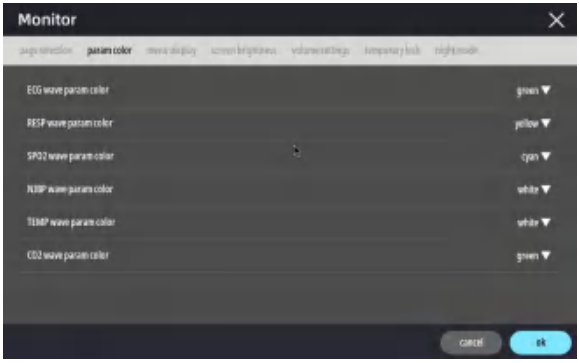


Figure 4-3-3 Parameter color

4.3.4 Menu display

Select the "Menu Display" item in the "Monitor Settings" task bar of the "Main Menu". The window shown in Figure 4-3-4 will pop up.

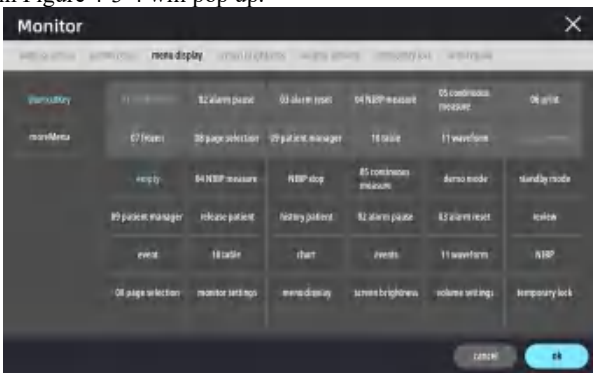


Figure 4-3-4 Menu display

On the "Menu Display" page, you can change the button icons in the "Shortcut Function Area". The operation method is as follows:

Click the name of the button to be replaced in the "Shortcut Area" above. After selecting it, click the corresponding button name below to replace it. After selecting, click the "OK" button in the lower right corner of the page to complete the replacement operation.

4.3.5 Screen brightness

Select the "Screen Brightness" item in the "Monitor Settings" task bar of the "Main Menu" or "More" in the "Quick Area", and the "Screen Brightness" window as shown in Figure 4-3-5 will appear. Click the "-" or "+" button to adjust "screen brightness" and "battery-powered screen brightness".

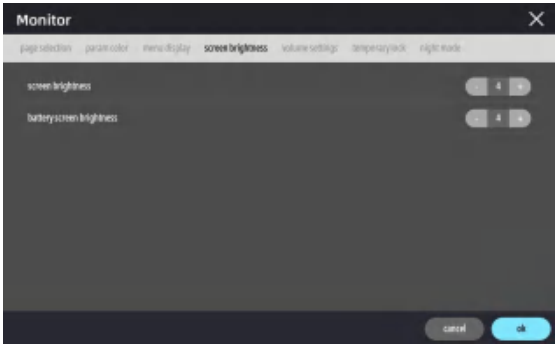


Figure 4-3-5 Screen brightness

⚠**Notice**

●When using AC power, please set the screen brightness. When using battery power, please set the battery power screen brightness.

4.3.6 Volume

Click the "Volume" item in the "Monitor Settings" task bar of the "Main Menu".The window shown in Figure 4-3-6 will pop up.

Click the "-" or "+" button to adjust the "alarm volume", "heartbeat volume" and "button volume". The options include ten levels "1→10"**.**

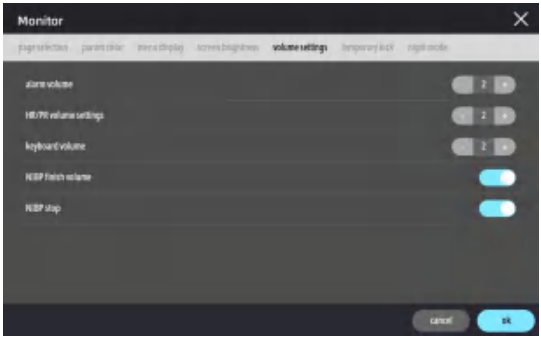


Figure 4-3-6 Volume

NIBP completion tone: You can choose "on" or "off".

NIBP stops measurement: You can choose "On" or "Off".

⚠**WARNING**

●When the alarm volume of the system is turned off ("Close" is selected), if an alarm occurs, the monitor cannot sound the alarm. Therefore, operators should cautiously use this function.

●If you select "Off" for the alarm volume in the SILENCE or alarm pause state, the system will automatically end the SILENCE state or alarm pause state.

●When the alarm volume is "Off", if the operator selects "Mute" or "Alarm Pause", then the system will restore the alarm volume to the alarm volume before the sound is turned off, and at the same time, the system will enter the mute state or alarm pause state.

⚠**Notice: "Alarm volume" is only valid for the current setting. It will return to the medium volume after shutting down and then turning it on again. Operators should carefully check this function before use to avoid delaying patient treatment due to silent or too low alarm sounds.**

4.3.7 Print settings

Click the "Print Settings" item in the "Monitor Settings" task bar of the "Main Menu".The window shown in Figure 4-3-7 will pop up. In this window, you can set the waveform to be printed and the printing time. Click "OK" to complete the settings.

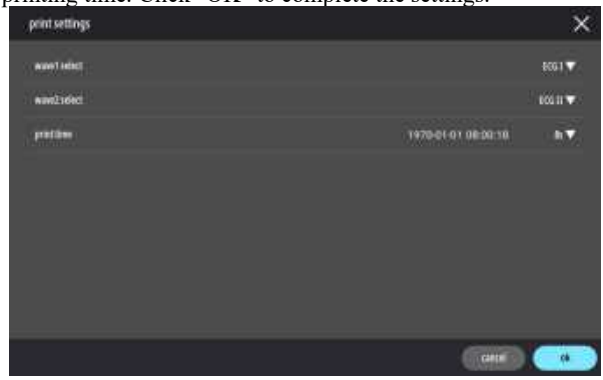


Figure 4-3-7 Print settings

Waveform selection: Both waveform 1 and waveform 2 can choose "ECGI, ECGII, ECGIII, ECGV, ECGV2, ECGV3, ECGAVR, ECGAVL, ECGV4, ECGV5, ECGV6, SP02, RESP, CO2". Up to two waveforms can be printed at the same time.
Printing time: optional "10S before, 5S after, 0S after, 5S after, 10S after, 15S after, 20S after".

4.4 Special mode

In the "Special Mode" task bar, users can perform the following operations:

4.4.1 Standby mode

Click the "Standby Mode" item in the "Special Mode" task bar of the "Main Menu", the "Enter Standby +Mode" dialog box will pop up, as shown in Figure 4-As shown in 4-1. The user can temporarily stop patient monitoring by entering standby mode without turning off the monitor.

Figure 4-4-1 Enter standby mode

Select: "Cancel" to maintain the current working status of the monitor and exit the menu.
Select: "OK" to enter standby mode and exit the menu.
After entering standby mode, the monitor behaves as follows:

Stop all parameter measurements and alarms. The monitor screen is black and the alarm indicator light is always blue.

⚠**WARNING**

●**Be aware of the potential risks of placing the monitor in standby mode. In standby mode, the monitor stops all parameter measurements and stops all alarm indications.**

Exit standby mode

Click any button on the front screen of the monitor to exit the standby mode.

4.4.2 Night mode

Click the "Night Mode" item in the "Special Mode" task bar of the "Main Menu" and a pop-up will appear as shown in Figure 4-4-2-1. Night mode is a special clinical monitoring mode. To avoid disturbing patients, users can use this mode.

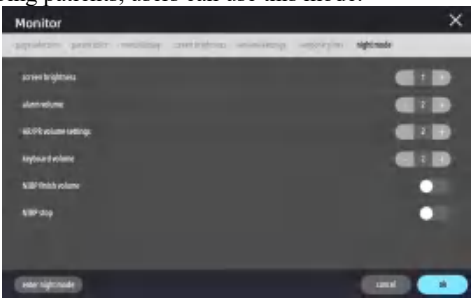


Figure 4-4-2-1 Night mode

By default, Night Mode is set as follows:

Screen brightness: 4	Alarm volume: 10	Heartbeat volume 10;
Key volume: 10	NIBP completion tone: off	NIBP Stop Measurement: Off

If necessary, you can change the night mode settings in the "Night Mode" window. Click "Enter Night Mode" in the lower left corner of the window. The monitoring mode is adjusted to night mode. The word "Night" appears at the top of the screen, and the option here automatically changes to " Exit night mode".

⚠ **WARNING:Before entering Night Mode, verify the Night Mode settings. If the setting value is low, be aware of the potential risks.**

Exit night mode

Select the "Exit Night Mode" item in the lower left corner of the "Night Mode" window (formerly "Enter Night Mode"), and the "Exit Night Mode" dialog box will pop up, asking if you are sure to exit Night Mode:

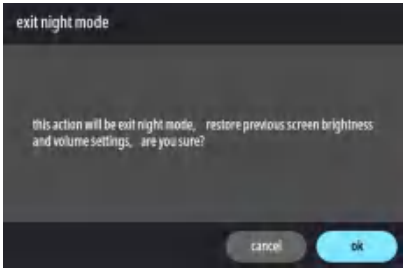


Figure 4-4-2-2 Exit night mode

Select: "Cancel" to maintain night mode and exit the dialog box.
Select: "OK" to exit night mode, restore the previous screen brightness and volume settings, and exit the dialog box.

4.4.3 Enter Demonstration

Select the "Enter Demonstration" item in the "Special Mode" task bar of the "Main Menu" to pop up the "Enter Demonstration Mode" dialog box. After entering the security key (5188) and clicking "OK", the system enters the demo waveform state.
The demonstration waveform is a simulation demonstration waveform set by the manufacturer only to demonstrate the machine performance and help users with training. In actual clinical use, the function of demonstrating waveforms is disabled because it may cause medical staff to mistake the waveforms and parameters of the patient for monitoring, affecting patient monitoring and delaying diagnosis and treatment. Therefore, this menu has a password, as shown in Figure 4-As shown in 4-3.

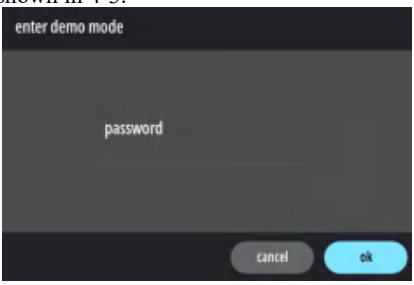


Figure 4-4-3 Entering demonstration mode

4.4.4 Temporary lock screen

In the "Monitor Settings" task bar of the "Main Menu", the user can click the "Temporary Lock Screen" item, and the option here turns blue (such as ), the words "Lock Screen" appear at the top of the screen, and the monitor screen enters a temporary screen lock state.

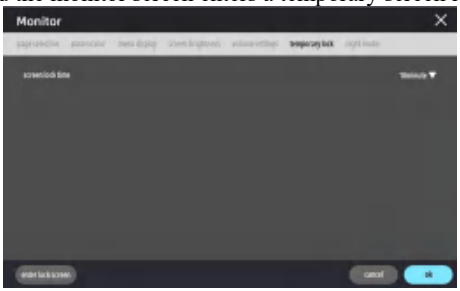


Figure 4-4-4-1 Temporary lock screen

Lock screen time setting

Enter the "Temporary Lock Screen" window and click "Lock Screen Time" to set the lock screen time in the drop-down menu that appears. You can choose "10 minutes, 30 minutes, 1 hour, 3 hours, 6 hours, 12 hours, 24 hours" and click the "Confirm" button to complete the setting.

Enter temporary lock screen

The user can click the "Enter Temporary Lock Screen" button in the "Temporary Lock Screen" window, and the monitor screen will enter the temporary lock screen state, and the button display here will change to "Exit Temporary Lock Screen".

Exit temporary lock screen

When the monitor is locked, click anywhere on the screen, and the "Exit Temporary Lock Screen" dialog box will pop up, asking if you are sure to exit the temporary lock screen, as shown in Figure 4-4-4-2.

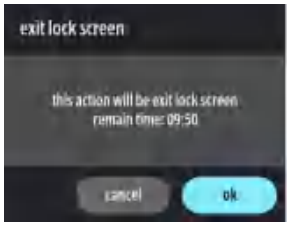


Figure 4-4-4-2 Exit temporary lock screen

Select "Cancel": the monitor remains temporarily locked and exits the dialog box.
Select "OK": the monitor exits the temporary lock screen and exits the dialog box.

4.4.5 Information interconnection

Click the "Information Interconnection" item in the "Special Mode" task bar of the "Main Menu" and a pop-up will appear as shown in Figure 4-The window shown in 4-5. The window positions of KC16, KC19, and KC22 are slightly different. By default, the monitoring data of the current bed monitor, ventilator, and infusion pump are displayed.

Set the network IP of the device and the monitor in the same LAN segment. Click "Current Bed" at the top of the "Information Interconnection" window, a drop-down menu will appear, and you can choose to view the equipment status of other beds in the current LAN.

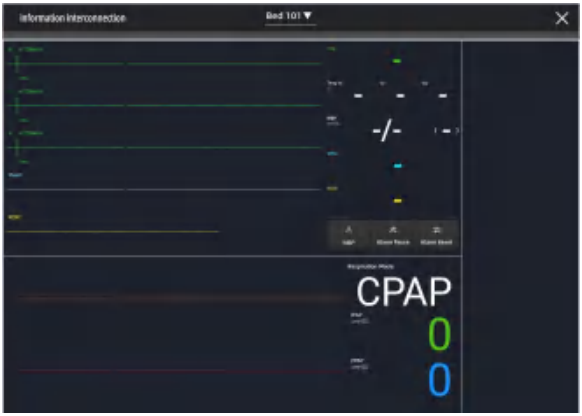


Figure 4-4-5 Information interconnection

Display Area

The information interconnection interface is divided into the following parts: alarm bar, monitor indicator area, ventilator indicator area, and infusion pump indicator area.

Figure 4-4-5-1 Monitor indicator area (information interconnection)

Monitor indicator area

The monitor displays the real-time data of the waveform and indicators on the monitor bound to the current bed. The specific display content is as follows:

Waveform area: Displays the waveform transmitted from the monitor. If an alarm occurs in the module involved in a waveform, a prompt will pop up on the waveform corresponding to the area.

Parameter area: Display the corresponding parameter value on the monitor.

Shortcut button: Click the button here to control the "NIBP measurement", "alarm pause" and "alarm reset" of the bedside monitor.

Waveform parameters: The waveforms currently supported for display include: ECGII, ECGI, ECGV, Pleth, and RESP. Currently supported parameters are: ECG, TEMPT1\T2\TD, NIBP, SpO_2, RESP.

Figure 4-4-5-2 Ventilator indicator area (information interconnection)

Ventilator indicator area

This area displays the breathing mode of the ventilator connected to the patient's bed, as well as key indicators and waveforms in this mode. The specific display content is as follows:

Waveform area: Displays the waveform transmitted from the monitor. If an alarm occurs in the module involved in a waveform, a prompt will pop up on the waveform corresponding to the area.

Parameter area: Displays the corresponding ventilator mode on the ventilator. The corresponding indicator parameters are: breathing mode, expiratory pressure, and inspiratory pressure.

No waveform prompt: If there is no waveform, the waveform area will display "Current parameter has no waveform".

Not connected prompt: If the patient is not connected to the monitor, "Not Connected" will be displayed in the indicator area.

Infusion pump indicator area

This area displays the parameters of the syringe pump and infusion pump connected to the patient's bed.

Parameter area: Demonstrates dosing speed on a single pump.

Drug name label area: If the drug name is displayed on the infusion pump, this area will display the drug name.

Infusion pump display area: Display the corresponding infusion pump status: online, offline, start and stop.

Not connected prompt: If the patient is not connected to the infusion pump, the indicator area displays "Not Connected".

Figure 4-4-5-2 Ventilator indicator area (information interconnection)

Switch beds

Click "Current Bed" at the top of the "Information Interconnection" window, and a drop-down menu will appear. You can choose to view the equipment status of other beds in the current LAN.

⚠**Notice**

●All alarm information and parameter information displayed by the equipment status are based on the actual bedside equipment, and the information interconnection is only responsible for viewing and display.
●Information interconnection does not have the alarm sound of other bedside devices.
●Devices currently supporting information interconnection include:
a. Lianying monitor: KB12A (T)
b. Lianying ventilator: LA20B bi-level automatic ventilator
c. Lianying syringe pump: MS37
d. Lianying infusion pump: MI27
●If you want to use the information interconnection function, you need to set the network IP of the device in the same LAN segment.

4.5 System Maintenance

In the "System Maintenance" task bar, users can perform the following operations:

4.5.1 User maintenance

Click the "User Maintenance" item in the "System Management" task bar of the "Main Menu", and the dialog box shown in Figure 4-5-1 will pop up.

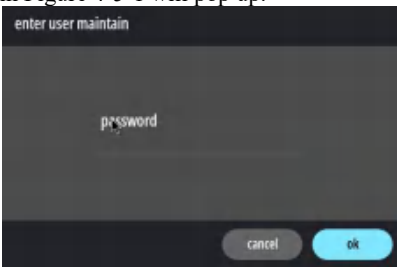


Figure 4-5-1 Entering user maintenance

In the "Enter User Maintenance" dialog box, enter the security key (2016), click the "OK" item, and the "User Maintenance" menu will pop up, as shown inAs shown in Figure 4-5-1-1, you can perform alarm settings, network settings, and other settings. Users cannot perform manufacturer maintenance functions. This function is only open to the company's designated maintenance personnel.

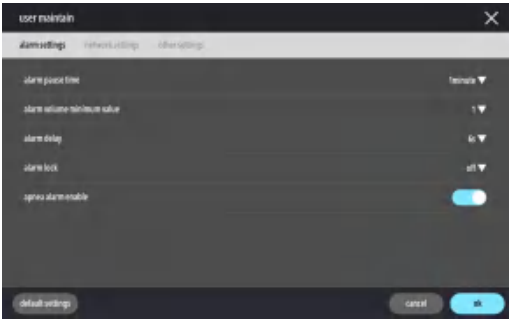


Figure 4-5-1-1 User maintenance (alarm setting)

Alarm pause time

Click "Alarm Pause Time" in the "Alarm Settings" window and select the alarm pause time in the drop-down menu. The system will not perform any alarm processing during this time period.

Optional "1 minute" or "2 minutes".

Minimum alarm volume

Click "Alarm Volume Minimum" in the "Alarm Settings" window and select the alarm pause time in the drop-down menu. Optional "0", "1".

⚠Notice

●When the alarm volume is set to "0", the monitor will not sound an alarm even if a new alarm occurs. Pay attention to whether you want to set the minimum alarm volume value to "0".

●Adjusting the alarm volume to a low level may cause harm to the patient. Always ensure that the alarm volume is appropriate for the patient care environment and always monitor the patient closely.

Alarm delay

Click "Alarm Delay" in the "Alarm Settings" window and select the alarm delay time in the drop-down menu. For continuously measured parameters, the user can set the alarm delay time. If the alarm condition is resolved within the delay time, the monitor will not display the alarm.

Alarm latch

Click "Alarm Latch" in the "Alarm Settings" window, and select "On" or "Off" in the drop-down menu.

Respiratory asphyxia alarm

Click " Asphyxia Alarm" in the "Alarm Settings" window to adjust "On" or "Off".

Default setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "Alarm Settings" to the system default configuration.

Network settings

When the monitor needs to perform operations related to wired or wireless networking and program upgrades, it is necessary to set up the local network so that other devices can discover or connect to the device.

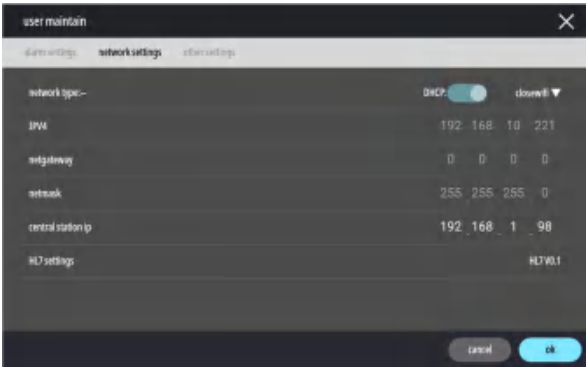


Figure 4-5-1-2 User maintenance (network settings)

Operation method: Menu-User Maintenance-Security Key 2016-OK-Network Settings, the following window will pop up, click "Network Mode" and select "WIFI" or "Wired" network

in the drop-down menu. Click "OK" to complete the settings.

Other settings

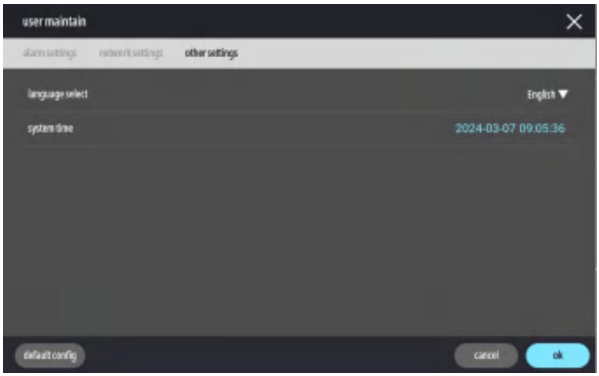


Figure 4-5-1-3 User maintenance (other settings)

Language selection

Users can set the text displayed on the screen to "Chinese" or "English", and the specific options are determined by the user's configuration.

Default setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore "Other Settings" to the system default configuration.

Chapter 5 Maintenance and Cleaning

5.1 Inspections

Before using this equipment, the following checks must be carried out:
(1) Check the product for any mechanical damage.
(2) Check all exposed wires, plug-in parts and accessories.
(3) Check the functions of all products that may be used to monitor patients, and ensure that the products are in good working order.
(4) If you find signs that the product function is damaged, this monitor must not be used to perform any monitoring on the patient. Please contact the hospital's medical equipment engineer or our company's maintenance engineer.
(5) A comprehensive functional inspection, including safety inspection, must be carried out by professionals every 6-12 months and after each repair.

⚠**WARNING**

●If hospitals or medical institutions responsible for maintaining this product fail to maintain this product as planned, it may cause the product to fail and ultimately endanger the patient's health.

●Equipment or accessories must be powered off before being disinfected or cleaned.

●All safety inspections or maintenance work that requires dismantling the equipment should be performed by professional maintenance personnel. Operations by non-professionals may cause equipment failure and may endanger personal safety.

●If any problems are found with the equipment, such as accidental dampness, please contact the maintenance personnel or manufacturer.

⚠**Notice**

●If the accessories (such as ECG cables, blood oxygen probes, body temperature probes) equipped with the equipment are damaged or show signs of deterioration, they are forbidden to be used again. Please replace the original accessories of our company in time.

●If the blood pressure cuff and extension tube used with the device leak, please replace them in time.

●If all accessories are dirty, please clean and disinfect them in time.

●Various disposable accessories shall not be reused. Please recycle and discard disposable accessories according to specifications after use.

●Please use accessories with corresponding specifications for different patient types.

●When the device is in use, except for the removable battery, other parts or accessories cannot be maintained. Please shut down the device and unplug the AC power connection before maintenance.

5.2 General Cleaning

This equipment should be placed in a clean environment.
It is recommended to clean the outer surface of the case and the monitor screen. To clean the case, use a non-abrasive cleaner such as soap and water.

5.3 Use of Cleaning Agents

In addition to the solutions listed in the "Careful " section below, any solution that can be classified as a product with the following properties may be used as a cleaning agent:
The surface of the monitor and its sensors can be wiped with medical alcohol or isopropyl alcohol, and allowed to air dry or clean with a clean, dry cloth.
Our Company is not responsible for the effectiveness of these chemicals as a means of controlling infectious diseases. Please consult with your hospital's infection control leader or infectious disease specialist.

⚠**Careful**

●Do not use strong solvents such as acetone.

●Most detergents must be diluted before use. Follow each manufacturer's instructions for dilution.

●Never use abrasive materials for cleaning (such as steel wool or silver polish).

●When the main unit or its accessories are being disinfected or cleaned, liquid must not enter the joints, and liquid must not enter the main unit. Any liquid remaining on the surface after cleaning or disinfection must be removed.

●Accessories must not be cleaned or disinfected by high temperature, high pressure, or liquid immersion.

5.4 Disinfection

You can disinfect this monitor according to the disinfection procedures of your hospital. This monitor should be cleaned before disinfection.

a. ECG lead wire

1) When cleaning or disinfecting, do not connect the lead wire to the monitor;

2) Clean or disinfect before use on new patients;

3) Use 70% isopropyl alcohol or alcohol solution to clean the surface of the ECG electrode.

4) When cleaning, first dip a clean, dry sponge pad into cleaning fluid. Use this sponge pad to wipe all surfaces of the electrodes and cables; then dampen another clean, dry sponge pad with sterile or distilled water. Use this sponge pad to wipe all surfaces of the electrodes and cables; finally wipe all surfaces of the electrodes and cables with a clean, dry sponge pad;

5) Caution: The connector pins must not come into contact with cleaning fluid, otherwise it will cause damage to the monitoring equipment and human body.

b. Blood pressure cuff

1) Prepare enzymatic cleaner (such as ENZOL produced in the United States or Cidezyme enzyme cleaner produced in the United Kingdom) and 10% bleach in separate spray bottles.

2) Spray the cleaner evenly on the sleeves, ductwork and hoses. If the dirt has dried, leave it on the clean surface for one minute.

3) Use a lint-free cloth to wipe the smooth surface. If there are visible stains or irregular surfaces, use a soft-bristled brush to clean them. Rinse with plenty of distilled water.

4) When disinfecting, spray 10% bleach solution on the cuff until it is saturated, and leave the product for 5 minutes.

5) Wipe off excess solution, rinse with distilled water again, and let the sleeve air dry naturally.

c. Blood oxygen probe

1. Do not connect the probe to the monitor during cleaning or disinfection.

2. The probe must be disinfected before use.

3. To clean the contact surface between the probe and the patient, use a soft medical cloth dipped in medical cleaning fluid to wipe it.

4. Disinfect the probe and wipe the contact surface between the probe and the patient with disinfectant for at least 1 minute. We recommend 75% isopropyl alcohol as a disinfectant.

5. The probe can withstand 200 times of cleaning and disinfection.

6. Patients should not clean and disinfect themselves, but must let medical staff do it.

d.Medical temperature sensor

Disinfection must be carried out by the hospital or user before use. Disinfectants commonly used in hospitals (such as ethanol, isopropyl alcohol, etc.) can be used to wipe the probe and the wire body in contact with the human body: first wipe with medical alcohol cotton balls, and then use 75% ethanol. Soak for more than 5 minutes and wipe clean.

⚠**Careful: To prevent damage to the monitor, do not use gascorrosive(EtO) or formaldehyde to disinfect the monitor.**

5.5 Sterilization

Sterilization of this monitor, related products, or accessories is not permitted unless otherwise stated in the accompanying instructions.

5.6 Maintenance

In order to ensure that the monitor is available at any time, routine maintenance of the monitor is required. Routine maintenance includes the following inspection items: (1) shift inspection; (2) automatic detection; (3) user detection; (4) ECG cable test; (5) Pace test; (6)

NIBP test; (7) NIBP overvoltage protection test, etc.
Cables, probes, and sensors such as ECG cables, blood oxygen probes, and body temperature probes are all important components for obtaining biological signals, and they are prone to wear and tear and should be included in the shift inspection list. The unit using the product should make a maintenance plan.

5.6.1 Routine inspection

(1) Power-on self-test. Each time the monitor is turned on, the alarm light will flash red and yellow alternately, and then it will make a "beep" sound to complete the self-test.
(2) Visual inspection. The operator should visually inspect the accessories before each use to confirm that they are not damaged.
(3) CO_2 zero calibration: The operator should perform zero calibration of CO_2 before each use, enter CO_2 Settings - Zero Calibration, and complete the zero calibration.
(4) 1m (operator's position) priority of visual alarm signal:
"*" indicates the low priority, "**" indicates the middle priority, and "***" indicates the high priority

Chapter 6 Alarm

- This chapter introduces general information about alarms and the measures to be taken when an alarm occurs.
- Information about alarms and prompts for each parameter can be obtained in the chapters about each parameter setting.

6.1 Overview

The so-called alarm means that when the patient being monitored undergoes abnormal changes in vital signs, or the machine itself malfunctions and the patient monitoring cannot be carried out smoothly, the monitor will notify the user and medical staff through sound, light, text, etc. tips.

⚠**WARNING**

●Using different alarm presets for the same or similar equipment in any single area, such as an intensive care unit or cardiac operating room, is potentially dangerous.

●Do not set an alarm limit value that exceeds the limit value on the monitor, otherwise the alarm system will fail.

6.2 Alarm attributes

6.2.1 Alarm type

(1) Physiological alarm: If this alarm originates from changes in the patient's vital signs, that is, the monitored patient's physiological parameters exceed a specific range or the patient has physiological abnormalities that cannot be measured by a single physiological parameter exceeding the range, it is called a physiological alarm.

(2) Technical alarm: If this alarm originates from the machine itself, that is, an alarm occurs when patient monitoring cannot be performed accurately due to technical obstacles in the use of the monitor or a malfunction of the machine itself.

(3) Prompt information: The monitor will display some prompt information related to the system status. This information generally does not involve the patient's vital signs. Strictly speaking, prompt information is not an alarm. Prompt information is generally displayed in the prompt information area at the bottom of the screen. Treatment prompt information is displayed in the corresponding treatment information area.

Examples of physiological alarms and technical alarms:

Patient or machine condition	Category of alarm generated

The patient's heart rate was measured as114bpm,Exceeds the heart rate alarm range set by the user.	Physiological alarm
The patient was found to have ventricular fibrillation	Physiological alarm
ECG Measurement module discovery ECG lead off	Technical alarm
SPO_2 Measurement module failed	Technical alarm

6.2.1.1 Physiological alarm classification

Physiological alarms are divided into two situations. One is when the physiological parameters of the monitored patient exceed a specific range, and the other is when the patient has physiological abnormalities that cannot be measured by a single physiological parameter exceeding the range.

The latter is an alarm that can temporarily block the former. The specific ones are as follows: The ECG signal is too weak; asystole; ventricular fibrillation/ventricular tachycardia; pulse not found; RESP cardiac interference; RESP respiratory asphyxia; others belong to the former situation.

6.2.1.2 Alarm level

Each alarm, whether it is a technical alarm or a physiological alarm, has a level characteristic. The higher the level, when the alarm occurs, the system will prompt the alarm in a more alert way. All technical alarm levels cannot be changed by the user. Some physiological alarm levels can be set by the user, while others are specified by the system and are not allowed to be changed.

Alarm level	Physiological alarm	Technical alarm
Advanced alarm	The patient is in critical condition and may be life-threatening and should be rescued immediately. Such as asystole, ventricular fibrillation/ ventricular tachycardia, etc.	Serious machine failure or misoperation may fail to detect the patient's critical state or result in treatment failure, putting the patient's life in danger. For example, the battery is low.
Intermediate alarm	If the patient's physiological signs appear abnormal, corresponding measures or treatment should be taken immediately.	Certain machine failures or misoperations may not threaten patient safety, but they may also affect the normal monitoring of key physiological parameters and patient treatment.
Low alarm	If the patient's physiological signs are abnormal, corresponding measures or treatment may be required.	Certain monitoring functions may not function properly due to machine failure or improper operation, but this will not threaten patient safety.

⚠**Notice:**

●It is recommended that operators treat alarm conditions that may result in minor injury and

delayed generation of potential injury as low alarm conditions.

6.3 Alarm prompt form

When an alarm occurs, there will be sound, light and text prompts. Alarm characteristics: sound pressure level, amplitude, frequency, etc.

⚠**Notice**

●If the sound pressure level of the auditory alarm signal is lower than the ambient noise, it will prevent the operator from identifying the alarm state. The operator should adjust the sound pressure level of the alarm system to prevent the operator from being unable to identify the alarm state.

The sound pressure level ranges for each alarm priority are as follows:

1) The sound pressure range of intermediate alarm: the minimum volume is 45dB, the maximum volume is 85dB;

2) The sound pressure range of advanced alarm: the minimum volume is 45dB, and the maximum volume is 85dB.

Characteristics of prompt signals and the time interval between two prompt signalsLess than 1s.

6.3.1 Sound and light characteristics

Different levels of alarm sound characteristics and light characteristics

Alarm level	Alarm sound characteristics	Alarm light characteristics	Alarm information
Advanced alarm	The mode is "Beep-Beep-Beep---Beep-Beep", sounding once every 11 seconds (the interval count is from the start of this sound to the next start)	The alarm light flashes in red with a fast flashing frequency	“***” logo appears on the device screen
Intermediate alarm	The mode is "Beep-Beep-Beep", which sounds once every 25 seconds (the interval count is from the beginning of this sound to the beginning of the next sound)	The alarm light flashes yellow with a slow flashing frequency	"**" mark appears on the device screen
Low alarm	The mode is "beep-beep-", which sounds once every 25 seconds (the	The alarm light remains on in blue	"*" mark appears on

	interval count is from the start of this sound to the next start)		the device screen

6.3.2 Text characteristics

Background color: The background color of high-level alarm is red, the background color of intermediate alarm is yellow, and the background color of low-level alarm is blue.

The color of the string: Except for the NIBP technical alarm prompt area, it is always black regardless of the alarm level. The color of the string displayed in the NIBP technical alarm prompt area has nothing to do with the alarm level. Advanced alarm is displayed in red, intermediate alarm are displayed in yellow, and low alarms are displayed in blue. When the measured parameter exceeds the set alarm limit to induce a physiological alarm, the parameter value that triggered the alarm flashes.

6.3.3 Alarm status icon

In addition to the above alarm methods, the following alarm icons will also appear on the screen, indicating different alarm states.

 Indicates that all alarms are suspended. All alarm prompts are temporarily turned off until the alarm pause time expires or the operator manually cancels the alarm pause setting. The system then restores the prompt.

 Indicates that the alarm has been reset

 Indicates that the alarm sound is turned off. The sound prompt function of the alarm has been artificially and permanently turned off until the operator releases the setting of turning off the alarm volume.

 Indicates that the alarm of a single measurement module is turned off.

When multiple alarms of different levels are generated at the same time, the sound and light prompt will be based on the highest level among the current alarms.

⚠**Notice: When**  **appears, the system will not be able to give an alarm sound prompt, so the operator should use this function with special caution.**

6.4 Alarm status

6.4.1 Overview

For each alarm, there are two states: triggered state and cleared state. It can only be in one state at a time.

(1) Trigger state: The state when the alarm exists.

(2) Clear state: The state in which the alarm does not exist.

All possible alarms are in the cleared state when starting work. When the alarm conditions are met at subsequent times, the alarm enters the triggered state.

For the entire alarm system (that is, for all alarms), the following states are available:

1. Normal state: refers to the state where the alarm can carry out all prompts (including sound, light and text) in the triggered state.

2. Alarm pause state: refers to the state where the alarm is triggered, but no audible and visual text prompts are provided temporarily.

3. Alarm silence state: refers to the state where the alarm is triggered, with light and text prompts but no sound prompts.

⚠**Notice: At each moment, the entire alarm system can only be in one state.**

After powering on, the status indicator light lights up and the device automatically performs a safety check. If the self-check passes, you will hear a short "beep" sound, indicating that the alarm system is normal. If the status indicator light does not light up or there is no beep after powering on, it means that the alarm system is faulty and the equipment cannot be used normally and needs to be repaired before it can be put into use.

When an alarm occurs, the operator can accurately detect it 1m away from the alarm system.

The maximum alarm status delay and maximum alarm signal generation delay time can be set to 0~6s, and the default display time is 6s.

●The difference between the alarm tone and the alert tone:

The pulse tone alert signal is related to the pulse rate; the higher the pulse rate, the higher the pitch of the alert tone. Pulse tone when the pulse rate is 60 then broadcast a pulse tone once a second; heartbeat tone when the heart rate is 60 then broadcast a heartbeat tone once a second.

6.4.2 Alarm SILENCE state

The alarm silence state means that the alarm prompt sound is turned off.

6.4.3 Alarm pause state

The following processing is performed when the alarm is suspended:

All alarm sounds and light prompts are prohibited.

All physiological alarm text prompts are prohibited.

The physiological alarm description area displays the number of seconds left until the alarm is suspended. (The default alarm pause time is 1 minute)

6.4.4 Status switching

Under normal conditions:

1. Press "PAUSE" to enter the alarm pause state, and press "SILENCE" to enter the alarm silent state.

In paused state:

1. Press "PAUSE" to enter the normal state, and press "SILENCE" to enter the alarm silent state.

2. If no button is pressed until the pause end time is reached, it will enter the normal state.

3. During the pause period, if there is a new technical alarm, the alarm pause state will end and enter the normal state.

4. During the pause period, if there is a new physiological alarm, the system will still be in the alarm pause state.

In the alarm silent state:

1. If a new technical or physiological alarm is generated, the current alarm silent state will end and enter the normal state.

2. Press "PAUSE" to enter the normal state, and press "SILENCE" to enter the normal state.

In any state:

1. In the user settings, set the alarm sound switch to off and enter the alarm sound off state.

2. In the user settings, set the alarm sound switch to on and enter the normal state.

6.5 Alarm method

6.5.1 Overview

There are two alarm modes: latching mode and non-latching mode.

Latching: When the alarm condition does not exist, the system still prompts the alarm, which is called latch mode. Only after resetting the alarm system can the alarm no longer be prompted.

Non-latching: The feature of no longer alarming when the alarm condition does not exist is called non-latching mode.

6.5.2 Corresponding latching methods

1. All physiological alarms can work in locking mode. 2. All technical alarms can only work in non-latching mode.

6.5.3 Alarm prompt after locking

When an alarm is latched (meaning that the alarm has occurred but is not in the alarm triggering state at this time), the prompt mode related to the alarm will change as follows:

1. Measurement parameters and related alarm limits no longer flash.

2. After the alarm description prompt entry, there is the system time of the last time it entered

the trigger state.

6.5.4 Clearing the latch method

Clearing the latch mode is also called alarm reset. The user can use the alarm pause function to reset the latch alarm. When the latch alarm is cleared, those alarms that have occurred in the past but are still prompting alarms when the alarm conditions no longer exist due to the latch method will be cleared.

When working in non-latching alarm mode, the alarm pause key on the keyboard module only has the function of pausing the alarm but has no reset function.

6.6 Alarm settings

Public alarm content settings

1. You can set the high alarm limit, low alarm limit and alarm level of each parameter in the "Alarm Settings" menu.

2. The alarm volume can be set in the "Monitor Settings" menu.

a) Alarm limit display: You can see the set upper and lower alarm limits in each display parameter area.

b) Alarm volume: There are four options, namely "low", "medium", "high" and "off"

3. The alarm pause time and parameter alarm form can be set in the "User Maintenance" menu of "Maintenance".

a) Alarm pause time: refers to the alarm pause time. There are four options, namely 1 minute and 2 minutes.

b) Parameter alarm form: latching mode and non-latching mode.

Alarm settings for each measurement parameter

The alarm settings for each parameter are in the corresponding parameter setting menu. Select the parameters that need to be set in "Parameter Settings", and you can set the alarm switch and alarm record of each parameter individually.

When the intended use includes monitoring patients who do not receive constant attention from clinical operators, it is recommended that the alarm tone be set to level 2 or higher.

Default alarm settings

project		default setting
heart rate	Alarm upper limit	Adult: 120; Children: 160
	Alarm lower limit	Adult: 50;

		Children: 75
	Alarm level	Intermediate
blood oxygen	Alarm upper limit	Adult: 100; Child: 100
	Alarm lower limit	Adult: 90; Child: 90
	Alarm level	Intermediate
pulse rate	Alarm upper limit	Adults: 120; Children: 160
	Alarm lower limit	Adult: 50; Child: 75
	Alarm level	Intermediate
systolic blood pressure	Alarm upper limit	Adult: 160; Child: 120
	Alarm lower limit	Adult: 90; Child: 70
	Alarm level	Intermediate
mean pressure	Alarm upper limit	Adults: 110; Children: 90
	Alarm lower limit	Adult: 60; Child: 50
	Alarm level	Intermediate
diastolic blood pressure	Alarm upper limit	Adult: 90; Child: 70
	Alarm lower limit	Adult: 50; Child: 40
	Alarm level	Intermediate
respiratory rate	Alarm upper limit	Adult: 30; Child: 30
	Alarm lower limit	Adult: 8; Child: 8
	Alarm level	Intermediate
body temperature	Alarm upper limit	Adult: 39.0; Child: 39.0
	Alarm lower limit	Adult: 36.0; Child: 36.0
	Alarm level	Intermediate
EtCO2	Alarm upper limit	Adult: 50; Child: 50
	Alarm lower limit	Adult: 15; Child: 20
	Alarm level	Intermediate
FiCO2	Alarm upper limit	Adults: 4; Children: 4
	Alarm lower limit	/
	Alarm level	Intermediate
AWRR	Alarm upper limit	Adult: 30; Child: 30
	Alarm lower limit	Adult: 8; Child: 8
	Alarm level	Intermediate

⚠**Notice**

●Only the alarm settings made 3 seconds before the power interruption can be successfully saved in the alarm settings.

●It is recommended that alarm systems required by the patient population use factory default settings, preferred alarm settings and alarm presets.

6.6.1 Alarm shutdown

Alarm shutdown refers to the failure of the alarm function of a single measurement module. At this time, even if the measurement module meets the alarm conditions, the system will not issue any alarm prompts, print alarms, or store alarms.

When any measurement module just starts working, all alarms related to the module will be automatically turned off within 30 seconds after the module starts working, and other alarms will not be affected.

6.6.2 The lead falls off when turning on the machine

When powering on, if the open parameter module does not have a lead connected:

1. For ECG or SPO_2 modules, the product changes the lead-off alarm prompt to a prompt message (that is, the sound and light are automatically cleared), and then prompts the user.

2. There is no lead loss alarm for other modules.

6.7 Parameter alarm

Alarm parameters can be set independently in each parameter menu, and users can set alarm limits and alarm status.

When a parameter alarm is turned off, a "  " prompt symbol is displayed next to the parameter in the parameter display area. Can independently set alarm switches for each parameter.

For parameters that set alarms, when the value of one or several parameters exceeds the alarm limit, the monitor automatically alarms and performs the following processing:

1) A prompt appears on the screen in the form described in Alarm Mode;

2) If the alarm volume is set, the alarm sound will be sounded according to the set alarm level and alarm volume;

3) The alarm light flashes (if the machine has an alarm light).

6.8 Measures to be taken when an alarm occurs

⚠**Notice: When an alarm occurs, the patient's condition should be checked first.**

The alarm information is displayed in the system information area or system alarm information area. It is necessary to identify this alarm and take corresponding measures according to the cause of the alarm.

(1) Check the patient's condition.

(2) Identify which parameter is alarming or which alarm is occurring.

(3) Identify the cause of the alarm.

(4) If necessary, set the alarm to be muted.

(5) When the alarm condition is relieved, check whether the alarm is eliminated.

Alarm information and prompt information about parameters can be found in each parameter monitoring chapter.

6.9 Alarm reset

⚠**Notice: The alarm reset operation can only be performed in the latch state. Alarm reset cannot be performed in non latch state.**

Alarm reset operation method:

Pressing the alarm reset button can reset the currently occurring alarm, display  in the information bar, and display a prompt message "Alarm reset in progress". If there is no new alarm that has been reset, the alarm will no longer be displayed.

6.10 Password protected alarm settings

The following alarm settings are password protected:

1. Alarm delay time

2. Alarm pause time

3. Parameter alarm form

4. Alarm sound range

5.Latching and non-latching settings

Chapter 7 ECG/RESP

7.1 ECG monitoring instructions

7.1.1 Definition of ECG monitoring

ECG monitoring generates a continuous waveform of the patient's cardiac electrical activity to accurately assess the patient's physiological state at that time. For this reason, the normal connection of the ECG cable should be ensured so that correct measurement values can be obtained. With five-lead or 12-lead device for monitoring, the monitor in the normal working state, the standard interface shows three waveforms, and other interfaces show different waveforms, such as: large font interface shows one ECG waveform; ECG multi-conductor interface shows seven ECG waveforms;

(1) The parameters displayed by the monitoring include heart rate (HR).

(2) All the above parameters can be used as alarm parameters.

7.1.2 Precautions for ECG monitoring

⚠**WARNING**

●During defibrillation, do not touch the patient or any connected objects such as tables or products that come into contact with the patient.

●When using a monitor for ECG signal monitoring, you must use the ECG cable recommended by our company.

●If the patient needs to be defibrillated, a defibrillation-resistant ECG cable must be used, otherwise the device may be damaged or the patient may be harmed.

●When you connect electrodes or cables, make sure there is absolutely no contact with any other conductive parts or with ground. In particular, make sure that all ECG electrodes, including the neutral electrode, are attached to the patient to prevent them from coming into contact with conductive parts or ground.

●Regularly check the skin and pads where the ECG electrodes are placed. If there are signs of allergy, replace the electrode pads or change the placement of the electrode pads. Do not use expired electrode pads.

●For patients with built-in pacemakers, the detection function switch should be turned on in the patient information and ECG settings to ensure that the pacemaker can calculate normally. Please focus on this item.

⚠**Notice**

●Interference from ungrounded products near the patient and ESU interference can cause

waveform distortion.

●If operated according to the conditions specified in YY 9706.102-2021 (when the anti-radiation capability is 3V/m), the field strength exceeding 1V/m may cause errors in various frequency measurements. Therefore, it is recommended not to use the device in the vicinity of electrocardiographic/respiratory measuring equipment.

●Electrode pads should be of the same model and should not exceed their service life.

●The heart rate value may be affected by the operation of cardiac pacing pulses or arrhythmia.

7.2 ECG monitoring operation method

7.2.1 Preparation

1) Prepare the patient's skin before placing electrodes.

a. The skin is a poor conductor, so to obtain good contact between the electrode and the skin, the patient's skin pretreatment is very important.

b. If necessary, shave body hair where the electrodes are placed.

c. Wash skin thoroughly with soap and water. (Do not use ether or pure alcohol as this will increase the impedance of the skin).

d. Dry rub the skin to increase capillary blood flow to the tissues and remove skin flakes and oil.

2) Install the spring clip or snap button before placing the electrode.

3) Place the electrode on the patient. If you are using an electrode without conductive paste, apply conductive paste before placement (or operate according to the requirements of the electrode manufacturer).

4) Connect the electrode leads to the patient cable.

5) Confirm that the monitor is powered on.

⚠**WARNING**

●The electrodes should be placed carefully and make sure the contact is good.

●The ECG electrode patch should be checked daily for irritation of the patient's skin. If there are signs of allergy, replace electrodes or change position every 24 hours.

●It is necessary to check whether the leads are normal before starting monitoring. After unplugging the ECG cable, the screen will display the prompt "Sensor is off" and trigger an audible alarm at the same time.

7.2.2 Install the cardiac conductor

Position of ECG monitoring electrodes

The electrode placement of the five lead device is shown in Figure 8-1. Only RA, LA, and LL need to be connected during the three lead process.

(1) RA white (right arm) electrode 1 is placed under the clavicle, close to the right shoulder.

(2) LA black (left arm) electrode 1 is placed under the clavicle, close to the left shoulder. Place it on the chest wall as shown below.

(3) RL green (right leg) electrode 1 is placed on the right lower abdomen.

(4) The LL red (left leg) electrode is placed on the left lower abdomen.

(5) The V brown (chest) electrode is placed on the chest wall as shown in Figure 8-2.

The following table lists the lead names in European and American standards respectively. (In the European standard, each lead is represented by R, L, N, F, and C, while in the American standard, it is represented by RA, LA, RL, LL, and V.)

USA		Europe	
Lead Name	Color	Lead Name	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White

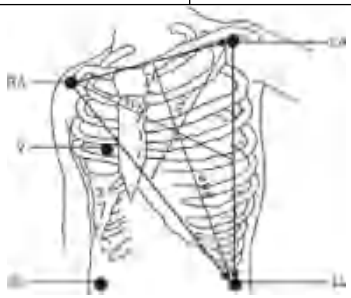


Figure 7-1 5-lead electrode placement location

⚠**Notice**

●To ensure patient safety, all leads must be connected to the patient.

⚠**WARNING**

●When using electrosurgical (ES) equipment, place the ECG electrode halfway between the ES ground plate and the electrosurgical blade to avoid burns. Cables from electrosurgical

equipment should not be entangled with ECG cables.

●When using electrosurgical (ES) equipment, never place the electrode close to the ground terminal of the surgical electrical equipment, otherwise there will be a lot of interference on the ECG signal.

●The placement of ECG leads depends on the type of surgery being performed. For example, for open-heart surgery, electrodes can be placed across the side or back of the chest. In the operating room, due to the use of surgical electrosurgical equipment, sometimes artifacts may affect the ECG waveform. To help reduce artifacts, electrodes can be placed on the left and right shoulders, near the left and right sides of the abdomen, and the chest leads can be placed on the left side of the center of the chest. Avoid placing the electrodes on the upper arm, otherwise the ECG waves will become very small.

Characteristics of a good signal

Tall, narrow and without incision. The R wave is tall and lies completely above or below the baseline. The pacing signal is no greater than the height of the R wave. The T wave is less than 1/3 the height of the R wave. P waves are much smaller than T waves.

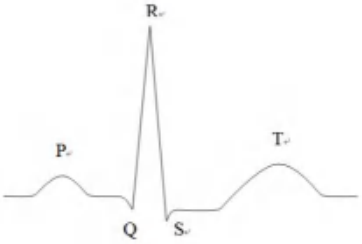


Figure 7-2 Standard ECG waveform

You can use the 1mV ECG calibration wave to calibrate the ECG. At this time, the screen prompts "The patient cannot be monitored during calibration."

Using a five-lead ECG device

Users can arrange the leads on channels 1, 2, and 3 according to their needs. The lead labels on the three channels are displayed on the left side of the corresponding waveform and can be changed in the ECG menu. You can select appropriate leads from I, II, III, AVR, AVL, AVF, and V for channels 1, 2, and 3 respectively, as shown in Figure 8-4. When the user selects the same lead, the monitor automatically adjusts to a different lead.

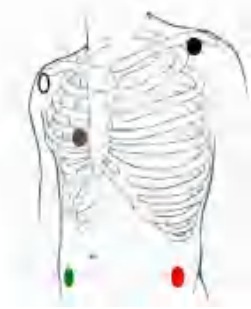


Figure 7-3 ECG lead diagram

⚠**Notice**

●If the electrodes are attached correctly but the ECG waveform is inaccurate, the lead wires need to be replaced.

●Interference from ungrounded products near the patient and ESU interference can cause waveform problems.

7.3 ECG Menu

ECG setup menu

Click the "ECG" parameter area on the screen to pop up the "ECG Settings" window, as shown in Figure 7-3-1:

Figure 7-3-1 ECG setting (alarm limit)

HR/PR alarm high limit: used to adjust the alarm upper limit of each parameter. When the measured value is greater than the set alarm upper limit, the message "HR/PR too high" appears on the screen. This message disappears when the measured value returns to normal.

HR/PR alarm lower limit: used to adjust the alarm lower limit of each parameter. When the measured value is less than the set alarm lower limit, the message "HR/PR too low" appears

on the screen. This message disappears when the measured value returns to normal.

Alarm level: HR/PR alarm high limit/low alarm limit can be selected from two levels: "medium and high". The HR/PR limit alarm level is fixed to "High".

The adjustment range of the alarm high and low limits is as follows:

alarm limittype	Alarm limit range
High limit (adult)	100~200bpm
High limit (children)	100~250bpm
Low limit (adults and children)	30~100bpm

⚠Notice

●The upper and lower alarm limits should be set according to the clinical situation of each patient.

●The heart rate alarm upper limit setting is very important in monitoring. The upper limit should not be set too high. Taking into account changing factors, the upper limit of the heart rate alarm should not be set 20 beats/min higher than the patient's heart rate.

Default setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "ECG alarm limit" to the system default configuration.

ECG settings

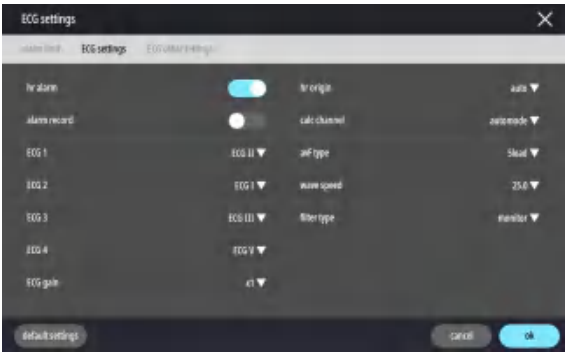


Figure 7-3-2 ECG settings

Heart rate alarm

Select "On" to prompt the alarm when the heart rate alarm occurs. Select "Off" to not alarm and prompt "".

Alarm record

Select "On" to store the heart rate alarm, and select "Off" to not store it.

ECG channel

There are three channels in total, namely: ECG 1, ECG 2, and ECG 3. Optional leads include ECGI, ECGII, ECGIII, ECGV, ECGaVR, ECGaVL, ECGaVF, ECGV2, ECGV3, ECGV4, ECGV5, and ECGV6.

ECG gain

There are six options in total: automatic, ×0.25,×0.5, ×1, ×2.

⚠**Notice**

●When the input signal is too large, the wave peak may be truncated. At this time, the user can refer to the actual waveform to manually change the gain level of the ECG waveform to avoid incomplete waveform display.

The gain of each calculation channel can be selected, and a 1mV scale is given on the left side of each ECG waveform. The height of the 1mV scale is proportional to the amplitude.

Heart rate source

You can choose to detect heart rate by ECG (electrocardiogram) or SOP_2 (oxyplethysmography wave); select "Auto" and the monitor will determine the heart rate source based on signal quality; if you select "Simultaneous", the monitor will display the heart rate and heart rate at the same time. Pulse rate. If provided by SOP_2, it prompts PULSE (pulse) and has a pulse rate sound.

When the heart rate source is selected as SOP_2, the heart rate alarm judgment is not performed, but the pulse rate alarm judgment is performed.

When the "select all" option is selected, the measurement value of PR is displayed on the right side of the main screen SOP_2; HR and PR alarm at the same time. The heartbeat sound is based on HR. If HR has data, it will give a sound prompt. If there is no HR data, it will give a sound prompt for PR.

Calculation channel

(1) "Channel 1" and "Channel 2" represent the calculation of heart rate based on the waveform data of the first or second ECG wave.

(2) "Auto mode" means that the monitor automatically selects the channel for calculating heart rate.

Lead type

Choose from 3-lead, 5-lead or 12-lead.

Waveform speed

The ECG waveform scanning speed is available in three levels: 12.5, 25.0 and 50.0mm/s.

Filtering method

There are three filtering methods available: "monitoring", "reference", and "surgery". Filtering can result in cleaner or more precise waveforms. The reference mode displays unfiltered ECG waves; the monitoring mode filters out artifacts that may cause false alarms; and the surgical mode reduces artifacts and interference from electrosurgical equipment in the operating room.

Default setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "ECG Settings" to the system default configuration.

ECG other settings

Select this item to enter the "ECG Other Settings" window, as shown in Figure 7-3-2:

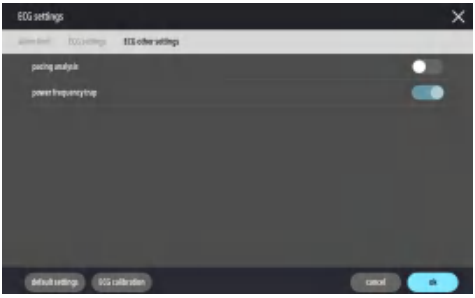


Figure 7-3-2 Other ECG settings

Heartbeat Volume: You can choose the volume levels "High", "Medium", "Low" and "Off".

Pacing Analysis: You can select "On" or "Off".

Power frequency notch: You can choose "On" or "Off". Turning on can suppress grid interference.

ECG calibration: Click this button to enter ECG self-test.

Default Settings: Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore "ECG Other Settings" to the system default configuration.

⚠**Notice: When the input signal is too large, the wave peak may be truncated. At this time, the user can refer to the actual waveform to manually change the gain level of the ECG waveform to avoid incomplete waveform display.**

7.4 ECG alarm information and prompt information

Alarm information

Alarms that may occur during ECG measurement are divided into physiological alarms and technical alarms. At the same time, the ECG measurement process may also generate various prompt messages. When these alarms or prompts occur, the visual representation and auditory representation of the monitor can refer to the relevant descriptions in the alarm function chapter. On the display screen, physiological alarms and general prompt information (general alarms) are displayed in the alarm area of the monitor, while technical alarms and prompt information that cannot trigger the alarm are displayed in the information area of the monitor. When the alarm recording switch in the relevant menu is turned on, physiological alarms caused by parameters exceeding alarm limits may trigger the recorder to automatically output alarm parameter values and related measurement waveforms.

The following category list describes the various alarms that may be generated by this measurement part.

Physiological alarm:

Prompt Message	Cause	Alarm Level
ECG signal is too weak	Undetectable patient's ECG signal	high
HR is too high	HR measurement value is higher than the set alarm high limit	User selectable
HR is too low	HR measurement value is lower than the set alarm low limit	User selectable

Technical alarm:

Prompt Message	Reason	Alarm Level	Countermeasures
All ECG leads or one lead reported missing	The ECG electrodes fall off the patient or the ECG cable falls off the monitor.	Low	Make sure the electrodes, leads and cables are all connected properly.
	Intentionally disconnected by clinical operator	Low	The operator can turn off the alarm by pressing the "alarm reset" button.
ECG module communication stopped	ECG measurement module failure or communication failure	High	Stop using the measurement function provided by the ECG module and notify the biomedical engineer or our company's maintenance personnel.
HR alarm limit error	Functional safety failure	High	Stop using the HR alarm function and notify biomedical engineers or our company's maintenance personnel.
ECG interference is too great	ECG measurement signals are greatly affected by	Low	Be sure to keep the patient quiet, ensure the electrodes are connected reliably, and the AC

	interference		power supply system is well grounded.

Prompt information (including general alarm information):

Prompt message	Cause	Alarm level
HRMeasurement out of bounds	HRThe measured value exceeds the measuring range	high

7.5 Respiration measurement

How is breathing measured?

The monitor measures respiration from the thoracic impedance values of two electrodes, and the change in impedance between the two electrodes (due to thoracic activity) produces a respiratory waveform on the screen.

Respiratory monitoring settings

No additional electrodes are required to monitor respiratory parameters, but the placement of the electrodes is important. In some patients, due to their clinical condition, the thoracic cage expands laterally resulting in negative intrathoracic pressure. In this case, it is best to place the two RESP electrodes on the right midaxillary line and the left side of the thorax when the patient's respiratory activity is maximum to obtain the best respiratory waveform.

⚠**Note: Respiratory monitoring is not suitable for patients with a large range of motion, as this may lead to false alarms.**

RESP Guardianship Check:

1) Prepare the patient's skin before placing electrodes.

2) Install the electrodes on the patient as described below.

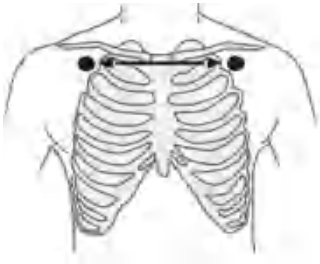
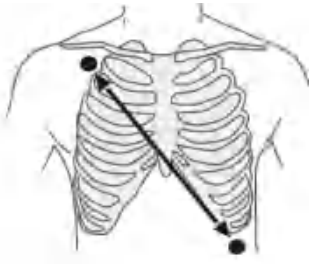


Figure 7-5 I-lead RESP measurement electrode position diagram



II-lead RESP measurement electrode position diagram

⚠**Notice:**

●Place the white RA and red LL electrodes diagonally to obtain the best respiratory waveform in the II lead, or place the RA and LA electrodes in order to obtain the I lead respiratory waveform. When selecting different respiratory leads, be careful to select the

corresponding calculation lead in RESP Settings - Respiratory Lead Settings, otherwise the correct result cannot be measured. Placing the liver and ventricles in line with the respiratory electrode should be avoided to avoid artifacts from cardiac coverage or pulsatile blood flow.

RESP settings menu

Click the "RESP" parameter area on the screen to pop up the "RESP Settings" window, as shown in Figure 7-5-1:

RESP settings (alarm limits)

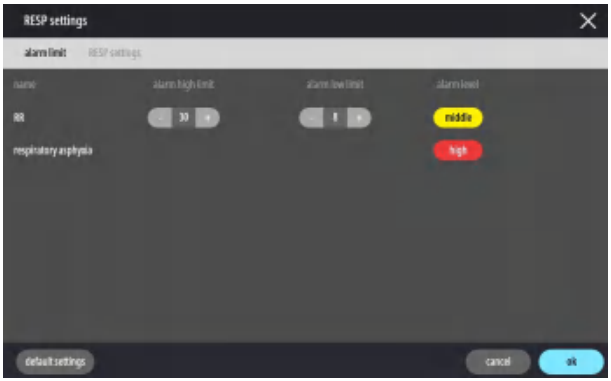


Figure 7-5-1 Alarm limit (RESP)

Alarm high limit: used to adjust the alarm upper limit of each parameter. When the measured value is greater than the set alarm upper limit, the message "RR too high" appears on the screen. This message disappears when the measured value returns to normal.

Alarm lower limit: used to adjust the alarm lower limit of each parameter. When the measured value is less than the set alarm lower limit, the message "RR too low" appears on the screen. This message disappears when the measured value returns to normal.

The adjustment range of the RESP alarm upper and lower limits is as follows:

model	maximum limit	minimum floor	Single adjustment amount
RRadult	120	7	1
RR children	147	7	1

Respiratory asphyxia: Failure to detect breaths within a specific time interval.

Alarm level: The RR alarm high/low limit can be selected from three levels: "low, medium, and high", and the apnea alarm level is fixed at "high".

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "RESP alarm limit" to the system default configuration.

RESP settings

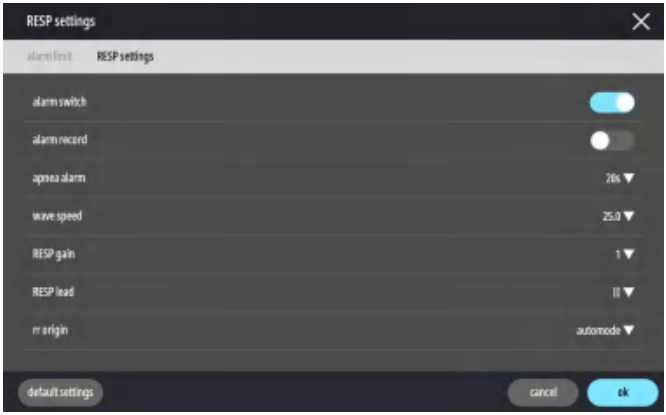


Figure 7-5-2 RESP settings

Alarm switch

Select "On" to prompt and store the alarm when the respiratory rate alarm occurs. Select "Off" to not alarm and prompt "".

The respiratory rate alarm is based on the set high limit and low limit. When the respiratory rate exceeds the set value, an alarm occurs.

Alarm record

Select "On" to store the respiratory rate alarm, select "Off" to not store.

Asphyxia alarm

Set the time to judge whether the patient is suffocating, between 10 seconds and 40 seconds, with a difference of 5 seconds for each option.

Waveform speed

The optional respiratory wave speeds include "6.25mm/s, 12.5mm/s, and 25.0mm/s".

Breathing gain

Users can set the magnification display of RESP waveform, and the magnification options are "1, 2, 4, 0.25, 0.5".

Respiratory leads

Users can set the respiratory lead type, optionally "I" or "II".

Respiratory rate source

There are three optional respiratory rate sources: "automatic mode, RESP, and CO2".

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "RESP Settings" to the system default configuration.

7.6 RESP Alarm Information and Prompt Information

When the alarm recording switch in the relevant menu is turned on, those physiological alarms caused by parameters exceeding the alarm limit will trigger the recorder to automatically output alarm parameter values and related measurement waveforms.

The physiological alarms, technical alarms and prompt messages that may occur during RESP measurement are listed in the following table:

Physiological alarm:

Prompt message	Cause	Alarm level
RR is too high	RESP measured value is higher than the set alarm high limit	User selectable
RR is too low	RESP measured value is lower than the set alarm low limit	User selectable
RESP respiratory apnea	Breathing cannot be measured within a specific time interval	high

Technical alarm:

Prompt message	reason	Alarm level	Countermeasures
RESP alarm limit error	Functional safety failure	high	Stop using the RESP alarm function and notify biomedical engineers or our company's maintenance personnel.

Prompt information (including general alarm information):

Prompt message	Cause	Alarm level
RR measurement out of bounds	RR measurement value exceeds the measurement range	high

Chapter 8 Blood Oxygen Saturation (SPO_2)

8.1 Instructions for blood oxygen saturation monitoring

The SPO_2 can be used on adults and children, and the pulse oximeter device is calibrated to display functional oxygen saturation. The SPO_2 accuracy of the pulse oximeter device is the root mean square of a difference and is less than or equal to 4.0% SpO_2 in the range of 70% to 100%SaO2. SpO_2 should be expressed as functional oxygen saturation, not as oxyhemoglobin fraction.

Definition of SPO_2 Monitoring

The SPO_2 plethysmography parameter measures arterial oxygen saturation, which is the percentage of total oxyhemoglobin. For example, if 97% of the total hemoglobin molecules in the red blood cells of arterial blood are combined with oxygen, then the blood has an SPO2 oxygen saturation of 97%, and the SPO_2 value reading on the monitor should be 97%. The SPO_2 value shows the percentage of oxygen-carrying hemoglobin molecules that form oxyhemoglobin. The SPO_2 plethysmography parameter also provides pulse rate signals and plethysmography waves.

(1) Blood oxygen saturation is measured using pulse oximetry. This is a continuous, non-invasive method of measuring hemoglobin oxygen saturation. It measures the amount of light emitted from the sensor light source that passes through the patient's tissue (such as a finger or ear) and reaches the receiver on the other side. The wavelength that the sensor can measure is usually 660nm for red LED and 905nm for infrared LED. The maximum optional output power of LED is 4 mW.

(2) The amount of light passing through depends on a variety of factors, most of which are constant. However, one of these factors, arterial blood flow, changes over time because it pulsates. By measuring the light absorbed during the pulsation, it is possible to obtain the oxygen saturation of the arterial blood. Detecting the pulsation itself gives a "plethysmographic" waveform and pulse rate signal.

⚠**Notice**

●Because the measurement values of pulse oximeter equipment are distributed based on statistical probability, only about 2/3 of the measurement values of pulse oximeter equipment fall within ±Arms of the value measured by the carbon monoxide-blood gas analyzer.

●Functional testers cannot be used to evaluate the accuracy of pulse oximeter probes or pulse

oximeter monitors.

⚠**WARNING**

●If carboxyhemoglobin, methemoglobin or dye diluting chemicals are present, the SPO2 value will be biased.

●Please use the blood oxygen sensor recommended in the manual and refer to its manual for use.

●Before use, users need to check the compatibility between the monitor, sensors, and cables, otherwise the patient may be injured or the equipment may be damaged.

●When a patient has a tendency to be hypoxic, an oximeter should be used to analyze the blood sample to fully understand the patient's blood oxygen changes.

●Avoid using this device and blood oxygen sensor in the environment of MRI equipment, otherwise nuclear magnetic induction current may cause severe burns to the patient.

●When patients are continuously monitored for a long time, the probe attachment position should be checked every 2 hours, and when the skin changes or the measurement position is changed every 4 hours, some patients (patients with perfusion disorders or skin sensitivity) may require more frequent examine. Continuous long-term monitoring may increase skin risks such as irritation, redness, blistering, or pressure necrosis.

SPO_2 plethysmography parameter measurement

(1) The "SPO_2" value and "plethysmography" waveform can be displayed on the main screen.

(2) SPO_2 in this manual refers to human functional blood oxygen saturation measured by non-invasive methods.

(3) The measured data update period is 1 second.

(4)In order to stabilize the blood oxygen waveform in the display area, the blood oxygen waveform is normalized.

⚠**Notice**

●The product will detect when a finger falls off by searching for the pulse, and the "SPO_2 finger off" alarm will be delayed for 3s-5s.

●If carboxyhemoglobin, methemoglobin or dye diluting chemicals are present, the SPO2 value will be biased.

●Electrosurgical equipment cables must not become entangled with sensor cables.

●Do not place the sensor on a limb that has an arterial catheter or an intravenous line.

●Before starting monitoring, check whether the sensor cable is normal. When the SPO_2 sensor cable is unplugged from the socket, the screen will display a "sensor off" error

message and trigger an audible alarm.

●If the disposable packaged sensor shows signs of damage, do not use the SPO2 sensor and return it to the manufacturer.

●Do not place the blood oxygen probe on the same limb as the blood pressure cuff for blood pressure measurement, because blood flow occlusion during blood pressure measurement will affect the blood oxygen saturation reading.

1) Make sure your nails cover the light.

2) The probe wire should be placed on the back of the hand.

●The SPO_2 value is always displayed in a fixed place, and the pulse rate is only displayed under the following circumstances:

1) Set "Heart Rate Source" to "SPO_2" or "Auto" in the ECG menu.

2) Set "Heart Rate Source" to "Auto" in the ECG menu, and there is no ECG signal at this time.

●The SPO_2 waveform is not proportional to pulse volume.

●Functional test equipment or blood oxygen simulators cannot be used to verify the accuracy of blood oxygen saturation monitors and pulse oximeters. The accuracy of oxygen saturation monitors and pulse oximeter probes needs to be verified by clinical data.

●The blood oxygen probe and extension cable used with the monitor have been confirmed and tested for compliance with YY 9706.261-2023.

8.2 Blood Oxygen Saturation Monitoring Operation Method

SPO_2 plethysmography measurement

1) Turn on the monitor;

2) Place the sensor on the appropriate position of the patient's finger;

3) Insert the connector at one end of the sensor cable into the SPO2 hole.

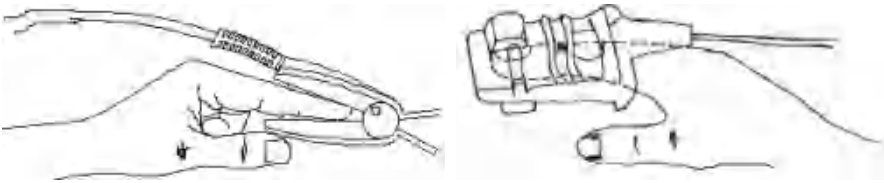


Figure 8-1 Adult blood oxygen probe

⚠**Notice**

●If the test site and probe cannot be accurately positioned, it may lead to inaccurate blood

oxygen saturation readings, or even failure to search for pulse waves and prevent blood oxygen monitoring. In this case, the probe should be repositioned.

●Excessive movement of the measurement part may cause inaccurate measurement. At this time, the patient should be kept quiet or the measurement part should be changed to reduce the impact of excessive movement on the measurement.

●The device displays the Signal Integrity Indicator" when the displayed pulse oximeter or pulse rate value may be incorrect“ ? ”logo.

⚠**WARNING**

●During long-term continuous monitoring, check the peripheral circulation and skin conditions of the measurement site every 2 hours or so. If adverse changes are found, the measurement site should be changed in time.

●During long-term continuous monitoring, the positioning of the probe should be checked periodically to avoid changes in the positioning of the probe due to movement and other factors, which would affect the accuracy of the measurement.

●The way this product confirms the accuracy of blood oxygen measurements is by comparing the reading with the value from the blood gas analysis.

8.3 Blood oxygen saturation monitoring measurement limitations

During operation, the following factors can affect the accuracy of blood oxygen saturation measurement:

1) High-frequency electrical interference, including interference generated by the host system itself or interference from electrosurgical products such as those connected to the system.

2) Do not use photooximeters and blood oxygen sensors during magnetic resonance imaging (MRI) scans. Induced current may cause burns.

3) There is dye injection into the vein.

4) The patient moves too frequently.

5) External light radiation.

6) The sensor is improperly installed or in improper contact with the object.

7) Sensor temperature (the optimal temperature should be in the range of 28℃~42℃).

8) Place the sensor on the limb with a blood pressure cuff, arterial catheter, or intravascular catheter.

9) High concentrations of dysfunctional hemoglobin such as carboxyhemoglobin and methemoglobin.

10) Blood oxygen saturation is too low.

11) Poor circulatory perfusion at the monitoring site.

12) Shock, anemia, hypothermia, and the use of vasoconstrictor drugs may reduce arterial blood flow to unmeasurable levels.

13) The measurement also depends on the absorption of light of specific wavelengths by oxyhemoglobin and reduced hemoglobin. If other substances that absorb the same wavelength are present, they can cause spurious or low SPO_2 values in the measurement. Such as: carbonized hemoglobin, methemoglobin, methylene blue, carmine indigo.

14) The recommended SPO_2 sensor in the attachment is not used.

8.4 Blood Oxygen Saturation Menu

$SP0_2$ setup menu

Click the "SP02" parameter area on the screen to pop up the "SPO2 Settings" window, as shown in Figure 8-4-1:

SP02 setting (alarm limit)

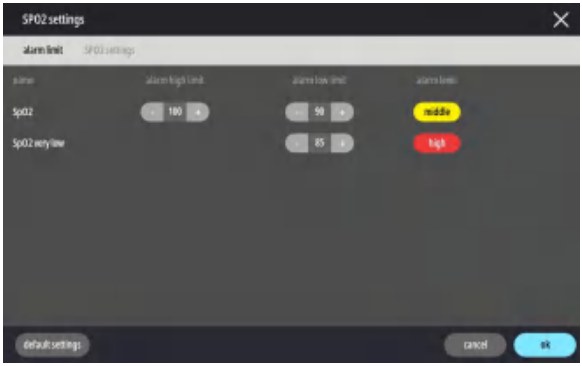


Figure 8-4-1 Alarm limit (SPO2)

Alarm high limit: used to adjust the alarm upper limit of each parameter. When the measured value is greater than the set alarm upper limit, the message "SPO2 too high" appears on the screen. This message disappears when the measured value returns to normal.

Alarm lower limit: used to adjust the alarm lower limit of each parameter. When the measured value is less than the set alarm lower limit, the message "SPO2 too low" appears on the screen. This message disappears when the measured value returns to normal.

SPO2 alarm range:

parameter	maximum limit	minimum floor	Single adjustment amount
SPO2	100	0	1

Alarm level: SPO2 alarm high limit/low alarm limit can be selected from two levels:

"medium and high". SPO2 extremely low alarm low limit alarm level is fixed to "high".

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "SPO2 alarm limit" to the system default configuration.

⚠WARNING

●Setting the SPO2 alarm upper limit to 100% is equivalent to turning off the upper limit alarm. High oxygen levels predispose premature infants to postlental fibrosis. Therefore, the upper alarm limit for blood oxygen saturation must be carefully selected based on accepted clinical practice experience.

SP02 settings

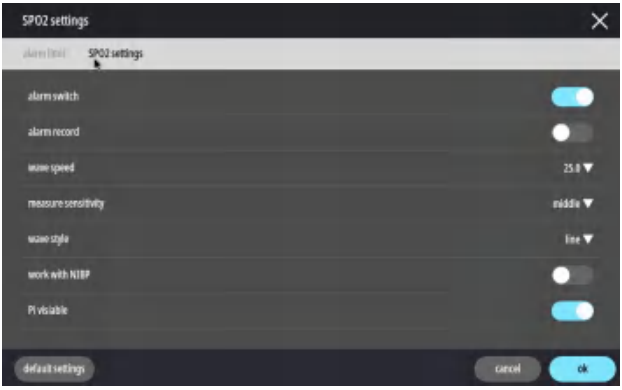


Figure 8-4-2 SPO2 settings

Alarm Switch

Select "On" to prompt and store the alarm when SPO2 alarms. Select "Off" to not alarm and prompt "".

Alarm Record

Select "On" to store when SPO2 alarms, select "Off" to not store.

Waveform speed

The SPO2 plethysmography waveform scanning speed has two options: "12.5mm/s" and "25.0mm/s".

Pulse Volume

The volume levels "High", "Medium", "Low" and "Off" can be selected.

Measurement sensitivity

Select the averaging time for calculating SPO2 values. Selecting "low", "middle" or "high"

means taking the average SPO2 within 16 seconds, 8 seconds or 4 seconds respectively.

Wave style

Users can set the SPO2 waveform style, optionally "line" or "fill".

Work with NIBP

You can choose to work with NIBP "on" or "off".

Does PI display

You can select whether the PI display is "on" or "off".

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore "SPO2 Settings" to the system default configuration.

The default alarm range of SPO2 and PR under default settings:

Parameter		Maximum limit	Minimum lower limit
SPO2	aldult	100	90
	child	100	90

8.5 Blood Oxygen Saturation Alarm Information

SPO2 alarm information

When the alarm recording switch in the relevant menu is turned on, those physiological alarms caused by parameters exceeding the alarm limit will trigger the recorder to automatically output alarm parameter values and related measurement waveforms.

The physiological alarms, technical alarms and prompt messages that may occur during SPO2 module measurement are listed in the table below.

Physiological alarm:

Prompt Message	Reason	Alarm Level
SPO2 is too high	The SPO2 measured value is higher than the upper alarm limit.	User selectable
SPO2 is too low	The SPO2 measured value is lower than the lower alarm limit.	User selectable

Technical alarm:

Prompt Message	Reason	Alarm Level	Remedies
SPO2 sensor falls off	SpO2 sensor detaches from patient or monitor	Low	Make sure the sensor is placed on the patient's finger or other part, and that the monitor and cable are connected properly.
SPO2 module communication stops	SPO2 module error or communication error	high	Stop using the SPO2 module measurement function and notify biomedical engineers or our company's

			distributors.

Prompt information (including general warnings):

Prompt Message	Reason	Alarm Level
SPO2 measurement out of bounds	SPO2 measurement value is out of range	high
search pulse	The SPO2 module is searching for a pulse	No alarm
Pulse not found	The SPO2 module cannot detect the SPO2 signal for a long time.	high

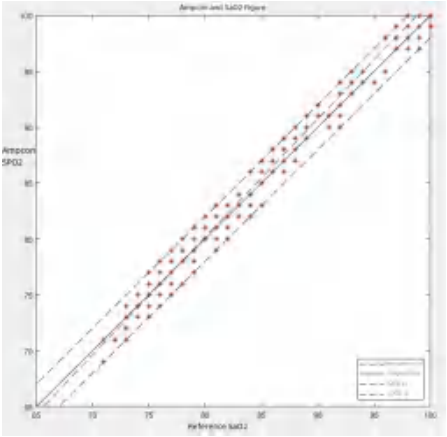
8.6 Blood Oxygen Saturation Accuracy

The calculated value of the root mean square of the blood oxygen value (SPO2) measured by the monitor and the blood gas analysis value (SaO2) of the corresponding blood sample is used as an indicator to evaluate the accuracy. The blood oxygen accuracy should be ≤2% to be qualified. The calculation formula is:

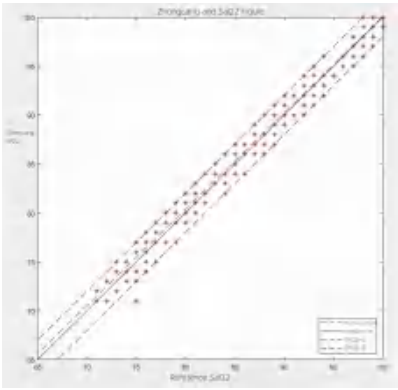
$$A_{rms} = \sqrt{\frac{\sum_{i=1}^{n} (SpO_{2i} - SaO_{2i})^2}{n}}$$

8.6.1 Main evaluation index-scatter plot (i.e. Bland-Altman plot)

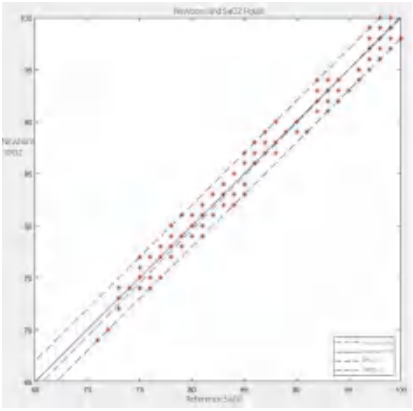
(1) SPO2 and SaO2 scatter plot with Ampcon adult finger clip blood oxygen probe



(2) SPO2 and SaO2 scatter plot of adult finger-clip blood oxygen probe equipped with Zhongcang



(3) SPO2 and SaO2 scatter plot of blood oxygen probe with Zhongcang newborn package



Chapter 9 Body Temperature (TEMP)

9.1 Instructions for Temperature Monitoring

The monitor can use a temperature probe to measure body temperature data. The operating mode adopted by this equipment is the direct mode, and the output temperature is an unadjusted temperature, which represents the temperature of the measurement part contacted by the probe. The recommended measurement site is the human armpit (rated output range: 36.0℃~37.0℃) or the temperature measurement point required by the user.

Figure 9-1 Illustration of body temperature measurement parts

Temperature measurement settings

(1) If a disposable temperature probe is being used, the temperature cable must be inserted into the socket, and then the probe and cable must be connected. For a reusable temperature probe, you plug it directly into the socket.

(2) Attach the temperature probe firmly to the patient.

(3)Place the temperature probe close to the skin, and the value will be accurate after 10 minutes of heat conduction in the skin or cavity.

⚠**WARNING**

●Before starting monitoring, check whether the probe cable is normal. Unplug the temperature probe cable from the jack, the screen will display the error message "Body temperature sensor is off" and an alarm sound will sound.

⚠**Notice**

●Disposable temperature probes can only be used once.

●During the startup process of the monitor, the temperature measurement circuit will automatically self-check and calibrate once, which will not affect the normal operation of temperature monitoring.

9.2 Body Temperature Menu

Click the "TEMP" parameter area on the screen to pop up the "TEMP Settings" window, as

shown in Figure 9-2-1:

TEMP setting (alarm limit)

Figure 9-2-1 Alarm limit (TEMP)

Alarm high limit: used to adjust the alarm upper limit of each parameter. When the measured value is greater than the set alarm upper limit, the message "SPO2 too high" appears on the screen. This message disappears when the measured value returns to normal.

Alarm lower limit: used to adjust the alarm lower limit of each parameter. When the measured value is less than the set alarm lower limit, the message "SPO2 too low" appears on the screen. This message disappears when the measured value returns to normal.

The adjustment range of the upper and lower alarm limits is as follows:

Parameter	Maximum Limit	Minimum lower limit	Single Adjustment Amount
T1, T2	50	0	0.1

Alarm level: T1/T2/ΔT alarm high limit/alarm low limit can be selected from three levels: "low, medium and high". T1 limit/T2 limit/ΔT limit alarm level is fixed to "High".

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "TEMP alarm limit" to the system default configuration.

TEMP settings

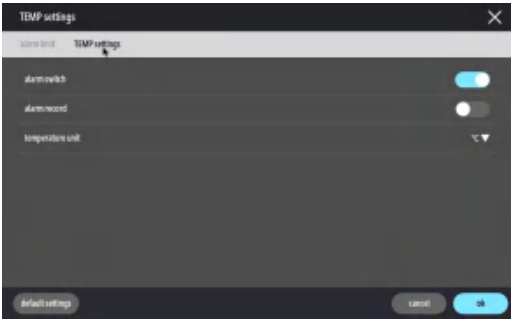


Figure 9-2-2 TEMP settings

Alarm switch

Select "On" to prompt and save the alarm when TEMP (body temperature) alarms. Select "Off" to not alarm and prompt "".

T1 alarm is based on the set high limit and low limit. When the temperature exceeds the high limit or is lower than T1, it represents the temperature of channel 1.

Alarm Record

Select "On" to store when TEMP alarm occurs, select "Off" to not store.

Temperature Unit

Select Celsius ℃ or Fahrenheit ℉.

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore "TEMP Settings" to the system default configuration.

9.3 Body temperature alarm information and prompt information

When the alarm recording switch in the relevant menu is turned on, those physiological alarms caused by parameters exceeding the alarm limit will trigger the recorder to automatically output alarm parameter values and related measurement waveforms. Physiological alarms, technical alarms and prompt messages that may occur during TEMP measurement are listed in the table below.

Physiological alarm:

Prompt message	Cause	Alarm level
T1/T2, too high	The body temperature measurement value is higher than the set alarm high limit	User selectable
T1/T2, too low	The body temperature measurement value is lower than the set alarm low limit	User selectable

Technical alarm:

Prompt Message	Cause	Alarm Level	Countermeasures
TEMP sensor falls off	Temperature probe detaches from monitor	Low	Make sure the probe connection is reliable.
TEMP alarm limit error	Functional safety failure	high	Stop using the TEMP alarm function and notify biomedical engineers or our company's maintenance personnel.

Prompt information:

Prompt message	Cause	Alarm level
TEMP measurement out of bounds	Body temperature measurement value is outside the measurement range	high

Chapter 10 Non-Invasive Blood Pressure (NIBP)

10.1 Instructions for non-invasive blood pressure monitoring

- Non-invasive blood pressure (NIBP) measurement uses the oscillation method and is suitable for adults and children.
- The blood pressure value measured by the monitor is equivalent to the value measured by auscultation or invasive methods.
- The clinical significance of NIBP measurements must be determined by the physician.

Non-invasive blood pressure measurement mode:

Manual, automatic and continuous measurements. Each mode displays systolic, mean and diastolic blood pressure.

(1) Manual mode: only perform one measurement.

(2) Automatic mode: Measurement is repeated. The interval can be set to 1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes.

(3) Continuous mode: Measure continuously within five minutes.

NIBP measurement will exert a certain pressure on the patient through cuff inflation. Doctors should determine whether the patient is suitable for NIBP measurement based on the patient's actual condition.

⚠**Notice**

●Non-invasive blood pressure measurements should not be performed on patients with sickle cell disease and anyone with skin lesions or anticipated lesions.

●For patients with severe coagulation disorders or severe thrombosis, the decision whether to perform automatic blood pressure measurement should be based on clinical evaluation, because there is a risk of hematoma at the friction point between the limb and the cuff.

●When taking measurements on pediatric patients, it is important to ensure that the correct mode setting is selected (see Patient Information Menu Settings). Using the wrong patient model has the potential to compromise patient safety, for example higher adult blood pressure levels are inappropriate for children.

●Do not perform NIBP measurements on a limb with intravenous infusion or cannulation, as infusion slowdown or blockage may occur during measurement inflation, which may result in damage to tissue surrounding the measurement site.

●Continuous cuff pressure caused by bends in the connecting tubing, causing blood flow disruption and harm to the patient.

●Do not measure blood pressure too frequently as this may cause injury to the patient due to interference with blood flow.

●Cuff application and pressurization on any limb undergoing endovascular intervention or therapy, or arteriovenous (AV) shunting, as this temporarily interferes with blood flow and can result in patient injury.

●Cuff application and compression on arm on mastectomy or lymphadenectomy side.

●Cuff pressurization can cause temporary loss of function of monitoring ME equipment used simultaneously on the same limb.

10.2 Non-invasive blood pressure monitoring operation methods

10.2.1 Non-invasive blood pressure measurement

In order to obtain accurate routine resting blood pressure values in hypertensive conditions, it is recommended that operators and patients take the following preparatory measures:

1) The patient to be tested should choose a comfortable sitting position, including legs not crossing, feet flat on the ground, back and arms supported, and the midpoint of the cuff at the same level as the right atrium of the heart;

2) Advise patients to relax as much as possible and not to talk during the measurement procedure;

3) It is recommended that there should be a 5-minute pause before the first measurement;

4) During normal use, the operator should keep an appropriate distance from the patient;

5) The operator should choose an appropriate measurement position and check the patient's limbs, patient posture (standing, sitting, lying down), movement or patient's physiological condition before use to reduce the impact that may affect measurement accuracy. If there are environmental or operational factors that affect blood pressure measurement readings (such as common cardiac arrhythmias such as premature ventricular or atrial contractions or atrial fibrillation, arteriosclerosis, poor perfusion, diabetes, age, pregnancy, preeclampsia, renal disease, patient movement, tremors, trembling), the measurement should be stopped.

The inflatable tube connecting the blood pressure cuff and monitor should be smooth and not tangled.

(1) Insert the inflation tube into the blood pressure cuff interface of the monitor and turn on the product power.

(2) Follow the method below to tie a blood pressure cuff on the patient's upper arm or thigh, as shown in Figure 10-2-1.

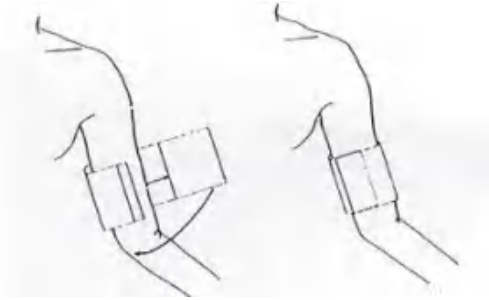


Figure 10-2-1 Use of cuff

a. Make sure the cuff is completely deflated.

b. Use an appropriately sized cuff on the patient, ensuring that the φ mark is exactly on the appropriate artery. Ensure that the cuffs are not too tightly wrapped around the limbs, otherwise it may cause discoloration or even ischemia at the distal end of the limbs.

⚠**Notice**

●The cuff width should be 40% of the limb circumference. (50% for children), or 2/3 of the length of the upper arm. The inflated portion of the cuff should be long enough to surround 50 to 80% of the limb. Choosing an incorrectly sized cuff can produce erroneous readings, such as a cuff that is too small. Use a larger cuff to reduce the error.

Adult/Pediatric Reusable Cuff Sizes

Patient Type	Limb Circumference	Cuff Width	Inflatable Tube Length
Child	18～26cm	10.6cm	1.5m～3m
Adult	25～35cm	14cm	
Adult (obese)	33～47cm	17cm	

Please check to make sure that the edge of the cuff falls within the range of the "<->" symbol, otherwise, please change to a more suitable cuff.

(3) Connect the cuff to the inflation tube. The limb used for manometry should be placed at the same level as the patient's heart. If this is not possible, the following correction methods must be used to correct the measurement results:

a. If the cuff is higher than the level of the heart, 0.75mmHg (0.10kPa) should be added to the

displayed value for each centimeter difference.

b. If the cuff is lower than the level of the heart, 0.75mmHg (0.10kPa) should be subtracted from the displayed value for each centimeter difference.

(4) Confirm whether the monitoring mode is correct (the monitoring mode is displayed in the monitor information area, to the right of the bed number). If you need to change the monitoring mode, please enter the "Patient Information Settings" in the "System Menu" and change the "Patient Type".

(5) Select the measurement mode in the NIBP menu. For specific methods, see the "Operation Tips" below.

(6) Press the "blood pressure" (start) button on the front panel to start pressure measurement.

Operation tips

1) Carry out an automatic measurement

Enter the "NIBP Settings" menu and select the "Interval Time" item. The user can select the time interval value for automatic measurement. After that, press the "NIBP" button on the front panel, and the system will automatically perform inflation measurements according to the set interval.

⚠**Notice**

●If the non-invasive pressure measurement time in automatic mode is set too long, the limbs in contact with the cuff may develop purpura or defects. Blood and nerve damage. While monitoring the patient, frequently check the color, warmth, and sensitivity of the distal extremities. Once any abnormality is observed, change the cuff placement or stop blood pressure measurement immediately.

After the short-term automatic mode measurement is completed, the device should return to long-term automatic mode or manual mode. The operator can also intentionally activate short-term automatic mode again.

2) Stop automatic measurement

Pressing the "NIBP" key at any time during the automatic measurement process will stop the automatic measurement.

3) Carry out a manual measurement

a. Enter the "NIBP Settings" menu, select the "Interval" item, set the value to "Manual", and then press the "Blood Pressure" key on the front panel to start a manual measurement.

b. During the idle time of automatic measurement, press the "NIBP" key to start a manual measurement. If at this time

Press the "NIBP" key again to stop manual measurement and continue automatic measurement.

4) Perform a manual measurement during the automatic measurement process

Press the "NIBP" button on the control panel.

5) Stop a manual measurement midway

Press the "NIBP" button on the control panel again.

6) Make continuous measurements

Enter the "NIBP Settings" menu and select the "Continuous Measurement" item to start continuous measurement. This process will last for 5 minute.

7) Stop continuous measurement midway

The continuous measurement can be stopped at any time during the continuous measurement by pressing the "NIBP" button on the control panel.

⚠**Notice**

●If you have any doubts about the product's measurement parameters, please use other equipment or methods to check the patient's vital signs before checking whether the monitor is functioning properly.

Measurement limitations

Because of the diversity of patient conditions, oscillometric measurement has limitations. This measurement monitors the regular pulse waveform generated by arterial pressure. Under this method, when the patient's condition makes monitoring difficult, the measured parameters become unreliable and the measurement time increases. Users should be aware that the following conditions may interfere with measurements. In some cases, a patient's condition makes monitoring impossible:

(1) Patient movement

If the patient is moving, shaking or spasming, monitoring will be unreliable or even impossible because these conditions may interfere with the detection of arterial pressure pulses and the manometric time will be extended.

(2) Arrhythmia

If the patient shows arrhythmia resulting in irregular heartbeats, monitoring will be unreliable or even impossible, and the pressure measurement time will be extended.

(3) Heart-lung machine

If the patient is connected to an artificial heart-lung machine, monitoring will not be possible.

(4) Pressure changes

If at a certain time, arterial pressure pulsation is being analyzed to obtain measurement values, and the patient's blood pressure changes rapidly, monitoring will be unreliable or even impossible.

(5) Severe shock

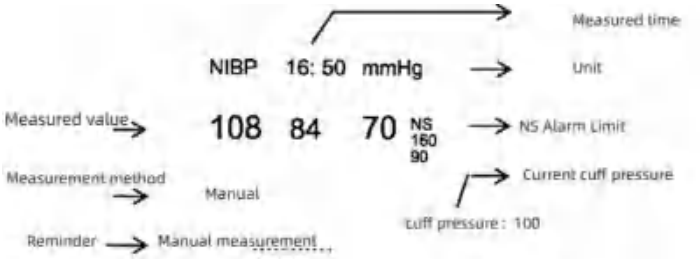
Monitoring will be unreliable if the patient is in severe shock or hypothermic. Because reduced blood flow to the periphery results in reduced arterial pulsation.

(6) Extreme heart rate

Blood pressure monitoring cannot be performed when the heart rate is lower than 40bpm (beats per minute) and higher than 240bpm (beats per minute).

Non-invasive blood pressure parameter setting and adjustment

The measurement results and corresponding information of NIBP are displayed on the screen as follows:



10.3Non-Invasive Blood Pressure Menu

Click the "NIBP" parameter area on the screen to pop up the "NIBP Settings" window, as shown in Figure 10-3-1:

NIBP settings (alarm limits)

Figure 10-3-1 Alarm limit (NIBP)

Alarm high limit: used to adjust the alarm upper limit of each parameter. When the measured value is greater than the set alarm upper limit, the message "NIBP too high" appears on the screen. This message disappears when the measured value returns to normal.

Alarm lower limit: used to adjust the alarm lower limit of each parameter. When the measured value is less than the set alarm lower limit, the message "NIBP too low" appears on the screen. This message disappears when the measured value returns to normal.

The adjustment range for the upper and lower limits of alarms is as follows:

Blood Pressure	Adult(mmHg)	Children (mmHg)
Systolic blood pressure alarm high limit	42–260	42–230
Systolic blood pressure alarm low limit	40–258	40–228
Average pressure alarm high limit	22–240	22–170
Average pressure alarm low limit	20–238	20–168
Diastolic blood pressure alarm high limit	12–220	12–160
Diastolic blood pressure alarm low limit	10–218	10–158

Alarm level: NIBP-S, NIBP-D and NIBP-M have two optional levels: "medium and high" for high alarm limit/low alarm limit. The alarm levels of NIBP-S limit, NIBP-D limit and NIBP-M limit are fixed to "High".

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "NIBP Alarm Limit" to the system default configuration.

NIBP settings

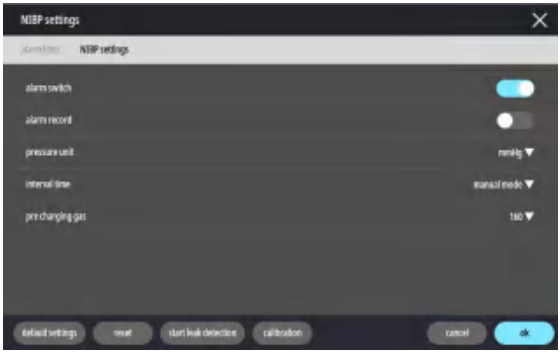


Figure 10-3-2 NIBP settings

Alarm switch

Select "On" to prompt and store the alarm when the pressure alarm occurs. Select "Off" to not alarm and prompt next to NIBP in the parameter area of the screen.  .

The pressure alarm is based on the set high limit and low limit. When the pressure exceeds the high limit or is lower than the low limit, an alarm is issued. Alarm settings can be set separately for systolic blood pressure, mean blood pressure and diastolic blood pressure.

Alarm Record

Select "On" to store when NIBP alarms, select "Off" to not store.

Pressure Unit

Optional "mmHg" or "kPa".

Intervals

Automatic measurement interval time (in minutes). You can choose from 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240, 480 minutes. After selecting the interval, a prompt will appear in the NIBP prompt area saying "Please press the 'blood pressure' (start) button". This is the first automatic inflation measurement to begin by pressing the 'NIBP' button. To end automatic measurement, select "Manual" and return to manual mode during the measurement interval.

Pre-charge value

Default configuration	Default pre-charge value (mmHg/kPa)	Manually selectable pre-charge value in NIBP menu (mmHg/kPa)
Adult default configuration	160	80～250
Child default configuration	140	80～200

Press this key to select the initial pressure value for the next cuff inflation. Under different default configurations, there are different pre-inflation value selection ranges, as shown in the following table:

After the user presses the "Menu" key on the front shell, he enters the "Default Configuration" menu in the "System Menu". After confirming the default configuration, he returns to the main interface and selects the NIBP menu hotkey in the NIBP parameter area to enter "NIBP settings". You can see that the initial value corresponding to the "Pre-inflation value" item is the initial inflation pressure value corresponding to the selected default configuration, as shown in the table above. Move the cursor to the "Pre-charge value" option and press it. You can see the range of pre-charge values available for manual adjustment as shown in the table above.

⚠**Notice**

●The "Pre-inflation value" option is to help the user select the next cuff inflation pressure, but the pre-inflation value for subsequent measurements will be based on the last systolic blood pressure measurement of the same patient. The system memorizing this value can shorten the measurement time of the same patient and increase the accuracy of the measurement.

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore "NIBP Settings" to the system default configuration.

⚠**Notice**

●When the user only sets the "Patient Type" in the "Patient Information Settings" without making any selection in the "Default Settings", the system will initially set the relevant module parameters according to the "Patient Type". And changes to the default type settings in "Default Settings" will also change the "Patient Type" in "Patient Information Settings".

Measurement mode

You can choose "automatic measurement" or "manual measurement".

Reset

(1) The measurement status of the blood pressure pump can be reset.

(2) Press this key to restore the inflation value of the blood pressure pump to its initial setting.

(3) It is recommended to use this key when the blood pressure pump is not working properly but the monitor cannot indicate the cause of the problem. This allows the blood pressure pump to perform a self-check, allowing it to automatically recover if the pump is not working abnormally due to unexpected reasons.

⚠**WARNING**

●Calibration of NIBP measurements should be performed every two years (or as per your hospital's maintenance schedule). Its performance should be checked in the following details.

Air leak detection

It is used to detect whether the NIBP measurement pump is leaking. When the NIBP cuff is connected, you can use this key to start the NIBP inflation process to find out whether the sealing condition of the NIBP air path is good. If the air leak test passes, the system will not give any prompt; if it fails, there will be a corresponding error prompt in the NIBP information area.

⚠ **WARNING**

●This air leakage detection is different from what is described in the EN 1060-1 standard and

is for users to simply detect whether there is air leakage when NIBP is inflated. If the system shows NIBP air leakage at the end of the test, please contact our company's maintenance engineer.

Air leakage detection process:

1) Connect the cuff to the NIBP air hole of the monitor.

2) Wrap the cuff around a cylinder of appropriate size.

3) Enter the "NIBP Settings" menu.

4) Turn the knob, move the cursor to the "Air Leak Detection" item, and press the knob. At this time, "Air leakage detection..." will be displayed below the NIBP parameter area on the screen, indicating that the system has started to perform air leakage detection.

5) The system automatically inflates to a pressure of 180mmHg.

6) After about 20 seconds, the system will automatically open the air release valve to indicate that the air leakage measurement is completed.

7) If there is no prompt message in the NIBP parameter area, it means that there is no air leakage in the system. If "Pump leaks..." is displayed, it means there may be a leak in the air circuit. At this time, the operator should check whether the entire connection is loose. After confirming that the connection is correct, perform the air leakage test again. If the fault message still appears, please contact the manufacturer for repair.

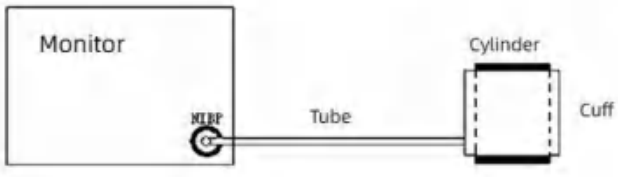


Figure 10-4 NIBP air leakage detection connection diagram

Continuous Measurement

Click this button to perform continuous automatic measurement of NIBP at set intervals.

Calibration

NIB accuracy calibration should be performed every two years or when the user has doubts about NIBP measurements.

10.4 NIBP Alarm Information and Prompt Information

Physiological alarms caused by parameters exceeding the alarm limit may trigger the recorder to automatically output parameters and related measurement waveforms at the time of alarm occurrence, provided that the alarm recording switch in the relevant menu is turned on.

Physiological alarms, technical alarms and prompt messages that may occur during NIBP measurement are listed in the following table:

Physiological alarm:

Prompt message	Cause	Alarm level
NS is too high or too low	NIBP systolic blood pressure measurement is above or below the set alarm limit	User selectable
ND is too high or too low	NIBP diastolic blood pressure measurement is above or below the set alarm limit	User selectable
NM is too high or too low	NIBP average pressure measurement value is higher or lower than the set alarm limit	User selectable

Technical alarm 1 (displayed in the prompt area below the NIBP pressure value):

Prompt Message	Reason	Alarm Level	Countermeasures
NIBP self-test error	Sensor or other hardware error in NIBP measurement module	High	Stop using the NIBP measurement function and notify biomedical engineers or our company's maintenance personnel.
NIBP communication error	Communication with NIBP measurement module failed	High	If the fault persists, stop using the NIBP function and notify biomedical engineers or our company's maintenance personnel.
The cuff is too loose or not connected	The cuff is not tied properly or there is no cuff	Low	Tie the cuff.
Cuff inflation tube leaking	Damaged cuff, hose or connector	Low	Check and replace leaking parts, and if necessary, notify biomedical engineers or our company's maintenance personnel.
Air pressure error	Unable to obtain stable pressure value, such as hose tangles	Low	Check whether the hose is tangled. If the fault persists, notify the biomedical engineer or our company's maintenance personnel.
Signal too weak	The cuff is too loose or the patient's pulse is too weak	Low	Use other methods to measure blood pressure.
Pressure out of range	The measurement range exceeds the specified upper limit	High	Reset the NIBP measurement module. If the fault persists, stop using the NIBP measurement function and notify biomedical engineers or our company's maintenance personnel.
Arm movement	Affected by arm movement, too much signal noise or irregular pulse rate	Low	Ensure that the patient being tested is quiet and does not move.
Overvoltage	The pressure exceeds	High	Measure again. If the fault persists,

protection	the specified safety limit		stop using the NIBP measurement function and notify the biomedical engineer or our company's maintenance personnel.
Signal saturation	Large movements	Low	Do not allow the patient to exercise.
Pump leaking	Leak found during air leakage test	Low	Check and replace leaking parts, and if necessary, notify biomedical engineers or our company's maintenance personnel.
NIBP system error	Blood pressure pump system malfunction	High	Stop using the NIBP measurement function and notify biomedical engineers or our company's maintenance personnel.
Wrong cuff type	Cuff type does not match patient type	Low	Use appropriate cuffs.
Measurement timeout	Measurement time exceeds 120 seconds (adult/child)	High	Measure again or use another pressure measurement method.
NIBP reset error	Module reset is abnormal	High	Use the reset function again.
Measurement error	The system cannot perform measurement analysis or calculations while a measurement is being taken.	High	Check the cuff, make sure the patient is not moving during monitoring, and measure again.

Prompt information (displayed in the prompt area below the NIBP pressure value):

Prompt message	Cause	Alarm level
Manual measurement…	During manual measurement	No alarm
Continuous measurement…	During continuous measurement	
Automatic measurement…	During automatic measurement	
Please press the start button	After selecting the measurement interval in the menu	
Measurement terminated	During the measurement process, press the start key to stop the measurement.	
Calibration…	Calibrating	
Calibration terminated	The calibration process has ended	
Air leak detection…	Air leak detection in progress	
Air leak detection completed	Air leak detection completed	
Module reset…	Reset the NIBP module after loading	
Manual reset…	During NIBP reset (user trigger)	
Reset error	Reset action failed	

Chapter 11 End-Tidal Carbon Dioxide (CO2)

11.1 CO2 monitoring instructions (This function is optional, and the instrument you are using may not be equipped with this function)

This module measures the carbon dioxide pressure of the patient's airway and can obtain the end-tidal carbon dioxide content (EtCO2), the minimum amount of carbon dioxide inhaled (InsCO2) and the airway respiratory rate, and display the CO2 pressure waveform. Equipped with automatic atmospheric pressure compensation function.

Under the conditions of indoor temperature of 23 ℃, sampling gas temperature of 37 ℃, and sampling relative humidity of 100%, the maximum time interval for operators to intervene in the water vapor treatment system is 120 hours, the maximum gas sampling flow rate is 60ml/min, and the minimum gas sampling flow rate is 38ml/min.

11.1.1 CO2 measurement settings

1) Confirm the configured CO2 module type (mainstream or sidestream).

2) Connect the module to the CO2 module socket of the monitor.

3) Make connection settings according to different types

Mainstream CO2 settings:

First plug the adapter into mainstream CO2 module, and then string both ends of the adapter into the air path, as shown in Figure 11-2 below.

Sidestream CO2 settings:

Firstly, insert the dryer end of the sampling tube into the inlet of the bypass CO2 module. Then, according to usage needs, connect the sampling tube inlet to an L-shaped tee. Finally, connect the tee in series into the gas path, as shown in Figure 11-3. If using a nasal tube to directly monitor and test patients, first insert the dryer end of the sampling tube into the inlet of the bypass CO2 module, then connect the screw end of the nasal tube to the sampling tube, and connect the other end to the patient's nostril. Adjust the tightening clip of the sampling tube to the appropriate position to prevent it from falling off. As shown in Figure 11-4.

4) The CO2 module of this device defaults to measurement mode. After inserting the module, a technical prompt of "CO2 preheating" will appear on the display until the sensor reaches the operating temperature. The preheating time is 5 minutes.

5) The values tested during the preheating process are not included in the reference. After the preheating is completed, effective and accurate measurement of CO2 begins.

Figure 11-1 EtCO2 module connection diagram

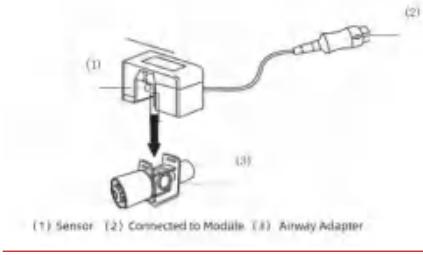


Figure 11-2 EtCO2 adapter connection diagram

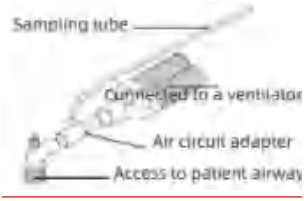


Figure 11-3 Airway adapter connection diagram

Figure 11-4 Nasal oxygen tube connection diagram

The respiratory rate can be adjusted from 0 to 150 with a step size of 5 using a respiratory rhythm fixture. The gas outlet can be connected to a mainstream adapter or a bypass sampling tube to adjust the respiratory rate setting. Different concentrations of standard gases can be changed, and the accuracy of the measured gas concentration can meet the requirement of ± (0.43%+8% of gas concentration).

⚠**Notice**

●This equipment needs to be zeroed when the place of use or environment changes. Before zeroing, remove the sampling tube from the air connection and place it in an air environment 0.5 meters away from the original sampling port and the patient, and wait for each CO2 display value. After reaching zero, perform the zero calibration operation again.

●When the shunt RGM cannot maintain the normal flow rate, it will alarm the block.

⚠**WARNING**

●Collision and vibration of the CO2 module should be avoided as much as possible.

●If the sampled gas is returned to the respiratory system, there is a risk of patient cross-infection.

●This equipment should not be used with gas supplied from an oxygen concentrator.

⚠**Careful**

●Do not use the instrument in an environment containing flammable anesthetic gases.

●The instrument can only be operated by professionals who have received professional training and are familiar with this manual.

⚠**Notice**

●If the package has been opened or the accessory inside is damaged, please do not use the accessory and return it to the supplier.

●When the information "CO2 Warming" and "CO2 Sensor Warming" are displayed on the screen, it means that the sensor is being warmed up and started. When this message disappears from the screen, standard measurements can be taken.

●Side-flow sampling tubes and sinks are disposable items and cannot be re-sterilized and used by patients.

●If other harmful gases are used during medical treatment, users should pay attention to environmental protection issues.

11.2 CO2 Menu

CO2 setup menu

Click the "CO2" parameter area on the screen to pop up the "CO2 Settings" window, as shown in Figure 11-2-1:

CO2 setting (alarm limit)

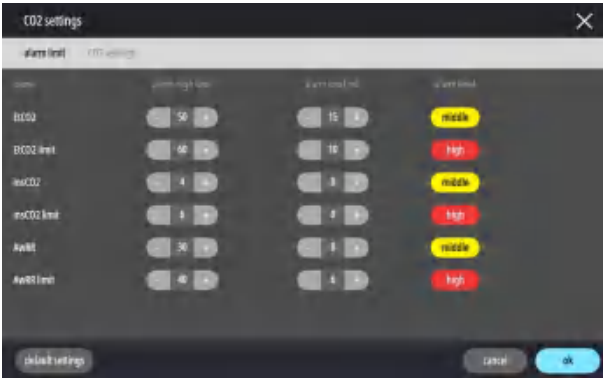


Figure 11-2-1 Alarm limit (CO2)

EtCO2 alarm high limit: used to adjust the alarm upper limit of EtCO2. When the measured value is greater than the upper alarm limit of CO2, the message "CO2 too high" appears on the screen. This message disappears when the measured value returns to normal.

EtCO2 alarm lower limit: used to adjust the lower alarm limit of EtCO2. When the measured value is less than the lower alarm limit of CO2, the message "CO2 too low" appears on the screen. This message disappears when the measured value returns to normal.

INSCO2 alarm high limit: used to adjust the alarm upper limit of InsCO2. When the measured value is greater than the upper alarm limit of InsCO2, the message "INS too high" appears on the screen. This message disappears when the measured value returns to normal.

INSCO2 alarm high limit: used to adjust the alarm upper limit of InsCO2. When the measured value is greater than the upper alarm limit of InsCO2, the message "INS too high" appears on the screen. This message disappears when the measured value returns to normal.

AWRR alarm high limit: used to adjust the alarm upper limit of AwRR. When the measured value is greater than the upper alarm limit of AwRR, the message "RR too high" appears on the screen. This message disappears when the measured value returns to normal.

AWRR alarm lower limit: used to adjust the alarm lower limit of AwRR. When the measured value is greater than the lower alarm limit of AwRR, the message "RR too low" appears on the screen. This message disappears when the measured value returns to normal.

The adjustment range of the upper and lower alarm limits is as follows:

EtCO2: 0～152mmHg (0～20%); AWRR: 0～140brpm

Alarm levels: EtCO2, INSCO2, and AWRR have three selectable alarm high/low limits, which are "high", "medium", and "low". The limit alarm levels for EtCO2, INSCO2, and AWRR are fixed to "high".

The change of "Alarm Level" only affects the physiological alarm level of carbon dioxide parameters (including EtCO2 upper limit, EtCO2 lower limit, InsCO2 upper limit, AwRR upper limit and AwRR lower limit).

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "CO2 alarm limit" to the system default configuration.

CO2 settings

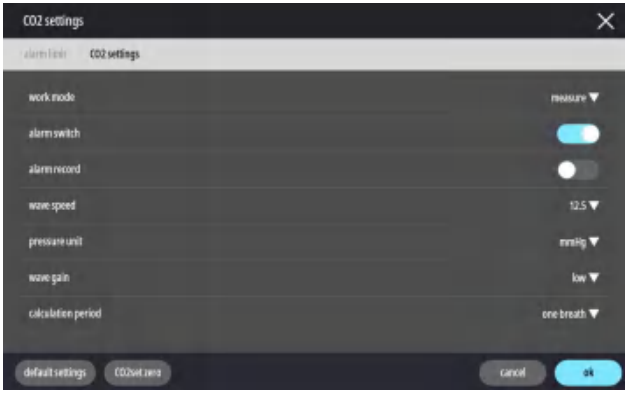


Figure 11-2-2 CO2 settings

Operating mode

Used to change the working mode of carbon dioxide, you can choose "measurement" mode or "standby" mode. The default is "standby" mode. When CO2 monitoring is required, select the "Measurement" mode. "Standby" mode will turn off the air pump of the side flow module, the sensor of the mainstream module and the infrared IR source, which can reduce power consumption and extend the service life of the IR source and the entire CO2 module.

Alarm switch: "On" will prompt and store the alarm when there is an alarm in the CO2 parameter, "Off" will not alarm.

Alarm Record

Select "On" to store when CO2 alarm occurs, select "Off" to not store.

Waveform speed

Used to adjust the display speed of CO2 waveform. The available options are "6.25 mm/s", "12.5 mm/s", and "25.0 mm/s".

Pressure Unit

Used to change the display unit of CO2 and InsCO2 parameters. You can select "mmHg" or "kPa".

Waveform gain

Used to adjust the amplitude of the carbon dioxide waveform display area. You can select "Low" or "High". The default value is "low".

Calculation cycle

Used to adjust the calculation period of the CO2 waveform. The options are "one breath", "10s", and "20s".

⚠**Notice**

●When multiple alarms occur simultaneously, the screen will display the highest level alarm information.

●When the CO2 monitoring function is not used, it is recommended that users do not connect to the mainstream sensor or side flow tank, and adjust the CO2 working mode to "standby".

Default Setting

Click this item to pop up the "Restore Default Settings" dialog box. Click "OK" to restore the "CO2 Settings" to the system default configuration.

11.3 CO2 alarm information and prompt information

When the alarm recording switch in the relevant menu is turned on, those physiological alarms caused by parameters exceeding the alarm limit will trigger the recorder to automatically output alarm parameter values and related measurement waveforms.
The physiological alarms, technical alarms and prompt messages that may occur during CO2 module measurement are listed in the following table:

Physiological alarm:

Prompt message	Cause	Alarm level
CO2 is too high	EtCO2 measured value is higher than the set alarm high limit	User selectable
CO2 is too low	EtCO2 measured value is lower than the set alarm low limit	User selectable
INS is too high	InsCO2 measured value is higher than the set alarm limit	User selectable
AWRR is too high	AwRR measurement value is higher than the set alarm high limit	User selectable
AWRR is too low	AwRR measurement value is lower than the set alarm low limit	User selectable
CO2 breathing asphyxia	Respiratory arrest(No breathing detected within the set delay time)	high

⚠**Notice**

- The interference gas of the gas concentration provided by this device has no impact on the quantification of gas readings and is not shared with anesthetic gases.
- The following factors may have known adverse effects on the claimed performance:
  a. Quantitative effects of sampling gas humidity or condensation;
  b. Leakage of sampled gas or internal exhaust;
  c. Periodic pressure rising to 10kPa (100cmH2O);
  d. Other sources of interference.

Chapter 12 Recorder (optional)

(This function is optional, and the product you are using may not be equipped with this function)

12.1 General information about the recorder

The recorder used on this monitor is a thermal array recorder, and the printing width of the waveform is 48mm.

Logger performance

(1) The recorder can operate at a rate of 25mm/second or 50mm/second when outputting waveforms;

(2) Up to two waveforms can be recorded;

(3) Chinese and English output;

(4) Record time, waveform, and six parameter data in real time.

(5) During alarm recording, the monitor automatically selects the waveform related to the alarm parameters.

12.2 Types of records

(1) Press the print key or click the print hotkey to perform manual printing and print the current waveform and parameters.
(2) In each parameter setting menu, select the alarm printing switch to On. When the alarm occurs and is triggered, the product will automatically print the waveform and data of the current alarm.
(3) In each review trend graph, trend table, alarm review and other items, click the current print option to print the current data.

⚠**Note: When the output operation is being performed, if you press the print key again, the parameter output will wait until the current output is completed before outputting.**

12.3 Record output

Date and time HR——Heart rate PR——Pulse rate SPO2——Blood oxygen saturation SYST——Systolic pressure MEAN——Mean pressure DIAS——Diastolic pressure TEMP1——Body temperature 1 TEMP2——Body temperature 2 RESP——Respiration LEAD—— lead

12.4 Recorder operation and status information

Requirements for recording paper

You must use thermal recording paper that meets the requirements, otherwise it may result in the inability to record, a decrease in recording quality, or damage to the thermal head.

Normal Operation

(1) When the recorder is running, the recording paper is fed out at a constant speed. Do not pull it out with force at this time to avoid damaging the recorder.

(2) The recorder cannot be used without recording paper.

(3) Recorder paper replacement steps

(4) Open the recorder door;

(5) Insert the new paper directly into the paper inlet, with the printing surface facing the thermal head;

(6) When the paper is exposed from the other side, pull it outward, making sure to straighten the paper and align the edges;

(7) Close the recorder door.

⚠**Notice**

●The paper change movement should be gentle and do not hit the thermal head. Do not leave the recorder door open unless you are changing paper or troubleshooting.

Clear paper jam

When you hear the sound of the recorder running and the output of recording paper is abnormal, you should open the door of the recorder and check whether there is a paper jam.

When clearing a paper jam:

(1) Open the recorder door;

(2) Reposition the paper and align the edges;

(3) Close the recorder door

Set up the recording grid

Function: Print the recording grid to facilitate intuitive measurement of waveforms. Therefore, it is necessary to turn this function on when using blank printing paper, and turn off this function when using printing paper with a network.

Setting method: Enter the print settings menu and select "On" or "Off" in the grid switch.

⚠**Careful**

●During the output process of the recorder, do not pull the recording paper outward with force, otherwise the recorder may be damaged.

●Do not leave the recording door open unless changing paper or troubleshooting.

●Do not use anything that could damage heat-sensitive parts, such as sandpaper.

●Do not squeeze the thermal print head with force.

Chapter 13 Common Troubleshooting Methods

Fault name	Fault description	Possible causes of failure	Solution
Black screen	Turn on but black screen appears	1. The screen backlight is loose	1. Re-plug the cable plug
		2. The display is damaged	2. Replace the display screen
		3. The adapter is damaged	3. Replace the power adapter
		4. The adapter is not plugged in yet.	4. Re-plug the adapter or change the power socket
White screen	Turns on but displays white screen	1. The connection cable between the motherboard and the screen is loose.	1. Re-fix the display cable
		2. The screen cable is loose	2. Re-fix the display cable
		3. LCD screen is damaged	3. Replace the LCD screen
		4. The motherboard is damaged	4. Replace the motherboard
Can't enter the monitoring interface	Boot and stop at LOGO or other location	1. The motherboard is damaged	1. Replace the motherboard
		2. The program chip is loose or damaged	2. Reinstall or replace the program chip
Blood pressure measurement error	Abnormal blood pressure measurement with no results	1. Blood pressure cuff or trachea leaks	1. Wrong cuff selection, replace the blood pressure cuff or related connections
		2. Overvoltage protection	2. Patient type and cuff selection are uncomfortable or the extension tube is bent and blocked.
		3. Large deviation in measurement values	3. The cuff is too tight or too loose, the measurement position is wrongly selected, excessive exercise, etc.
		4. Wrong air pressure	4. Replace the slow release valve or other air-blocking parts
ECG function not working	No ECG waveform	1. ECG clutter or instability	1. The patient is noisy, the ECG electrode attachment points are not cleaned, and the electrode pads are not bonded well, etc.
		2. The ECG lead is switched to or not connected to the lead.	2. Replace the ECG lead to the ECG lead wire
		3. The ECG lead falls off or the wire is broken	3. Reconnect the ECG leads or replace the lead wires

		4. The connection line between the ECG plug and the ECG board is loose or broken.	4. Reconnect the ECG socket to the ECG module cable or replace the ECG socket and cable
		5. ECG clutter	5. Excessive interference from peripheral electronic equipment
Blood oxygen is not working properly	Unable to measure blood oxygen saturation	1. The blood oxygen probe falls off	1. Connect the blood oxygen probe to the patient's finger
		2. The blood oxygen probe is damaged	2. Replace the blood oxygen probe
		3. The blood oxygen socket connection cable is loose or disconnected.	3. Reconnect the blood oxygen socket cable
		4. The blood oxygen signal line is loose	4. Reconnect the blood oxygen signal line
The end-tidal carbon dioxide module is not working properly.	Unable to measure end-tidal carbon dioxide	1. The sampling line is kinked.	1. Reconnect the carbon dioxide sampling line.
		2. The drain trap is blocked.	2. Replace the water trap with a new one
		3. The sampling line has been blocked.	3. Replace with a new sampling line.
Battery not charging	Short battery life	1. The battery is damaged and the voltage is very low.	1. Replace the battery
		2. The power supply is damaged and the charging power is low.	2. Replace the power board

⚠ **Note: Non professionals are not allowed to disassemble the machine! If the malfunction exceeds the scope described in the above adverse information or cannot be resolved based on the above solutions, please contact our company's after-sales service department directly!**

Chapter 14 Appendix

The supporting accessories recommended by our company are as follows:

14.1 Electrocardiogram (ECG) accessories

Name	Model	material number	Patient category	Instruction	Manufacturer	Test Options
ECG cable	SG5143S	12.02.0051 C	/	Anti defibrillation, push button, five-lead, 2.9m, reusable	Shenzhen SINO-K Medical Technology Co.,Ltd.	√
	SG3143S	12.02.0057 C	/	Anti defibrillation, push button, three-lead, 2.9m, reusable	Shenzhen SINO-K Medical Technology Co.,Ltd.	√
	SK1211B	12.02.0047 C	/	Anti defibrillation, push button, twelve-lead, 2.9m, reusable	Shenzhen SINO-K Medical Technology Co.,Ltd.	√

14.2 Blood Oxygen (spo2) accessories

Name	Model	material number	Patient category	Instruction	Manufacturer	Test Options
SpO2 Probe	SP9325A	12.02.0063C	Adult	Finger Clip Sensor with 300cm Cable , reusable	Shenzhen SINO-K Medical Technology Co.,Ltd.	√
	SP8325A	12.02.0058C	Adult	Finger Sleeve Sensor with 300cm Cable , reusable	Shenzhen SINO-K Medical Technology Co.,Ltd.	√
	SP7119 A	12.02.0044C	Child	Finger Clip Sensor with 300cm Cable , reusable	Shenzhen SINO-K Medical Technology Co.,Ltd.	
	SP6119	12.02.0045C	Child	Finger Sleeve Sensor with	Shenzhen	

	A			300cm Cable , reusable	SINO-K Medical Technology Co.,Ltd.	
Nellcor SpO2 Probe	DS100A	12.02.0066C	Adult	Finger Clip Sensor with 70cm Cable , reusable	TYCO	√
Masimo SpO2 Probe	LNCS DCI	12.02.0067C	Adult	Finger Clip Sensor with 70cm Cable , reusable	Masimo	√

14.3 temperature (temp) accessories

Name	Model	material number	Patient category	Instruction	Manufacturer	Test Options
Temperature probe	ST2305	12.02.0056C	Adult	Body cavity sensor.3m.reusable	Shenzhen SINO-K Medical Technology Co.,Ltd	√
	ST1305	12.02.0055C	Adult	Body surface sensor.3m.reusable	Shenzhen SINO-K Medical Technology Co.,Ltd	√

14.4 non-invasive blood pressure (nibp) accessories

Name	Model	material number	Patient category	Instruction	Manufacturer	Test Options
NIBP tube extender	SH0908S	12.02.0025C	/	Strait plug connector to pagoda connector,2.5m	Shenzhen SINO-K Medical Technology Co.,Ltd.	√
	SH0910S	12.01.0012C	/	Strait plug connector to spring joint,2.5m	Shenzhen SINO-K Medical Technology Co.,Ltd.	√
NIBP Cuff	SC2711	12.01.0002C	Adult	Brown color, reuseable	Shenzhen SINO-K Medical Technology	√

					Co.,Ltd.	
	SC2611	12.01.0017 C	Child	Brown color, reuseable	Shenzhen SINO-K Medical Technology Co.,Ltd.	√

14.5 end-tidal carbon dioxide (co2) accessory

Name	Model	material number	Patient category	Instruction	Manufacturer	Test Options
CO2 Sensor	TL1000A	12.01.0063C	/	main stream	Suzhou Troline Technology Co., Ltd.	√
	TL2000A	12.01.0064C	/	external side-stream	Suzhou Troline Technology Co., Ltd.	√
Airway adapter	TL_Madapter	12.02.0061C	/	main stream	Suzhou Troline Technology Co., Ltd.	√
	TL_Sadapter	12.01.0044C	/	external side-stream	Suzhou Troline Technology Co., Ltd.	√
Sampling tube	TL_Sampline	12. 01. 0049 C	/	external side-stream	Suzhou Troline Technology Co., Ltd.	√

14.6 Other accessories

Name	Model	material number	Patient category	Instruction	Manufacturer	Test Options
14.8V2.2 AH Li-ion battery	ICR18650	02.10.0001 C	/	SMP-02V(JST)connector 32.56wh	Shenzhen Xinlong Ding Technology Ltd.	√

⚠WARNING

●Please use recommended accessories. Using other accessories may damage the monitor or fail to achieve the accuracy of each parameter specification claimed in the manual.

●The listed accessories must be used in conjunction with our company's equipment. Before using the accessories, please read the instructions of the equipment and accessories to confirm the compatibility of the accessories with the product. Otherwise, the patient may be injured or

the measurement accuracy may be affected.

●Disposable accessories can only be used once and reuse can lead to cross-contamination and performance degradation.

⚠**Notice**

●Pay attention to the packaging label for accessories that have a safe use period. Do not use expired accessories.

●Sterilization accessories should be packaged completely and cannot be used if they are damaged or leaking.

⚠**Careful**

●The use or storage environment of accessories should meet the instructions, otherwise it may not achieve the performance claimed in its specifications.

●If you find that the accessories are expired, the packaging is damaged, or the cables are damaged, please do not use it.

●Please refer to local regulations or hospital systems for the disposal of disposable accessories, expired, and scrapped accessories.

Appendix I Product Specifications

I.1 Monitor type (classified according to GB9706.1)

Standard electric shock resistance type	Class I, equipment with internal power supply
EMC category	Class A
Standard level of resistance to electric shock	ECG (RESP), SPO2, TEMP,; NIBP and CO2 are BF type
Degree of liquid prevention	IPX2
Disinfection/sterilization methods	See Chapter 5 for details
Way of working	continuously working

I.2 Monitor specifications

I.2.1 Monitor dimensions and weight

See the packaging markings on the outer box of each model.

I.2.2 Working Environment

Temperature range	Working: 5℃～40℃
	Transportation and storage temperature: (-20～+55)℃
Humidity range	Working: 15%～85% (no condensation)
	Transportation and storage humidity: ≤93% (no condensation)
Altitude range	Work: (-500-3,000) meters (-1,600－9843)foot
	Transportation and storage altitude: (-500-13,100) meters (-1,600-43,000) feet
Electrical specifications	a.c.100V-a.c.240V, 50Hz/60Hz
	Input power: <65VA
	Fuse: T1.6AL 250V d.c.15V/2A (7～15V) Breaking capacity >1.5A, over 1.6A breaking

I.2.3 Display information

(1) Color LCD monitor, 15.6 inches (1024*600 pixels). /18.5 inches/21.45 inches.
(2) Up to 6 waveform displays and one alarm indicator light (red/yellow/blue).
(3) Three sound alarm modes corresponding to the alarm status

I.2.4 Battery

(1)14.8V/2200mAh lithium-ion battery.
(2) The working time of full power in normal state is more than 150 minutes.
(3) After the first low battery alarm, it can continue to work for 10 minutes, and then it will automatically shut down.
(4)The battery charging time is not more than 5 hours, and the AC indicator will be steady on when charging.
(5) The charging time for KC series batteries from depleted state to 90% charge is 4 hours.
(6) Expected battery life: 8 years.

I.2.5 Recorder (external optional)

Record width	80mm	Paper feeding speed	25mm/s
Tracing waveform	3 lanes	Record type	8 seconds, 16 seconds real-time recording

I.2.6 Review

Trend table	Review of trend data within 1 month
Resolution	1 minute, 5 minutes, 10 minutes, 30 minutes, 60 minutes
Trend	Review of trend data within 1 month
Alarm event	Review of alarm event data within 1 month
Holographic waveform	Review of holographic waveform measurement data within 1 month
NIBP review	Review of NIBP measurement data within 1 month

I.3 ECG specifications

Standards compliant	GB 9706.227-2021
Lead configuration	Lead mode: three-lead, five-lead
	Standard three-lead cable: RA, LA, LL
	Standard five-lead cable: RA, LA, LL, RL, V
	Standard twelve-lead cable: RA, LA, LL, RL, V1, V2, V3, V4, V5, V6
	Three-lead lead mode: I, II, III
	Five-lead lead mode: I, II, III, avr, avl, avf, V
	Twelve-lead mode: I, II, III, AVR, AVL, AVF, V1, V2, V3, V4, V5, V6
Gain	0.25 (2.5mm/mv), 0.5 (5mm/mv), 1 (10mm/mv), 2 (20mm/mv), automatic
	The errors are all less than±5%
Heart rate measurement range	Adult: 15 ~ 300bpm (beats/minute)
	Children: 15 ~ 350 bpm (beats/minute)
Heart rate accuracy	Accuracy ±10% or ±5bpm, whichever is greater; resolution 1 bpm (beats/minute).
ECG signal range	0.2～8mv
Input resistance	>5 (megaohms)
Bandwidth	Reference mode 0.05Hz ～ 100Hz; Monitoring mode 0.5Hz ～ 40Hz; Surgery mode 1Hz～20Hz
Common mode rejection ratio	Reference mode > 90 db; Monitoring mode > 100 db; Surgery mode > 100 db
Electrode polarization voltage range	±300mv
Pacing pulse detection	For pacing pulses that meet the following conditions, it can be detected: Amplitude: ±2mV～±700mV; Width: 0.5ms ~ 2ms; Rise time: 10μs ~ 100μs
Pacing pulse suppression	When the pacing analysis switch is turned on, pacing pulses that meet the following conditions can be suppressed without affecting heart rate calculation; Amplitude: ±2 mv ~ ±700mv; Width: 0.1ms ~ 2ms; Rise time: 10μs～100μs

Baseline recovery time	<5 seconds after defibrillation
Calibration signal	1mv (peak to peak), accuracy±5%
Lead off detection current	＜0.1μA
System noise	Not more than 30μV
Heart rate average	Calculate the heart rate average by: If the last three consecutive RR intervals are greater than 1200 ms, thenrightthe 4 most recent RR intervals are averaged to calculate heart rate; otherwise, the 12 most recent RR intervals are taken, the maximum and minimum values are subtracted, and the average is calculated to calculate heart rate. The heart rate value displayed on the screen is refreshed every second.
Tachycardia alarm time	<15s

I.4 Respiratory specifications

Measurement method	Ra-ll, ra-la impedance method
Respiratory impedance detection range	(0.3～3)ω
Base impedance range	(200～4000)ω
Bandwidth	(0.1～2.5)hz
Respiratory rate range	Adult: 7bpm～120bpm
	Children: 7bpm～147bpm
Respiration rate resolution	1 bpm;
Respiration rate accuracy	±2 bpm
Suffocation alarm	10~40 seconds

I.5 SPO2 specifications

Standards compliant	YY 9706.261-2023
Pulse oximeter measurement range	70～100%
Pulse Oximeter Accuracy	(90%～99%) error is ±2%; (70%～89%) error is ±4%
Pulse rate measurement range	25bpm～300bpm
Pulse rate accuracy	±3bpm
Masimo blood oxygen module measurement range	25bpm～240bpm
Masimo blood oxygen module accuracy	±3bpm

I.6 TEMP specifications

Standards compliant	YY 9706.256-2023
Applicable temperature	YSI series, CYF series

sensor	
Number of channels	2 channels
Measuring range	0℃～50℃
Measurement accuracy	25℃ ～ 45℃, error ±0.2℃; accuracy in other ranges is not defined

I.7 NIBP specifications

Standards compliant	YY 9706.230-2023
Measurement method	Pulse wave oscillation method
Operating mode	Manual measurement/automatic interval measurement/continuous measurement
Measurement interval time in automatic measurement mode	(1,2,3,4,5,10,15,30,60,90,120,180,240,480) minutes
Measurement time in continuous measurement mode	5 minutes
Pulse rate range	40 – 240 bpm
Measuring range (KC series monitor and Suntech blood pressure module)	Aldult: Systolic blood pressure 40–260mmhg (5.3–36.0kpa) Average pressure 20–240mmhg (2.7–30.7kpa) Diastolic blood pressure 10–220mmhg (1.3–28.0kpa)
	Child: Systolic blood pressure 40–230mmhg (5.3–30.7kpa) Average pressure 20–170mmhg (2.7-22.0kpa) Diastolic blood pressure 10-160mmhg (1.3–20.0kpa)
Measuring range	0mmhg～260mmhg
Display resolution	1mmhg (0.133kpa)
Average error	±5mmhg
Standard error	±8mmhg
Overvoltage protection	Adult: 300 mmhg±3 mmhg
	Children: 280 mmhg±3 mmhg

I.8 CO2 specifications

Standards compliant	GB 9706.225-2022
Measurement display range	0～20%(0～152 mmHg)
Measurement accuracy	± (0.43%+8% of reading)
Resolution	0.1%(1 mmHg)
Airway respiratory rate measurement display range	0～160 brpm
Airway respiratory rate measurement accuracy	±1 brpm

Airway respiratory rate measurement resolution	1 brpm	
Rated respiratory rate	0-150 times/minute	
An overview of test methods for determining the rated respiratory rate range and the corresponding effects of changes in the accuracy of end-expiratory gas readings with respiratory rate [requirements in 201.7.9.2.9.101i and j)]	The rated breathing rate is set at 30,60,100,140 times/minute, using 5% standard CO2 gas, and the accuracy of the end-expiratory gas reading is within the claimed standard rang	
The measurement error of CO2 may be affected by the following:	1. Use immediately after calibration zero. 2. Use during the warm-up period of the CO2 module. 3. Sampling gas flow rate is less than 38 ml/min. 4. When the respiratory rate is not at the claimed respiratory rate (0-140brpm). 5. The CO2 sensor is overheated. Note: I:E and airway respiration rate will not affect the measurement accuracy	
The minimum sampling flow rate that meets the measurement accuracy of the shunt RGM	38ml/min±10ml/mins	
CO2 sampling gas flow rate and tolerance	50ml±10ml	
Drift in measurement accuracy	Meet accuracy requirements within 6 hours	
Total response time of mainstream systems	<4seconds	
bypass system at rated flow rate	Total response time	≤5.0s, @50ml/mins
	rise time	≤450ms,@50ml/mins

I.9 Alarm specifications

Alarm level: high, medium and low level alarm, in compliance with YY9706.108-2021
Alarm type: physiological alarm, technical alarm
Alarm indication: red, yellow and blue alarm indicators.

Appendix II Summary of Performance

Requirements description	Minimum maximum	Unit	Min/max
Normal working conditions			
Ambient temperature	scope	℃	0~40
Relative humidity	scope	%	≤85% (no condensation)
Atmospheric pressure	scope	hPa	700~1060
Network (power) frequency	scope	Hz	50±1
Network (power supply) voltage (rms)	scope	V	100-240V
Preheat time	smallest	min	2
ECG part			
Overload protection: no damage after loading 1V, power frequency, differential mode AC voltage for 10s	smallest	V	1
Auxiliary output (if provided)	none		
No damage under short circuit condition			
Respiration, lead-off detection and active noise suppression	have		
DC current in active leads			
QRS wave detection			
QRS wave amplitude and width range—for the pulse shown in Figure 6			
Amplitude	scope	mV	0.5~5
Width (adult monitor)	scope	ms	70~120
Width(children)	scope	ms	40~120
No response to the following signals			
Amplitude (except in child working mode)	maximum	mV	0.15
Width when amplitude is 1mv (except children's operating mode)	maximum	ms	10
Power frequency voltage tolerance	smallest	uV	100
Drift tolerance			
Triangular wave amplitude	not applicable	mV	4
QRS wave amplitude	not applicable	mV	0.5
QRS wave width	not applicable	ms	100
QRS complex repetition rate	not applicable	bpm	80
Heart rate meter range and accuracy			
Scope(adult monitor)	scope	bpm	15~300

Scope(child monitor)	scope	bpm	15~350
Error: or	maximum	%	±10
Or (whichever is greater)	maximum	bpm	±5
Display heart rate for a heart rate less than the minimum nominal heart rate	maximum	bpm	30
Display heart rate for signals with repetition rate = 300 bpm (adult mode)	smallest	bpm	295
Display heart rate for signals with repetition rate = 350bpm (children)	smallest	bpm	345
Alarm system requirements			
Alarm limit range			
Maximum limit (adult)	smallest	bpm	100~200
Upper limit (children)	smallest	bpm	100~250
Lower limit (adults and children)	smallest	bpm	30~100
Alarm resolution, or	smallest	bpm	1
Alarm limit error, or	maximum	%	±10
Or (whichever is greater)	maximum	bpm	±5
Start time of asystole alarm	maximum	s	10
Low heart rate alarm start time	maximum	s	10
High heart rate alarm start time	maximum	s	10
Silence alarm	Provides SILENCE and restart settings		
Alarm disabled	Display alarm is disabled		
Monitor with ECG waveform display capability			
Enter dynamic range			
Input signal amplitude	maximum	mV	±5
Rate	maximum	mV/s	320
DC offset voltage	scope	mV	-300~+300
Output signal changes	maximum	%	±10
Cannot work display (reduce the degree before display)	maximum	%	50
Input impedance: signal minus (0.67Hz~40Hz)	maximum	%	20
System noise	maximum	uV	30
Multi-channel crosstalk: Channels without signals are interfered by channels with signals	maximum	%	5
Gain control and stability			
Gain selection			
All shown	smallest	mm/mV	2.5
Display permanently	required	mm/mV	10
Allows continuous change of gain control, manual override			
Gain changes per minute	maximum	%/min	0.66
Total gain change within 1 hour	maximum	%	±10
Time base selection and accuracy			
Time base selection			
—Display permanently	required	mm/s	25
—Non-permanent display	not applicable	mm/s	12.5, 25, 50

Time base maximum error	maximum	%	±10
Output display			
Channel width	smallest	mm	30
Aspect ratio	not applicable	s/mV	0.2, 0.4, 0.8
Input signal reconstruction accuracy			
Total system error: or	maximum	%	±20
Or (whichever is greater)	maximum	uV	±100
Frequency response			
Sine input	scope	Hz	0.67~40 (minus -3dB)
B) Response to input 20ms width triangular wave	scope	%	The peak value of the wave decreases from 0 to 25
Response to 0.3mv.s impact outside the impact range			
Offset	maximum	mV	0.1
Slope	maximum	mV/s	0.30
Electrode weighting factor	smallest	%	±5
Offset 15mm hysteresis effect	maximum	mm	0.5
Scaling voltage			
Common mode rejection allows 10V line frequency noise	maximum	mV	1
Baseline control and stability			
Recovery time after reset	maximum	s	3
Drift rate within 10s	maximum	uV/s	10
Baseline drift within 1 hour	maximum	uV	500
Line drift under operating temperature	maximum	uV/℃	50
Pacing pulse: display - when the amplitude is 2mv~700mv, the width is 0.5ms~2ms, the maximum rise time is 100μs, ECG display when a pacing pulse of 100 pulses per minute occurs.	smallest	mV	0.2
Sync Pulse: Time interval from R wave peak to sync output pulse, plus published amplitude, width and output impedance Z	not applicable	ms	35
Electrosurgical interference suppression: heart rate changes compared with before interference	maximum	%	±10

Require	Declaration
Warning information on whether overloading electrosurgical equipment will damage the equipment	Do no harm
Breathing, lead off detection, active noise suppression	No more than 30μA
High T-wave suppression capability: The heart rate displays the maximum T-wave amplitude within the specified error limit. If performance is affected by low frequency response, options need to be published	Diagnosis and monitoring mode 0.9mv Surgical mode 0.3mv
Heart Rate Average: Averaging algorithm for calculating minute heart rate	Average of eight shots, display refresh speed 1s
Heart Rate Accuracy and Response to Arrhythmias: Heart Rate Display of Waveforms in Figure 3	They are 80bpm±5bpm, 60bpm±5bpm, 120bpm±5bpm, and 90bpm±5bpm respectively.
The response time of the heart rate meter to changes in heart rate: 1. The number of seconds required for the heart rate meter to increase from 80bpm to 120bpm2, and to decrease from 80bpm to 40bpm	1. ＜10s; 2. ＜10s
Start time of tachycardia alarm: Alarm time for the waveform in Figure 4	<10s
Pace pulse suppression warning label: Because the heart rate meter may include pacemaker pulses in the heart rate value during cardiac arrest or arrhythmia, patients with pacemakers need to be closely monitored.	For patients with a pacemaker, the heart rate monitor may include pacemaker pulses in the heart rate value during cardiac arrest or arrhythmia. Don't rely entirely on heart rate monitor alarms
Auditory Alarm Announcement: Sound Source Location and Sound Frequency	The speaker is placed on the rear of the product; the sound frequency is 1khz
Visual alarm announcement: location, color, size and flash frequency	The alarm light is on the upper left side of the front of the product; 1. The high-level alarm red light lights up, 11 seconds/time; 2. The intermediate alarm yellow light lights up, 25 seconds/time; 3. The low-level alarm yellow light lights up, 25 seconds/time
Battery powered monitor: minimum operating time, battery charging time, battery consumption indication, functional description	When fully charged, it can work for 100 minutes by measuring blood pressure every half hour; the maximum charging time of the battery does not exceed 12 hours; there is a battery power indicator in the lower right corner of the product; the charging time to charge to 90% of the

	battery when the battery is consumed: 3 hours. When the battery is under-voltage, the power indicator turns red and the power automatically cuts off after 10 minutes.
Telemetry	Not applicable
Mains Isolated Monitor Transients: Warning Messages and Methods to Reduce Interference	Connect the product to the ground correctly, treat the patient's skin correctly when attaching electrodes, and use electrodes produced by regular manufacturers.
Special published requirements for monitors with non-permanent ECG waveform display: valid time base, aspect ratio adjustment range	Time bases are 12.5mm/s, 25 mm/s, 50 mm/s; aspect ratios are 0.2s/mv, 0.4 s/mv, 0.8 s/mv
Electrode Polarization: Cautionary Statement Regarding the Impact of Electrode Type on System Overload Recovery, Particularly Post-Defibrillation Recovery Time	Electrodes from the manufacturer specified by the company should be used, otherwise the recovery time after defibrillation will be affected.
Auxiliary outputs: If auxiliary outputs are provided, provide instructions for proper connection to other equipment, paying particular attention to risk current characteristics, including bandwidth, gain, transmission delay, and handling of pacing pulses.	Not applicable
Alarm Silencing: Publishes the time the alarm will be reactivated after it has been silenced. If this time is adjustable, publish the range of its time interval	The time interval is 60s, 120s and the alarm is turned on and displayed on the screen
Battery Disposal: Proper Guidance on Disposal of Used Batteries	Dispose of according to local end-of-life regulations for electronic products, or return to manufacturer for recycling
Precautions for use: Description of the intended use and usable functions of the equipment; procedures for checking the controls and functions; information about the electrodes - the number of electrodes required, the polarity of the cable (if different from the standard cable); necessary for compliance with the requirements of this standard Description of any special cable characteristics; warnings about using electrodes of	OSEN8000 series multi-parameter monitor is used in all levels of hospitals for patients to conduct electrocardiography, blood pressure, oxygen saturation, respiration, body temperature and other vital signs parameters are monitored and displayed on the screen in digital or waveform open, and can be recorded on the electrocardiogram and pulse oximetry output; the ECG electrode uses 5 electrodes, white is RA, black is LA, red is LL, green is RL, and brown is C; the electrodes are copper, and different metal materials are not allowed. ; When the

dissimilar metals; settings necessary for child supervision	monitor is used for children, it must be set to the corresponding mode, otherwise the data may not be measured, the data may be inaccurate, and there may be safety risks to the patient.
Application field description	Includes: in the operating room, induction of anesthesia and postoperative resuscitation, in the intensive care unit, emergency care, cardiac care, neurological care, dialysis care, geriatric care, obstetrical care, medical and surgical care.
Service Instructions: Proper care, preventive maintenance, and repair procedures; complete electrical instructions to ensure proper on-site repair and specify acceptable repair equipment; recommended preventive maintenance frequency	If the customer requests it, maintenance instructions can be provided to the customer: the maintenance instructions include maintenance and preventive maintenance information as well as repair instructions. Includes circuit diagrams, block diagrams, wiring diagrams, and part numbers, information that ensures skilled technicians will complete the maintenance items specified in the service instructions that can be performed by a service representative.
Pacemaker pulse suppression capability/no overshoot Pacemaker pulse suppression: In the operator's instructions and maintenance instructions, the suppression capability of pacing pulses without overshoot in the following ranges: ±2mv to ±700mv amplitude, 0.1ms to 2.0ms width , the overshoot is less than 0.05ap [Figure 5a], the stabilization time is less than 5us; the start, rise and fall of the pulsedropthe time does not exceed 100us; the pulse start time is 40ms before the start of the QRS wave or shorter than 40ms; there is an identical pulse with a time lead of 150ms to 250ms before the above pacing pulse.	When the pacing analysis switch is turned on, pacing pulses that meet the following conditions can be suppressed without affecting heart rate calculation; Amplitude: ±2 mv ~ ±700mv; Width: 0.1ms ~ 2ms; Rise time: 10μs ~ 100μs
Pacemaker pulse suppression with overshoot: Pacemaker pulse suppression with overshoot (charging) time constant between 4ms and 100ms is published in the operator's instructions and maintenance instructions. The other parameters are the same as the above except that the overshoot (charge) time constant is between 4ms and 100ms. Overshoot has Two definition methods. Is	Use Method A and Method B

the announcement using Method A or Method B or both?	
Suppression of fast ECG signals by pacing pulse detectors; the typical minimum input slew rate, expressed in V/srti, that can render the pacing pulse detector inactive must be published in the operator's instructions and service instructions	5V/srti
Display of pacing pulses on the auxiliary output: When there is a pacing pulse on the auxiliary output, the filtering of the pacemaker pulses and any substitutions are announced	Not applicable
Pace Pulse Detector Failure: Publish operating modes or signal conditions that cause pacing pulse detection to fail or be ignored	Pacing analysis is off or pacing analysis is on but the product is operating in surgical mode

Appendix III Declaration Table of Toxic qnd Harmful Substances or Elements in Products

Part name	Toxic and harmful substances or elements					
	Lead (pb)	Hg (hg)	Cadmium (cd)	Hexavalent chromium (cr(vi))	Polybrominated biphenyls (pbb)	Polybrominated diphenyl ethers (pbde)
Shell	○	○	○	○	○	○
Operation panel	○	○	○	○	○	○
Pcba	○	○	○	○	○	○
Label	○	○	○	○	○	○
Display	×	×	×	×	×	×
Packaging materials	×	×	○	○	×	×
Connector	○	○	○	×	○	○
Power cable	○	○	○	○	○	○
Battery	×	○	×	○	○	○
Accessories and sensors	×	○	○	○	○	○

Remarks: ○: Indicates that the content of the toxic and hazardous substance in all homogeneous materials of the part is below the limit requirements specified in the SJ/T 11363-2006 standard;

×: Indicates that the toxic and hazardous substance is present in at least one homogeneous material of the part The content in the material exceeds the limit requirements specified in the SJ/T 11363-2006 standard.

When disposing of products and batteries after normal use, please comply with the laws and regulations of each local government for disposal.

The product contains certain toxic and harmful substances, which can be used with confidence within the environmental protection use period. After the environmental protection use period exceeds, it should enter the recycling system.

Appendix IV EMC

This equipment generates and radiates radio frequency energy. This equipment can cause electromagnetic interference between other medical or non-medical equipment and radio communications. According to the statement in YY 9706.102-2021, this product belongs to the first group of emission restrictions, Class A medical equipment, and corresponding protection measures should be provided to avoid interference. However, there is no complete guarantee that electromagnetic interference will not occur under specific installation conditions.

When it is found that this equipment causes interference (it needs to be confirmed by switching the equipment on and off), the operator (or authorized maintenance personnel) can eliminate the interference according to the following measures:

1. Adjust or relocate affected equipment;
2. Increase the distance between this device and the affected device;
3. Use another power source to power this device;
4.Consult a service technician for further advice.

⚠WARNING

●The use of non-original accessories, sensors, and cables may increase the device's electromagnetic emissions or reduce its electromagnetic immunity.

●The equipment shall be securely mounted in a location where it can be easily observed, operated and maintained.

⚠Notice

●Before using this equipment, please make sure that the EMC requirements required by this equipment are met.

●This section will list the contents described in the YY 9706.102-2021 table. It is the user's responsibility to ensure that this equipment and its nearby equipment comply with the radio frequency interference parameters indicated in the general safety requirements.

●Do not use equipment that intentionally emits RF signals (cell phones, radio transceivers or radio-controlled products) in the vicinity of this equipment as this may cause operation to exceed specified values. Please turn off this type of equipment when near it. It is the operator's responsibility to instruct the patient or other persons accessing this device to fully

comply with the above requirements.

●The manufacturer will not be responsible for any interference caused by the use of non-recommended internal connecting cables or by unauthorized changes or modifications to this equipment.

Table I

Guidance and Manufacturer's Statement---Electromagnetic Emissions		
[Systems and equipment] are expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment.		
Launch test	Conformity	Electromagnetic Environment - Guidance
RF emissions GB 4824	Group 1	[The system or device] uses radio frequency energy only for its internal functions. Therefore, its RF emissions are very low and have a low potential to cause interference in nearby electronic equipment.
RF emissions GB 4824	Class A	[System or equipment] Applicable to non-domestic use and all facilities not directly connected to the public low-voltage power supply network for domestic use.
Harmonic emissions GB 17625.1	Class A	
Voltage fluctuations/flicker emissions GB 17625.2	Conform	

Table II

Guidance and Manufacturer's Statement---Electromagnetic Immunity			
[Systems and equipment] are expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge GB/T 17626.2	±6 kv contact discharge ±8 kv air discharge	±6 kv contact discharge ±8 kv air discharge	Floors should be wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical burst GB/T 17626.4	±2 kv to power line ±1 kv for input/output lines	±2 kv power line	Mains power should be of a quality typically used in a commercial or hospital environment.
Surge GB/T 17626.5	±1 kv line-to-line ±2 kv line to ground	±1 kv line-to-line ±2 kv line to ground	Mains power should be of a quality typically used in a commercial or hospital environment.
Voltage sags, short interruptions and	<5% UT for 0.5 cycles (On UT, >95% dip) 40% UT for 5 cycles	< 5% UT (drop > 95% UT) 0.5	Mains power should be of a quality typically used in a commercial or hospital

voltage changes on power input lines GB/T 17626.11	(On UT, 60% dip) 70% UT for 25 cycles (On UT, 30% dip) <5% UT, lasting 5s (On UT, >95% dip)	period 40% UT (drop 60% UT) 5 cycles 70% UT (drop 30% UT) 25 cycles <5% UT (drop > 95% UT) 5 seconds	environment. If the user of [equipment or system] requires continuous operation during a power outage, it is recommended that [equipment or system] be powered by an uninterruptible power supply or battery.
Power frequency magnetic field (50/60Hz) IEC 61000-4-8 GB/T17626.8	3 A/m	3 A/m	Power frequency magnetic fields should have power frequency magnetic field level characteristics typical of a typical location in a typical commercial or hospital environment.
Note: UT refers to the AC network voltage before applying the test voltage.			

Table 3

Guidance and Manufacturer's Statement---Electromagnetic Immunity			
[Systems and equipment] are expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic Environment - Guidance
RF conduction GB/T 17626.6	3Vrms 150k ～ 80mhz	3Vrms	Portable and mobile RF communications equipment should not be placed closer than recommended to any part of this mobile equipment, including cables. This distance should be calculated by the formula corresponding to the frequency of the transmitter. Recommended isolation distance
Radiofrequency radiation GB/T 17626.3	3V/m 80M ～ 2.5ghz	3V/m	$d=1.2\sqrt{P}\ \sqrt{P}$ $d=1.2\sqrt{P}\ \sqrt{P}$ 80mhz~ 800mhz $d=2.3\sqrt{P}\ \sqrt{P}$ 800mhz~2.5ghz In the formula: P--according to the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W); d---Recommended separation distance, unit is meters (m). The field strength of fixed RF transmitters is determined by a survey of the electromagnetic

			field a and should be lower than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol.

Note 1: At the frequency point of 80mhz to 800mhz, the higher frequency formula is used.
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.

a. Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and land mobile radios, amateur wireless, AM and FM radio broadcasts, and television broadcasts, the field strengths of which cannot be predicted accurately theoretically. To assess the electromagnetic environment of fixed RF transmitters, a survey of the electromagnetic field should be considered. If the mobile device is exposed to measured field strengths above the applicable RF compliance levels above, the mobile device should be observed to verify normal operation. If unusual performance is observed, additional measures may be necessary, such as reorienting or relocating the mobile device.
b. In the entire frequency range of 150khz~80mhz, the field strength should be lower than 3V/m.

Table 4

Recommended isolation distance between portable and mobile radio frequency communications equipment and [equipment or system]

[Equipment or system] is intended for use in an electromagnetic environment where radio frequency radiation disturbance is controlled. Based on the maximum rated output power of the communications equipment, the purchaser or user of [equipment or system] can prevent electromagnetic interference by maintaining the minimum distance recommended below between portable and mobile radio frequency communications equipment (transmitters) and [equipment or system]

Maximum rated output power of the transmitter in W	Calculate the isolation distance (meters) based on the frequency of the transmitter		
	150kHz to 80MHz $d=1.2\sqrt{P}\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.37
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	twenty three

For the rated maximum output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the transmitter provided by the transmitter manufacturer. The maximum output power rating of the machine, in watts (W).
Note 1: At frequencies 80 MHz and 800 MHz, the formula for the higher frequency range applies.

Note 2: These guidelines may not be suitable in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and human bodies.

Contact Information

Registrant/Production unit/After-sales service: MDKMed Medical Technology Co., Ltd.

Registered address: 502A, Building 7, No. 22, Xinyan Road, Donghu Street, Linping District, Hangzhou City, Zhejiang Province, P. R China 311323

Production address: No.22, Cangling Rd, Huzhen Town, Jinyun County, Lishui City.Zhejiang Province, P. R. China 321404

Tel: 0571-88040712

Postal code: 321404

Service hotline: 400-880-8392

Email: sales@graseby.com

Date of preparation: April 3, 2023