KP KM KB Series Multi Parameter Patient Monitor User Manual

MDKMed Medical Technology Co., Ltd.

Content

Product Information

The registered trademark of the product is:MDKMed
Product name:Multi parameter patient monitor
Specifications:the instruction can be used as general instruction for KM/KP/KB series,the models included are as follow:
KM series:KM8A.KM8AT;KM10A.KM10AT;
KP series:KP13A.KP13AT;KP15A.KP15AT
KB series:KB12A.KB12AT.KB12B.KB12BT.KB12C.KB12CT;KB15A.KB15AT.

Registration address of the manufacturer: 502A, Building 7, No. 22, Xinyan Road, Donghu Street, Linping District, Hangzhou City, Zhejiang Province 311100, P.R.,China
Production address: No. 22, Cangling Road., Huzhen Town, Jinyun County, Lishui City, Zhejiang Province 321404, P.R.China
Date of manufacture/Lifetime:check the label
Structure and composition:the product is composed of host.battery.power cord(adapter).accessories. Accessories include ECG cable, temperature sensor, SPO2 probe, and blood pressure cuff.

The company has obtained ISO13485 certificate.

Statement

This manual is applicable to our monitor, the content is not allowed to change without consent, the company reserves the right to improve the product in technology, parts, software and hardware. Users who require further information about the products may contact the company or its distributor.

Copyright

The company holds the copyright of this non-published instruction and treats it as confidential information. This manual is only used as reference for the use, maintenance and repair of the product. Other people have no right to disclose the contents of this manual to others.

This manual contains proprietary material protected by copyright law. All rights reserved. No part of this manual may be photocopied, reproduced or translated into any other language without our written consent.

The company does not make any form of guarantee for this material, including (but not limited to) the implied guarantee of marketability and suitability for a specific purpose. The company is not responsible for the errors contained in this information or the incidental or indirect damages caused by the provision, actual performance and use of this manual.

The contents contained in the specification can be changed without notice.

Responsibility on the manufacturer party

The manufacturer is responsible for safety, reliability and performance of this equipment only in the condition that:

- all installation, expansion, change, modification and repair of this equipment are conducted by qualified personnel; and,
- applied electrical appliance is in compliance with relevant National Standards; and,
- the monitor is operated under strict observance of this manual.

The company does not make any form of guarantee for errors, installation errors, and operating errors in this manual, and does not assume any legal responsibility for incidental or inevitable damages.

⚠ **NOTE**

This equipment is not intended for family usage.

This equipment is limited to one patient usage at a time.

According to the requirements of EN ISO 80601-2-61:2019, claims of SPO2 accuracy shall be supported by measurements of a full range clinical studies, and functional testers shall not be used to evaluate the accuracy of pulse oximetry probes and pulse oximetry monitors.

Expired products or batteries shall be disposed of or returned to the manufacturer for recycling in accordance with local electronics scrap regulations

⚠ **Warning**

This monitor is not a device for treatment purpose.

product only plays a supporting role in diagnosis, doctors made diagnosis in

conjuctions with patient's clinical situations.

It is important for the hospital or organization that employs this equipment to carry out a reasonable maintenance schedule. Neglect of this may result in machine breakdown or injury of human health.

Upon request, may provide, with compensation, necessary circuit diagrams, calibration illustration list and other information to help qualified technician to maintain and repair some parts, which may define as user serviceable.

Attention

1. This instrument can only be used by one patient at the same time.
2. According to the requirements of EN ISO 80601-2-61:2019, the claim of blood oxygen saturation accuracy should be supported by clinical research measurements covering the entire range. The function tester cannot be used to evaluate the accuracy of pulse oximetry probes and pulse oximetry monitors.
3. Expired products or accessories shall be processed in accordance with the scrap specifications of electronic products or returned to the manufacturer for recycling, and processed in accordance with local regulations.

Warning

In order to use this equipment safely and continuously, the listed instructions must be followed. The instructions listed in this manual cannot replace medical procedures that are already being performed.

- Do not rely solely on the audible alarm system to monitor the patient. When monitoring the patient, if the volume is set too low or turned off completely, it may cause disaster to the patient. Remember that the most reliable method of patient monitoring is to combine the proper use of monitoring equipment with close personal monitoring of the patient.
- This device is intended to be used only by trained health care professionals in health care facilities.
- To reduce the risk of electric shock, do not open the device. If necessary, ask qualified personnel to repair it.
- This device may interfere with the ultrasound imaging system, which appears as an interference signal on the ultrasound display. Keep the distance between these two devices as far as possible.
- Exposing electrical contacts or connecting devices to physiological saline or other liquids and conductive glue is very dangerous. Electrical contacts and connections such as cable connectors, power supplies, parameter module plug-in connectors, rack connectors, etc. must be kept clean and dry. If they are contaminated with liquid, they must be thoroughly dried. For further decontamination, please contact your biomedical department or our company.

Warranty

Scope of Free services

Any equipment that meets the requirements of the company's warranty service regulations can enjoy free service.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANT ABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Exemptions

1.It's obligation or liability under this warranty does not include any transportation or

other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the substitution upon it of parts or accessories not approved by or repaired by anyone other than a authorized representative.
2.This warranty shall not extend to any instrument which has been subjected to misuse, negligence or accident; any instrument from which 's original serial number tag or product identification markings have been altered or removed, or any product of any other manufacturer.

Safety, Reliability and Performance

Manufacturer is not responsible for the effects on safety, reliability and performance of the monitor if:

- Assembly operations, expansion, readjustment, improvements and repairs are all performed by personnel approved by our company;
- the monitor is not used in accordance with the instructions for use, or the electrical installation of the relevant room does not comply with NFPA 70: National Electric Code or NFPA 99: Standard for Health Care Facilities (Outside the United States, the relevant room must comply with all electrical installation regulations mandated by the local and regional bodies of government).

Return Policy

If need to return product to manufacturer, the following procedure shall be followed:
1. Obtain return authorization. Contact the Service Department and obtain a Customer Service Authorization number. The number must appear on the outside of the shipping container. Return shipments will not be accepted if the number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return.
2. Freight policy. The customer is responsible for freight cost when equipment is shipped to for maintance service (this includes customs clearance cost).

After sales service:

When you need technical service support, please contact agents and distributors, or the company office nearby, you can also contact the company service Dept.:
Production address: No. 22, Cangling Road, Huzhen town, Jinyun county, Lishui, Zhejiang Province 321404, P.R.China
Tel:0578-88040712
Hotline:400 880 8392
Email: sales@mdkmed.com
Please make sure to record the following information before you call us:
1.Model & series No.;
2.Production date ;
3.Life time;
4.Description of the problems

Preface

1.This manual gives detailed description to multi parameter patient monitor concerning its performance, operation, and other safety information. Reading through this manual is the first step for the user to get familiar with the equipment and make the best out of it.
2.Following symbols indicates some important facts that you have to pay special attention to:

Danger:Warning of an imminently dangerous situation which, if not avoided, could result in death serious injury or damage to property.

Warning: Indicates a potentially dangerous or unsafe operation which, if not avoided, could result in death or serious injury or property damage.

Caution: Indicates a potentially dangerous or unsafe operation which, if not avoided, could result in minor personal injury or product malfunction, damage or property loss.

Attention: Highlight important considerations and provide instructions or explanations for better use of the product.

They are pointed to be noted to avoid injury to the patient, the operator or damage to the equipment.
This monitor is a portable multi-parameter monitor that can be used in healthcare facility occasions such as surgery, surgery/anesthesia recovery, emergency room, etc., to monitor the vital signs of adults, and pediatrics.
The monitor can be powered by built-in battery or AC power. Convenient to carry and transfer.

Scope of application:

This monitor is suitable for medical institutions to monitor patients' electrocardiogram (ECG), respiration (RESP), non-invasive blood pressure (NIBP), blood oxygen saturation (SpO2), pulse rate (PR), body temperature (TEMP)).The device is not applicable for newborns.

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.

Danger

● Do not open the housing of the device, otherwise there may be a risk of electric shock. The repair or upgrade of the device can only be performed by personnel trained and

authorized by the company.

● Do not use this equipment in an environment rich in oxygen or containing flammable or explosive materials such as anesthetics to prevent fire or explosion. At the same time, ensure that the instrument and the surrounding area are clean and dry.

● Do not touch the patient or keep a sufficient distance from metal objects connected to the patient during defibrillation. Otherwise it may cause serious injury or death.

Warning:

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

● Before use, check the equipment, connecting wires and accessories to ensure that it can work normally and safely. The equipment should be self-checked when it is turned on.

● This equipment should not be used in the presence of magnetic resonance (MR) equipment, otherwise the induced current will cause burns to the patient.

● This equipment should not be used in occasions with excessive electromagnetic radiation or EMC equipment, otherwise the measurement accuracy will be affected.

● In order to avoid personal injury, no one except qualified technicians can repair the equipment.

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

Note:

● Before use, verify that the calibration is correct and that the device is working properly.

● Pay attention to the placement of power cords, conduits and all cables to avoid the risk of strangling patients or tripping other people.

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

● If liquid is spilled into the cabinet of the device, please disconnect the power immediately and contact the maintenance personnel immediately.

● The service life of this equipment is five years. The product should be stored in an environment of temperature (-20℃～+55℃), humidity (≤93%), and altitude (-500m～13,100m). 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 (such as ECG lead wires, blood oxygen probes, batteries) that have storage life requirements, follow their corresponding instructions.

● In order to avoid contamination or infection of personnel, the environment or other equipment, equipment and accessories that have reached the service life must be disposed of in accordance with relevant local regulations or hospital systems.

● The equipment should be installed in a location where it is easy to observe, operate and maintain.

● This operation manual is a general specification for KM, KP, KB, series monitor, and the product you purchased may not have certain configurations or functions.

Warning

- The multi-parameter monitor is used for clinical patient monitoring. Only doctors and nurses are allowed to use this monitor. The monitor only plays a supporting role in diagnosis, doctors made diagnosis in conjunctions with patient’ s clinical situations
- Do not open the casing of the instrument to avoid possible electric shock. Any maintenance and upgrade of the monitor must be carried out by service personnel trained and authorized by the company.
- Do not use the instrument where flammable materials such as anesthetics are placed to prevent explosion.
- Before use, the user should check whether the instrument and its accessories can work normally and safely.
- To prevent delay in treatment, please make adequate alarm settings for each patient. At the same time, it should be ensured that an alarm sound can be emitted when an alarm is issued.
- Do not use mobile phones near the monitor. Mobile phones can generate excessively strong radiation fields and thus interfere with the function of the monitor.
- During defibrillation, do not touch the patient, table, or equipment.
- The equipment interconnected with the monitor should form an equipotential body (effectively connected to the protective ground).
- When the monitor is shared with electrosurgical equipment, the user (doctor or nurse) should take care to ensure the safety of the patient being monitored.
- The packaging must be disposed of in accordance with the currently implemented waste control regulations, and the packaging must be placed out of the reach of

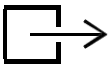
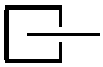
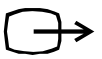
children.

- For patients with pacemakers! The heart rate monitor may count pacemaker pulses when the heart is arrested or arrhythmia occurs. Don't rely solely on the heart rate monitor to alarm. Patients with pacemakers should be closely monitored. Refer to this manual for the device's ability to suppress pacing pulses.

Caution

- When the products and accessories described in this manual are about to exceed their service life, they must be disposed of in accordance with the relevant product disposal specifications. If you want to know more about the relevant information, please contact our company or its representative office.
- When in doubt about the integrity of the external grounding of the monitor and its arrangement, the internal battery must be used for operation.

Equipment symbol

	Note! Check files		AC		ECG
	Battery		Protective Ground		Equipotentiality
	NIBP		Computer Network		Lead Selection
	Unlocking		Graphical Recorder		Input/Output
	Gas Output		USB Interface		Gas Input
	Temperature limit		Date of Manufacture		Serial Number
	Non-ionizing electromagnetic radiation		Dangerous voltage		Video output
	License mark for manufacturing measuring instruments		Humidity limitation		Atmospheric pressure limitation

	On/off		Defibrillation-proof type CF applied part		Defibrillation-proof type BF applied part
	Alarm off		Alarm pause		Alarm reset
	Alarm mute		Attention, refer to operation instruction.		

Chapter 1 Introduction

■ For an overall introduction to the monitor, please refer to **this General Information**.
■ For various messages displayed on the screen, please refer to **Screen Display**.
■ For basic operating instructions, please refer to **Button Function.**
■ For allocation of interface sockets, please refer to **Interfaces**.
■ For important facts to be noted during the battery recharging procedure, please refer to **Built-in Battery**.

1.1 General Information

The monitor (Figure 1-1) is adaptable to adult and pediatric usage. It can monitor vital signals as ECG, Respiratory Rate, SpO_2, NIBP, TEMP, and PR. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Replaceable built-in battery facilitates transportation of patient. Large high-resolution display provides clear view of 5 waveforms and full monitoring parameters.

Environment:

Working Temperature: 5 ~ 40 (°C) Transport and Storage: -20 ~ 55 (°C)
Working Humidity: 15%～80% Transport and Storage: ≤ 93 %
Atmospheric pressure: 86.0kPa～106.0kPa
Power Supply: a.c.100V～a.c.240V 50Hz/60Hz, or external adapter for D.C. 15V input
Built in battery: KM8/10: 7.4V/4.8AH;KP13/15: 14.8V/2.2AH;KB12/15: 14.8V/2.2AH

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

General instruction:

The POWER switch is on the left quarter of the front panel (in Figure 1- 1). The POWER indicator(in Figure 1- 1) and the BATT indicator (in Figure 1- 1) lights when the device is powered on. The ALARM indicator flashes or lights when alarm occurs (in Figure 1- 1).The sockets of the sensors are at the right side. The recorder socket is at the left side. Other sockets and power plug-in are at the back.

The monitor is a user-friendly device with operations conducted by a few buttons on the front panel (Figure 1- 1) and a rotary knob (Figure 1- 1). Refer to **Button Functions** for details.

Abbreviations:

Abbreviations	Descriptions	Abbreviations	Descriptions
ECG	Electrocardiography	HR	Heart rate
RESP	Respiration	RR	Respiratory rate
TEMP	Body temperature	PR	Pulse rate
NIBP	Non-invasive blood pressure	SYS	Systolic pressure
SpO_2	Blood oxygen saturation	MAP	Mean pressure
DIA	Diastolic pressure		

Intended Purpose

The monitor is intended to be used in occasions such as surgery, surgery/anesthesia recovery, emergency room to monitor patients' electrocardiogram (ECG), respiration (RESP), non-invasive blood pressure (NIBP) (not applicable to newborns), blood oxygen saturation (SpO_2), pulse rate (PR), and body temperature (TEMP) vital signs parameters.

Intended Use

The monitor is intended to be used for measuring and monitoring patients' electrocardiogram (ECG), respiration (RESP), non-invasive blood pressure (NIBP), blood oxygen saturation (SpO2), pulse rate (PR) , and body temperature (TEMP).The device is not intended for newborns.

The monitors are to be used in healthcare facilities including surgery, surgery/anesthesia recovery and emergency room, suitable for adults, pediatric patients. The monitors are excluded for ambulance use, in hospital transport or wall mounted.

Intended User

The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. They should only be used by persons who have received adequate training in their use.

Patient population

The target population are adults and children who need to monitor their ECG electrocardiogram (ECG), respiration (RESP), non-invasive blood pressure (NIBP) (not applicable to newborns), blood oxygen saturation (SpO_2), pulse rate (PR), and body temperature (TEMP) vital signs parameters. The device is not suitable for the newborns.

Indications

The monitor is intended to be used for monitoring, storing, recording, and reviewing of, and to generate alarms for, multiple physiological parameters of adults and pediatrics. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO_2), pulse rate(PR), and non-invasive blood pressure (NIBP)

The monitors are not intended for MRI environments.

Contraindications, Warnings and Cautions

Contraindications:

Do not use for patients with sickle-cell disease or with skin lesion or might have skin lesion after measurement..

Do not use for a thrombasthemia patient or patient with severe coagulation mechanism disorder.

Do not use patients' limb that has an intravenous infusion or catheter in place.

Do not use for patients with skin sensitisation.

Warnings and Cautions:

Warning

1.The monitor must be used by professional medical staff in the user manual.
2.There could be hazard of electrical shock by opening the monitor casing. All servicing and future upgrading to this equipment must be carried out by personnel trained and authorized by MDKMed.
3.Possible explosion hazard if used in the presence of flammable anesthetics.
4.The user must check that equipment and accessories function safely and see that it is in proper working condition before being used.
5.Alarm must be set up according to different situation of individual patient. Make sure that audio sounds can be activated when alarm occurs.
6.Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such devices may result in strong interference with the monitor performance.
7.Do not touch the patient, table nearby, or the equipment during defibrillation.
8.The equipment and devices connected to it should form an equipotential body to ensure effective grounding.
9.When the monitor is used with Electrosurgery equipment, the operator (surgeon and nurse) must give top priority to the patient safety.
10. The device cannot be used in the ambulances.

Caution

- When the products and accessories described in this manual are about to exceed their service life, they must be disposed of in accordance with the relevant product disposal specifications. If you want to know more about the relevant information, please contact our company or its representative office.
- When in doubt about the integrity of the external grounding of the monitor and its arrangement, the internal battery must be used for operation.
- The parts and accessories for this device must be recommended or approved by MDKMed.
- If sustained a severe impact or drop,the device should not be used until it has been checked by trained Technical staff.
- Fix the monitor in a horizontal and secured position before and during operation.

- Be careful when placing the power cords and other cables, so as to avoid clinical risks caused by amass of wires.
- Do not block the back of the device, so as to dissipate heat.
- This manual introduces the product according to the complete configurations. The product you bought may not have some configurations or functions.

1.2 Screen Display

The display of the monitor may be color or monochrome liquid crystal display. The patient parameters, waveforms, alarm messages, bed number, date, system status and error messages can be reflected from the screen.

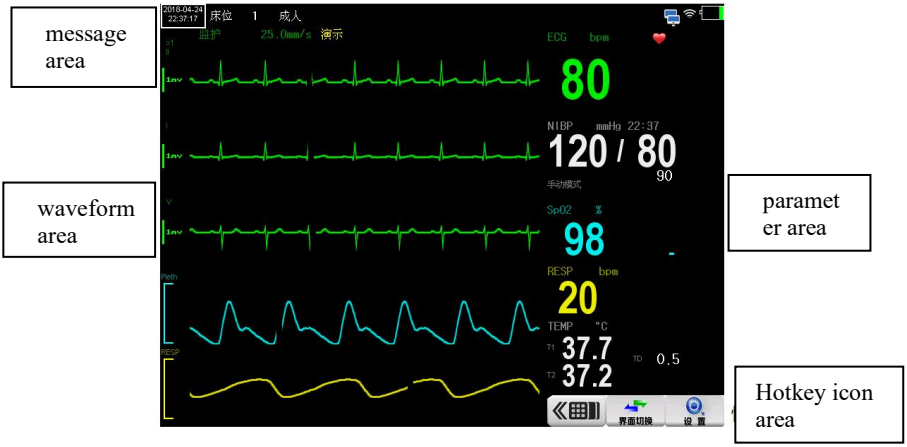


Figure 1- 1 Patient Monitor screen

Hotkey icon explain:

icon explain(from left to right):silence,print;feeze;patient information;Trend review;nibp;parameter set up; Keyboard expansion switch; screen switch; menu

1.Message Area

The message area is at top of the screen displaying operating state of the monitor and status of the patient.

The messages and their meanings are:

2.BED NO Bed number of the monitored patient

3.ADU Type of patient

4.“2006-5-13” Current date

5."13:51:32" Current time

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

- The monitor prompt information, report the status of the monitor or sensor, will

always appear at the area behind "adult".

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

 Indicates the alarm pause time mark. Long press the "alarm pause" button (more than 4 seconds) to mute the alarm, which means that all alarm sounds have been temporarily turned off. The system will not resume the sound until press the "alarm pause" button to manually turn off alarm pause or the alarm pause time is over. The alarm pause time can be set to "1 minute" or "2 minutes".

 Indicates that the alarm volume is off. Indicates that the sound notification function of the alarm has been artificially and permanently turned off. Until the operator removes the setting of alarm volume off.

 Indicates alarm reset.

 Indicates that the system is in an alarm off state.

Attention

When "  **" mark appears, the system can not give the audio alarm prompt. Therefore, the operator should** use this function with caution**.**

Parameter alarm message is displayed at the right most area.

"FREEZE" appears when the waveforms are frozen.

■ The "———" indicates that the monitored parameters are invalid.

Waveform/Menu Area

1.five waveforms can be displayed at the same time. The waveforms from top to bottom are: ECG I, ECG II, SpO2 Plethysmogram, RESP (possibly coming from ECG module). Waveforms to be displayed are user-selectable. Refer to **Tracing Waveforms Selection** for details.

2.The names of the waveforms are to their left. Gain and filter of this ECG channel are displayed as well. A 1mv scale is marked on the left of ECG waveform. The same menu always appears at a fixed area on the screen. When the menu is displayed, some waveforms become invisible. The size of the menu is also fixed, covering the lowest 2, 3 or 4 waveforms.

3.The waveforms are refreshed in a user-set rate. Refer to the related chapters for details of sweep speed..

Parameter Area

Parameters are displayed at a fixed position.

1.ECG Heart Rate (Unit: bpm) ST-segment analysis of Channel 1 & 2 (Unit: mv)
2.NIBP (From left to right) Systolic, Mean, Diastolic (Unit: mmHg or kPa)
3.SpO2 SpO2 (Unit: %)
4.RESP Respiration Rate (Unit: breath/min)
5.TEMP Temperature (Unit:℃)

The above monitoring results are displayed in the Parameter Area.

The parameters refresh every second, except that NIBP values refresh each time the measurement is over.

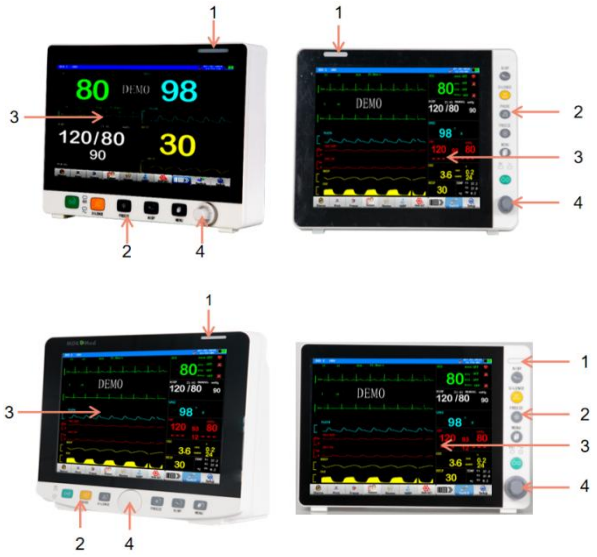
User can select the monitor parameters, and the screen display will change accordingly.

Alarm indicator:

In normal mode, no indicator on.

When an alarm occurs, the alarm light flashes or keeps 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 content of each parameter in the relevant chapters.

1.3 Front view



Functional description:1.alarm indication 2.Parameter and waveform display area 3.Indicator light and function button area 4.Encoder

Chapter 2 Installation

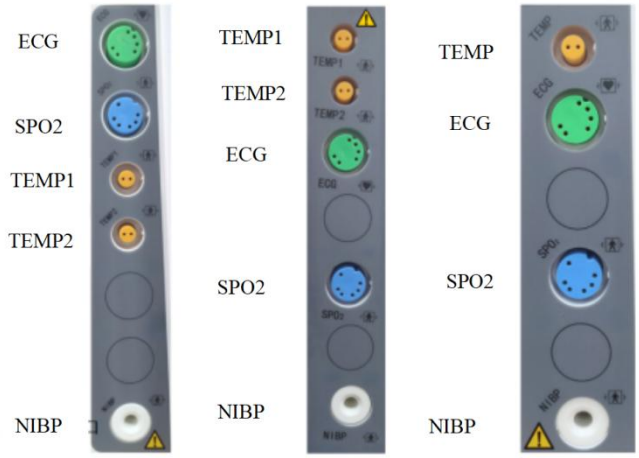
2.1 Button functions and basic operations

The operation on the monitor can be done through the buttons and knobs. As shown in the following table:

	Long press for 3 seconds to turn on or off		Battery status indicator: the light is always on when charging, the light is off when the battery is full, and the light is flashing when the battery is working
	AC indicator:light on when connect to AC power		inflating the cuff and start blood pressure measurement.. During the measurement, press the button to stop and vent.
	Press to enter freeze mode(graphics stay still for easier read waveform and patient data),repress the button,graphica come back to normal.		Pop up the main menu, users can choose to set up various system information from the main menu and perform corresponding operations. Press this key again to return back to the home screen
	This key can be used as a multiplexing key (only for KM series). Short press this key (< 2s) to enter the alarm pause state, long press this key (≥2s) to enter the alarm mute state.		Attention, refer to operation instruction.
	This key is the alarm mute button. Press this key to perform the alarm mute function and block all sounds (such as alarm sound, heartbeat sound and pulse sound)., meanwhile, a“  ”symbol will be shown on interface, repress the button to restore and the symbol “  ” will disappear		
	1. Can pause for 2mins(optional for“1min”.“2min”),during the pause, there will be a “  ”symbol on interface. 2. When the alarm type is set to latch, this key will perform the alarm reset function, and long press this key to pause the alarm.		
Encoder	The knob is able to turn forwards and backwards to change the cursor position, select the menu, press the control button to enter the corresponding menu and modify the current setting. The rectangular symbol on the screen that moves when turn forward or backward of the knob, is the cursor. You can edit settings wherever the cursor appear.		

2.2 External Interfaces

Different parameter external interface 1

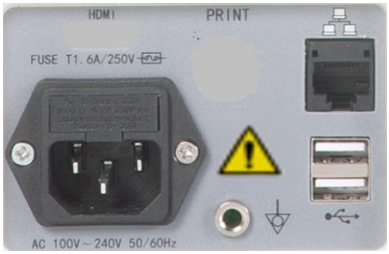


KM/KB/KP Series ECG:ECG socket SPO2:SPO2 probe socket
NIBP:cuff socket TEMP:Temperature probe socket

Specifications for the sockets on rear panel:

7./8./10inch device DC/NET/USB connector

12.1/15inch device USB/NET connector



13.3/15.6inch device AC\\NET\USB connector

16 inch device AC connector

12.1/15inch device AC connector

19/22 inch device AC connector

(1) AC:AC power, 100V-240VAC, 50Hz/60Hz;
(2) HDMI:external display,capable for HDMI monitor.
(3) NET:network interface,connect to our central monitor system through a cable with with RJ45connector
(4) Equipotential earthing terminal
(5) Fuse,standard T 1.6AL/250V fuse.
(6) USB: can connect to USB flash disk,or scanners/card readers with USB connector
(7) DC: External power adapter 10—15V\2A (KM series) or DC power source (KB/ KP series).

Warning

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for MEDICAL INSTRUMENT equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input or output port configures a MEDICAL INSTRUMENT system, will be responsible to ensure that the system complies with the requirements of the valid version of the standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

2.3 Built-in Battery

The monitor is equipped with a replaceable lithium ion rechargeable battery.

When operating on battery power, the monitor will alarm when the battery is low. When the battery is about to run out, the monitor will trigger an advanced alarm that emits a continuous beep. Andpop up " Battery voltage is low "in the message area. At this point, plug in the AC power supply and recharge the battery immediately. If still use battery power, the monitor will automatically disconnect before running out of power (approximately 10 minutes after the alarm).

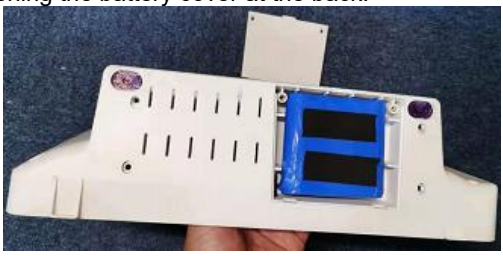
Battery status indicator: when the network is connected to POE and no battery is installed, the AC light will keep on and the POWER light is off. When the battery is charging, the AC light and the POWER light keeps on. After the battery is full, the POWER indicator light will be off. When the battery supplies POWER to the device, the

AC indicator is off and the POWER indicator blinks.

The warranty of the battery is 1 year. You need to charge and discharge the battery every three months. Otherwise, the battery life will be severely shortened. Usually,battery damage or life time decline were caused due to manufacturer inventory - logistics inventory - dealer inventory - customer inventory.

KB12/15 has a built-in 14.8V/2200mAH 18650 lithium ion battery, which can be removed and replaced by opening the battery cover at the back.

KM8/10 has a built-in 7.4V 4400mAH 21700 lithium ion battery, which can be removed and replaced by opening the battery cover at the back.



KP13/15 has a built-in 14.8V/2200mAH 18650 lithium ion battery, which can be removed and replaced by opening the battery cover at the bottom.

Warning

Don't pull off battery when the monitor is working.

When operating on battery, the monitor will prompt alarm automatically when the energy is low. When the battery runs out, the monitor will trigger an advanced alarm with a continuous "beep..." and display "BATTERY TOO LOW" in the Message Area. Connect

the monitor to AC power to recharge the battery immediately. If keep operating on the battery, the monitor will shut off automatically (about 10 minutes since alarming) upon exhaustion of the battery.

There is battery status light on device: when AC light on and power light off, it indicates that currently is using A.C. power supply, and no battery was installed; when charging battery, you will see both A.C. light and power light on; when battery fully charged, power light off; when operating only using battery power, you will find A.C. light off, power light flash.

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.

2.4 Open the Package and Check

Open the package and take out the monitor and accessories carefully, if there's any damage, contact with the transportation company immediately. Keep the package as possible for future transportation or storage. Check the components according to the packing list.

- Check for any mechanical damage.
- Check all the cables, modules and accessories.

When installing, leave at least 2 inches (5 cm) of space around the monitor to ensure air circulation. The operation environment should avoid vibration, dust, corrosive or explosive gas, extreme temperature and humidity, etc.

If there is any problem, contact the distributor immediately.

When device was transferred from one place to another, there might be condensation due to differences in temperature or humidity. At this moment, must wait until the condensation disappear before use.

⚠ Warning

Packaging materials may cause pollution to the environment. When dealing with the packaging materials, you must comply with the relevant local regulations or the hospital's waste disposal policies. Please keep packaging materials away from children.

The device might be contaminated by microorganism during storage, transportation and use. Please confirm whether the package is in good condition before use, especially for the disposable accessories. If found the package damaged, please do not use.

2.5 Connect the Power Cables

Connection procedure of the AC power line:

(1) Make sure the AC power supply complies with following specification: 100~250 VAC, 50/60 Hz.

(2) Apply the power line provided with the monitor. Plug the power line to INPUT interface of the monitor. Connect the other end of the power line to a grounded 3-phase power output.

⚠ NOTE

1.Connect the power line to the jack special for hospital usage, if uncertain about grounding, use battery power.

2.Make sure that the POWER lamp now lights. If it does not light, check your local power supply. If the problem still exists, contact the local Customer Service Center.

3.The battery need to be charged after transportation or storage. If the power supply is not properly connected before turning on the monitor, it may not work properly because of insufficient power. Connect the power supply to charge the battery.

4.When the power supply is cut off for more than 30 seconds, the monitor will switch to internal power supply, and all alarm limit Settings and other related parameter Settings are the same as the one before power off.

2.6 Power on the Monitor

Press POWER for 3 seconds to power on the monitor, and our logo or model will appear within about 2 seconds latter. Then a beep will be heard and at the same time the indicator will flash in yellow and red alternately. After 10 seconds or so, the system will enter monitoring screen after self-test, and you can perform normal monitoring now.
During self-test, the software version will display.

NOTE

1.If the monitor finds any fatal error during self-test, it will alarm.
2.Check all the functions that might be used to monitor and make sure that the monitor is in good status.
3.The battery must be recharged fully after each use to ensure adequate electricity reserve.
4.The interval between twice press of POWER should be more than 1 minute.

Warning

If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical INSTRUMENT engineer in the hospital or Customer Service Center immediately.

2.7 Connect Patient Sensors

Connect all the necessary patient sensors between the monitor and the patient.

2.8 Start to monitor

1.Identify which monitoring mode is needed.
2.Check if patient cable and sensor are correct type.
3.Connect patient cable and sensor.
4.Enter the monitoring mode to be used and check if the parameter settings and alarm settings meet current needs.details about different parameter setup and system setup, please refer to other relevant chapters.

Chapter 3 System Menu

Monitor features flexible configurations. You can configure various aspects of the monitor, including the parameters to be monitored, sweeping speed of the waveforms, audio signal volume, and printout text.
Press the “MENU” hot key on the lower right part of the screen to call up “SYSTEM MENU”. The configuration is realized through operations on the SYSTEM MENU, as shown below.

Figure 3- 1 SYSTEM MAIN MENU

3.1 Patient Information Setup

NOTE

To erase present patient data, refer to the section of New Patient Enrolment for details.

Pick "PATIENTINFORMATION" in SYSTEM MENU to call up the following menu.

You can setup the following patient record: Figure 3- 2 PATIENT SETUP

BED NO	Patient bed number (Range: 1-200)
PACE	Pace ON or OFF(the function is not available for this device)
SEX	Patient gender (Available options: "F" for Female, "M" for Male)
TYPE	Patient type (Available options: ADU, PED, and NEO)
UPDATE PATIENT	Admission of new patient

Also in this menu, the user may select “UPDATE PATIENT” item to access “CONFIRM TO UPDATE PATIENT” dialog box as shown below, in which the user decide whether to monitor a new patient. Figure 3- 3

Figure 3-2 PATIENT SETUP

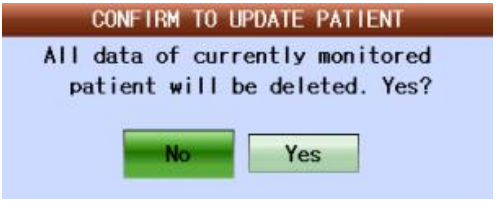


Figure 3-3 UPDATE PATIENT

Select "Yes", delete all information about the patient under your care, and exit the menu.
Select "No" to continue saving patient information, and exit the menu.

Note

Selecting "YES" will delete all information about the currently monitored patient.

3.2 Default Setup

In this sub-menu, the user can select the factory default and the user-defined default. Also in this sub-menu, the user can save the current system configuration as a user-defined default configuration. But at this time, the former user-defined configuration will be replaced by the current one.

To restore all settings of parameter menu and the ECG lead, gain, and filter to default settings, select the desired default, and pick EXIT to call up the following menu: Figure 3-4 CONFIRM SAVE DEFAULT CONFIG

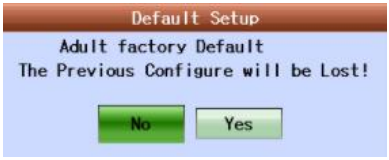


Figure 3-4 CONFIRM SAVE DEFAULT CONFIG

Select YES to erase stored record of the previous patient and exit the menu.
Select NO to refuse the new patient and keep the previous information and exit the menu.

NOTE

After selecting "EXIT" item, the "CONFIRM SAVE DEFAULT CONFIG" dialog box will pop up, in which the user may choose YES to confirm the selection or NO to give up the selection.

3.3 Review Function

Select Review in the SYSTEM MENU, as shown in the figure below. Figure 3-5 review

Figure 3-5 REVIEW

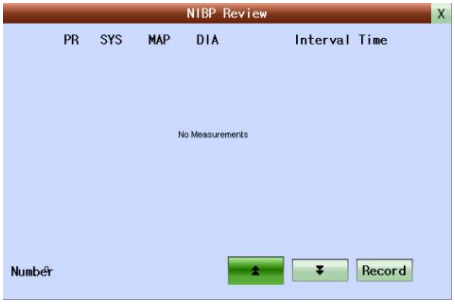


Figure 3-6 NIBP REVIEW

3.3.1 NIBP Review

The monitor can review the latest 1000 NIBP measurement data.

Pick NIBP **Review** in the SYSTEM MENU to invoke the result and time of the latest 10 measurements, as shown in the figure below. Figure 3-6 NIBP **Review**

Data is listed chronologically from the latest to the earliest. 10 measurements can be displayed in one screen. Pick UP-DOWN to view other trend curve up to 1000 results. Pick REC to print out all measurement data of NIBP **Review**.

3.3.2 Alarms review

Can review about 1000 records of recent alarms, and review alarm parameters and waveform.

3.3.3 Trend graph review

■ can display the latest 2-hour trend graph in increment of one data every second or every 5 seconds;

■ can display the latest 360-hour trend graph in increment of one data every minute or every 5 minutes or 10 minutes.

Select “trend graph display”in the menu, you will see the below window:

Figure 3-7 trend graph display

vertical axis indicates the measurement value, horizontal axis indicates measurement time, the symbol“↓”is trend graph cursor,the measured data of the position indicated by the cursor was shown below the graph,while the measurement time was shown above the graph. All the trends are displayed as continuous curve(expect for NIBP).On NIBP trend graph,”SYS”is for Systolic blood pressure; and “DIA” is for diastolic blood pressure, “MAP” is for mean blood pressure.

Select different parameters for trend graph display:
Select option for “parameter selection”, press the knob when it appears the exact parameter you want, you will see the relevant trend graph then.

Select 1-hour or 360-hour trend:
Select option for “Resolution”, if want to review trend graph within 1-hour, select resolution 1second or 5 seconds; if want to review trend graph within 96-hour, select resolution 1minute or 5 minutes or 10 minutes.

To review trend graph even more earlier or latter:
If there’s an“→”,press the “right”button,turn the knob clockwise, to review the latter graph, and if there’s “←”,press the “left”button,turn the knob anti-clockwise, to review earlier graph.

To revise display scale:
Use the "Adjust Amplitude" button to revise the vertical scale and the trend curve scale will change accordingly. the data greater than the maximum will be represented using the maximum data.

How to get exact data for a specific moment on current trend graph:
Select the cursor, and turn the knob left or right, the cursor will move accordingly, time changes too, the data will be shown below the horizontal axis. If there’s “→ ”on right side of the screen, when cursor move to this position,the trend graph will automatically come to next page; while if there’s “←”on the left side of screen, when cursor move to this position,the trend graph will automatically come to a former page, so you can see the earlier trend graph then.

Operation examples:
To review NIBP trend graph for past 1-hour:
- press“menu”button,then press“system menu”;
- select“review”option,then select“trend graph review”;
- select parameter:select“parameter selection”option,turn the knob,until there is“NIBP”:
- select“resolution”option, can select “1 second”or“5 seconds”;
- select“left & right”,turn the knob,check the change on time and trend curve;
- stop when it comes to the time period you want to recheck, can revise the display scale to see more clearly. (by press the “adjust amplitude” button)
- if want to know exact data for a specific moment on current trend graph, select the cursor,move the cursor to the exact position to check, time will be shown above, and measure data will be shown at bottom.
- press “quit” to exit trend graph.

3.3.4 Trend table review

■ recent 360-hour trend table can be shown with resolution 1 minute, 5 minutes, 10 minutes, 30 minutes, 60 minutes.

Press “system menu”and then press “trend table review”, you will see below interface:

Figure 3-8 trend table setup menu

The time relevant to each group of trend data is displayed in the left side of column, with the date in parentheses.The event column will show the events have been marked, which corresponds to the time marked the event. The parameters in the trend table can be divided into 10 groups as below: HR.SPO2.PR.SYS.MAP.DIA.RR.T1.T2.TD
The display of NIBP trend data has its particularity.Beside the measured value, time for NIBP measurement is also displayed under "Measuring Point". If there are multiple measured values during this time period, only one value can be displayed on screen,others will be displayed at "MORE" with a "*" means there are two or more measurement results.

How to review trend table with different resolution:

Select cursor, then select “resolution”, turn the knob to revise the option, then select different time interval.

To review trend table even more earlier or latter::

If there’s an“ ⏫ ”,press the “upper”button,turn the knob clockwise, to review the latter table, and if there’s “ ⏬ ”,press the “down”button,turn the knob anti-clockwise, to review earlier table.

Select different parameters for trend table:

Select “left & right”, can review one of the parameters among the 14 of them.there’s “▶”on the right side of the parameter, which means can come to the right page; there’s “◀”on the left side of the parameter, which means can come to the left page.

3.4 Monitor Information

Select the [Monitor information] item in “monitor maintenance” to know more info about the monitor. Figure 3-9 version

Figure 3-9 monitor information

3.5 Monitor Set

Select the [MONITOR SETUP] item in the “Main Menu” to see below Figure 3-10 Monitor Setup

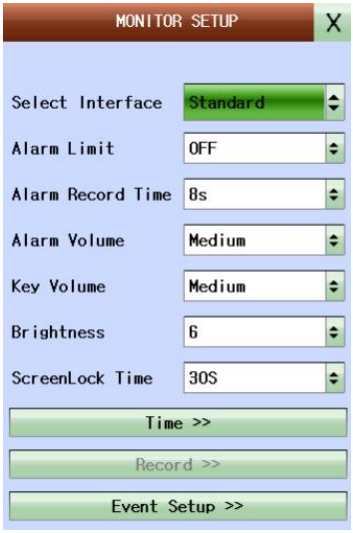


Figure 3-10 monitor setup

Through "Monitor Set Up" menu, user can set the following parameters:

3.5.1 Interface selection:

In “interface select”, user can choose the interface wanted, standard interface was set as default.

3.5.2 Alarm Limit

The system can display and setup the alarm limit. The method is:

Select “alarm limit” in “monitor setup” menu, can select ”on” or “off” accordingly. when

select “on”, there will be a range of alarm limit display together with the parameter on screen; while if select “off”, will only display the parameter, no alarm limit range.

3.5.3 Alarm Record time

Select “Alarm Rec Time” in “monitor setup”, turn the knob to adjust the time setting.

Three options available: 8secs, 16 secs, 32 secs.

The system may record the information prior to and after the occurring of alarm if physiological alarm occurs. Three recording time is provided: 8s, 16s and 32s, which are the total length of the time prior to and after the alarm. For example, 8s contains the respective information of 4s before and after the alarm. 16s contains the respective information of 8s before and after the alarm, etc.

The user may select different recording time based on clinical requirement. The method is listed below;

Select “ALARM SETUP” in “MONITOR SETUP” to access the sub-menu of “ALARM SETUP”. In the “ALARM REC TIME” item, the user may choose the length of alarm record. There are three options for user to select: 8s, 16s or 32s.

3.5.4 alarm pause time

Select “Alarm Pause Time” in “monitor setup”, turn the knob to adjust the time for pause. There will be no alarms during the period selected. Three options to choose: 1 min, 2 mins, 3mins.

3.5.5 parameter alarm form setup

Select “customer maintenance” in “system maintain”, enter pass word, select “parameter alarm form” turn the knob to select “alarm latch” “non-latch”.

3.5.6 alarm volume setup

Select “ alarm volume” in “monitor setup”, turn the knob, can adjust the alarm volume. There are 4 options: “low”, “medium”, “high”, “off”,, Note: option ”off” means mute.

⚠ Warning

When alarm volume select”off”, when alarm triggered, there will be no alarm sounds. So please operate with caution.

When under mute mode or alarm pause, select alarm volume “off”, system will automatically end mute mode and alarm pause.

When alarm volume = “0”, select “mute”or “alarm pause”, system will recover to the volume before turn off, meanwhile, system will enter mute mode or alarm pause.

⚠ Note

The setup in “alarm volume” is still valid the next time when device is turn on. Please make sure to check the settings before use, so as to avoid delaying patient’s treatment caused by low alarm sound or silence.

3.5.7 Time Setup

Select “TIME SETUP” item in “MONITOR SETUP” menu to access the sub-menu of “TIME SETUP” as shown below. System time is in format of year, month, day, hour, minute and second. Pick the item you wish to modify and turn the knob, the figure will increase or decrease by 1 at each switch. Then select “EXIT” item to return to the previous menu.

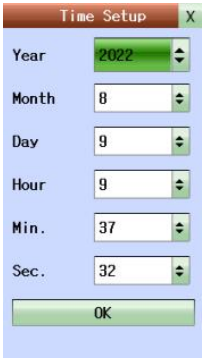


Figure 3-11 time setup

Figure 3-12 enter pass word

Note

It is better to setup time when turn on the device(in case user want),otherwise there might be incorrect time when review parameters concerning a certain time period.

3.5.8 Mark Event

In “system setup”, select “event setup” to mark event.

3.6 Maintenance

Select “MAINTAIN” item in “SYSTEM MENU” access “ENTER MAINTAIN PASSWORD” dialog box as shown above, in which the user may enter password and set up the user-defined maintenance settings. The user may not execute the factory maintenance function, which is only available for appointed personnel of the Company. Enter pass word: 2016 to access “user maintain”, see below picture: figure 3-13 user maintenance.

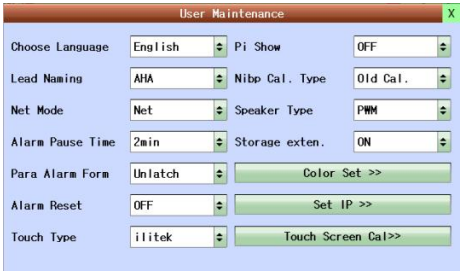


Figure 3-13 user maintenance

Figure 3-14 color custom

- LANUGAGE: two selections are available:CHINESE and ENGLISH.
- LEAD: refers to the net No.
- COLOR custom: is used by the user to define the color of the waveform displayed on the screen. Five colors can be chosen from green, cyan, red, yellow and white. Figure 3-14 COLOR custom

3.7 DEMO function

Select the [DEMO] item in the “SYSTEM MENU”,to call up the “ENTER DEMO

PASSWORD" dialog, then enter "5188". After entering the password, the system enters DEMO status. Figure 3-15 Input Demo Key

Figure 3-15 Input Demo Key

The purpose of waveform demonstration is only to demonstrate the machine performance, and for training purpose. In clinical application, this function is not forbidden because the DEMO will mislead the MEDICAL INSTRUMENT staff to treat the DEMO waveform and parameter as the actual data of the patient, which may result in the delay of treatment or mistreatment. Therefore before entering this menu, you shall enter password.

3.8 Alarm setup

Figure 3-16 Alarm setup

To set up alarm limit and levels for different parameters. Pass word "2016" is required for safety concern. See above Figure 3-16 Alarm setup

3.9 Parameters setup

Figure 3-17 Parameter setup

Set ECG.RESP.TEMP.SPO2.NIBP parameters through “system menu” or keyboard shortcut, see above Figure 3-17 Parameter setup.

3.10 Internet setup

1、 When the monitor require wired or wireless networking like program upgrade or other related operations, will need to set up network for this device and make sure other devices can find or connect to it.

2、 Setup method:setup — maintain — enter pass word: 2016 — confirm — set IP address, you will see below interface, can revise the number by touchscreen or cursor.see below Figure 3-18 IP setup

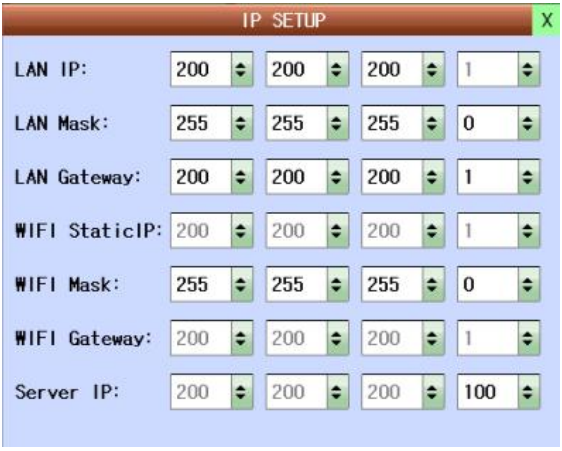


Figure 3-18 IP setup

Chapter 4 Patient Safety

The monitor is designed to comply with the International ~~National~~ Safety requirements IEC 60601-1, EN 60601-1, IEC60601-2-27, EN 60601-2-27, EN IEC 80601-2-30:2019 for MEDICAL INSTRUMENT electrical equipment. This device has floating ground inputs and is protected against the effects of defibrillation and electrosurgery. If the correct electrodes are used and applied in accordance with the manufacturer instructions, the screen display will recover within 10 seconds after defibrillation.

This symbol indicates that the instrument is IEC 60601-1/EC60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.

Warning

Do not touch the patient, bed or instrument during defibrillation.

Environment

1.Follow the instructions below to ensure a completely safe electrical installation. The environment where the Monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

2.The monitor operates within specifications at ambient temperatures between 5℃ and 40℃. Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5cm) space around the instrument for proper air circulation.

Grounding the Monitor

To protect the patient and hospital personnel, the cabinet of the monitor must be grounded. Accordingly, the monitor is equipped with a detachable 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electrician. If completeness of the protective grounding wire is in doubt, the equipment must be operated with internal power supply.

Warning

Do not use a 3-wire to 2-wire adapter with this instrument.

Connect the grounding wire to the equipotential grounding terminal on the main system. If it is not evident from the instrument specifications whether a particular instrument combination is hazardous or not, for example due to summation of leakage currents, the user should consult the manufacturers concerned or else an expert in the field, to ensure that the necessary safety of all instruments concerned will not be impaired by the proposed combination.

Equipotential Grounding

Protection class 1 instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug.

For internal examinations on the heart or the brain, the monitor must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the instrument rear panel and the other end to one point of the equipotential grounding system. The equipotential grounding system assumes the safety function of the protective grounding conductor if ever there is a break in the protective grounding system. Examinations in or on the heart (or brain) should only be carried out in MEDICAL INSTRUMENTly used rooms incorporating an equipotential grounding system. Check each time before use that the instrument is in perfect working order. The cable connecting the patient to the instrument must be free of electrolyte.

Warning

1.If the protective grounding (protective earth) system is unstable, the monitor must be supplied by internal power only.

Condensation

Make sure that during operation, the instrument is free of condensation. Condensation can form when equipment is moved from one building to another, because of being exposed to moisture and differences in temperature.

2.Possible explosion hazard if used in the presence of flammable anesthetics.

Explanation of Symbols used on the Monitor

 1.This symbol means 'BE CAREFUL '. Refer to this manual.

 2.this symbol indicates that the instrument is IEC 60601-1/EC60601-1 Type CF equipment. an F-Type floating ground isolater was equiped especially for permissible leakage current, and is resistant to defibrillation.

 3.this symbol indicates that the instrument is IEC 60601-1/EC60601-1Type BF equipment. It is designed with special anti-defibrillation device (an F-type floating-ground isolator is equipped, especially for permissible leakage current), and is suitable for use during defibrillation.

Please refer to the preface for descriptions of other security matters.

Chapter 5 Maintenance / Cleaning

5.1 System Check

Before using the monitor, do the following inspection:

(1) check if there is any mechanical damage;

(2) check all the outer cables, inserted modules and accessories;

(3) check all the functions of the monitor to make sure that the device is in good condition.

(4) If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical INSTRUMENT engineer of the hospital or our Customer Service immediately.

(5) Do overall check of the monitor, including the safety check, which must be performed only by qualified personnel once every 6 to 12 month, and each time after maintenance.

You should check the synchronism of the defibrillator in the frequency described in the hospital regulations. At least every 3 months, it should be checked by a qualified customer service technician.

Warning

·If the hospital or agency that is responding to using the monitor does not follow a satisfactory maintenance on schedule, the monitor may become invalid, and the patient health may be endangered.

·Refer only to our service technician when concerning the battery replacement .

·All the checks that need to dismantling the monitor should be performed by qualified customer service technician. The safety and maintenance check can be conducted by persons from our company. You can obtain the material about the customer service contract from the local office.

·Turn off the device, remove the battery, disconnect the power source when doing disinfection or cleaning.

·If there is problem with the device, for example, if the device is affected by unexpected moisture, contact the maintenance personnel or the manufacturer.

Note

· If the accessories (such as ECG cable, oxygen probe and temperature probe) are damaged or deteriorated, they are prohibited to be used again. Please replace with our original accessories in time.

·If found the non invasive blood pressure cuff and extension tube , please replace in time.

·If the accessories are dirty, please clean and disinfect them in time.

·When disinfecting or cleaning the device or its accessories, the connectors and device shall not dip into the liquid, the liquid on surface shall be cleaned after cleaning or disinfecting.

·All the disposable accessories shall not be reused. After the use of disposable accessories, please recycle and scrap them according to the specifications.

·For different types of patients, please use the appropriate specifications of the accessories.

5.2 General Cleaning

The Monitor must be kept dust-free.

Regulatory cleaning of the monitor shell and the screen is strongly recommended. Use only non-caustic detergents such as soap and water to clean the monitor shell.

5.3 Cleaning Agents

Examples of disinfectants that can be used on the instrument casing are listed below:

■ Diluted Sodium hypochlorite (Bleaching agent).

Concentration ranging from about 500 parts per million (1:100 diluted

household bleach) of sodium hypochlorite to 5,000 parts per million (1:10 diluted household bleach) are effective, it depends on how much organic matter (blood, animal and plant mucus) is present on the surface.

■ Diluted formaldehyde 35-37% , hydrogen peroxide 3%, 70% ethanol, 70% isopropanol, diluted ammonia acetaldehyde

Note

Please pay special attention to the following items:

1. **Avoid using strong solvents such as acetone.**
2. **Most cleaning agents must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.**
3. **Don't use abrasive material to clean, such as steel wool etc.**
4. **Don't let the cleaning agent get into the chassis of the system, or leave the cleaning agents at any part of the device or accessories or connectors.**
5. **Don't clean or disinfect the accessories by soaking in high temperature, high pressure or liquid environment.**

5.4 Disinfection

You can disinfect the defibrillation monitor according to hospital's disinfection procedures. The defibrillation monitor should be cleaned before disinfection.

a.ECG lead

1)Do not connect the lead wire to the monitor when cleaning or disinfecting;

2)Clean or disinfect before using for new patients;

3)Use 70% isopropanol or alcohol to clean the surface of the ECG electrodes.

4)When cleaning, first dip a clean, dry sponge pad in the cleaning liquid. Wipe the surfaces of electrodes and cables with this sponge pad; dip another clean, dry sponge pad in sterile or distilled water. Wipe the surfaces of electrodes and cables with this sponge pad; then wipe the surfaces of the electrode and cable dry with a clean, dry sponge pad at last;

5)Caution:Do not touch the cleaning solution with the pins at the connection end, or it will cause damage to the monitoring instrument and the patient.

b. Blood pressure cuff

1) Prepare enzyme cleaners (for example, ENZOL produced in the USA or Cidezyme enzyme cleaners in the UK) and 10% bleach agents in separate spray bottles.

2) Spray the cleaner evenly on sleeves, piping and hoses. If the dirt is dry, leave the cleaner on the cleaning surface for one minute.

3) Wipe the surface with a dust-free cloth, clean the visible stains or irregular surface with a soft brush and rinsing 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 the excess solution and rinse with distilled water again, and let the sleeve air dry naturally.

c. SPO2 sensor

1 For SPO2 probe from APK Technology Co., Ltd. , we suggest:

1)Do not connect the probe to the monitor when cleaning or disinfecting.

2)Disinfect the probe before use.

3)Clean the probe and patient contact surface using a soft medical cloth dipped in medical cleaning solution to wipe.

4)To disinfect the probe, wipe the probe and patient contact surfaces using a disinfectant solution for at least 1 minute. We recommend 75% isopropyl alcohol as the disinfectant solution.
5)The probe can withstand 200 times of cleaning and disinfection.
6)Do not do your own cleaning and disinfection, you must let the medical staff to do it.
2 For SPO2 probe from Shenzhen SINO-K Medical Technology Co., Ltd , we suggest:
1)Do not connect the probe to the monitor when cleaning or disinfecting;
2)Clean or disinfect before using on new patients;
3)Clean the surface of the sensor with 75% alcohol. Never use undiluted bleach solution (5% to 5.25% sodium hypochlorite) or any cleaning solution other than the recommended solution, as this may cause permanent damage to the sensor.
4)To clean, first dip a clean, dry sponge pad in cleaning solution. Wipe all surfaces of the sensor and cable with this sponge pad; then dip another clean, dry sponge pad in sterile or distilled water. Wipe all surfaces of the sensor and cable with this sponge pad; finally, dry all surfaces of the sensor and cable with a clean, dry sponge pad.
Note:The connector end pins must not touch the cleaning fluid, otherwise it will cause permanent damage to the sensor and blood oxygen instrument.
d. TEMP probe
Before use, it shall be disinfected by the hospital or the users. Disinfectants commonly used in the hospital (such as ethanol, isopropanol, etc.) can be used to wipe the probe and the wire that in contact with the human body: firstly, wipe it with a medical alcohol tampons, and then soak it in 75% ethanol for more than 5 minutes.

⚠ **Caution**

Do not use EtO gas or formaldehyde to disinfect the monitor.

5.5 Sterilization

Sterilization is not permitted to the defibrillation monitor, related products or accessories, unless it is stated separately in the accompanying manual.

5.6 maintenance

In order to make sure that the monitor is available at any time, it is necessary to carry out routine maintenance, which includes the following inspection aspects:
1.inspection during shift change 2.automatic self-inspection 3.user inspection 4.recorder inspection 5.ECG cable inspection 6.pacing inspection 7.NIBP inspection.8.NIBP Over Voltage Protection Test
ECG cable, SPO2 probe, temp probe are very important accessories for collecting bio medical information, and are all easy to wear, so it is better to check during shift change too. The product user shall make a maintenance plan.

5.6.1 routine inspections

(1) auto self-inspection: when power on, system will do auto self-inspection, alarm light flashes yellow and red, then a "beep" sound is to say self inspection complete.
(2) ECG self inspection: Go to ECG Settings -- Other Settings -- ECG Calibration. Complete ECG self-inspection.
(3) NIBP self-inspection:there will be auto self-checking circuit when turn on the device.for other inspections, please go to NIBP setup—leakage inspection—calibration to complete NIBP self-inspection.(See detailed operation method in No. 10 NIBP chapter)
(4) SPO2 self-inspection:connect the SPO2 probe to your finger, normally the SPO2 is >96%.
(5) Temp self-inspection:there will be self-inspection when power on, if connect to

Temp. probe, will display current air temperature.

Chapter 6 Alarm

■ This chapter gives general information about the alarm and corresponding remedies.

■ Alarm setup and prompt messages are provided in respective parameter setup sections.

6.1 Overview

Alarm refers to the prompt sound, light, text and other ways made by the monitor to tell the medical staff or user that the patient has abnormal vital signs change or the machine itself fails to monitor the patient smoothly.

⚠Warning

1.In any single area(such as an intensive care unit or cardiac operating room), different alarm presets for the same or similar devices is potentially dangerous.

2.Do not set the alarm limit exceeding the limit value, which will lead to alarm system failure.

6.2 Alarm attributes

6.2.1 Alarm type

There are 2 alarm types: If the alarm is caused by patient's physiological vital signs change: that is, the patient's physiological parameters exceed a specific range or the patient has physiological abnormalities that cannot be measured by a single physiological parameter, it is called the physiological alarm; while If the alarm is caused by the machine itself, that is, due to technical obstacles or failure of the machine itself, the alarm occurs when the patient cannot be monitored accurately, it is called a technical alarm.

Notes:The monitor displays a number of reminders related to the status of the system, which are generally not related to the patient's vital signs.Strictly speaking, reminders are not alarms. These reminders will be displayed at bottom of the screen in a reminder information area. And some treatment reminders will be displayed in a particular treatment information area on screen.

6-1examples for technical alarm and physiological alarm

Patient or device condition	Alarm type
Patient's heart rate is 114bpm, exceeded the alarm rate range	physiological alarm
ECG measurement modular detected ECG lead fall off	Technical alarm
SPO2 measurement modular failure	Technical alarm

6.2.1.1 Physiological alarm type

There are 2 types in physiological alarm, one is patient's physiological parameters exceed a specific range, another is patient has physiological abnormalities that cannot be measured by a single physiological parameter.

The latter physiological alarm type can temporarily shield the former one, specified as below:

ECG signal too weak;cardiac arrest;no perceptible pulse;RESP cardiac

disturbance;RESP asphyxia;others all belong to former type of physiological alarm.

6.2.1.2 Alarm Level

Alarms are classified into three categories, which are physiological alarm, technical alarm and general alarm. Physiological alarm refer to those alarms triggered by patient's physiological situation which could be considered dangerous to his or her life, such as heart rate (HR) exceeding alarm limit (parameter alarms). Technical alarm refer to system failure which can make certain monitoring process technically impossible or make monitoring result unbelievable. Technical alarm is also called System Error Message. General alarm belongs to those situations that can not be categorized into these two cases but still need to pay some attention.

has preset the alarm level for the parameters. You can also modify the alarm level using the method described in this chapter.

Alarm level of the System Error Message (technical alarm) is pre-set in the system.

All technical alarm level and general alarm level, some of the physiological alarm level are pre-set in the system and can not be changed by user.

Each alarm, either technical or physiological, has its own level. For alarm of higher level, when it occurs, the system will give prompt in a more alert way. Some alarm's level can be set by the user via software. Others can not by changed once defined by the system.

Alarms are divided into three levels, that is, high, medium and low.

High-level alarm indicates the patient's life is in danger or the monitor under using has serious problem in technical respect. It is the most serious alarm.

Medium-level alarm means serious warning.

Low-level alarm is a general warning.

	Physiological alarm	**Technical alarm**
High level alarm	Patient is in a critical and possibly life-threatening condition and should be resuscitated immediately.	Severe machine malfunctions or misoperation may fail to monitor patient's critical condition or result in treatment failure, putting the patient's life at risk. Such as low battery.
Medium Level alarm	patient's physiological signs are abnormal, appropriate measures or treatment should be taken immediately.	Certain machine malfunctions or misoperations may not threaten patient safety, but may also affect proper monitoring of key physiological parameters and patient treatment.
Low level alarm	Patients with abnormal physiological signs may need to take appropriate measures or treatment.	Some monitoring function may not work properly due to machine malfunction or improper operation, but it will not threaten the patient's safety.

6.3 Alarm forms

When alarm triggered, there will be different sound and light level to alarm and text alarms.

6.3.1 Characteristics of alarm sound and alarm light

6-2 Characteristics of alarm sound and alarm light for different level alarms

Alarm level	Alarm sound characteristics	Alarm light characteristics
High	Alarm sounds like“Beep-beep-beep ------beep-beep, beep-beep-beep ------beep-beep”,in every 11 seconds(counts from the start of one“beep”sound to another start of “beep”sound)	Alarm light flashes in red color, flash at high frequency
Medium	Alarm sounds like“Beep-beep-beep”, in every 25 seconds(counts from the start of one“beep”sound to another start of “beep”sound)	Alarm light flashes in yellow color, flash at low frequency
Low	Alarm sounds like “Beep-beep”,in every 25 seconds(counts from the start of one“beep”sound to another start of “beep”sound)	Alarm light always in yellow color

6.3.2 Characteristic for text alarms

Text alarm background:High level alarm:background is red,Medium level alarm & Low level alarm: background is yellow.

Character string color:expect for NIBP technical alarm area, all the string color is in black.In NIBP technical alarm area, different string colors has nothing to do with different alarm levels: for high level alarms, string color is red; and for medium and low level alarms, string color is yellow.when the measured parameter exceed the limit parameter and trigger physiological alarm, the parameter that triggers alarm will flash.

6.3.3 Alarm symbols

In addition to the above alarm forms, there will be different alarm symbols on screen,indicating different status of alarms.

 indicates all alarms were suspended

 indicates alarms were reset

 indicates alarm sound was turned off

 indicates alarm for single measurement module was turned off

When different alarms triggered at the same time, the sound and light alarm will take the highest level in current alarms as priority.

6.4 Alarm status

6.4.1 Over view

For each alarm, there are two states: trigger state, and clear state. You can only be in one state at a time.

Trigger state:when alarm occur.

Clear state:when alarm cleared.
At the beginning, all possible alarms are in the clear state. In the subsequent time, when the alarm conditions are met, the alarm enters the triggering state.
For the entire alarm system (that is, for all alarms), there are following states:
1.normal state:Refers to the state in which the alarm can carry out all prompts (including sound, light and text) when alarm triggering.
2.alarm pause state:Refers to the state when alarm triggered, but the sound and light text prompt is temporarily not carried out.
3.alarm mute state:Refers to the state when alarm triggered, alarm can carry out by light and text, but no sound alarm.
At any moment, the alarm system can only stay in one state.

6.4.2 Alarm mute state

Alarm mute state means that any audio cues from the monitor (including alarms, buttons, pulse sounds, etc.) are turned off.

6.4.3 Alarm pause state

When in alarm pause state, it can:
Disable all alarm sound and light.
Disable all physiological alarm text alarm.
Displays the time left for alarm pause in physiological alarm information area.

6.4.4 Status switching

Normal status:
1.When the monitor has both "PAUSE" and "SILENCE" keys, press "PAUSE" to enter the alarm PAUSE state, and press "SILENCE" to enter the alarm mute state. If the monitor only has the "SILENCE" button, short press the "SILENCE" button (< 2s) to enter the alarm pause state, and long press the "SILENCE" button (≥2s) to enter the alarm mute state.

Pause status:
1.When the monitor has both PAUSE and SILENCE keys, press PAUSE to enter the normal state and SILENCE to enter the silent alarm state. If the monitor only has the "SILENCE" button, short press the "SILENCE" button (< 2s) to enter the normal state, and long press the "SILENCE" button (≥2s) to enter the alarm mute state.
2.If no button were pressed when reach the alarm pause time, it will come back to normal state then.
3.During the alarm pause, if there's new technical alarm triggered, the current pause will be ended and come back to normal state.
4.During the alarm pause, if there's new physiological alarm triggered, system will stay in alarm pause state.

Alarm mute status:
1.if there's new technical alarm or physiological alarm, it will end the current alarm mute state, and come back to normal state.
2.When the monitor has both "PAUSE" and "SILENCE" keys, press "PAUSE" to enter the normal state, and press "SILENCE" to enter the normal state. If the monitor only has the "SILENCE" button, short press the "SILENCE" button (< 2s) to enter the pause state, and long press the "SILENCE" button (≥2s) to enter the normal state.

In any state:
1.in user settings, if the alarm sound was turned off, alarm sound was disabled then.
2.in user settings, if the alarm sound was turned on, means come back to normal state now.

6.5 Alarm mode

6.5.1 Over view

There are 2 modes:latch and un-latch.

Latch mode:When the alarm condition does not exist, the system still carries out the alarm, it is called latch. Only after reset the alarm system, it can no longer prompt the alarm that does not exist.

Un-latch mode:When the alarm condition does not exist, the alarm is no longer prompted, is it called un-latch.

6.5.2 Corresponding locking mode

1.all physiological alarms can work at latch mode.2.all technical alarms can only work at un-latch mode.

6.5.3 Alarm prompts after latch

When an alarm is latched (it means that the alarm has occurred before but currently the alarm is not triggered), the alarm prompts related to this alarm will change as follow:

1.measured parameter and its related alarm limit will not flash.

2.The time it was triggered last time will be showing after the alarm description.

6.5.4 Clear the latch

Clear the alarm latch, can also be called reset the alarm, users can use alarm pause function to reset the alarm.when the alarm latch was cleared, those alarms that already occurred before, but currently don't meet the condition to retrigger, will also be removed. When in the un-latch alarm mode, the alarm pause key on the keyboard module only has the function of suspending the alarm but not resetting.

6.6 Alarm Setup

The setup of the alarms can be realized in the alarm menu.

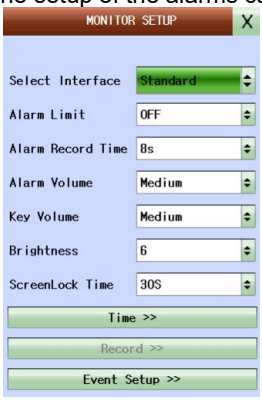


Figure 6- 1 ALARM SETUP Alarm limit

■ **COMMON ALARM SETUP**

(1) You can set the alarm high limit, alarm low limit and alarm level of each parameter in the "Alarm Setting" menu

(2) You can set alarm limit display, alarm recording time and alarm volume in the "Monitor Settings" menu

a) ALM limit display: select "on", can see the alarm limit for different parameters.

b) ALM REC TIME: which has three selections: 8S, 16S, 32S.

c) Alarm volume: Four options, respectively "low", "medium", "High" and "Off"

(3) You can set the alarm pause time and parameter alarm type in the user Maintenance menu: "Maintenance".

a) ALM PAUSE TIME: refers to the alarm suspension time span, there are two options:

1MIN, 2MIN.
b) PARA ALM TYPE: which has two selections: LATCH, UNLATCH.
c) Alarm reset: can be turned on and turned off

■ **Alarm setup of each parameter**

Alarm set up of each parameter In the corresponding parameter setting menu, select the parameter need to set in "Parameter Setting", you can set up whether to turn on or turn off the alarm and alarm record of each parameter separately.

Warning

Alarm settings shall be done 3S before power off, thus it can be successfully saved in the alarm setting.

6.6.1 Automatic alarm off

Alarm off means to disable alarm function of a single measurement module. At this time, there will be no alarms even that measurement module have met alarm condition, no alarm printing nor alarm storage.
When any of the measuring module just starts working, the moment it starts to work, all alarms related to that module will be automatically turned off within 30 seconds, but other alarms will not be affected.

6.6.2 Lead fall off when power on

When power on,if the opened parameter module doesn't connect to the lead, you can operate like below:
1.For ECG or SPO2 module,revise the lead drop alarm to a text alarm(remove its sound and light alarm), to remind the user.
2.For other modules, there's no lead drop alarm.

6.7 Parameter Alarm

The setup for parameter alarms is in their menus. In the menu for a specific parameter, you can check and set the alarm limit, alarm status. The setup is isolated from each other.

When a parameter alarm is off, a symbol  displays near the parameter. If the alarms are turned off individually, they must be turned on individually.
For the parameters whose alarm is set to ON, the alarm will be triggered when at least one of them exceeds alarm limit. And the following actions shall be taken :

1. Alarm message displays on the screen as described in alarm mode;
2. The monitor beeps in its corresponding alarm class and volume;
3. Alarm lamp flashes;

6.8 What to do when an Alarm Occurs

Warning

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

The alarm message appears at the top of the screen on the right side. It is needed to identify the alarm and act appropriately, 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. Mute the alarm, if necessary.
5. When cause of alarm has been eliminated, check that the alarm is working properly.

You will find the alarm messages for the individual parameter in their appropriate

parameter chapters of this manual.

6.9 Alarm reset

Note:we can reset alarm only when in latch mode; unlatch mode doesn't support this function.

1)alarm reset operation method:click the "silence"button(or press"PLUSE"button, if available)can reset the current occurring alarm, and a alarm reset symbol  will be displayed on screen, there will be also prompt message "Alarm reset".For the reset alarms, if no new alarm occurs, the alarm will not be displayed.

Chapter 7 ECG/RESP

7.1 Instructions for ECG monitoring

7.1.1 What Is ECG Monitoring

Monitoring the ECG produces a continuous waveform of the patient's cardiac electric activity to enable an accurate assessment of his current physiological state. Only proper connection of the ECG cables can ensure satisfactory measurement. In normal working condition, the monitor can display 3 ECG waveforms at the same time.

- Using a 5-lead set, the ECG can derive up to 3 waveforms from 3 different leads.
- The monitor displays the Heart Rate (HR), ST segment and Arrhythmia analysis(optional).
- All of the parameters above can be set as alarm parameters.

7.1.2 Precautions during ECG Monitoring

Warning

1.Do not touch the patient, table nearby, or the equipment during defibrillation.

2.Use only the original ECG cable or the recommended ECG cable for monitoring.

3.If the patient needs to do defibrillation, must use an anti-defibrillation ECG cable. Otherwise the device may be destroyed or patient might get injured.

4.When connecting the cables and electrodes, make sure no conductive part touch the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient.

5.Regularly check the skin where the ECG electrode is placed, and the electrode plate. If there are signs of allergy, replace the electrode plate or change the placement position of the electrode plate. Do not use expired electrode plate.

6.For patients with built-in pacemaker, the detection function should be turned on at the patient information and ECG Settings to ensure that the pacemaker can calculate normally. Need to pay close attention to it.

NOTE

1. Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

2. If operate in accordance with the conditions specified in EN60601-1-2(resistance to to radiation is 3v/m), radiation greater than 1 volt/m may cause measurement errors at various frequencies, so it is better not to use the device near ECG/ respiratory measurement

equipment.
3. It is better to use the same electrode plate model, and do not use expired ones.

7.2 Monitoring Procedure

7.2.1 Preparation

1. make the patient's skin prepared to placing the electrodes.

a. Our skin is a poor conductor for electricity, therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.
b. Shave hair from sites, if necessary.
c. Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).
d. Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

2. Attach clip or snap to electrodes prior to placement.
3. Put the electrodes on the patient. Before attaching, apply some electrode cream on the electrodes (or according to the electrode manufacturer's requirements.
4. Connect the electrode lead to the patient's cable.
5. Make sure the monitor is power on.

⚠ Warning ⚠

1.The electrode should be carefully placed and well connected.
2. Shall check everyday whether there is skin lesion resulted from the ECG electrodes. If so, replace electrodes every 24 hours or change their sites.
3.Verify lead fault detection prior to the start of monitoring phase. Unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm is activated.

⚠ Note

For protecting environment, the electrodes must be recycled or disposed properly.

7.2.2 Installing ECG lead

Placing the Electrodes for ECG Monitoring
Electrode placement for 5-lead set (Figure 8- 2)

- Red (R) electrode - Be placed near the right shoulder, directly below the clavicle.
- Yellow (L) electrode - Be placed near the left shoulder, directly below the clavicle.
- Black (N) electrode - Be placed on the right hypogastrium.
- Green (F) electrode - Be placed on the left hypogastrium.
- White (C) electrode - Be placed on the chest as illustrated in the F Figure 8- 3

⚠ Note: the following table gives the corresponding lead names used in Europe and America respectively. (Lead names are represented by R, L, N, F and C respectively in Europe, whose corresponding lead names in America are RA, LA, RL, LL and V.)

America		Euro	
Lead names	Color	Lead names	color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White

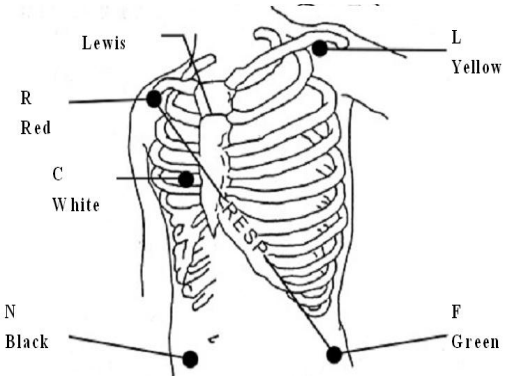


Figure 7-1 Electrode placement for 5-lead set

NOTE

To ensure patient's safety, all leads must be attached to the patient.

Warning

1.When using Electrosurgery equipment, ECG electrodes should be placed in a position with equal distance from Electrosurgery electrotome and the grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.

2.When using Electrosurgery equipment, never place an electrode near the grounding terminal of the Electrosurgery device, otherwise there will be a great deal of interference with the ECG signal.

The placing of the ECG leads depends on the type of surgery that is being performed. For example, with open chest surgery the electrodes may be placed horizontally on the side of the chest or on the back. In the operating room, artifacts can sometimes affect the ECG waveform due to the use of ES (Electrosurgery) equipment. To help reduce this you can place the electrodes on the right and left shoulders, the right and left sides near the stomach, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms, otherwise the ECG waveform will be too small.

Characteristics for standard ECG waveform:

Tall and narrow with no notches.
With tall R-wave completely above or below the baseline.
With pacer spike no higher than R-wave height.
With T-wave less than one-third of the R-wave height.
With P-wave much smaller than the T-wave.

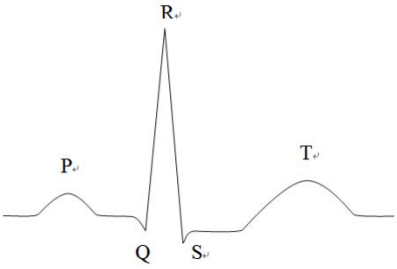


Figure 7-2 standard ECG waveform

You can calibrate the ECG using 1 mv calibrated ECG wave, pick the ECG CAL button in the ECG SETUP menu. A message "when CAL, can't monitor! " prompts on the screen.

■ Using 5-lead ECG set

The default setting is ECG CH1 corresponding to Channel II, and ECG CH2 to Channel I, you can modify the setting to meet your needs. You can set them to correspond to any two from I, II, III, AVR, AVL, AVF and V. If you set both to the same value, one of them will be adjusted to another option automatically. (Figure 8-4)

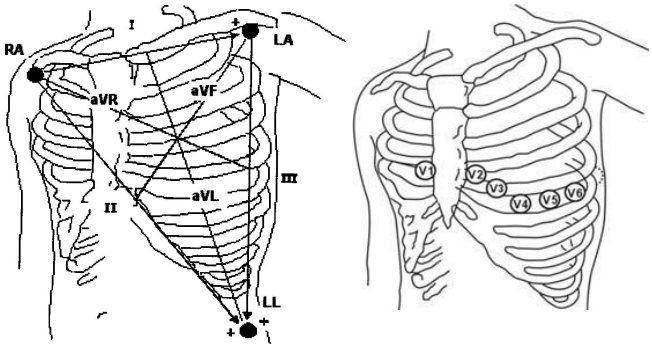


Figure 7-3 ECG lead

NOTE

1.If a ECG waveform is not accurate, while the electrodes are tightly attached, try to change the lead.

2.Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

7.3 ECG Menu

ECG SETUP Menu

Turn the knob, move the cursor to ECG hot key, press the knob, and the following menu will pop up.Figure 7-4 ECG SETUP menu

Figure 7-4 ECG SETUP menu

ECG alarm setting

- HR ALM: select "ON" to enable prompt message and data record during the ECG alarm; select"OFF" to disable the alarm function, and there will be a  beside “ECG”.
- ALM REC: select "ON" to enable report printing upon ECG alarm.

⚠NOTE

·Please set the alarm limits according to clinical condition of individual patient.
·Heart rate alarm upper limit setting is very important in monitoring. The upper limit should not be set too high, considering variable factors.
·The upper limit shall not exceed 20 beat/min higher than the patient's heart rate.

ECG channel**:**There are three channels, respectively as below:ECG1.ECG2.ECG3.The optional leads are: Ⅰ, Ⅱ ,Ⅲ,aVR,aVL,aVF,V.

ECG gain:there are 5 options: ×0.25 ×0.5.×1.×2 and automatic.

⚠NOTE

·When the input signal is too large, the crest may be truncated. In this case, you can manually change the gain of the ECG waveform based on the actual waveform to avoid incomplete waveform display.
·The gain of each channel can be selected accordingly, and a 1mV scale is displayed on the left side of each channel ECG waveform. The height of the 1mV scale is proportional to the amplitude of the wave.

HR source

ECG, SpO2, AUTO and BOTH can detect heart rate. AUTO distinguishes heart rate source according to the quality of signal. If select BOTH, the monitor will display Heart rate & pulse rate. if selecting SpO2, the monitor prompts PULSE and activates pulse beep.

When the heart rate source is selecting SOP2, the alarm judgment of heart rate is not activated, but only carry on the alarm judgment of pulse rate.

When BOTH mode is selected, PR parameter will be displayed to the right side of SpO2, HR and PR alarm simultaneously, The sound of HR beat has the priority, i.e., if HR data is available, voice prompt will be sent out, but if HR data is not available, then the voice prompt will be given to PR.

HR CHANNEL

(1) “CH1”,”CH2”,”CH3” represents the heart rate were calculated according to the 1st, 2nd, or 3rd ECG waveform data.
(2) "AUTO" means the monitor selects a channel automatically
(3) LEAD TYPE 5 LEADS or 3 LEADS are available.
(4) SWEEP Available options for SWEEP are 12.5, 25.0, and 50.0 mm/s.

OTHER SETUP

select this item to access ECG OTHER SETUP menu as shown below Figure 7-5 ECG other setup:

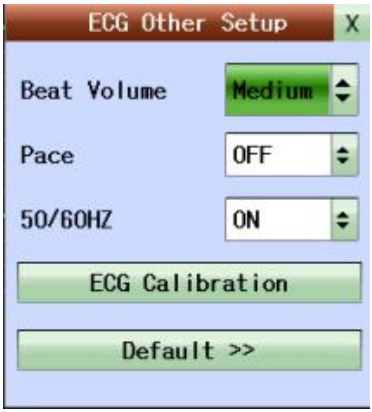


Figure 7-5 ECG other setup

In the sub-menu, following functions are available:

(1) ECG monitor type: select "normal display" to display two ECG wave forms in 5 lead. Select "full-screen multi-lead display", then 6 ECG wave forms can be displayed in the waveform area of the screen.

(2) BEAT VOL: 4 selections are available: low, medium, high, off.

(3) PACE: can select on or off accordingly.

(4) Power frequency suppression: suppress network electrical interference.

(5) ECG CAL: select this item to start calibrating ECG automatically.

(6) DEFAULT: Select this option to enter the ECG default configuration dialog box. You can select the system default configuration.

NOTE

When the input signal is too strong, the peak of the waveform might be truncated. Users can manually adjust the ECG waveform gain according to the actual waveform to avoid incomplete waveform display.

For each different channel ECG waveform gain, there are 4 options: ×0.25 ×0.5.×1.×2 . A scale of 1mv was displayed on the left side of each channel ECG waveform. The height of a 1mv scale is proportional to the amplitude of the waveform.

By filtering, can obtain more pure and accurate wave forms.

There are 3 ways to filter.in reference mode, the ECG waveform displayed is without filtering; in monitoring mode, can filter the artefact that causes false alarm; while in operation mode,can reduce artefact and interference from electrosurgical equipment

Warning

System can provide an unprocessed real ECG signal only under other mode. If under “monitoring” and “operation” mode, the ECG waveform will have distortion more or less. At this time, the system can only provide the basic state of ECG, and might have a great impact on the analysis of ST segment.Therefore,we usually recommend use diagnostic mode to monitor the patient when the interference is small.

7.4 ECG Alarm Information and Prompt

Alarm Message

Alarms occurring in the process of ECG measurement contain two types: physiological alarm and technical alarm. Prompt message may also appear in the mean time. For the

audio and visual features during these alarms and prompt messages in ECG measurement, please refer to the related description in Chapter Alarm. on the screen, physiological alarm messages and the prompt messages able to trigger alarms (general alerts) all displayed in the alarm area of the monitor while technical alarms and prompt messages unable to trigger alarms are then displayed in the information area of the monitor. This section does not describe the content about Arr. and ST analysis.

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in the related menu is On.

Tables below describe respectively the possible various alarms those may occur during the measurement.

Physiological alarms:

Message	Cause	Alarm level
ECG LOST	No ECG signal of the patient is detected.	HIGH
HR TOO HIGH	HR measuring value is above the alarm high limit	User-selectable
HR TOO LOW	HR measuring value is below the alarm low limit	User-selectable

Technical alarms:

Message	Cause	Alarm level	Remedy
ECG LEAD OFF	ECG electrodes fall off the skin or ECG cables fall off the monitor.	LOW	Make sure that all electrodes, leads and patient cables are properly connected.
ECG COMM STOP	Occasional communication failure	HIGH	If failure persists, notify biomedical INSTRUMENT engineer or service staff.
HR ALM LMT ERR	Functional safety failure	HIGH	Stop using HR alarm function, notify biomedical INSTRUMENT engineer or service staff.
ECG NOISE	ECG measuring signal is greatly interfered.	LOW	Make sure the patient is quiet, the electrodes are properly connected and AC power system is well grounded.

Prompt messages (include general alerts):

Message	Cause	Alarm Level
HR EXCEED	HR measuring value exceeds the measurement range.	HIGH

7.5 Measuring RESP

How to measure RESP?

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

Setting Up RESP measurement

For RESP monitoring, it is not necessary for additional electrodes, however, the placing of electrodes is important. Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of breathing movement to optimize the respiratory waveform.

NOTE

It is not recommended using the RESP monitoring on patients who are very active, as this can cause false alarms.

Checklist for RESP Monitoring

(1) Prepare the patient's skin prior to placing the electrodes.

(2) place the 2 electrodes according to the following pictures

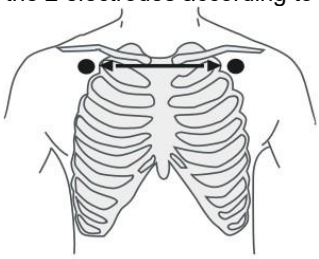
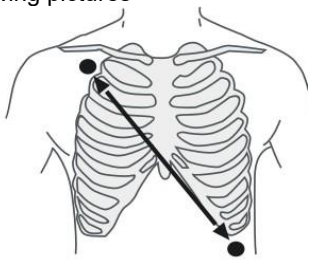


Figure 7-6 I lead RESP electrode placement



II lead RESP electrode placement

Note

Place white RA and red LL electrodes diagonally to obtain Ⅱ lead respiration waveform, and can also place RA and LA electrodes to obtain Ⅰ lead respiration waveform. When using different RESP leads, remember to select the corresponding calculation lead in RESP setup - respiratory lead setting, otherwise can't get the correct result. Avoid to place the RESP electrodes to liver area and ventricle, so as to eliminate cardiac overlay or artifacts from pulsating blood flow.

RESP menu

RESP SETUP Menu

Turn the knob, move the cursor to RESP hot key, press the knob to enter RESP setup menu, see figure 7-7 RESP setup:

Figure 7-7 RESP setup

RESP alarm setting

(1) ALM switch: select "ON" to enable prompt message and data record during the RESP alarm; select "OFF" to disable the alarm function, and there will be a beside “RESP”.

(2) ALM REC: select "ON" to enable report printing upon RESP alarm.

RESP alarm is activated when the respiration rate exceeds set ALM HI value or falls below ALM LO value.

RESP alarm limits are as follows:

	Upper limit	lower limit	step
RR adults	120	7	1
RR pediatric	150	7	1

RESP alarm limits:

(3) APNEA ALM: to set the standard of judging an apnea case. It ranges from 10 to 40 seconds, increases / decreases by 5.

(4) SWEEP: Available options are 6.25, 12.5 and 25.0 mm/s.

(5) WAVE AMP: The user may set up the displaying amplitude of the RESP waveform. The selections are 0.25, 0.5, 1, 2, 4.

(6) DEFAULT: select this item to access the RESP DEFAULT CONFIG dialog box, in which the user may select whether the FACTORY DEFAULT CONFIG or the USER DEFAULT CONFIG is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user’s confirmation.

7.6 RESP Alarm message

When the alarm recording switch is turned on, the physiological alarms caused by parameter exceeding alarm limit will trigger the recorder to automatically output the alarm parameter data and the related measurement waveform.

The physiological alarm and technical alarm and prompt information that may occur during RESP measurement are listed as below:

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in the related menu is On.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during RESP measurement.

Physiological alarms:

Message	Cause	Alarm Level
RR TOO HIGH	RESP measuring value is above alarm high limit.	User-selectable
RR TOO LOW	RESP measuring value is below alarm low limit.	User-selectable
RESP APNEA	RESP can not be measured within specific time interval.	HIGH

Technical alarms:

Message	Cause	Alarm Level	Remedy
RESP ALM LMT ERR	Functional safety failure	HIGH	Stop using RESP alarming function, notify biomedical INSTRUMENT engineer or service staff.

Prompt message (general alerts):

Message	Cause	Alarm Level
RR EXCEED	RR measuring value exceeds the measure range.	HIGH

Chapter 8 SpO_2

8.1 What is SpO_2 Monitoring

Definition of SpO_2 monitoring

SpO2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO2 oxygen saturation of 97%. The SpO2 numeric on the monitor will read 97% .The SpO2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

(1) Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures the amount of light emitted from one side of the sensor's light source, that transmitted through a patient's tissue (such as a finger or an ear) reaches a receiver on the other side. The sensor measurement wavelengths are nominally 660nm for the Red LED and 940nm for Infrared LED. Maximum optical power output for LED is 4 mW.

(2) The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.

⚠Warning

•Pulse oximetry can overestimate the SpO_2 value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.

• Only use the specified blood oxygen sensor mentioned in this instruction, and

refer to the sensor user manual when use.

• Before usage, the user should check the compatibility of the monitor, probe and cable, otherwise it may cause injury to the patient or damage to the equipment.

• If the patient has the tendency of hypoxia, a blood oximeter should be used so as to fully grasp the patient blood oxygen.

• Avoid using the device and blood oxygen sensor in NMR environment. Otherwise, may cause severe burns to the patient.

• For prolonged and continuous monitoring, check per 2 hours the sensor placement and change the measurement site every 4 hours if the skin deteriorates. It is especially important to check the sensor placement and patient of immature dermogram by light collimation and proper attaching strictly according to changes of the skin. Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. More frequent examinations may be required for different patients.

$SP0_2$ Plethysmogram parameter measurement:

(1) The SpO_2 value and the PLETH waveform can be displayed on the main screen.
(2) The SPO2 in this manual refers to blood oxygen saturation measured by non-invasive methods.
(3) The measured data will be updated every 1 second.
(4) The plethysmography waveform was not normalized.

⚠ **Warning**

When the finger falls off from the SPO2 sensor, system will detect by searching the pulse, and the alarm of "SpO2 finger falls off" will be delayed for about 3s-5s.

• Pulse oximetry can overestimate the SpO_2 value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.

• ES (Electrosurgery) equipment wire and SpO2 cable must not be tangled up.

• Do not put the sensor on extremities with arterial catheter or venous syringe.

• Verify sensor cable fault detection before beginning of monitoring phase. Unplug the SpO_2 sensor cable from the socket, the screen will display the error message "SPO2 SENSOR OFF" and the audible alarm is activated.

• Do not use the sterile supplied SpO_2 sensors if the packaging or the sensor is damaged and return them to the vendor.

• Do not perform SpO_2 measuring and NIBP measuring in same arm at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO_2 value.

(1) Make sure the nail covers the light window;
(2) The wire should be on the backside of the hand.

• SpO_2 value always displays at the same position. Pulse Rate will display in the following cases:

1) when HR source is set at "SPO2", "auto" in the ECG SETUP menu.

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

• SpO_2 waveform is not proportional to the pulse volume.

• Functional test equipment or oxygen simulators cannot be used to verify the accuracy of oxygen saturation monitors and pulse oxygen probes. The accuracy of a Pulse Oximeter and pulse oximetry probe needs to be validated with clinical data.

• The SPO2 sensor and extension cable should pass test in EN ISO 80601-2-61:2019.

8.2 SPO2 Monitoring Procedure

SpO_2 plethysmogram measurement

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient finger.
3. Plug the connector of the sensor extension cable into the SpO_2 socket on device.

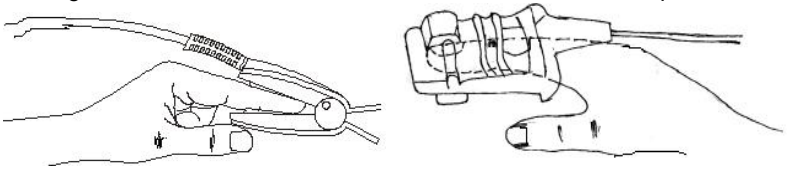


Figure 8-1 mounting of the sensor (adults)

Note

• if the SPO2 sensor was placed improperly on patient's finger, it may result in inaccurate SPO2 measuring data, or even can't detect SPO2 because of no pulse, so please try adjust the sensor position.

• Excessive movement of the measuring part may result in inaccurate measurement,try ask patient keep quiet or change to another measuring part, so as to reduce the impact of excessive movement on the measured data.

Warning

• During prolonged and continuous monitoring, remember to check the peripheral circulation and skin condition of the measured part every 2 hrs, if not in a good condition, adjust the sensor position in time.

• During prolonged and continuous monitoring, the positioning of the sensor should be checked periodically, so as to avoid inaccurate measurement cause by moving or other factors.

8.3 Limitations for Measurement

Measurement Limitations

In operation, the accuracy of oximetry readings can be affected by:

- **High-frequency electrical noise, including noise created by the host system, or noise from external sources, such as electrosurgical apparatus, which is admitted by the host system.**
- **Do not use oximeters and oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current might potentially cause burns.**
- **Intravascular dye injections.**
- **Excessive patient movement.**
- **External emission of light.**
- **Improper sensor installation or application.**
- **Sensor temperature (maintain between 28°C and 42°C for best operation)**
- **Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular catheter.**
- **High concentrations of dysfunctional hemoglobin, such as**

carboxylhemoglobin and methemoglobin.

- **SPO2 too low**
- **Shock, anemia, hypothermia, and the use of vasoconstrictor drugs may reduce arterial blood flow to unmeasured levels.**
- **The measurement also depends on oxyhemoglobin and reduced hemoglobin's absorption of specific wavelengths of light. If there's other matters absorbs same wavelengths of light, will lead to false or low SP02 values in the measurement. E.g.: Carbonized hemoglobin, methemoglobin, methylene blue, Rouge indigo.**
- **It is recommended to use SpO_2 sensors described in chapter Accessories and Ordering Information.**

8.4 SpO_2 Menu

SPO2 SETUP Menu

Turn the knob to move the cursor in the display interface to the SPO2 hot key on the screen, press the button to call up the SPO2 SETUP menu as shown below.

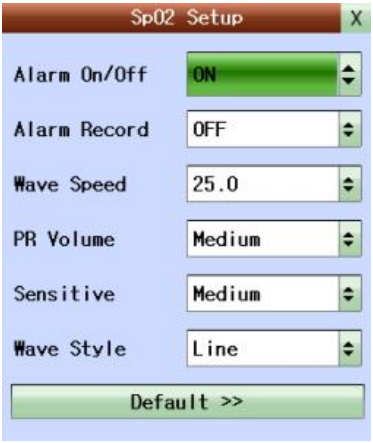


Figure 8-2 SPO2 SETUP menu

Warning

Setting the SpO_2 upper alarm limit to 100% is equivalent to switching off the alarm on upper limit. High oxygen levels may predispose a premature infant to retrolental fibroplasia. Therefore, the upper alarm limit for oxygen saturation must be carefully selected in accordance with commonly accepted clinical practices.

SpO_2 alarm setting

- ALM switch: select "ON" to enable prompt message and data record during the SpO_2 alarm; Select "OFF" to turn off the alarm function, and there will be a next to "SpO_2".
- ALM REC: select "ON" to enable report printing upon SpO_2 alarm.

SpO2 & PR alarm limit:

Parameter	Upper limit	Lower limit	step
SpO2	100	0	1
PR	300	0	1

Default SpO2 & PR alarm limit:

Parameter		Upper limit	Lower limit
SpO2	Adults	100	90
	Pediatrics	100	90
PR	Adults	120	50
	Pediatrics	160	75

SWEEP
Available options are 12.5, 25.0 mm/s.
(1) PR SOUND
Pulse beep volume. Options are low, medium, high, off
(2) AVG TIME
4S, 8S, 16S represent times that SpO_2 average value is counted.
(3) DEFAULT:
Select this item to access the SPO2 DEFAULT CONFIG dialog box, in which you can choose the system default configuration .

8.5 Alarm Description and Prompt

SpO_2 Alarm Message

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in the related menu is On.
Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during SpO2 measurement.

Physiological alarm:

Message	Cause	Alarm Level
SPO2TOO HIGH	SpO2 measuring value is above alarm high limit.	User-selectable
SpO2 TOO LOW	SpO2 measuring value is below alarm low limit.	User-selectable
PR TOO HIGH	PR measuring value is above alarm high limit.	User-selectable
PR TOO LOW	PR measuring value is below alarm low limit.	User-selectable

Technical alarms:

Message	Cause	Alarm Level	Remedy
SPO2 SENSOR OFF	SpO2 sensor could be disconnected from the patient or the monitor.	LOW	Make sure that the monitor and the patient are in correct connection with the cables.
SPO2 module Comm. Err.	SPO2 modular communication error	High	Stop use the SPO2 module measurement function, and notify the biomedical engineer or our distributors.
PR alarm limit error	Functional safety failure	High	Stop use the PR module measurement function, and notify the biomedical engineer or our distributors.

Prompt message (include general alerts):

Message	Cause	Alarm Level
SPO2 exceed limit	SPO2 measured data exceed the set limit	High
PR exceed limit	PR measured data exceed the set limit	High
SEARCH PULSE	SpO2 module is searching for pulse.	No alarm
NO PULSE	SpO2 module cannot detect SpO2 signal for a long time.	HIGH

Chapter 9 TEMP

9.1 TEMP Monitoring

The portable monitor uses a temperature probe to measure the patient's temperature .

TEMP monitoring setup

■ If you are using disposable TEMP probes, you need to plug the TEMP cable into the monitor and then connect the probe to the cable. With a reusable TEMP probe you can plug the probe directly into the monitor

■ Apply the TEMP probe(s) securely to the patient.

Warning

1.Verify probe cables fault detection before beginning of monitoring phase. Unplug the temperature probe cable from the socket, the screen will display the error message "TEMP SENSOR OFF" and the audible alarm is activated.

Note

1.Disposable TEMP probe can only be used once for one patient.

2.The self-test of the temperature measurement is performed automatically once per hour during the monitoring. The test procedure lasts about 2 seconds and does not affect the normal measurement of the temperature monitoring.

9.2 TEMP SETUP Menu

Turn the knob to move the cursor to the TEMP hot key in parameter area on the screen, and press the knob to call up the TEMP SETUP menu shown as below:

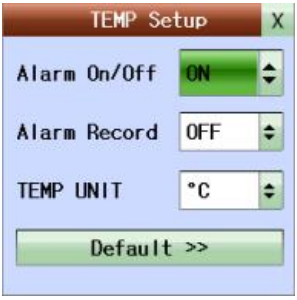


Figure 9-1 TEMP SETUP Menu

TEMP alarm setting

(1) ALM switch: Select "ON" to enable prompt message and data record during the TEMP alarm; Select "OFF" to disable the alarm function, and prompt the symbol beside TEMP numeric.

(2) ALM REC: used to start/stop recording TEMP alarms. Select "ON" to enable report printing upon TEMP alarm.

(3) Alarm for T1 occurs when the measured temperature exceeds set alarm high limit or falls below alarm low limit.

TEMP alarm limits:

Parameter	Max. TEMP H	Min. TEMP LO	**Step**
T1 .T2	50	0	0.1

(4) UNIT
To set temperature unit (ºC).
(5) DEFAULT
Please refer to ECG Default Configuration in ECG/TEMP Monitoring.

9.3 TEMP Alarm message

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in the related menu is On.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during TEMP measurement.

Physiological alarms:

Message	Cause	Alarm Level
T1,T2 TOO HIGH	Measuring value of sensor is above alarm high limit.	User-selectable
T1,T2 TOO LOW	Measuring value of sensor is below alarm low limit.	User-selectable

Technical alarms:

Alarm Message	Cause	Alarm Level	Remedy
TEMP SENSOR OFF	Temperature probe may be disconnected from the monitor.	LOW	Make sure that the cable is properly connected.
TEMP ALM LMT ERR	Functional safety failure	HIGH	Stop using alarming function of TEMP module, notify Biomedical INSTRUMENT engineer or service staff.

Prompt message:

Message	Cause	Alarm Level
TEMP EXCEED	Measuring value of sensor is beyond measuring range.	HIGH

Chapter 10 NIBP

10.1 Introduction

The Non-invasive Blood Pressure (NIBP) module measures the blood pressure using the oscillametric method.It is applicable for adult, pediatric, and neonatal usage.

The blood pressure measured by the monitor is equivalent to that measured by auscultation. The clinical significance of NIBP measurements must be determined by the physician.

There are three modes of measurement available: manual, automatic and continuous. Each mode displays the diastolic, systolic and mean blood pressure.

☐ In the MANUAL mode, only one measurement is conducted for each time.

☐ In the AUTO mode, the measurement is repeated; you can set the interval time to 1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes.

☐ In the continuous mode, the monitor measures the blood pressure as many times as possible in five minutes.

The NIBP measurement will exert pressure on the patient by inflating the cuff. The physician should determine whether the patient is suitable for the NIBP measurement based on the patient's clinical condition.

NOTE

1. You must not perform NIBP measurements on patients with sickle-cell disease or with skin lesion or might have skin lesion after measurement.

2. For a thrombasthemia patient or patient with severe coagulation mechanism disorder, it is important to determine whether measurement of the blood pressure shall be done automatically. The determination should be based on the clinical evaluation, as there will be risk of hematoma caused by friction between cuff and limb.

3. Ensure that the correct setting is selected when performing measurements on children . Using the wrong patient mode may cause risk to patient safety, for example, It may be dangerous for children to use adult pressure level.

4. Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the measuring site when infusion is slowed or blocked during cuff inflation.

10.2 NIBP Measuring

10.2.1 NIBP Measuring

Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.

1. Plug in the air hose to the blood pressure cuff and switch on the system.
2. Apply the blood pressure cuff to the patient's arm according to the instructions below (Figure 10-1).

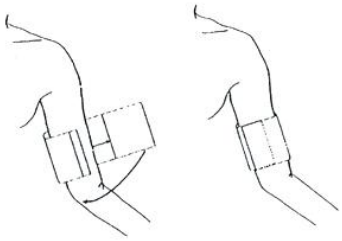


Figure 10-1 Applying Cuff

a. Ensure that the cuff is completely deflated.
b. Apply the appropriate size cuff to the patient, and make sure that the symbol "Φ" is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.

⚠**Note**

The width of the cuff should be either 40% of the limb circumference (50% for Child) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is too small, then use a larger cuff to reduce errors.

Size of reusable cuff for children/adult

Patient Type	Limb perimeter	Cuff width	Hose
Pediatric	18～26cm	10.6cm	1.5m～3m
Adult	25～35cm	14cm	
Large Adult	33～47cm	17cm	

Make sure that the cuff edge falls within the range of the mark <->. If not, use a larger or smaller cuff that fits better.

3. Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible you should apply the following corrections to the measured values:

a. If the cuff is placed higher than the heart level, add 0.75 mmHg (0.10 kPa) for each centimeter of difference.

b. If it is placed lower than the heart level, deduct 0.75 mmHg (0.10 kPa) for each centimeter of difference.

4. Check whether the patient mode is appropriately selected. Access PATIENT SETUP menu from SYSTEM MENU and pick PAT TYPE item and turn the knob to select the required patient type.

5. Select a measurement mode in the NIBP SETUP menu. Refer to the following paragraphs **Operation Hints** for details

6. Press the NIBP button on the front panel to start a measurement.

Operation Hints

1. To start auto measuring:

Access NIBP SETUP menu and select the INTERVAL item, in which the user may choose the selections other than MANUAL to set up the time interval for auto

measurement. After that, press NIBP button on the front panel to start the auto measuring according to the selected time interval.

NOTE

Prolonged non-invasive blood pressure measurements in Auto mode may cause purpura, ischemia and neuropathy on the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements or change cuff position.

After the short-term auto mode measurement is completed, the equipment should be returned back to long-term auto mode or manual mode. The operator can also intentionally activate the short-term auto mode again.

2. To stop auto measuring:

During auto measuring press NIBP button on the front panel at any time to stop auto measurement.

3. To start a manual measuring:

a. Access NIBP SETUP menu and select the INTERVAL item. Select the MANUAL selection. Then press the NIBP button on the front panel to start a manual measurement.

b. During the idle period of auto measuring process, press the NIBP button on the front panel at any time to start a manual measurement. Then press the NIBP button to stop manual measurement and the system continues executes auto-measuring program according to selected time interval.

4. To start a manual measuring during the AUTO mode:

Press NIBP button on the front panel.

5. To stop a manual measuring:

Repress the NIBP button.

6. To perform continuous measuring:

Access NIBP SETUP menu and select the CONTINUAL item to start the continuous measurement. The monitor will measure as many times of NIBP as possible within 5 minutes.

7. To stop continuous measuring:

During continuous measuring press NIBP button on the front panel at any time to stop continuous measurement.

Note

If you have any questions about the measurement data of the product, check the patient's vital signs by an alternative method or device before checking the functioning of the monitor.

Measurement Limitations

Due to different patient conditions, the oscillametric measurement has certain limitations. The measurement measures a regular pulse waveform generated by arterial pressure. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could interfere with the measurements, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible:

- **Patient Movement**

Measurements will be unreliable or may not be possible if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the

arterial pressure pulses. In addition, the measurement time will be prolonged.

- **Cardiac Arrhythmia's**

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time thus will be prolonged.

- **Heart-lung Machine**

Measurements will not be possible if the patient is connected to a heart-lung machine.

- **Pressure Changes**

Measurements will be unreliable and may not be possible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

- **Severe Shock**

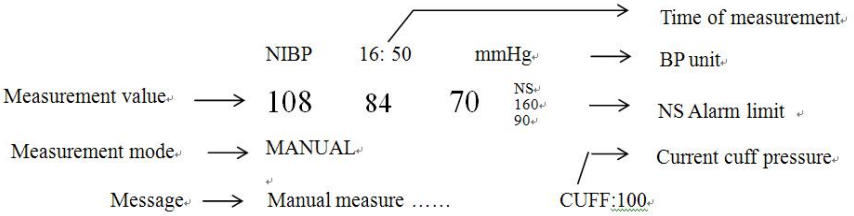
If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

- **Heart Rate Extremes**

Measurements can not be made at a heart rate of less than 40 bpm and greater than 240 bpm.

10.2.2 NIBP monitoring screen

NIBP measurement result and corresponding information are displayed on the screen as follows:



10.3 NIBP SETUP menu

Turn the knob, and move the curse to the NIBP hotkey area, press the knob to call up the NIBP menu shown as below:

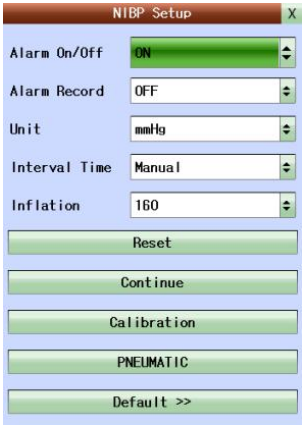


Figure 10-2 NIBP SETUP Menu

NIBP alarm setting

(1) ALM switch:Select "ON" to enable prompt message and data record during the NIBP alarm;Select "OFF" to disable the alarm function, and there will be a  beside “NIBP”.

(2) ALM REC:Select "ON" to enable report printing upon NIBP alarm.

(3) SYS ALM HI, SYS ALM LO, MEAN ALM HI, MEAN ALM LO, DIA ALM HI, DIA ALM LO are for the user to set up the alarm limit for each type of pressure. NIBP alarm is activated when the pressure exceeds set upper alarm limits or falls below lower alarm limits.

NIBP alarm limits:

Adult	Pediatric
SYS 40-260 mmHg	SYS 40-230 mmHg
DIA 10-220 mmHg	DIA 20-170 mmHg
Mean 20-240 mmHg	Mean 20-160 mmHg

RESET

(1) Reset measurement status.

(2) Select this item to restore initial settings of the pressure pump.

(3) When the blood pressure pump does not work properly and the system fails to give message for the problem,Select this item to activate self-test procedure, thus restore the system from abnormal performance.

CONTINUAL

Start continuous measuring.When this item is Selected, the menu will disappear automatically, and start to measure NIBP for as many times as possible within 5 minutes.

INTERVAL

Interval time for automatic measuring. Available selections: 1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes. After select the interval time, press NIBP button on the front panel to start the first auto measuring.

Pick MANUAL selection in INTERVAL item to set up the measuring mode to MANUAL.

Pre-inflated Value

Pressing this key allows you to select the initial pressure value for next inflation of the cuff. Under different default configurations, there are different pre-inflated value ranges for selection, as shown in the table below:

Default configuration	Default pre-inflated value (mmHg/kPa)	Manually selectable pre-inflated values in NIBP menu (mmHg/kPa)
Factory default for adults	160	80～250
Factory default for pediatrics	140	80～200

Press the “menu” button on front panel, enter “default”in“system menu”, after confirm the default setting, back to home page and select “NIBP”hot key to enter “NIBP setup”, you will see the initial pre-inflated value in “pre-inflated value”(see above table). move the cursor to “pre-inflated value”and press, can select the values manually.

Note

“pre-inflated value”is to help users set the pressure for next inflation of cuff in advance, but the pre-inflated value for subsequent measurements is based on the last measurement of systolic blood pressure for the same patient. System memorizing this measurement value can shorten the measurement time for the same patient and

increase measurement accuracy.

note

When users set “patient mode” only in “patient information setup”, without making any selection in the “Default Configuration”, system will initially set the relevant module parameters according to the "patient mode". while if change the “patient mode” in “default configuration”, it will also cause change "Patient mode" in "Patient Information Settings".

(1) UNIT

select this item to set measurement unit. (Option: mmHg or kPa)

(2) DEFAULT

Select this item to access the NIBP DEFAULT CONFIG dialog box, in which the user may select the FACTORY DEFAULT CONFIG or the USER DEFAULT CONFIG. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user’s confirmation.

WARNING

The calibration of the NIBP measurement is necessary for every two years (or as frequently as dictated by your Hospital Procedures Policy). The performance should be checked according to the following details.

(3) CALIBRATE

pressure calibration

The manufacturer recommends using a calibrated manometer (or mercury manometer) with an accuracy greater than 1 mmHg for calibration. Select the CALIBRATE item to start the calibration and the item will change into STOP CAL, if press the knob, the system will stop calibration.

Procedure of the Pressure Transducer Calibration:

Replace the cuff of the device with a rigid metal vessel with a capacity of 500 ml ± 5%. Connect a calibrated reference manometer with error less than 0.8 mmHg and a ball pump with a T-piece connector and hoses to the pneumatic system. Set the monitor in **CALIBRATE** mode. Inflate the pressure of the metal vessel to 0, 50 and 200 mmHg by ball pump separately. The difference between the indicated pressure of the reference manometer and the indicated pressure of the monitor will not exceed 3 mmHg. Otherwise, please contact our customer service.

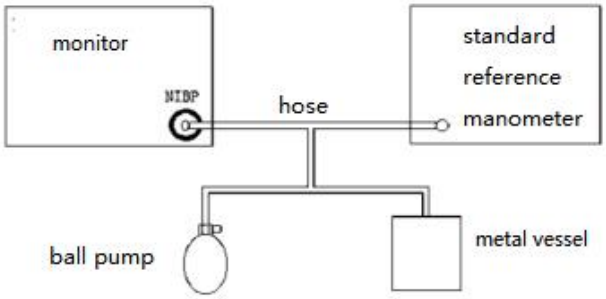


Figure 10-3 NIBP pressure calibration sketch

(4) PNEUMATIC test

This is used to check whether there is leakage for the NIBP measuring pump. When

connect the NIBP cuff, press the key to start the NIBP inflation process, so as to figure out whether the NIBP gas path is in good airtight condition. If passed the air leakage test, there will no prompt; but if failed, there will be error message showing in the NIBP message area.

⚠WARNING⚠

This pneumatic test other than being specified in the EN 1060-1 standard is only to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

Procedure of the air leakage test:

1) Connect the cuff securely with the socket for NIBP air hole.
2) Wrap the cuff around the cylinder of an appropriate size.
3) Access the NIBP SETUP menu.
4) Turn the knob to the PNEUMATIC item and press the knob. Then the prompt "Pneum testing…" will appear on the bottom of the NIBP parameter area indicating that the system has started performing pneumatic test.
5) The system will automatically iniflate the pneumatic system to about 180mmHg.
6) After 20 seconds or so, the system will automatically open the deflating valve, which marks the completion of a pneumatic measurement.
7) If no prompt appears on the bottom of the NIBP parameter area, it indicates that the airway is in good situation and no air leaks exist. However if the prompt "PNEUMATIC LEAK" appears in the place, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the pneumatic test. If the failure prompt still appears, please contact the manufacturer for repair.

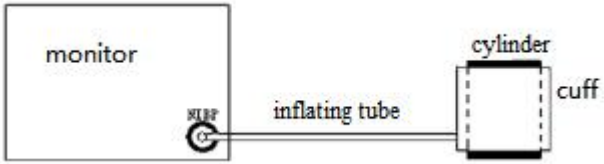


Figure 10-4 NIBP air leakage test connection sketch

Default configuration:select "default configuration" to enter NIBP default setting,can select the system default configuration.

10.4 NIBP Alarm information and prompt

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the parameters and related measured waveform when the alarms occur on the condition that the alarm record switch in the related menu is On.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during NIBP measurement:

Physiological alarms:

Message	Cause	Alarm level
NS too high or too low	NIBP measured systolic blood pressure above the set upper limit or below the set lower limit	User-selectable
ND too high or too low	NIBP measured diastolic blood pressure above the set upper limit or below the set lower limit	User-selectable
NM too high or too low	NIBP measured mean blood pressure above the set upper limit or below the set lower limit	User-selectable

Technical alarm 1(displayed in information area below NIBP value):

Message	Cause	Alarm level	Solutions
NIBP self check Err.	NIBP measurement module sensor error or other hardware error	High	Stop using measuring function of NIBP module, notify biomedical engineer or maintenance staff.
NIBP Comm. Err.	NIBP communication error with measuring module	High	If the error persist,Stop using measuring function of NIBP module, notify biomedical engineer or maintenance staff.
Cuff Loose or not connected	The cuff is not well wrapped	Low	wrap the cuff properly
Inflate hose leakage	Damage on cuff, hose, connector	Low	Inspect and replace the leaking parts and notify the biomedical engineer or our maintenance staff if necessary.
Air pressure Err.	Unstable pressure values, such as hose entanglement	Low	Check entanglement,if the erroe persists,notify the biomedical engineer or our maintenance staff.
Weak signal	The cuff is too loose or the patient's pulse is too weak	Low	Try other way to measure NIBP
Pressure exceed limit	Measured value exceed the limit	High	Reset NIBP measurement module,if the error persist,stop using measuring function of NIBP module, notify biomedical engineer or maintenance staff
Patient movement	Affected by patient movement, excessive signal noise or irregular pulse rate	Low	Ask patient to keep quiet
Overpressure protection	The pressure exceeds the prescribed safety limit	High	Try again and if the error persist,stop using measuring function of NIBP module, notify biomedical engineer or maintenance staff

saturation signal	patient's big movement	Low	Ask patient calm down
Pump leakage	Leakage was detected during a leak test	Low	Inspect and replace the leaking parts and notify the biomedical engineer or our maintenance staff if necessary.
NIBP system Err.	blood pressure pump failure	High	stop using measuring function of NIBP module, notify biomedical engineer or maintenance staff
Cuff size Err.	Wrong cuff size for patient type	Low	Change for correct cuff size
Measurement overtime	Measurement time over 120s(adult/pediatric)	High	Measure again or try other ways to measure
NIBP reset Err.	NIBO reset error	High	Try rest NIBP again.
Measurement Err.	Cannot perform measurement analysis or calculation while the measurement is being made	High	Check the cuff, make sure patient doesn't move during measurement, and try measure again.

Prompt message(displayed in information area below NIBP value):

Message	Cause	Alarm level
Manual measurement…	During manual measurement	No alarm
Continuous measurement…	During continuous measurement	
Auto measurement…	During auto measurement	
Press start button	After selecting the measurement interval	
Measurement end	Press the start button to stop the measurement during measurement	
Calibration …	During calibration	
Calibration end	Calibration finished	
Leakage test…	During test for leakage	
Leakage test end	Leakage test finish	
Reset …	During NIBP reset	
Manual reset …	During NIBP reset(user triggered)	
Reset Err.	Reset failure	

Chapter 11 Printer (Optional)

(This function is optional, the device you use may not be equipped with this function)

11.1 General Information on Recording

A thermal dot matrices recorder with 48mm wide printout paper is used for monitor.

Performance of the Recorder

(1) Waveform record is printed out at a rate of 25 or 50 mm/s.
(2) It can record up to 2 waveforms.
(3) English / Chinese printout.
(4) The real time recording time and waveform and 6 parameter data.
(5) The alarm recording waveform is automatically selected by the monitor.

11.2 Recording Type

(1) Press the print key or press the print hotkey to perform manual printing and print the current waveform and parameters.
(2) In parameter setting menu, the alarm printing is switched on, in this case, when the alarm occurs and triggers, the device will automatically print the waveform and data of the current alarm.
(3) In each review trend chart, trend table, alarm review, click print option to print the current data.

11.3 Record output

Date and time HR——heart rate PR——pulse rate SPO2——oxygen saturation
SYST——systolic pressure MEAN——mean blood pressure DIAS——diastolic pressure
TEMP1——temperature1 TEMP2——temperature 2 RESP——respiration LEAD——lead

11.4 Recorder Operations and Status Messages

Record Paper Requirement

Only standard 50 (+0/-1) mm thermosensitive record paper can be used, otherwise the recorder may not function properly, the recording quality may be poor, and the thermosensitive printhead may be damaged.

Function Properly

■ When the recorder is working, the record paper goes out steadily. Do not pull the paper, or the recorder will be damaged.
■ Do not operate the recorder without record paper.

Paper Out

When "RECORDER OUT OF PAPER" alarm is displayed, the recorder cannot start. Please insert record paper properly.

Inserting Paper

■ Open the recorder catch.
■ Pull down the switch on the left axis of the recorder.
■ Insert a new roll of paper into the paper cassette, printing side facing the thermosensitive printhead.
■ When the paper can be seen from the other side, pull it out. Ensure proper position and tidy margin.
■ Pull back the switch on the left axis of the recorder.
■ Give out the paper from the recorder outlet.
■ Close the recorder catch.

NOTE

Be careful when inserting paper. Avoid damaging the thermosensitive printhead. Unless when inserting paper or shooting troubles, do not leave the recorder catch open.

Removing Paper Jam

When the recorder functions or sounds improperly, open the recorder catch to check for a paper jam. Removing the paper jam in the following way:

- Cut the record paper from the feeding edge.
- Pull up the switch on the left axis of the recorder.
- Pull the paper from below.
- Re-insert the paper.

Set up the record grid

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

How to set up printing grid:enter “printing setup” menu,Select "On" or "Off" for the grid printing.

Caution

1、Do not pull the recording paper out forcefully when recorder is printing, otherwise the recorder might be damaged.

2、Do not leave the recorder catch open, unless when inserting paper or shooting troubles.

3.Do not use anything that can damage heat-sensitive parts, such as sandpaper.

4.Do not press the thermal print head too hard.

Chapter 12 Troubleshooting 1

Trouble	Trouble Descriptions	Causes	Solutions
Blank screen	When power on, shows blank screen	1.screen cable loose;	1.re-plug the cable;
		2.screen broken	2.replace with a new screen;
		3.power socket fuse blown	3.replace with a new fuse;
		4.power supply board damaged;	4.replace with a new power supply board;
		5.power supply socket broken or power cord broken;	5.replace a new power cord or socket;
White screen	When power on , shows white screen	1.cable between motherboard and screen loose;	1.re-attach the cable between motherboard and screen;
		2.screen cable loose;	2.re-plug the cable;
		3.screen broken;	3.replace with a new screen;
		4,.motherboard broken;	4.replace with new motherboard;
Unable to access the monitor interface	When power on, stop at LOGO page or welcome page	1.motherboard broken;	1.replace with new motherboard;
		2.programme chip loose or damaged;	2.re-install programme chip or replace with a new chip

Chapter 13 Troubleshooting 2

NIBP measurement failure	No result for NIBP measuremen t or abnormal measured value	1.leakage on cuff or inflating cable;	1.incorrect cuff selection, replace with right cuff size and reconnect;
		2.over pressure protection	2.cuff size and patient type doesn't match or extension tube block
		3.measured value is in large deviation	3.cuff wrapped too tight or too loose, or wrong measure position, or too much movement
		4.air pressure Err.;	4. replace with new slow release valve or other block parts;
ECG can't work properly	No ECG waveform	1.ECG clutter or unstable	1.patient movement or electrode not well cleaned when placing to patient, or electrode not well sticking
		2.ECG lead was switched to unconnected;	2.switch ECG lead to connected;
		3.ECG lead loose or drop off	3.re-connect to ECG lead or replace with a new lead cable;

		4.cable between ECG plug and ECG board loose or broken;	4.re connect the cable between ECG plug and ECG board, or replace with a new ECG plug and cable;
		5.ECG clutter;	5.excessive interference from surrounding electronic devices;
SPO2 can't work normally	Can't measure SPO2	1.SPO2 sensor drop off;	1.Connect SPO2 sensor to patient finger;
		2.SPO2 sensor broken;	2.replace with a new SPO2 sensor
		3.cable connect to SPO2 socket loose or unconnected;	3.re-connect the cable to SPO2 socket
		4.SPO2signal line loose;	4.re-connect SPO2 signal line;

Chapter 14 Troubleshooting 3

Built-in printer can't print	Printing button invalid and crashes	1.no printing paper installed;	1.install the printing paper;
		2.printing paper installed reversely;	2.check if printing paper installed properly;
		3.cable connect to printer is loose;	3.re-connect the cable to printer;
		4.incorrect voltage for printer;	4.replace with a new power cord or power supply;
		5.printer broken;	5.replace with a new printer;
Battery can't charge	Battery life short	1.battery broken,battery low voltage;	1.replace with new battery;
		2.something wrong with power supply ,low voltage;	2.change power board;

⚠ **Note:please do not disassemble the machine for non-professionals. if you have met other problems that can't be solved according to above suggestions, please contact with our after sales dept. directly.**

Chapter 15 Accessories

We recommend using the following accessories:

15.1 ECG accessories

Accessory Name	Model No.	Description	Manufacturer
12-pin in one five-lead ECG cable	SG5143S	Anti defibrillation, push button, five-lead, 2.9m, reusable	Shenzhen SINO-K Medical Technology Co., Ltd
12-pin in one three-lead ECG cable	SG3143S	Anti defibrillation, push button, three-lead, 2.9m, reusable	Shenzhen SINO-K Medical Technology Co., Ltd
12-pin in one five-lead ECG cable	SG5155S	push button, five-lead, 2.9m, reusable	Shenzhen SINO-K Medical Technology Co., Ltd
12-pin in one three-lead ECG cable	SG3155S	push button, three-lead, 2.9m, reusable	Shenzhen SINO-K Medical Technology Co., Ltd

15.2 SpO2 accessories

Accessory Name	Model No.	Description	Manufacturer
Reusable SpO2 probe	A0816-SA105PV	Adult Finger Clip Sensor with 300cm Cable Round 12pin, reusable	APK Technology Co.,Ltd.
Reusable SpO2 probe	A0816-SP105PV	Pediatric Finger Clip Sensor with 300cm Cable Round 12pin, reusable	APK Technology Co.,Ltd.
12 Pin Comen adult finger sensor	SP9361H	Adult Finger Clip Sensor with 300cm Cable Round 12pin, reusable	Shenzhen SINO-K Medical Technology Co., Ltd
12 Pin Comen adult finger sensor	SP9325A	Adult Finger Clip Sensor with 300cm Cable Round 12pin, reusable	Shenzhen SINO-K Medical Technology Co., Ltd
12 Pin Comen Pediatric finger sensor	SP7119	Pediatric Finger Clip Sensor with 100cm Cable, reusable	Shenzhen SINO-K Medical Technology Co., Ltd

12 Pin DB9 compatible SpO2 adapter extension cable	SP0225	2.2m reusable SPO2 probe	Shenzhen SINO-K Medical Technology Co., Ltd

15.3 TEMP accessories

Accessory Name	Model No.	Description	Manufacturer
Body cavity temperature sensor (adult)	ST2305	Body cavity sensor.3m.reusable	Shenzhen SINO-K Medical Technology Co., Ltd
Body surface temperature sensor (adult)	ST1305	Body surface sensor.3m.reusable	Shenzhen SINO-K Medical Technology Co., Ltd

15.4 NIBP accessories

Accessory Name	Model No.	Description	Manufacturer
NIBP extension tube	SH0908S	Strait plug connector to pagoda connector,2.5m	Shenzhen SINO-K Medical Technolog y Co., Ltd
NIBP extension tube	SH0910S	Strait plug connector to spring joint,2.5m	Shenzhen SINO-K Medical Technolog y Co., Ltd
NIBP cuff for adult	SC2711	Brown color, reusable	Shenzhen SINO-K Medical Technolog y Co., Ltd
NIBP cuff for pediatric	SC2611	Brown color, reusable	Shenzhen SINO-K Medical Technolog y Co., Ltd

15.5 other accessories

Accessory Name	Model No.	Description	Manufacturer
7.4V4.8AH Li-ion battery	2S1700	XHP-2(JST)connector 35.52wh	Shenzhen Xinlong Ding Technology Ltd
14.8V2.2AH Li-ion battery	ICR18650	SMP-02V(JST)connect or 32.56wh	Shenzhen Xinlong Ding Technology Ltd

Warning

1.Please only use the accessories recommended by the manufacturer, otherwise might cause damage to the device or fail to achieve the accuracy mentioned in the instructions.

2.The listed accessories should be used together with our products, please read the user manual for devices and accessories firstly before usage, so as to check the compatibility of the accessories and devices, otherwise might cause patient injury or affect accuracy for measurement.

3.Disposable accessories can only be used once, repeated use will cause cross-infection and performance degradation.

Note

1、 For the accessories with safety life time limitation, please check labels for

their life time, make sure do not use the accessories expired validity.

2、 Sterilized accessories should be well packed, check the package before usage, do not use the ones with damaged package.

Pay attention to the package of the accessories with safe use period. Do not use expired accessories

Caution

1、 The use or storage environment of the accessories should meet the requirements on instruction paper, otherwise it may fail to meet the standards stated on instructions or its performance will be affected due to environment.

2、 Please do not use the accessories if found it expired, package damaged or even the cable is damaged.

3、 Please deal with the disposable accessories, expired accessories, and scraps according to local regulations or hospital policies.

Appendix I

I.1 Monitor type(according to IEC 60601-1 and EC60601-1

Standard electrical shock resistance: KM series class II; KB & KP series class I equipment with internal power;

EMC grade	grade A
the degree of protection against electric shock	ECG (RESP)is type CF; SpO2.NIBP.TEMP is type BF;
Waterproof type	IPX2
Sterilization/disinfection method	See Chapter 5 for details.
Working mode	continuous working mode

I.2 Monitor Specifications

I.2.1 Monitor size and weight

Refer to the outer box mark for each model.

I.2.2 Working environment

Temperature:	
Working temperature	5℃～40℃
transportation and storage	(-20 ～ +55) °C
Humidity:	
Working humidity	15%～80 % (non-condensing)
transportation and storage	≤93% (non-condensing)
Altitude:	
Working altitude	(-500 — 4,600) m (-1,600 — 15,000)inch
transportation and storage	(-500 — 13,100)m (-1,600 — 43,000)inch
Electrical specifications:	
A.C.:	100V-a.c.240V,50Hz/60Hz,
input power:	KM8/KM10<45VA; KB12/KB15/KP13/KP15<65VA
Fuse: T1.6AL 250V	d.c.15V/2A(7—15V)

I.2.3 Display information

(1) Up to 9 waveform display,1 alarm indicator (yellow/red).
(2) 1 battery charging status indicator (green),,1 AC power status indicator
(3) Three sound alarm modes corresponding to the alarm state

I.2.4 Battery

14.8V/2200mAh or 7.4V/4800mAhq Li-ion battery
Can work over 150min on battery
After the first low power alarm, can continue to work for about 10 minutes. After 15 minutes, it will shut down automatically.
The maximum charging time for 14.8V battery is no more than 3 hours, and the maximum charging time for 7.4V battery is no more than 5 hours.

I.2.5 Recorder(optional)(external)

width	80mm;	speed	25 mm/S
waveform	3;	record type	8s.16s real time record

I.2.6 review

Trend review	
Short trend	2 hrs, Resolution 1 second or 5 seconds
Long trend table	336hrs,resolution 1 minute, 5 minute or 10 minute
NIBP measurement review	can review 1000 NIBP measurement value
Alarm event review	200,can reach 1000if using USB flash disk

Waveform review 1hr.can reach 24hrs if using USB flash disk

I.3 ECG

Standard: IEC 60601-2-27,EN 60601-2-27, ANSI/AAMI EC13:2002 (R)2007, IEC 60601-2-25, EN 60601-2-25, ANSI/AAMI EC11:1991/(R)2001/(R)2007

I.3.1 Lead configuration

Standard 3 - or 5-lead cable

3 leads:RA.LA.LL lead selection: Ⅰ,Ⅱ,Ⅲ

5 leads:RA.LA.LL.RL.V lead selection: Ⅰ,Ⅱ,Ⅲ,aVR,aVL,aVF,Ⅴ

I.3.2 ECG gain

Gain: ×2.5mm/mV, ×5.0mm/mV, ×10mm/mV, ×20mm/mV, auto, deviation≤±5%

I.3.3 heart rate

HR and Alarm

Range: Adult 15 ~ 300 bpm Ped 15 ~ 350 bpm

Accuracy ±10% or ±5bpm

Resolution 1 bpm

I.3.4 ECG signal range 0.2～8mV

I.3.5 Input Impedance

Differential Input Impedance > 5 MΩ

Ⅰ.3.6 Bandwidth

Reference mode 0.05Hz ～ 100Hz; Monitoring mode 0.5Hz ～ 40Hz; Operation mode:1Hz～20Hz

Ⅰ.3.7 Common mode rejection ratio(CMRR)

Reference mode ＞90 dB; Monitoring mode＞100 dB; Operation mode＞100 dB

I.3.8 Electrode polarization voltage range

Electrode offset potential ±300mV

I.3.9 Pace pulse detection

Can detect pacing pulses meet the following conditions:

Amplitude:1 mV ～ 10mV;width:0.5ms ～ 2ms;rise time:10μs～100μs

I.3.10 Pacing pulse suppression

When the pacing analysis switch is turned on, pacing pulses meeting the following conditions can be suppressed, without affecting the heart rate calculation:

Amplitude:±2 mV ～ ±700mV;width:0.1ms ～ 2ms;rise time:10μs ～ 100μs

I.3.11 Baseline recovery time

Baseline Recovery < 10 S After Defi.

I.3.12 Calibration Signal

Calibration Signal 1 (mV_{p-p}), Accuracy :±5%

I.4 RESPARATION

I.4.1 Measuring method

Method RA-LL.RA-LA impedance method

I.4.2 Measuring Impedance Range: 0.3~3.0Ω

I.4.3 Base line Impedance Range: 200 – 4000Ω

I.4.4 Bandwidth:0.1 ~ 2.5 Hz

I.4.5 Resp. Rate

Measuring and Alarm Range:Adult 7 ~ 120 bpm,Ped 7 ~ 150bpm

Resolution 1 bpm

Accuracy ±2 bpm

I.4.6 Apean Alarm:10 ~ 40 s

I.5 SpO_2

Comply with standard EN ISO 80601-2-61:2019

I.5.1 SPO2

Measuring Range 0~ 100 %

Accuracy 70% ~ 100%: ±3%;Within the range of 0% to 69%: not defined

I.5.2 Pulse Rate

Measuring and Alarm Range 25~300bpm

Accuracy ±3bpm

I.6 TEMPERATURE

Comply with standard EN ISO80601-2-56:2017/A1:2020

I.6.1 Applicable temperature sensor: YSI series,CYF series

I.6.2 Channel 2

I.6.3 measurement

Measuring Range 0 ~ 50 ℃

Accuracy 25 ~ 45℃ error ±0.2℃; Other range accuracy is not defined.

I.7 NIBP

Standard: EN IEC 80601-2-30:2019; ANSI/AAMI SP10:2002/A1:2003/(R)2008

I.7.1 Method Oscillometric

I.7.2 Mode Manual, Auto, STAT

I.7.3 Measuring Interval in AUTO Mode

1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240,480 (Min)

I.7.4 Measuring Period in STAT Mode 5 Min

I.7.5 Pulse Rate Range 40 ~ 240 bpm

I.7.6 Measuring and alarm range:

Adult: SYS 40 ~ 260 mmHg,DIA 10 ~ 220 mmHg,MEAN 20 ~ 240 mmHg

Pediatric:SYS 40 ~ 230 mmHg, DIA 10 ~ 160 mmHg,MEAN 20 ~ 170 mmHg

Measuring range: 0mmHg ~ 300 mmHg resolution: 0.133kPa(1mmHg)

Mean error: ±5mmHg, standard deviation: ±8mmHg

I.7.7 Overpressure Protection

Adult Mode 300±3 mmHg

Pediatric Mode 280±3 mmHg

I.8 Respiratory Carbon dioxide parameters

Meet the requirements of the ISO80601-2-55-2018.

I.8.1 Measurement

Measuring range: 0~20% (0~152 mmHg);

Measurement accuracy: ± (0.43% + 8% of the reading);

Resolution: 0.1% (1mmHg).

I.8.2 Airway respiratory rate

Measuring range: 0-160 brpm.

Measurement accuracy: ± 1 brpm.

Resolution: 1 brpm.

I.8 Alarm specification

Alarm level: high, medium and low, comply with IEC60601-1-8, EN 60601-1-8

Alarm type: physiological alarm, technical alarm, available in latch and unlatch two types.

Alarm indicator: red and yellow alarm indicator light.

Appendix Ⅱ

ANSI/AAMI EC13:2002 (R)2007 Summary of Performance requirements

standard clause	requirement description	min / max		unit	min /max value
4.2.1	Operating conditions				
	Temperature	Range		℃	0~40
	Relative humidity	Range		%	≤85%(non-condensing)
	Atmospheric pressure	Range		hPa	700~1060
	Line frequency	Range		Hz	50±1
	Line voltage(rms)	Range		V	220±22
	preheating time	Min		min	2
	ECG (electrocardiograph)				
4.2.2	Overload protection:AC voltage: no damage from differential ac voltage, line frequency, 1 V applied for 10 s		min	V	1
4.2.3	Auxiliary output (if provided)		No		
	No damage from short-circuit				
4.2.4	Respiration, leads-off sensing and active noise suppression:		Yes		
	Direct current any active lead				
4.2.5	QRS detection				
4.2.5.1	Range of QRS wave amplitude and duration—Meet 4.2.6 for pulses of Figure 6				
	Amplitude		Range	mV	0.5~5
	Duration (adult monitor)		Range	ms	70~120
	Duration (neonatal/pediatric)		Range	ms	40~120
	No response for signals				
	Amplitude (except for neonatal/pediatric		max	mV	0.15

	operation)			
	Duration with amplitude of 1 mV (except for neonatal/pediatric operation)	max	ms	10
4.2.5.2	Line frequency voltage tolerance	min	uV	100
4.2.5.3	Drift tolerance (0.1 Hz signal on train of QRS signals:			
	Triangular wave amplitude	N/A	mV	4
	QRS amplitude	N/A	mV	0.5
	QRS duration	N/A	ms	100
	QRS repetition rate	N/A	bpm	80
4.2.6	Range/accuracy of heart rate meter:			
	Range (adult monitor)	Range	bpm	30~300
	Range (neonatal/pediatric monitor)	Range	bpm	30~350
	Error: either	max	%	±10
	… OR (whichever greater)	max	bpm	±5
	Indicated rate for signal rate < disclosed rate meter min	max	bpm	30
	Indicated rate for signal rate = 300 bpm (adult operation)	min	bpm	300
	Indicated rate for signal rate = 350 bpm (neonatal/pediatric operation)	min	bpm	350
4.2.7	Alarm system requirement			
4.2.7.1	Alarm limit range:			
	Upper range (adult)	min	bpm	100~200
	Upper range (neonatal/pediatric)	min	bpm	100~250
	Lower range (adult and neonatal/pediatric)	min	bpm	30~100
4.2.7.2	Alarm resolution, either …	min	%	±10
	… OR (whichever greater)	min	bpm	±5
4.2.7.3	Alarm limit error either …	max	%	±10
	… OR (whichever greater)	max	bpm	±5
4.2.7.4	Time to alarm—cardiac standstill	max	s	10
4.2.7.5	Time to alarm—low heart rate	max	s	10

4.2.7.6	Time to alarm—high heart rate	max	s	10
4.2.7.7	Alarm silencing	Provision for silencing and resetting		
4.2.7.8	Alarm disabling	Indication that alarm is disabled		
4.2.8	Monitors with ECG waveform display capability			
4.2.8.1	Input dynamic range:			
	Input signal amplitude	max	mV	±5
	Rate	max	mV /s	320
	dc offset voltage	Range	mV	-300~+300
	Variance in output signal	max	%	±10
	Inoperability indication	max	%	50
4.2.8.2	Input impedance: signal reduction (0.67–40 Hz)	max	%	20
4.2.8.3	System noise	max	uV	30
4.2.8.4	Multichannel crosstalk: unwanted signal in other channels from applied signal	max	%	5
4.2.8.5	Gain control and stability:			
	Gain selections			
	—All displays	min	mm/mV	5
	—Permanent displays	Required	mm/mV	10
	Continuously variable gain control permitted, manual override required			
	Gain change per minute	max	%/min	0.66
	Total gain change in one hour	max	%	±10
4.2.8.6	Time base selection and accuracy:			
	Time base selection			
	—Permanent displays	Required	mm/s	25
	—Nonpermanent displays	N/A	mm/s	12.5.25.50
	Time base maximum error	max	%	±10

4.2.8.7	Output display:			
	Channel width	min	mm	30
	Aspect ratio	N/A	s/mV	0.2.0.4.0.8
4.2.8.8	Input signal reproduction accuracy:			
	Overall system error: either …	max	%	±20
	… OR (whichever greater)	max	uV	±100
	Frequency response			
	(A) Sinusoidal input ...	Range	Hz	0.67~40 (–3dB attenuation)
	(B) Response to a 20 ms wide triangular input …	Range	%	0 to 25 reduction in peak amplitude
	Impulse response to 0.3 mV/s impulse outside region of impulse			
	Displacement	max	mV	0.1
	Slope	max	mV /s	0.30
	Electrode weighting factors	min	%	±5
	Hysteresis after 15 mm deflection	max	mm	0.5
4.2.8.9	Standardizing voltage	see in 4.2.8.9		
4.2.8.10	Common mode rejection (allowable noise for 10 Vrms, line frequency)	max	mV	1
4.2.8.11	Baseline control and stability			
	Return time after reset	max	s	3
	Drift rate in 10 seconds	max	uV/s	10
	Baseline drift rate in one hour	max	uV	500
	Drift over temperature	max	uV/℃	50
4.2.8.12	Pacemaker pulse: indication— ECG signal display in presence of pacemaker pulses of amplitude ±2 mV to ±700 mV, duration 0.5 ms to	min	mV	0.2

	2 ms, maximum rise time of 100 µs, and frequency of 100 pulses per minute.			
4.2.8.13	Synchronizing pulse: time interval from R wave peak to sync pulse output, plus disclose amplitude, duration, and output Z	N/A	ms	35
4.2.8.14	Electrosurgical interference suppression: change in heart rate, relative to pre-interference rate	max	%	±10

Standard clause	Requirement	Published Criteria
4.1.2.1a)	Electrosurgery protection: Cautionary information if electrosurgical unit overload will damage device.	No damage
4.1.2.1b)	Respiration, leads-off sensing, and active noise suppression	Not applicable
4.1.2.1c)	Tall T-wave rejection capability: Maximum T-wave amplitude for which heart rate indication is within specified error limits. If performance is affected by low-frequency response, disclose for all choices.	Diagnostic and monitoring mode 0.9mV Operation mode 0.3mV
4.1.2.1d)	Heart rate averaging: Type of averaging used for computation of minute heart rate.	8 beats average, display refresh speed 1s
4.1.2.1e)	Heart rate meter accuracy and response to irregular rhythm: Indicated heart rate for waveforms of Figure 3.	Respectively 80bpm±5bpm.60bpm±5bpm.120bpm±5bpm.90bpm ±5bpm
4.1.2.1f)	Response time of heart rate meter to change in heart rate: Time in seconds for meter to indicate 40 bpm increase and 40 bpm decrease from 80 bpm.	1.＜10s; 2.＜10s
4.1.2.1g)	Time to alarm for tachycardia: Time to alarm (or failure to alarm, if applicable) for waveforms of Figure 4	＜10s

4.1.2.1h)	Pacemaker pulse rejection warning label: Warning of the need for close surveillance of pacemaker patients, since rate meters may count pacemaker rate during cardiac arrest or some arrhythmias.	For patients with pacemakers, the heart rate monitor may incorporate pacemaker pulses into the heart rate during cardiac arrest or arrhythmia. Don't rely entirely on the heart rate monitor alarm.
4.1.2.1i)	Audible alarm disclosure: Location of source and frequency of sound.	The speaker is placed in the back of the product; Sound frequency: 1KHz
4.1.2.1j)	Visual alarm disclosure: Location, color, size, and modulation.	The alarm light is in the upper left of the front of the product;1.Red light on for high level alarm,11 seconds per time;2.Yellow light on for medium level alarm,25second per time;3.Yellow light on for low level alarm,25second per time.
4.1.2.1k)	Battery-powered monitors: Minimum operating time, battery charge time, provision of battery depletion indicator, description of function.	Measuring blood pressure every half hour can work for 100 minutes on full charge;the maximum charging time of the battery shall not exceed 12 hours;the battery indicator is in the lower right corner of the product;It will take about 4.3 hours for KM8A&KM10A to charge up to 90% of the battery, and other models 3 hours(when working on battery). the battery indicator turns red when low battery, and automatic power off within 10 minutes.

4.1.2.1l)	Telemetry	Not applicable
4.1.2.1m)	Line isolation monitor transients: Cautionary information and methods of minimizing interference.	Ground the device correctly,treat the patient's skin properly before apply the electrode,use the electrodes produced by the authorized manufacturer.
4.1.2.1n)	Special disclosure requirements for monitors with nonpermanent ECG waveform display: Available time bases; range of adjustment of aspect ratio.	Available time bases are: 12.5mm/s.25 mm/s.50 mm/s;Available aspect ratio are: 0.2s/mV.0.4 s/mV.0.8 s/mV
4.1.2.1o)	Electrode polarization: Cautionary statement concerning effect of electrode type on system recovery from overload, especially recovery time after defibrillator pulses.	Please use the electrodes designated,otherwise, the recovery time after defibrillation will be affected.
4.1.2.1p)	Auxiliary output: Explanation of proper connection of other devices to auxiliary output, if provided, with special reference to maintenance of risk current characteristics, including bandwidth, gain, propagation delay, and dealing with pacer pulses.	Not applicable
4.1.2.1q)	Alarm silencing: Disclosure of time required for reactivation of alarm after alarm silencing and, if alarm reactivation time is adjustable, disclosure of the range of time intervals.	Available time interval are: 60s.120s and the ones displayed on the screen after turn on the alarm.
4.1.2.1r)	Battery disposal: Adequate instructions for disposal of batteries.	The dispose of electronic products shall in accordance with local scrap specifications or return

		to the manufacturer for recycling.
4.1.2.2	Application notes: Description of device's intended application and available functions; procedures for checking controls and functions; information concerning electrodes—number of electrodes needed, polarity of cables (if other than standard AAMI cable); any special cable characteristics needed to ensure conformance with standard; warning about use of electrodes of dissimilar metals; settings necessary for pediatric/neonatal monitoring.	The multi parameter patient monitor can be used in hospital for monitoring ECG, NIBP, SPO2, RESP, and TEMP vital signs of patients, and display them on the screen of the device, also can record and output the ECG and SPO2;there are 5electrodes,white RA.black LA.red LL.green RL.brown C;electrodes are made of copper,different metal material are not allowed;when monitoring pediatrics, the monitor shall be set to the appropriate mode,otherwise the date might not be measured or might be inaccurate and cause risks to patient.
4.1.3	Service manual: Adequate care, preventive maintenance, and repair instructions; electrical specifications complete enough to allow reasonable field repair and that identify acceptable repair facilities; recommended frequency of prevention maintenance.	we can provide service manual if customer asked:the manual shall contain information on maintenance and repair instructions.including circuit diagram, schematic block diagram, connection diagram, and component number,such information enables the technician to complete the maintenance items specified in the repair specification for which the service can be represented.

4.1.4.1	Pacemaker pulse rejection capability/Pacemaker pulse rejection, without overshoot: Disclosure in operator and service manual of pacemaker pulse rejection capability for pacing pulses without overshoot ±2 mV to ±700 mV amplitude, 0.1 ms to 2.0 ms duration, overshoot less than .05 a p (Figure 5a), and settling time less than 5 μs; pulse onset, rise, and fall time not greater than 100 μs; pulse onset 40 ms or less before QRS onset; and with an identical pulse preceding this pulse by 150 ms to 250 ms.	For pacemaker pulse with amplitude of 1mV ~ 10mV and width of 0.5ms ~ 2ms, like: Pulse amplitude × pulse width ≤2 mV. ms pulse signal can be suppressed
4.1.4.2	Pacemaker pulse rejection with overshoot: Disclosure in operator and service manual of pacemaker pulse rejection capability for pacing pulses with same parameters as above except overshoot (recharge) time constants between 4 ms and 100 ms, overshoot defined by choice of two methods. Disclose whether test method A or B or both are used.	Not applicable
4.1.4.3	Pacer pulse detector rejection of fast ECG signals: Disclosure must be made in the operator and service manuals of the minimum typical slew rate in V/s RTI that will trip its pacer detector.	5V/sRTI
4.1.4.4	Pacemaker pulse appearance in auxiliary output: Disclosure	Not applicable

	of filtering and any substitution done on pacemaker pulses as they appear in auxiliary output.	
4.1.4.5	Pacer pulse detector disabling: Disclosure of operating modes or signal conditions that cause the pacer pulse detector to be disabled or ignored.	Pacing analysis is off or pacing analysis is on but the product works in operation mode

Appendix Ⅲ

Table of Hazardous substance in product

Component	Hazardous substance					
	Plumbum(Pb)	Mercury(Hg)	Cadmium(Cd)	Hexavalent chromium(Cr(VI))	polybrominated biphenyls(PBB)	polybrominated diphenyl ethers(PBDE)
Shell	○	○	○	○	○	○
Operation panel	○	○	○	○	○	○
PCBA	○	○	○	○	○	○
Label	○	○	○	○	○	○
Screen	×	×	×	×	×	×
Package	×	×	○	○	×	×
Connector	○	○	○	×	○	○
Power cord	○	○	○	○	○	○
Battery	×	○	×	○	○	○
Accessories. Sensors	×	○	○	○	○	○

Key:○:Indicates that the content of the hazardous substance in all homogeneous materials of the part is in comply with the requirements of standard SJ/T 11363-2006.

×:Indicates that the hazardous substances in the part of a homogeneous material content is beyond the limit requirements in standard SJ/T 11363-2006.

When products and batteries are discarded after normal use, dispose of them in accordance with the laws and regulations of the local government.

Products contain hazardous substances can be safely used within the environmentally friendly use period, and shall enter the recycling system after the expiration.

Appendix Ⅳ

EMC

The device can generate and radiate RF energy.The device is capable of causing other non-medical devices or medical devices, and electromagnetic interference between the radio communication.According to the statement in IEC 60601-1-2, EN 60601-1-2,this product belongs to the first group of emission restrictions, Class A medical equipment, need to provide protective measures to avoid interference. However, it is not completely guaranteed that electromagnetic interference will not occur under certain installation conditions.

When it is found that the device causes interference (need to confirm with the switchgear), the operator (or authorized maintenance personnel) can eliminate the interference according to the following measures:

1、Adjust or relocate the affected device;

2、Increase the distance between this device and the affected device;

3、Use another power source to power the device;

4、Consult the maintenance staff for more suggestions.

Warning

1、Using non-original accessories, sensors, and cables may increase the electromagnetic emission of the device or reduce electromagnetic immunity.

2、The device cannot be used close to or stacked with other devices.If necessary, it should be closely observed whether it can be used normally.

Note

1、Before using this device, make sure the equipment required in the requirements regarding EMC are met.

2、The chapter will list the contents described in the IEC 60601-1-2, EN 60601-1-2 form, the user is responsible for ensuring that this device and nearby devicet comply with the radio interference parameters indicated in the general safety requirements.

3、Do not use equipment that intentionally emits RF signals near the device(such as mobile phones, radio transceivers or radio control products),otherwise, it may cause the operation to exceed the specified value.When near this device, please turn off this type of equipment.The operator shall be liable to prompt the patient or other persons related to this equipment fully comply with the above requirements.

4、Any interference due to the use of non-recommended internal connecting cable or device or unauthorized modifications to this alteration caused,the manufacturer will not be responsible for this.

Table 1

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

Table 2

Guidance and manufacture's declaration – electromagnetic immunity			
The Multi-parameter monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Multi-parameter monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. Make sure there is not impulse interference >1kV in use environment.
Surge IEC 61000-4-5	±1 kV wire to wire ±2 kV wire to ground	±1 kV wire to wire ±2 kV wire to ground	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) For 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Multi-parameter monitor requires continued operation during power mains interruptions, it is recommended that the Multi-parameter monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	If image distortion occurs, it may be necessary to position the Multi-parameter monitor further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacture's declaration – electromagnetic immunity			
The Multi-parameter monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Multi-parameter monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the P15G including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}\sqrt{P}$ $d=1.2\sqrt{P}\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}\sqrt{P}$ 800 MHz to 2.5 GHz Where*P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in metres (m). Field strengths from fixed RF

			transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

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

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

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Multi-parameter monitor

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}\sqrt{P}$
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	23

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

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

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

Contact:
Registrant/manufacturer/after-sales service:MDKMed Medical Technology Co., LTD
Registration address of the manufacturer:Room 502A, Building 7, No. 22, Xinyan Road, Donghu Street, Linping District, Hangzhou City, Zhejiang Province,China
Production address: No. 22, Cangling Rd., Huzhen town, Jinyun county, Lishui, Zhejiang, China
Postal code:321404
Telephone:0578-88040712
Hotline:400-880-8392

European Authorized Representative:
MedNet EC-REP C IIb GmbH
Borkstrasse 10,
48163 Münster, Germany

Date of Issue:Mar.07, 2024
Version:1.3