GIMA

PROFESSIONAL MEDICAL PRODUCTS

NEW CMS 8000 MULTIPARAMETER PATIENT MONITOR

User Manual

REF **CMS8000 (GIMA 35152)**

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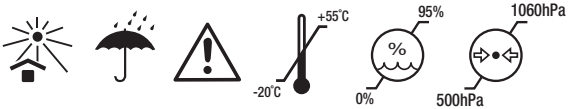
CE 0123



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Responsibility on the manufacturer party

Our company is responsible for safety, reliability and performance of this equipment only in the conditions that:

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

WARNING

- **This monitor is not a device for treatment purpose.**

NOTE

- **This equipment is not intended for family usage.**
- **Whether the instrument supports the functions described in this manual, please refer to the actual object.**

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

Warranty

Workmanship & Materials

Our company guarantees new equipment other than accessories to be free from defects in workmanship and materials for a period of 12 months (6 months for accessories) from date of delivery to purchaser. Our company's obligation under this warranty is limited to repairing only.

Exemptions

Our company'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 parts or accessories of the product or the substitution upon it not approved by us or repaired by anyone other than a our company authorized personal. This warranty shall not extend to any instrument which has been subjected to abnormal use, maintenance negligence or damaged; any instrument from which our company'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

Our company is not responsible for the effects on safety, reliability and performance of the Monitor if:

- The components are disassembled, stretched or re-adjusted.
- 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 Electrical 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

Return Procedure

In the event that it becomes necessary to return a unit to our company, the following procedure should be followed:

- Obtain return authorization. Contact our Service Department and tell us the product serial number. The number is marked on the outside of the shipping package. Return shipments would 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.
- Freight policy. The customer is responsible for freight charges when equipment is shipped to our company for service (this includes customs charges).

Preface

This manual gives detailed description to the Monitor concerning its performance, operation, and other safety information. Please read the user manual carefully before use in order to operate this product correctly and guarantee the safety of patient and operator.
Keep the user manual near the product for convenient and timely accessed when needed.

Following symbols represent some important facts that you have to pay special attention to:
Safety warnings indicate the severity of potential hazards.
Warning: prompting potential dangerous or unsafe operations, if not avoided, it may result in death or severe personal injury or property damage.
Caution: prompting potential dangerous or unsafe operations, if not avoided, it may result in slight personal injury, product failure or damage, or property damage.
Note: emphasizing important attentions, providing explanations or interpretations for better use.

NOTE

- **The user manual contains descriptions concerning all configurations, so part of the content may not suitable for the product your purchased. If you have any doubts, please contact with us.**
- **Refer to the device for its date of manufacture.**
- **Service life：Valid for 5 years from the date of production.**

This manual is intended for persons who are familiar with the functioning measurements and have experience in operating the monitoring equipment.

Contents

第1章

Chapter 1 Safety

1.1 Safety information

WARNING

- **Before using the device, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defect or signs of aging which may impair the safety or performance.**
- **The Monitor is intended for clinical monitoring application with operation only granted to appropriate medical staff.**
- **The monitor can be used on only one patient at a time.**
- **EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.**
- **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 our company.**
- **To prevent delayed treatment, sufficient alarm setup should be done according to individual patient situation and make sure that alarm sound can be activated when alarm occurs.**
- **Do not touch the patient, table, or the device during defibrillation.**
- **The device is available to connecting with the patient who using cardiac pacemaker or other electrical stimulation devices, but this may result in risks.**
- **When used with Electro-surgery equipment, the operator (doctor or nurse) must give top priority to the patient safety.**
- **The monitor and devices connected to it shall form an equipotential system (protective earthing).**
- **If the protective earthing system is unstable, the monitor should apply internal power supply.**
- **This device can only be connected to a power socket with protective earthing. If the power socket is not grounded, do not use the socket and the monitor should be power supplied by rechargeable batteries. Do not connect the three-wire cable to a second-wire plug.**
- **The information of physiological waveform, physiological parameters and alarm, etc., shown on the monitor is for medical reference only, it can not be regarded as the basis for clinical treatment directly.**
- **Be careful to place the power cord and various cables of accessories to avoid the patient being wound or suffocated, or the cable entangled together, or subject to electrical interference.**
- **No modification of this equipment is allowed.**
- **The disposal of scrap device, its accessories and packaging should follow the local laws and regulations, to avoid polluting to the local environment. And the packaging materials must be placed in the region where the children are out of reaching.**

CAUTION

- **At the end of its service life, the product described in this manual, as well as its accessories, must be disposed in compliance with related local regulations or hospital regulations. If you have questions concerning disposal of the product, please contact our company or representative institution.**
- **When you have questions about the integrity of the external grounding of the monitor and its arrangement, the internal battery must be used for operation.**
- **Electromagnetic fields can affect the performance of the monitor, so other equipment used near the monitor must meet the appropriate EMC requirements. Mobile phones, X-rays, or MRI devices are possible sources of interference because they could emit high-intensity electromagnetic radiation.**
- **Before turning on the power to the device, make sure that the supply voltage and frequency match the device's label or the requirements specified in this manual.**
- **When the battery is about to exceed its service life, remove the battery immediately from the monitor.**
- **To ensure patient safety, please use the accessories specified in this manual.**

NOTE

- **Install the equipment in a location that is easy to observe, operate and maintain.**
- **If the monitor gets damp accidentally, or the liquid is dumped on the equipment or accessories, especially if the liquid is likely to enter the monitor, please contact the service personnel in time.**
- **The software is developed in accordance with IEC62304. The possibility of risks caused by program error has been minimized.**
- **The pictures and interfaces in this manual are for reference only, please in kind prevail.**
- **The accompanying document of each probe, probe cable extender and probe cover accompanying with the monitor is only intended for use in this monitor. They are designed for use with specific thermometer or monitoring equipment,The operator is responsible for checking the compatibility of the thermometer or monitoring equipment, probe, probe cable extender and probe cover before use, and Incompatible components can result in degraded performance.**

1.2 Precautionary measures

- In order to avoid the accumulation of electrostatic charge, it is recommended to store, maintain and use the equipment at a relative humidity of 30% or more. The floor should be covered with ESD dissipated carpets or similar materials. In the use of the components, non-synthetic clothing should be wore.
- In order to prevent electrostatic discharging to the ESD-sensitive parts of the device, the personnel should contact the metal frame of the components or the large metal objects near the device. When using the device, especially when it is possible to contact the ESD-sensitive parts of the device, the operator should wear a grounded bracelet designed for ESD-sensitive devices. For more information on proper use, please refer to the

instructions provided with the bracelet.

ESD Precautionary procedure training

- All potential users are advised to understand the ESD warning symbols and receive training on ESD precautions.
- The most basic content of the ESD precautionary procedure training should include an introduction to electrostatic charge physics, voltage level in the conventional case, and damage to the electronic components when the operator with electrostatic charge contacts them. In addition, the methods for preventing electrostatic buildup, and the manner and reasons for the release of human body static electricity to the ground or equipment frame or the use of a bracelet to connect the human body to the equipment or the ground before establishing the connection should be described.

1.3 Symbols

Your device may not contain all the following symbols.

	Caution: read instructions (warnings) carefully		Follow instructions for use
	Battery		Manufacturer
	Alternating current		Expiration date
	Direct current		This way up
	Standby		Fragile, handle with care
	USB port		Keep in a cool, dry place
	Equipotentiality		Stacking layers limit
P/N	Part number		Atmospheric pressure limit
LOT	Lot number		Temperature limit
SN	Serial number		Humidity limit
	Date of manufacture		Internet access
EC REP	Authorized representative in the European community		Not made with natural rubber latex
	Type approval certificate number and mark of measuring instruments		A sign of anti-defibrillation ECG cable

CE 0123	Medical Device compliant with Directive 93/42/EEC
	WEEE disposal
	Defibrillation-proof type CF applied part.
REF	Product code

Chapter 2 General

2.1 Introduction

Structure and composing: main unit, accessories (ECG lead cables, SpO_2 sensor, NIBP extension tube, NIBP cuff, TEMP probe, etc.) and power cord.

The monitor is applicable for the clinical monitoring of adult, pediatric and neonate(SpO_2 function is inapplicable on neonate in American). Physiological parameters including ECG (including ST-segment measurement and arrhythmia analysis), RESP, SpO_2, PR, NIBP, TEMP,IBP and CO_2, can be monitored. The monitoring information could be displayed, reviewed and printed.

WARNING

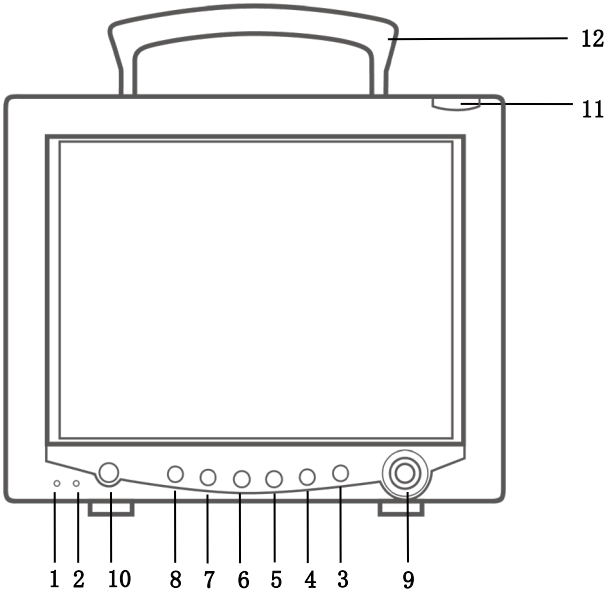
- **The monitor should be used by a qualified clinician or under the guidance of a professional clinician. Personnel who uses this monitor should be adequately trained. The personnel without authorized or who are not trained, shall not carry out any operation.**

2.2 Contraindications

No contraindications.

2.3 Main unit

Front view



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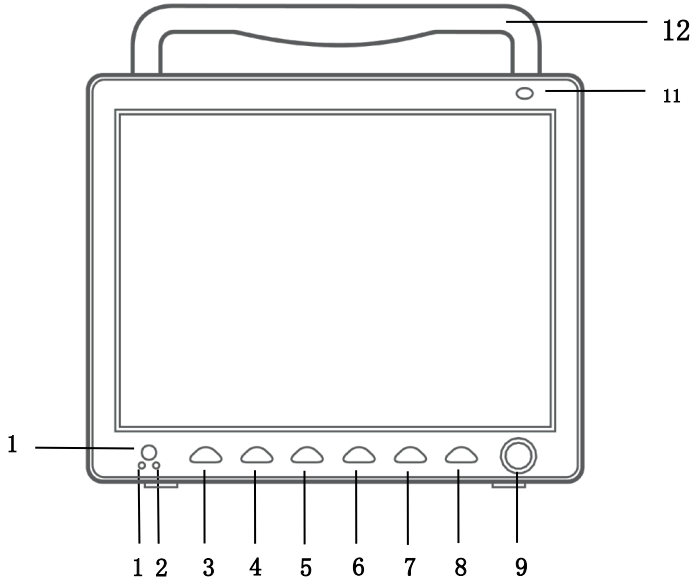

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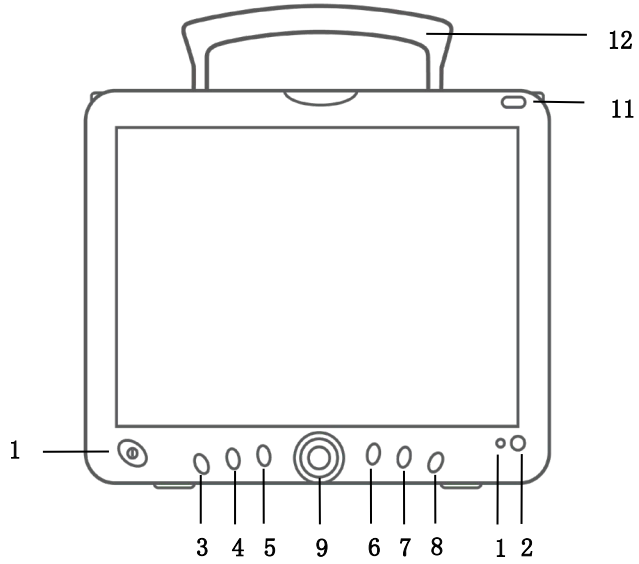
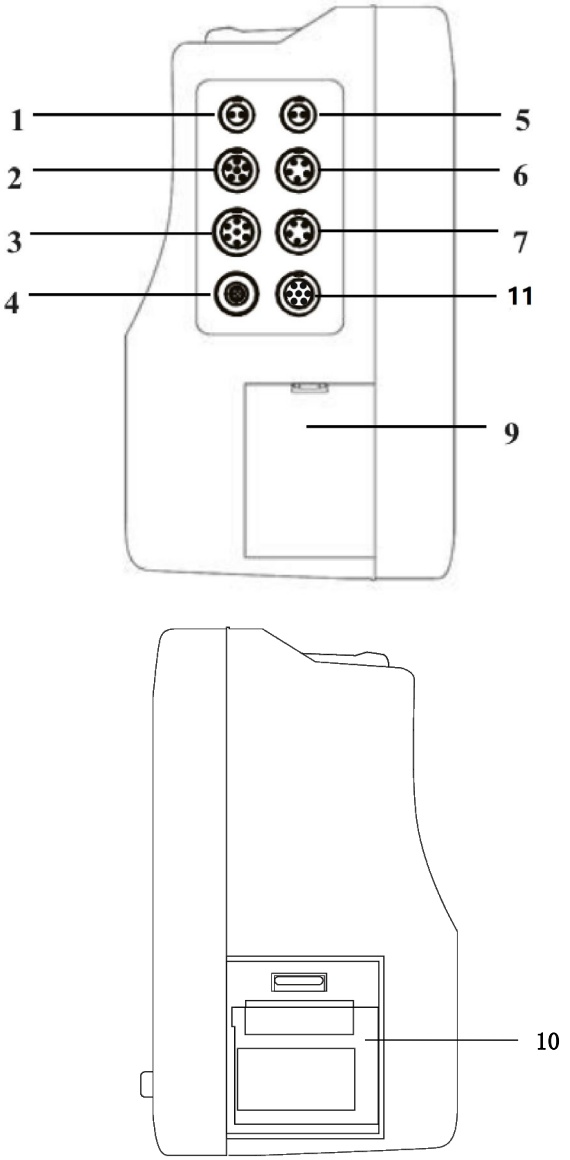


CMS9000

1	AC indicator: On: the monitor is connected to AC power supply; Off: the monitor is disconnected from AC power supply.
2	Battery status indicator: it displays green and flickers under battery-powered condition, it always displays orange in charging state and green after fully charged. Or Running indicator: when the device turns on, this indicator will be lighting, when it tuns off, this indicator will go out.Please make the object as the standard.
3	MENU：Press this button to call up the SYSTEM MENU, in which the user may set up system information and perform review operation.
4	NIBP：Press it to inflate the cuff to start a blood pressure measurement. When measuring, press it to cancel the measurement and deflate the cuff.
5	REC/STOP：Press it to start a real time recording. The recording time can be set in "RT REC TIME" item under "RECORD" menu.
6	SILENCE：Push this button to suspend the alarm (with 1 minute and 2 minutes selectable), and a  symbol appears in the alarm area. Push this button for more than 1 second to mute all kinds of sounds (including alarm sound, heart beat, pulse tone, key sound). At the same time, a  symbol appears. Push this button again to restore all kinds of sounds and the  symbol disappears from the screen.
7	FREEZE：Freeze or unfreeze the waveform
8	MAIN：Whatever levels of menu the system is in, press the button and the system will always return to the main screen.
9	Rotary knob ◆ Rotating: clockwise or counter-clockwise rotating to move the cursor ◆ Pressing: press the knob to execute certain operations, such as entering a menu or processing a command.
10	ON/OFF ◆ ON: press this button to turn on the monitor ◆ OFF: in turning on state, keep pressing this button for 3 seconds can turn off the monitor.
11	Alarm indicator: indicating alarm level by different color and flicking frequency
12	Handle

Side view



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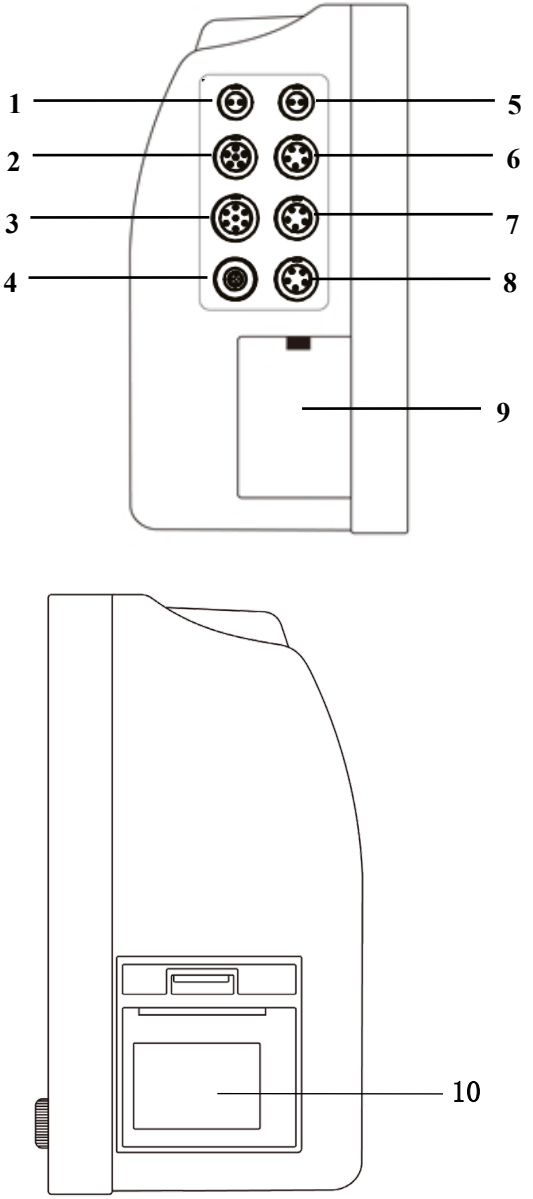

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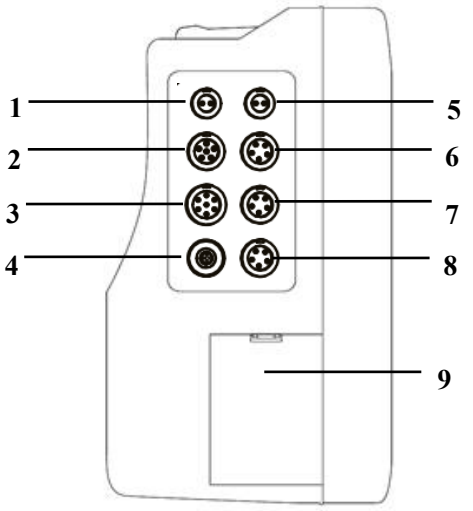
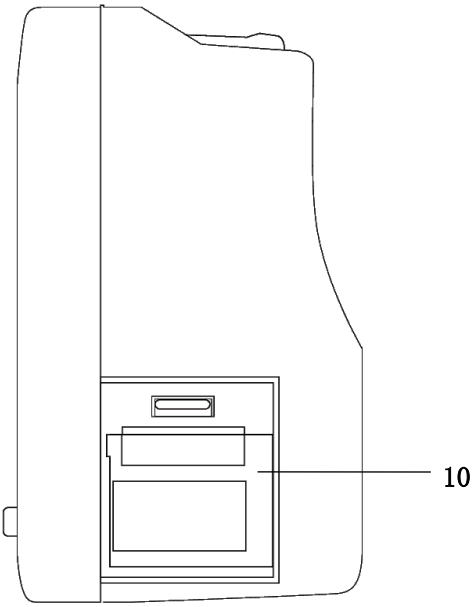
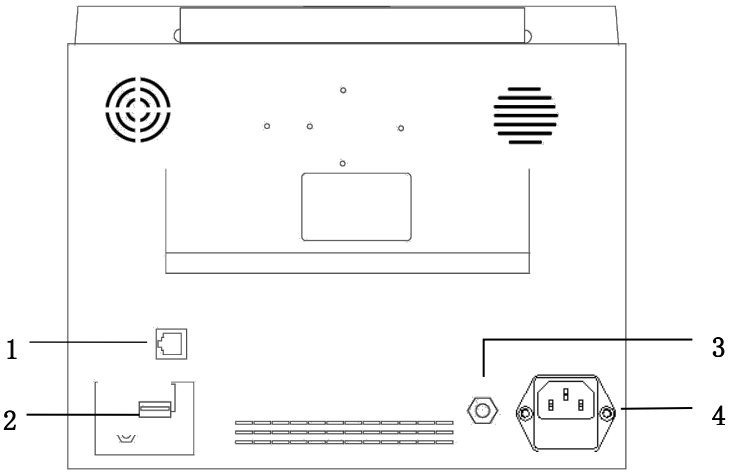




CMS9000

1	T1: Socket for channel 1 TEMP probe	
2	SpO_2: Socket for SpO_2 sensor	
3	ECG: Socket for ECG cable	
4	NIBP: Socket for NIBP cuff	
5	T2: Socket for channel 2 TEMP probe	
6	IBP/CO_2: IBP or CO_2 interface	Note: [6] and [7] can not be connected to a function at the same time; if connected, only the earlier connection is recognized.
7	IBP/CO_2: IBP or CO_2 interface	
8	Option: reserved interface	
9	Battery cover	
10	Recorder	
11	CO: Socket for CO cable	

Rear view



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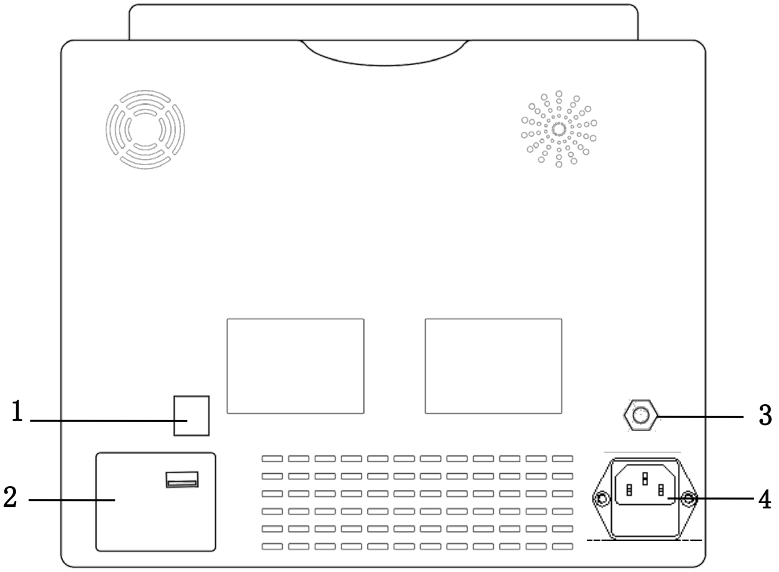

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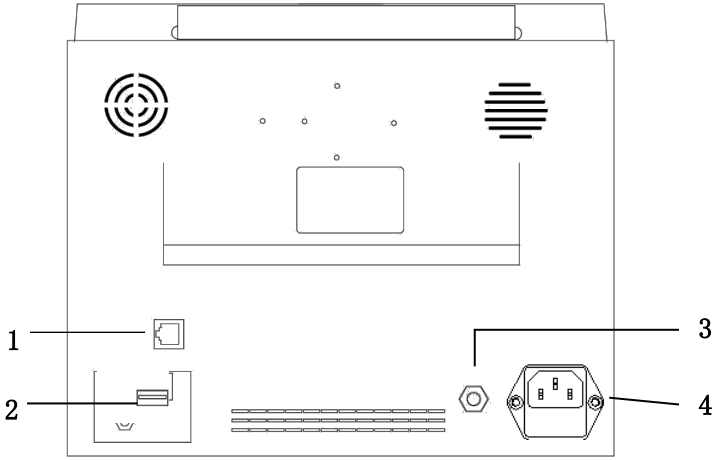


CMS9000

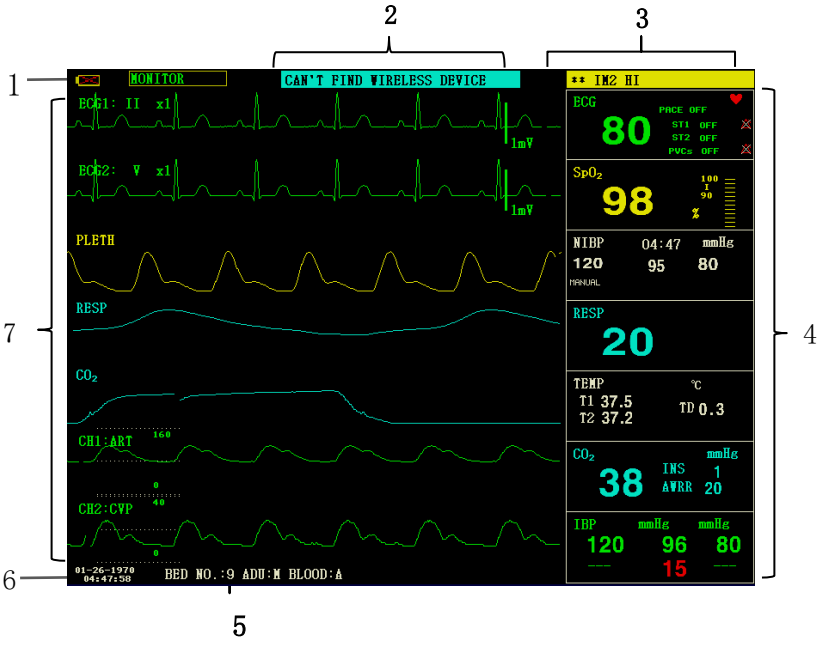
1	Network interface: standard RJ45 interface, connecting with the central monitoring system of our company by network cable
2	USB port: connecting with external memory devices
3	Equipotential grounding terminal: when the monitor is used together with other equipment, use a cable to connect other equipment to the equipotential terminal of the monitor, which eliminates the ground potential difference between the different devices to ensure safety.
4	AC power port. Fuse: T1.6AL250V

NOTE

- **Replacement of fuse: unplug the power cord, lightly open the fuse slot with a tool to replace the fuse.**
- **The network interface can only connect with the central monitoring system of our company to form a network monitoring system.**

2.4 Display

The monitor adopts high resolution color TFT LCD screen, which clearly displays all physiological parameters and waveforms of the patient. The following figure is a standard interface in normal monitoring state.



1.Battery indicator

 The battery works normally, the solid part represents battery level.

 Battery is low, it needs to be charged immediately, and the monitor generates low battery alarm.

2.Technical alarm area

Displaying technical alarms and prompt messages, cycle display for multiple pieces of information.

3.Physiological alarm area

Displaying physiological alarms, cycle display for multiple pieces of information.

4.Parameter area

Consisting of several individual areas, displaying the measured value corresponding to each parameter module. The name of an individual parameter is on the top left of its area.

5.Patient information area

"BED NO.": Bed number of patient under monitoring

"PAT TYPE": Patient type of the patient under monitoring

"SEX": Patient sex

"BLOOD": Patient blood type

6.Date and Time

Indicating current date and time, available to calibrated if necessary.

7.Waveform area

Mainly displaying the waveform of physiological parameters, the name of each waveform is on the top left.ECG lead is selectable according to the demand. The filter mode is displayed at the top of screen. Gain of each channel is displayed above its waveform, at the right side of the waveform, there is a scale of one millivolt.

When a menu pops up in the interface, it always locates a fixed area in the middle of the waveform area, which will cover parts of the waveform, while the waveform will appear after exit the menu.The waveform is refreshed at a certain speed, the speed adjustment please refer to the setup of each parameter.

Chapter 3 Installation

The portable monitor is designed to comply with relevant safety requirements of IEC 60601-1, IEC 60601-2-27 and IEC 80601-2-30 for medical electrical equipment. The system has a floating input for defibrillation proof and electrosurgical knife protection. If the correct electrodes (see the section about ECG Monitoring) are used and placed according to the manufacturer's instructions, the display will be restored within 5 seconds after defibrillation.

WARNING

- **If any sign of damage to the monitor function is detected, or an error message appears, do not use it on any patient. Contact biomedical engineer in the hospital or our maintenance engineer immediately.**
- **All analog and digital equipment connected to this device must be certified by specified IEC standards (e.g. IEC 60950 and IEC 60601-1), and all equipment shall comply with the requirements of IEC 60601-1-1 (valid versions) for connection. The person who connects the additional equipment to the input/output port, is responsible for the compliance with the IEC 60601-1-1 standard. If you have any questions, please contact us.**
- **When this device is connected to other electrical equipment in order to achieve a specific function, if the hazards of this combination can not be determined from the specifications of each equipment (for example, the risk of electric shock due to the accumulation of leakage current), please contact our company or experts in the hospital related this field to ensure that the necessary safety of all equipment in this combination will not be damaged.**
- **Please use our designated bracket (optional). When installing the bracket, please avoid the screws to touch the circuit board inside the machine.**
- **When the monitor is connected to the high-frequency surgical equipment,in order to prevent leakage current from burning the patient,the sensor and cable of the monitor should be avoided from contacting the high-frequency surgical equipment.**

NOTE

- **To ensure the monitor works normally, please read this chapter and the content about patient safety before use, and follow the requirements for installation.**
- **If the monitor finds any fatal error during self-test, it will alarm.**
- **Keep the package and packing materials for possible future transportation or storage.**

3.1 Open the Package and Check

Before opening the package, please check it carefully. If any damage is found, please contact the carrier immediately.

Open the package and take out the monitor and accessories carefully. Check the components according to the packing list to see whether the device has any mechanical damage or any part is

missing. If there is any problem, contact the our company immediately.

WARNING

- **The disposal of packaging materials should obey the local regulations or the hospital waste disposal system. The packaging material must be keep out of the reach of children.**
- **The device may get biological contaminated during storage, transport or use. Please confirm that the package is intact before use, especially the disposable accessories. If any damage is found, please don't put is into use.**

NOTE

- **Keep the package and packing materials for possible future transportation or storage.**

3.2 Environmental requirement

Please obey the following instructions to ensure the safety of electrical installation. The environment for potable monitor using shall properly away from vibration, dust, corrosive or flammable gas, extreme temperature or humidity and so on. When it is installed in a cabinet, there should be enough space in front of the device for convenient operation. When the door of the cabinet is opening, enough space at the back of the device should be guaranteed for convenient maintenance. Allow at least 2 inches (5 cm) of space around the instrument to ensure air circulation.

WARNING

- **The environment for use, storage and transport should meets the requirements described in this manual, otherwise the specifications of this product stated in this manual may not be able to achieved, or even cause damage to the device.**

Make sure that the device is free from condensation during working, when it is carried from one room to another room, condensation may appears. This is because it is exposed under humid air with different temperatures.

3.3 Install the Monitor

If everything goes well, please place the monitor on a flat surface or fix it on the wall. The installation of wall bracket please refer to its instructions.

3.3.1 Place on a Flat Surface

Place the monitor on a flat surface. The surface should be away from vibration, dust or corrosive drugs.

3.4 Connect the Power Cables

Please use the power cord equipped for the monitor. Plug the power cord to the power port on the monitor, and another end to a grounded three-core power socket.

If the monitor is equipped with an adopter, plug one end of the adopter to the power port on the

monitor, and another end to a grounded three-core power socket.

NOTE

- **Plug the power cord to the hospital outlet. If necessary, connect it with the equipotential ground wire.**
- **When the device is equipped with battery, it must be charged after transport or storage. If turn on the device directly without connecting with AC power supply, it may not work normally due to lack of electricity. The device can be charged after connecting with the AC power no matter it is turned on or not.**

Ground

In order to protect patients and medical personnel, the enclosure of portable monitor must be grounded. Therefore, the portable monitor is equipped with a removable three-wire cable, when it is inserted into a matching three-wire socket, the device will be grounded through the ground wire in the power cord. If there is no three-wire socket, consult the hospital's electrical management staff.

WARNING

- **Do not insert the three-core wire into a two-core socket.**

Connect the equipotential grounding terminal on the device to the grounding wire. If the hazards of a specific combination can not be determined from the specifications of each equipment (for example, the hazard caused by accumulation of leakage current), please contact the manufacturer or experts related this field to ensure that the necessary safety of all equipment in this combination will not be damaged.

Equipotential ground

The room protective grounding system is realized by power plugs grounding, it already includes the primary protection of the device. For internal examination of the heart or brain, the portable monitoring system must be individually connected to the equipotential grounding system. One end of the equipotential grounding wire (potential equalization wire) is connected to the equipotential grounding terminal on the rear panel of the device and the other end is connected to a connector of the equipotential system. If the protective grounding system is damaged, the equipotential grounding system undertakes the safety function of protecting the grounding wire. The examination of the heart (or brain) should only be carried out in a medical room with a protective grounding system. Before each use, check whether the device is in good working condition. The cable connecting the patient and the device must be free from electrolyte contamination.

3.5 Power on

3.5.1 Device inspection

1. Appearance inspection

   Appearance inspection for the installed monitoring system:

   • Carefully check the patient monitor for any mechanical damage.

   • make sure the monitor is correctly installed according to the specified installation

program.

• Make sure the cables connecting patient monitor and external equipment are undamaged, and connected to corresponding interfaces correctly.

• Make sure the external module is connected correctly.

• Make sure the battery cover is installed.

The chapter *Maintenance and Cleaning* provides detailed information about the cautions, requirements of cleaning, cleaning procedure and recommended cleaning agent.

2. Functional inspection

■ Start

1) Plug the power cord to the AC power port. If the device uses internal battery for power, please make sure that there is enough battery power in the battery.

2) Turn on the patient monitor, the user should observe from the front of the monitor,it should start normally:

• The red and yellow alarm lamp respectively light.

• The system beeps for each time of powering on, and the LED indicator on control panel or the screen flickers once. If no beep sound or flickering, please stop using this monitor, and contact out company for maintenance.

• There are no error messages appear on the screen.

3) Check all functions that the patient may need to ensure the device could work normally.

WARNING

- **When the monitor is powered on, the system will check whether the alarm function (audio and light alarms) is normal. If the alarm function works abnormally, this monitor can not be used for patient monitoring and contact the manufacturer's maintenance department.**

NOTE

- **Charge the battery to full for the first time of use. Keep the monitor connecting with main power supply before the battery is fully charged.**

■ Display

1) Ensure that all text are readable, and all images are clear.

2) Ensure that the device brightness is normal.

■ Main unit

Check whether the time displayed on screen is correct. If necessary, please adjust its time and date.

■ Check the Recorder

If your monitor is equipped with a recorder, open the recorder door to check if paper is properly installed. If it is out of paper, refer to the chapter *Recording* for details.

3.5.2 Start monitoring

1. Check whether the patient cables and sensors are correctly connected.

2. Check whether the settings of the monitor are correct, such as "PAT TYPE" and "Pacemaker".

3. For the detailed information about the measurement and monitoring of each parameter, please refer to relevant chapter.

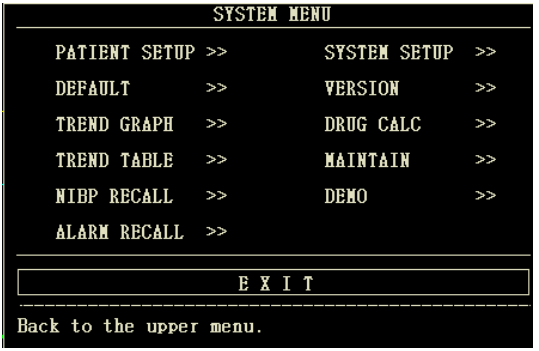
3.6 Power off

Turn off the monitor according to the following steps:

1. Unplug the cables and sensors connecting with the patient.
2. Keep pressing ON/OFF button for 3 seconds to turn off the monitor.

Chapter 4 System Menu

This monitor features flexible configurations. You can customize monitoring content, waveform sweep speed, sound volume, and output content.Press the MENU button on the front panel of the monitor, the interface shown in the following figure will appear:



4.1 Patient Information Setup

Select the "PATIENT SETUP" item in the "SYSTEM MENU", the following patient information can be set by user:

DEPT.:	the department that the patient receives treatment
PAT NO.:	case number of the patient
BED NO.:	selectable from 1～100
DOCTOR:	name of the attending doctor
NAME:	patient's name (Valid characters: a~z, A~Z, 0~9, and the space, 12 characters can be input at most)
SEX:	patient's gender (female, male)
PAT TYPE:	patient type (adult, pediatric, neonate)
ADMIT:	date of admission (format: year/month/day)
BIRTH:	patient date of birth (format: year/month/day)
HEIGHT (cm/inch):	patient's height (turning the knob with the increase/decrease of 0.5 cm/inch each time), the unit of height in other menus accord with the unit set here.
WEIGHT (kg/lb):	patient's weight (turning the knob with the increase/decrease of 0.5 kg/lb each time), theunit of weight in other menus accord with the unit set here.
BLOOD:	blood type of the patient ((Available options: A, B, AB, O, N, "N" means unknownblood type)
SAVE:	to save the changes of patient information, corresponding information will be displayed in Patient information area
DELETE:	to delete the information of current patient, and to register a new patient

After clicking the "DELETE" button in this menu, a dialog box "CONFIRM TO DELETE" will pop up, you could select "YES" or "NO" to decide whether to clear current patient information.

NOTE

- **If you choose "YES", the information of current patient will be deleted.**
- **Please click "SAVE" button if the information of current patient is changed, otherwise the changes will be invalid.**

4.2 Default setup

NOTE

- **After selecting any item in this sub-menu, the selected item will replace the current setup of the system and accordingly become the system default configuration.**

In this sub-menu, you can select both the factory default and the user-defined default. Also in this sub-menu, you can save the current system configuration as the user-defined default configuration. But at this time, the system will automatically save all the setups in the parameter menu, ECG gain and filter way as the user-defined default configuration according to the patient type. Also, a dialog box "CONFIRM TO SAVE" will pop up.

Select "YES" to save all configurations of current patient type as user-defined default configuration.

Select "NO" to give up the modification and the system will keep the previous configuration.

NOTE

- **After selecting any item in the "DEFAULT" menu and exiting the dialog box, the "CONFIRM TO SAVE" dialog box will pop up, in which you can select "YES" to confirm your selection or "NO" to give up your selection.**

4.3 Trend Review, Measurement Review and Alarm Event Review

In the "SYSTEM MENU", there are "TREND GRAPH", "TREND TABLE", "NIBP RECALL" and "ALARM RECALL" items. Please refer to *Chapter 8 Recall* for detailed information.

4.4 System setup

Select the "SYSTEM SETUP" item in the "SYSTEM MENU", the following menu will appear:

In the "SYSTEM SETUP" menu, user can set the following items.

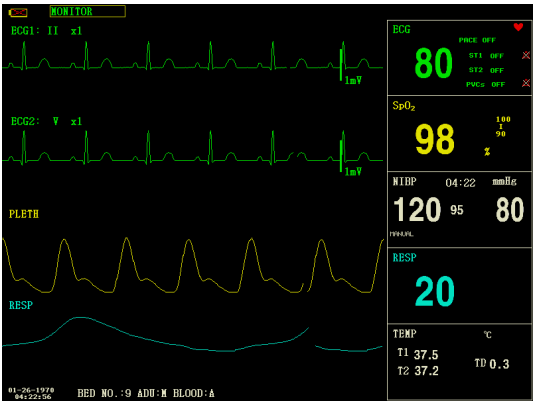
4.4.1 Face select

The system provides 5 display modes: "STAND SCREEN", "OxyCRG SCREEN", "TREND SCREEN", "BIG CHAR" and "VIEWBED SCREEN". You can choose any one of them according to clinical demand.

Select the "FACE SELECT" item in the "SYSTEM SETUP" menu to enter the following menu:

1. STAND SCREEN

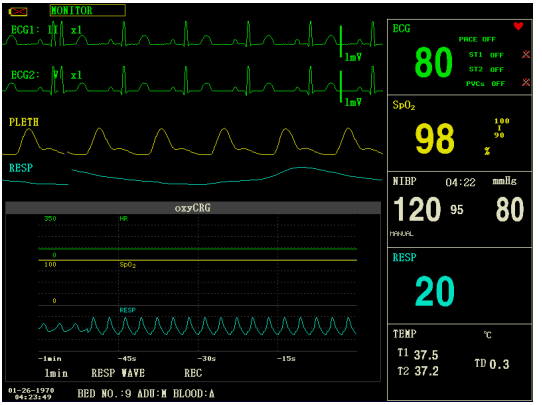
The "STAND SCREEN" is the default setting. If the current screen is not the standard screen, you may enter the standard screen by selecting "STANDARD SCREEN" and then selecting "EXIT" in FACE SELECT menu.



Stand Screen

2. OxyCRG SCREEN

If you want to enter the following interface, select "OxyCRG SCREEN" and then select "EXIT" in "FACE SELECT" menu.



OxyCRG Screen

OxyCRG screen is located at the lower part of the waveform area, consisting of the HR trend, the SpO_2 trend, and the RR (respiration rate) trend or the compressed RESP waveform. Below the RR trend or the compressed RESP waveform is the scale of the trend time. In addition, three labels are displayed beneath the time scale. The labels are detailed as below.

①. Trend length

This label allows you to select the time duration of the trend graphs displayed. You can select either 1 min, 2 min or 4 min.

②. Compressed RESP waveform/RR trend

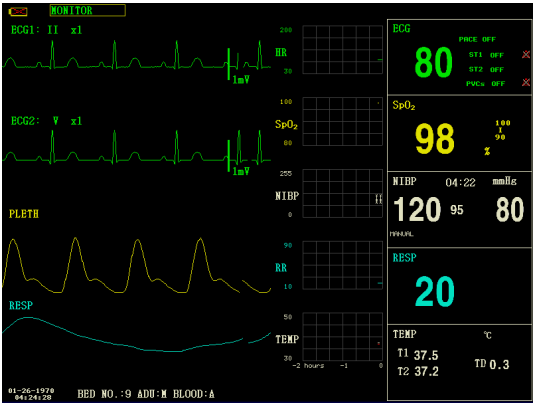
With this label, you can select to display the compressed respiration waveform or the RR trend. You can select either RESP WAVE or RR.

③. Recording

You can select the REC label to print out the trend or the waveform displayed in the oxyCRG screen.

3. TREND SCREEN

If you want to enter the following interface, select "TREND SCREEN" and then select "EXIT" in "FACE SELECT" menu.



Trend Screen

■ Trend graph

In the waveform area, the trend graph is located on the right side of the corresponding waveform, displaying the trends of one parameter of each module. The parameter labels, as well as their scales, are displayed on the left of the trend graph.

■ Trend length

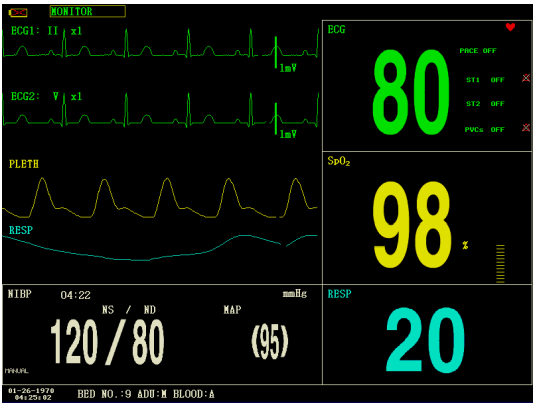
The trend length, located below the trend graph, is 2 hours. In the trend graph, the scale reading at the right end of X-axis is 0 hour, the reading at the left end is -2 hours.

■ Selecting a trend parameter

If a module has multiple trend parameters, you can select one from the parameter label options of the corresponding trend graph. The trend graph of the selected parameter will be displayed. For example, in the ECG trend graph, you can select either from the parameter label options: HR, ST, PVCs.

4. BIG CHAR

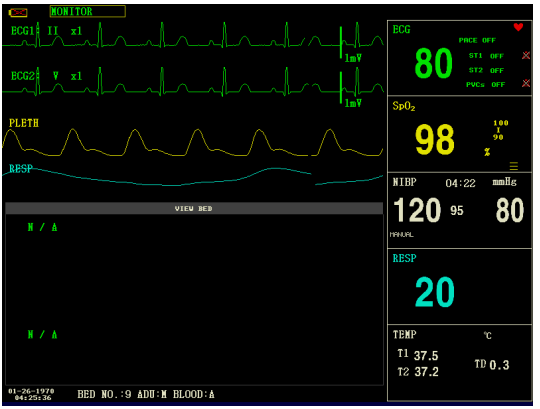
To view the parameter more clearly in a long distance.



Big Char

5. VIEWBED SCREEN

This monitor can display one parameter waveform and all measured data from another patient monitor in the same monitoring network system. To enter the following screen, open "FACE SELECT" menu, select "VIEWBED SCREEN" item, and then select "EXIT".



Viewbed Screen

The monitor that used to view the situations of other monitors, is called "host monitor". The monitor being viewed is called "viewbed monitor". The viewbed screen is always displayed at the lower part of the host monitor's waveform area. It consists of the following parts.

① Viewbed monitor label

The viewbed monitor label allows you to select the viewbed monitor you want to view. It displays the bed number and patient's name of the viewbed monitor.

② Viewbed parameter area

All parameter data of the viewbed monitor is displayed in this area.

③ Viewbed waveform label

The viewbed waveform label allows you to select a waveform of the viewbed monitor.

④ Viewbed waveform area

The viewbed waveform area is located beneath the viewbed waveform label. It displays the waveform selected through the viewbed waveform label. The scanning speed is 25 mm/s. In addition, information relating to the viewbed waveform is shown above the waveform.

4.4.2 Wave setup

1. Select "WAVE SETUP" item in the "SYSTEM SETUP" menu.
2. Adjust the wave type of a channel, the wave corresponding to this channel in the main interface will change accordingly.

4.4.3 Wave select

1. Select "WAVE SELECT" item in the "SYSTEM SETUP" menu.
2. The waveform in waveform area will show up or disappear accordingly by selecting corresponding parameter or canceling the selection. The parameter in gray is unadjustable.
3. If "FULL ECG" is selected, the full-lead ECG waveform will be displayed in the waveform area in one screen, if "STEP ECG" is selected, the step ECG waveform will be displayed in the waveform area.

NOTE

- **"FULL ECG" and "STEP ECG" are set off as default, and these two functions can not be turned on at the same time.**

4.4.4 Parameter setup

1. Select "PARAM SETUP" item in the "SYSTEM SETUP" menu.
2. You can set the font color in parameter area and the color of waveform. The color of parameter value activating the alarm is red.

4.4.5 Parameter select

1. Select "PARAM SELECT" item in the "SYSTEM SETUP" menu.
2. The waveform and parameter will show up or disappear accordingly by selecting corresponding parameter or canceling the selection.

4.4.6 Time setup

1. Select "TIME SETUP" item in the "SYSTEM SETUP" menu.
2. You can set the "Date" and "Time" items. Use cursor to highlight the item that you want to modify and turn the knob to select time.
3. Then select "SAVE SET" button.

NOTE

- **The system time shall be set when turning on the monitor (if you need to set the system time); otherwise, when you review the content containing time information, the system may not display the correct time.**

4.4.7 Alarm setup

Please refer to the sections about "Alarm".

4.4.8 Record setup

Select the "RECORD" item in the "SYSTEM SETUP" menu to pop up the following menu:

- REC WAVE1/REC WAVE2: The recorder could output up to 2 channels of waveform at a time. You can select the name of the waveform at the right column for "REC WAVE1" and "REC WAVE2". If you select "OFF", the waveform in this channel will not be output. These settings is applicable for real-time recording and timing recording.
- RT REC TIME: This item has two options, CONTINUAL and 8 s. "CONTINUAL" means once pushing the "REC/STOP" button on the recorder module or the monitor panel, the recorder will continuously print out the waveform or parameter until this button is pushed again.
- TIMING REC TIME: It represents the time interval between two recordings. Ten selections are available: "OFF, 10min, 20min, 30min, 40min, 50min, 1HOUR, 2HOURS, 3HOURS and 4HOURS". The system will start the recording process according to the selected time interval. The recording time is always 8 seconds.
- REC RATE: This item has two options, 25.0mm/s and 50.0 mm/s.
- REC GRID: It is used to determine output format: OFF is without grid, and ON is with grid.
- CLEAR REC TASK: When too many recording tasks existing, you can use this function to clear the alarm event that has been generated and is waiting for outputing.

NOTE

- **The setup of "RT REC TIME" takes priority over the "TIMING RECTIMING".**
- **The recorder is a optional component.**
- **If two same waveforms are selected, the system will automatically change one of the waveform to a different one.**

4.4.9 Event setup

In the process of monitoring a patient, the occurrence of some events may have impacts on the patient, resulting in some changes on the waveform or parameters. To analyse these effects, you can manually mark some specific events. The event will be displayed on the trend graph and trend table to assist the analysis of patient's parameters at the time of the event.

The monitor has four types of events. You can specify their representations by yourself.

Select the "MARK EVENT" item in the "SYSTEM SETUP" to modify the events.

How to mark the event:

1. Use the rotary knob to select one from event A, B, C and D.
2. The @ symbol will appear in the front of the event being selected.
3. Once making a wrong selection, you can push the knob on the event again to give up the selection. Select "EXIT" to exit the menu and consequently the selection will come into effect.

4.4.10 SD operate

Please refer to the chapter related to *SD Recall*.

4.5 Machine version

Select the "VERSION" item in the "SYSTEM MENU". In the popping up menu, you can learn the software version of the monitor.

Software name	CMS8000	CMS9000(CMS7000)
Specification	None.	None.
Version	2.50311162128.66817	1.50311162128.66817
Naming standard	"Major adaptive upgrade", "Major enhancive software upgrade", "Major improvement software upgrade", "Minor corrective software upgrades", "Build"	

4.6 Drug calculation

You can use the drug calculation and titration table function of the monitor to calculate the concentration of 15 kinds of drugs. Refer to the *Chapter Drug Calculation and Titration Table* for detailed information.

4.7 Maintain

4.7.1 User maintain

1. You need to select the "MAINTAIN" item in the "SYSTEM MENU", then select "USER KEY".
2. Input the password "70808"to enter the user maintain menu, then you can customize the maintenance settings. Items shown as below can be set:

- LANGUAGE: select the language you need
- LEAD NAMING: AHA or EURO
- HELP SETUP: ON/OFF
- NIBP OBSTRUCT SETUP: 1/2/3/4

This function is used to detect whether the patient moves during the blood pressure measurement. If the patient moves, the monitor will give an alarm message and stop the current measuring, or the measurement will be taken as usual.

1) This function is set "1" as default.

2) "1" represents the sensitivity is reduced to the minimum, "4" represents the sensitivity is increased to the maximum. The higher level the sensitivity is set and the easier to detect the interference of movement.

- "NETWORK CONFIGURATION": see *Section 4.7.3 Network Configuration* for details.
- HL7 server configuration:

  ①IP: 202.114.4.120. Input the IP address of the server.

  ②Port: 511. Input the server port.

  ③Sending interval: 1. Set the frequency of data sending, unit is “second”.
- ALARM SETUP:
  - ALM PAUSE TIME: two options: 1 min and 2 min.
  - ALM TYPE: UNLATCH.. "UNLATCH" refers to the situation that once the causes of alarm are eliminated, the alarm will disappear automatically.
  - ALM SOUND: it can be set as "OFF", and the symbol "  " will appear on the

screen.

The system will cancel the "OFF" of alarm sound in the following situations:

✧ The monitor is restarted;

✧ The alarm status is changed, for example, the system enters alarm pause status, or the alarm sound is Forbidden.

◆ ALM REMINDER: ON/OFF.

The alarm tone is silenced or turned off, the patient monitor issues a periodical reminder tone.

◆ REMINDER VOLUME: 1～7.

◆ REMINDER INTERVAL: 1min,2min or 3min.

◆ MINIMUM ALARM VOLUME: 1～7.

The minimum alarm volume refers to the minimum value you can set for the alarm volume, which is not affected by user or factory default configurations. The setting of minimum alarm volume remains unchanged when the patient monitor shuts down and restarts.

◆ HI ALM INTERVAL(s): 7～15.

◆ MED ALM INTERVAL(s): 7～30.

◆ LO ALM INTERVAL(s): 15～100.

WARNING

- **When the alarm sound is turned off, the monitor will not make any sound even if a new alarm is triggered. Therefore, user must carefully choose whether to turn off the alarm sound.**
- **In SILENCE or ALARM PAUSE status, set the alarm sound is as "OFF", then the system will automatically terminate the status of SILENCE or ALARM PAUSE.**
- **When the alarm sound is "OFF", if the operator selects "SILENCE" or "ALARM PAUSE", the alarm sound will be restored to the previous volume when it is turned off, and at this time, the system will enter the status of silence or pause accordingly.**
- **Do not rely on the sound alarm system only for patient monitoring, user should pay close attention to the patient's actual clinical situation.**

NOTE:

- **When alarm sound is turned off, a symbol "**  **" will be displayed in technical alarm area.**
- **The alarm sound off is only valid when the device keeps turning on, once the device is restarted, this setup to will be restored to the previous set value.**
- **The symbol "**  **" means that the alarm sound is turned off, the system could not make any sound for the alarm, so user must be careful when using this function.**
- **There is a way to exit this status:Set the alarm sound as "on"in the "ALARMSETUP".**

4.7.2 Factory maintain

1. You need to select the "MAINTAIN" item in the "SYSTEM MENU", then select "FACTORY KEY".
2. Input the password to enter the factory maintain menu, this function is available for specific maintenance personnel of our company only.

4.7.3 Network configuration

Click "NIT CONFIG" item, the following menu will pop up:

■ NET TYPE: CMS / CUSTOM

CMS:the Server IP is fixed, "202.114.4.119","LOCAL IP CONFIG" is unavailable.

CUSTOM:when this item is selected, CMS and machine's IP can be changed as you need.The following is "LOCAL IP SETUP"menu.

■ LAN CARD SET: Wireless / Wire

NOTE

- **The monitor supports wireless and wire .**

✧ **Wireless**

It is strongly required to use the accompanying wireless network card provided by manufacturer. The router complied with IEEE802.11 (ordinary or household wireless network router) should be used, and it shall support the authentication method of WPA, WPA2 or WEP. Wireless network router should access to the Internet by WAN.

✧ **Wire**

The device has an interface for wire network mode, it accesses to wire LAN complied with IEEE802.3 by RJ45 connector. Wire network should access to the Internet by WAN of the router.

- NET TYPE: CMS or CUSTOM, select the network type according to your need.

CMS

The Server IP is fixed "202.114.4.119". Once the monitor specifies the port number, the program

will automatically obtain the local IP address and the port to be connected.

CUSTOM

In this mode, the IP address and subnet mask of the server, as well as the two items of this monitor can be set by user.

- LAN CARD SET: WIRELESS/WIRE

NOTE

- **If the monitor is connected to central station, the central station software need to be installed on a server with fixed IP address, this address shall be set in the "SERVER IP".**

WIRELESS

After selecting wireless network, click "SELECT ROUTE" in "NET CONFIG" menu, then click "SEARCH ROUTES". All searched routers will be listed on the screen, you can select one of them to connect as your need. If you choose a router set with secure connection, a dialog box will pop up for you to enter the password.

When the network type is CMS, just make sure the connection between the device and the wireless router is successful. (The IP address of the server is 202.114.4.119, the IP address of this monitor and subnet mask are generated by the port number.)

When the network type is CUSTOM, if DHCP service is used, the device will automatically obtain the network support (dynamic IP of this monitor, gateway, DNS, etc.) through the DHCP. If specified IP is used, please set the IP address of this monitor and subnet mask, click "LOCAL IP CONFIG" button, the following menu will pop up:

Wire

When the network type is CMS, just make sure the connection between the device and the central station is successful. (The IP address of the server is 202.114.4.119, the IP address of this monitor and subnet mask are generated by the port number.)

When the network type is CUSTOM, make sure the monitor is connected to the router. If DHCP service is used, the device will automatically obtain the network support (dynamic IP of this monitor, gateway, DNS, etc.) through the DHCP. If specified IP is used, please set the IP address of this monitor and subnet mask.

- LOCAL NET NO: the physical bed number of the monitor
- SERVER IP: input the IP address or domain name of the server for central station software
- LOCAL IP CONFIG: when the "NET TYPE" is "CUSTOM", you can set the local IP address
- SELECT ROUTE: when the "LAN CARD SET" is set to "WIRELESS", click this button to enter the "SELECT ROUTE" menu, and start router searching and other operations.

4.8 Demo

Select the "DEMO" item in the "SYSTEM MENU" to enter the "DEMO KEY" dialog box. Input the password "2088", and click "CONFIRM" button, the system will enter DEMO status.

The demo waveform is an analog waveform set by the manufacturer only to show the performance of the machine and to train users.

In clinical application, this function is forbidden because it may mislead the medical staff to treat the DEMO waveform and parameters 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 the password.

Chapter 5 Alarm

When the patient being monitored appears abnormal changes in vital signs, or the monitor itself occurs failure and fails to monitor the patient, it will remind the medical workers through sound, light, etc.

WARNING

- **In any single area (e.g. intensive care unit or cardiac operating room), there is a potential hazard that the same or similar devices use different alarm preset.**
- **When the monitor is powered on, the system will check whether the alarm function (audio and light alarms) is normal.**
- **When turning on the monitor, the system will send a beep sound and the alarm light flickers once. This function is used to check whether the alarm function is normal. Therefore, user shall pay attention to these signs when turning on the device. If the alarm function works abnormally, this monitor can not be used for patient monitoring, please contact the manufacturer or the maintenance service center.**

5.1 Alarm classification

The alarm is classified as physiological alarm, technical alarm and prompt message based on the property of alarms.

1. Physiological alarm

Generally, physiological alarm is activated in the following situations: one of the patient's physiological parameters exceeds the alarm limits, or the patient appears physiological abnormal, for example, HR exceeding the set limit. The information of physiological alarm is displayed in physiological alarm area.

2. Technical alarm

Technical alarm represents the alarms activated by abnormal monitoring or monitoring result distortion due to system failure, such as lead-off or low battery. The information of technical alarm is displayed in technical alarm area.

3. Prompt message

Except the physiological alarm and technical alarm, these messages refer to the displayed information about system status, which are not involved with patient vital signs. Prompt messages are often displayed in technical alarm area. Besides, some prompt messages are displayed in parameter area, for example, the messages related to NIBP are displayed in NIBP area.

5.2 Alarm level

The alarm is classified as high-level alarm, medium-level alarm and low-level alarm according to its severity.

1. High-level alarm

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.

2. Medium-level alarm

Medium-level alarm means serious warning.

3. Low-level alarm

Low-level alarm is a general warning.

NOTE

- **The level of all technical alarms and prompt messages and some of the physiological alarms are determined by the system, which can not be changed by user.**
- **The level of most of the physiological alarms need to be set by user, such as alarm limits.**

5.3 Alarm mode

When alarm occurs, the monitor may draw the user's attention in three ways as below：

- Audio alarm
- Light alarm
- Alarm message

5.3.1 Audio alarm

When alarm occurs, the monitor will make different sound to indicate alarms in different levels.

High: "beep-beep-beep----beep-beep, beep-beep-beep----beep-beep", frequency: every 7~15 seconds, interval 1s

Medium: "beep--beep-beep", frequency: every 7~30 seconds, interval 1s

Low: "beep", frequency: every 15~100 seconds, interval 1s

Sound pressure range: 45 dB～85 dB

WARNING

If the pressure level of the audible alarm signal is less than the environmental noise,the operator will be prevented from recognizing the alarm status.

5.3.2 Light alarm

When alarm occurs, the alarm indicator will prompt different levels of alarms with different colors and flicker frequencies.

- High: alarm indicator flickers in red with high frequency,about 2Hz.
- Medium: alarm indicator flickers in yellow with low frequency,about 0.66Hz.
- Low: alarm indicator lights in yellow without flickering

5.3.3 Alarm message

When alarm occurs, alarm messages will be displayed in physiological alarm area and technical alarm area. For physiological alarms, the following marks will be used in front of the messages to indicate the alarm level.

- High: ***
- Medium: **
- Low: *

The system also adopts different background to indicate the alarm level of physiological alarm and technical alarm.

- High: red
- Medium: yellow
- Low: yellow

NOTE

- **If one monitoring system has multiple alarm equipment, when an alarm occurs, the visual and audio prompts generated by all alarm equipment should keep the same.**
- **The way of alarm prompting is related to its level.**
- **When alarms of different levels occur at the same time, the monitor prompts the highest level alarm among them.**

5.4 Alarm setup

Select "ALARM SETUP" item in the "SYSTEM SETUP" menu. Under this interface, user could set information about alarm sound and so on.

- ALARM VOL: selective from 1~7, 1 is the minimum volume, 7 is the maximum volume.
- ALM REC TIME: three options: 8 s, 16 s, 32 s.
- KEYVOL: selective from 1~7 and OFF.

WARNING

- **Before starting monitoring, please check whether the settings of alarm limit are suitable for patient.**
- **Invalid alarm system may occur when setting the alarm limit to the limit value.**
- **Do not rely solely on the audio alarm system to monitor the patient. Turning the alarm volume to a low level or turning the sound off during patient monitoring may be dangerous to the patient. Remember that the most reliable method of patient monitoring combines close personal supervision with proper operation of monitoring equipment. Verify the functionality of the alarm system after connecting the monitor to a central station or nurse call system.**

- **Parameter alarm setup**

  1. The parameter alarms can be set in "PARAM ALM SETUP", or their individual parameter menu.

  2. When a parameter alarm is off, a symbol "  " displays near the parameter.

  3. For the parameter whose alarm is set to "ON", the alarm will be triggered when at least one of the parameters exceeds alarm limit. The monitor will take the following actions:

  - The screen displays the alarm information in a mode as described above;
  - The monitor beeps in its corresponding alarm level and volume;
  - Alarm indicator lights or flickers;
  - Information of all parameter values at the alarm moment, and the waveform 4/8/16 seconds before and after the alarm are stored.

- If alarm recording is on, the recorder starts alarm recording. Refer to the chapter *Recording* for details.

4. The following information can be set in parameter alarm setup.

- ECG ALM SETUP: HR alarm, alarm level, alarm limits (high/low), ST alarm setup, ARR alarm setup;
- SpO_2 ALM SETUP: SpO_2 ON/OFF, alarm level, SpO_2 alarm limits (high/low), PR on/off, PR alarm limits (high/low);
- NIBP ALM SETUP: ON/OFF, alarm level, SYS alarm limits (high/low), MAP alarm limits (high/low),
- DIA alarm limits (high/low);
- RESP ALM SETUP: ON/OFF, alarm level, alarm limits (high/low), apnea alarm;
- TEMP ALM SETUP: ON/OFF, alarm level, T1 alarm limits (high/low), T2 alarm limits (high/low), TD alarm limits (high).
- IBP ALM SETUP: alarm switch, alarm level, upper and lower alarm limit of current label name.
- CO_2 ALM SETUP: alarm switch, alarm level, upper/lower limit of CO_2 alarm, upper limit of INS alarm, upper/lower limit of AWRR alarm, apnea alarm.

5.5 Alarm status

Except general alarm conditions, you can set the monitor to four different alarm status as below according to your need. The four alarm status have different symbols:

 Alarm pause

 Alarm off

 Silence

 Alarm sound off

5.5.1 Silence

Keep pressing the "SILENCE" button (over 1 second) on the control panel will turn off all alarm sounds. In SILENCE status, pressing the "SILENCE" button (no more than 1 second) will switch to the "ALARM PAUSE" status, and the alarm will be suspended temporarily in accordance with the time set before. In SILENCE status, keep pressing the "SILENCE" button (over 1 second), the system will exit current status and restore the alarm sound correspondingly, and back to normal alarm status. When the system is in "SILENCE" state, any new triggered alarm can terminate the "SILENCE" state, the system will return to normal alarm state (sound and light alarm).

5.5.2 Alarm pause

Press "SILENCE" button on the control panel to turn off all alarm sound, light prompt and physiological alarm information, so that the system will enter the "ALARM PAUSE" state. The countdown of alarm pause is displayed in the physiological alarm area and the symbol "  " is

displayed in this area as well.

Time period of Alarm Pause: 1 min and 2 min.

When the "SILENCE" button is pressed again, the system will restore to its normal state. In addition, a new triggered alarm can also eliminate the "ALARM PAUSE" state, and the symbol"  " disappears.

NOTE

- **After returning to the normal state, the presence of an alarm depends on whether the alarm condition is appropriate, but after the "SILENCE" button is pressed, the system will permanently turn off the alarm sound for lead-off or probe-off.**
- **The alarm pause time can be set in the "ALARM SETUP" menu as required, the default setting is 2 min.**

5.6 Measures for Alarm occurs

The alarm message appears in system information area or system alarm area. It is needed to identify the alarm and take actions appropriately according to the cause of the alarm.

1. Check the patient's condition;
2. Confirm the alarming parameter or the type of the alarm;
3. Identify the cause of the alarm;
4. Silence the alarm, if necessary;
5. When cause of alarm has been solved, check that the alarm is working properly.

You will find the alarm messages and prompts for each parameter in corresponding chapters related to this parameter in this manual.

5.7 Probe-off alarm

If the system alarms for probe falling off, user can long press the "SILENCE" button on the front panel of the monitor. At this time, the alarm indicator stops flicking and the speaker enters the ALARM STOP state.

Chapter 6 Freeze

When monitoring a patient, you may freeze the waveform to view it carefully. Up to 34 seconds waveform can be reviewed. Besides, the frozen waveform can be output by recorder. The Freeze function of this monitor has following features:

- Freeze status can be activated under any operating screen.
- When entering the Freeze status, the system exits all other operating menus. At the same time, the system freezes all waveforms in the Waveform area, or full-lead ECG waveforms and the extra waveform (if available) on the Full-lead ECG screen. Nevertheless the Parameter area refreshes normally.
- The frozen waveforms can be reviewed or recorded.

6.1 Enter/Exit Freeze Status

6.1.1 Enter Freeze Status

In the Non-Freeze status, press the "FREEZE" button on the front panel of the monitor to let the system exit the Menu being currently displayed (if available), then enter the Freeze status and display the popup "FREEZE" menu. In the Freeze status, all waveforms are frozen. In other words, the system will no longer refresh the waveforms.

6.1.2 Exit Freeze Status

In the Freeze status, executing any of the following operations will command the system to exit the Freeze status:

- Select the "EXIT" option on the "FREEZE" menu;
- Press the "FREEZE" button on the front panel again;
- Press the non-immediate-to-execute button on the front panel and system buttons of MAIN and MENU;
- Execute any operation that may trigger the adjustment of the screen or display of a new menu.

After exiting the Freeze status, the system will discharge the Freeze status, clear screen waveforms and resume to display real-time waveforms.

6.2 FREEZE Menu

Press the "FREEZE" button on the panel, the FREEZE menu will appear on the bottom part of the screen. At the same time, the system enters the Freeze status.

- WAVE 1: to select the first frozen waveform to record. The pull-down list of this item gives you the names of all frozen waveforms displayed on the screen.
- WAVE 2: to select the second frozen waveform to record. The pull-down list of this item gives you the names of all waveforms displayed on the screen.
- RECALL: to review frozen waveforms.
- REC: after selected, the system begins recording the frozen waveforms selected in "WAVE 1" and "WAVE 2".
- EXIT: after pressed, the system closes the FREEZE menu and exits the Freeze status.

6.3 Reviewing Frozen Waveform

By moving the waveform, you may review a waveform of 34 seconds before the moment when it

is frozen. For a waveform less than 34 seconds, the remaining part is displayed as a straight line. Use the rotary knob to move the cursor to the "RECALL" option on the FREEZE menu. Press the knob, the option displays "L-RIGHT". By turning the knob left or right, the frozen waveform on the screen will move left or right correspondingly. There is an arrow indicating upward under the right side of the last waveform. There is also a time scale beside the arrow. "0 s" is used to mark the moment when waveforms are frozen. With waveforms moving right, this time mark will turn into "-1 s, -2 s, -3 s…".

6.4 Recording Frozen Waveform

In the Freeze status, you may output displayed frozen waveforms via the recorder. Maximum 2 waveforms can be output at one time. On the FREEZE menu, the pull-down lists of both "WAVE 1" and "WAVE 2" give you all names of frozen waveforms on the screen, from which you may select two waveforms. Select the "REC" option on the FREEZE menu to output parameters generated upon the freezing moment and the two selected frozen waveforms. If one of the two selected waveforms is set off or not available, only parameters and the other waveform are recorded. If these two selected waveforms are all set off or not available, only parameters are recorded. As for the function of recording frozen waveforms, you can only record the waveforms displayed upon the freezing moment. The recording time length is the same as the length of the waveform displayed on the screen. For example, if the speed of a waveform is relatively fast, then it needs shorter time to record it. When recording frozen waveforms, the system is still in the Freeze status. After completion of this recording, if required, you may select another waveform to be output, and select "REC" option again to record until the all necessary waveforms are recorded. You may also record frozen waveforms by pressing the "REC/STOP" button on the front panel. If selecting "REC" option without installing a recorder, the system will prompt "RECORDER ERROR" in the status bar. For more detailed information about recording, please refer to the chapter *Recording*.

Chapter 7 Recording

NOTE

- **The recorder is an optional component.**

7.1 General Information for Recorder

A thermal array recorder is used for the Monitor.

Performance of the Recorder

- Recording speed: 25 mm/s or 50 mm/s.
- Waveform recording width: 48mm
- It can record up to 2 waveforms.
- The time and waveform of real-time recording are user-configurable.
- Auto recording interval is set by user, the waveform is in accordance with the real time recording.
- The alarm recording waveform is automatically selected by the monitor.

NOTE

- **It is recommended to stop the recording when low battery alarm generated. Otherwise, the device may shutdown for out of power.**

7.2 Recording Type

The monitor provides several stripe recording types:

- Continuous real-time recording
- 8 seconds real-time recording
- Auto 8 seconds recording
- Alarm recording
- Freeze waveform recording
- Trend graph/table recording
- ARR review recording
- Alarm recall recording
- NIBP recall recording
- SD recall recording
- Drug calculation titration recording

Real-time Recording

Real-time recording starts as you pressing the "REC/STOP" button on the recorder.

The waveforms for continuous real-time recording and continuous 8 seconds recording are set in system setup (usually the first two waveforms are displayed on the screen). You can also configure it through the menu. Refer to related section for details.

In RECORD SETUP menu, user can choose to print two different waveforms at the same time, or print only one waveform by setting the other waveform off. If two waveforms are set off, the real time record will print out measured parameters only.

NOTE

- **If certain recording is in process, and another parameter demands alarm recording, it will only be executed after the earlier recording is finished.**

Auto Recording

The monitor starts a recording for 8 seconds according to interval time set in the "TIMING REC TIME" of the "RECORD SETUP " menu. Refer to the section "RECORD" in system setup for details.

Alarm Recording

- Parameter Alarm

The monitor records waveforms 4/8/16 seconds before and after the alarm (totally 8, 16 or 32 seconds) (which can be selected in System Menu).

All parameter values during the alarm will also be recorded.

Two waveforms will be output according to the following rules:

1) If multiple parameter alarms are switched on and triggered simultaneously, the recorder will print out those of the highest level. If parameters have the same alarm level, the latest alarm will be printed out.
2) If an alarm occurs during the recording of another parameter, it will be printed out after the current recording is finished.
3) If many alarms occur at the same time, their waveforms will be stored, and then printed in turn.

- ST Segment Alarm

The monitor records 2-channel ECG waveforms 4, 8, or 16 seconds prior to and after the ST alarm (totally 8, 16, or 32 seconds) (which can be selected in the menu). All parameter values during the alarm will also be recorded.

- Arrhythmia Alarm

The monitor records the waveform 4 seconds prior to and after the alarm (totally 8 seconds). All measurement results during the alarm will also be recorded.

Freeze Waveform Recording

The monitor prints out the selected waveforms under the FREEZE mode. In this way you can capture the abnormal waveforms on the screen by freezing and record it.

Trend Graph/Table Recording

The monitor can print out the trend graph and table in the current trend review interface.

Arrhythmia Review Recording

The monitor can print out the arrhythmia alarm event in the current ARR RECALL interface.

Alarm Recall Recording

The monitor can print out the alarm events in the current ALARM RECALL interface.

NIBP Recall Recording

The monitor can print out all the NIBP review events in NIBP RECALL interface.

SD Recall Recording

The monitor can print out the trend data of the case currently review.

Titration Table

The monitor can print out the messages in the current TITRATION interface.

Notes on Recording

- Recording type:
  Real-time recording
  Periodic recording
  Para alarm recording
  Arrhythmia recording
  Freeze waveform recording
  Trend Graph
  Trend Table
  Para alarm review
  NIBP review
  Titration Table
- Alarm parameters, alarm time and freeze time
- Patient bed number, sex, height, weight, date of birth, admission date
- Parameter name and value
- Recording time
- Waveform name
- Waveform amplitude (for ECG waveform only)
- ECG lead, scale, filter mode (if having ECG waveforms, it will be printed out within the first second or when changing the lead, gain and filter mode during real-time recording.)
- Date and time

7.3 Recording Start&Stop

Here are the methods for how to start the recording of each type:

Continuous real-time recording	Press REC/STOP to start/stop the recording.
8 seconds real-time recording	Press REC/STOP to start recording. It will automatically stop after 8 seconds recording.
Auto recording	The monitor starts a recording according to interval time set in the "TIMING REC TIME" of the "RECORD" menu. It will automatically stop after 8 seconds recording.
Alarm recording	When alarm recording is set ON, it automatically starts a recording when alarm occurs.
Frozen waveform recording	After accessing FREEZE menu, use knob to select two waveforms to be output. Then press REC button in the menu to print out the waveforms. If both "WAVE 1" and "WAVE 2" are set to "OFF", the measured parameters in frozen are printed out only.

Trend graph recording	Select "REC" button in the "TREND GRAPH" menu to print out the currently displayed trend graph.
Trend table recording	Pick "REC" button in the "TREND TABLE" menu to printout the currently displayed trend table.
Arrhythmia review recording	Select "REC" button in the "ARR RECALL" menu to print out the currently displayed arrhythmia waveform and related parameters.
Alarm review recording	Access the "ALARM RECALL" interface from "SYSTEM MENU", select "REC" button to print out the waveform and related parameters currently displayed.
NIBP review recording	Access the "NIBP RECALL" interface from "SYSTEM MENU", select "REC" button to print out the NIBP values currently displayed.
Titration table recording	Access the "TITRATION" interface from "DRUG CALC" menu, select the "REC" button to print out the titration information currently displayed.

Access the "RECORD" menu from the "SYSTEM SETUP" menu. Then select the "CLEAR REC TASK" button, all recording tasks will be stopped, and all stored alarms will be cleared.

NOTE

- **You can press REC/STOP button on the control panel to stop any current recording process.**

7.4 Recorder Operations and Status Messages

Requirement for Record Paper

Only record paper satisfied the requirement can be used, otherwise the recorder may not work normally, or the recording quality may be poor, or the thermosensitive printer head may be damaged.

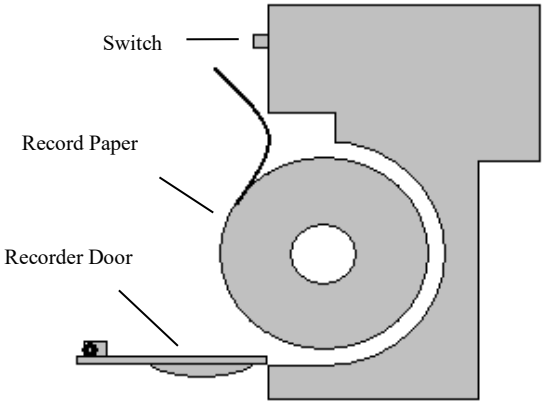
Proper Functioning

- 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



- Press the switch to open the recorder door.
- Insert a new roll of paper into the paper cassette, put the paper correctly and pay attention to the edges.
- Give out the paper from the recorder outlet.
- Close the recorder door.

NOTE

- **Be careful when inserting paper. Avoid damaging the thermosensitive printer head. Unless replacing the recorder paper or troubleshooting, do not leave the recorder door open.**

Removing Paper Jam

When the recorder functions or sounds improperly, open the recorder door to check whether paper jam exists. If yes, re-install the recorder paper.

Recorder Status Message (Technical Alarm)

Message	Cause	Alarm Level	Solution
RECORDER OUT OF PAPER	Record paper runs out.	Low	Insert a new roll of record paper.
RECORDER ERROR	The communication of recorder is abnormal.	Low	Tun off the monitor and restart it.

After restarting the monitor, if error still exists, contact our service engineers please.

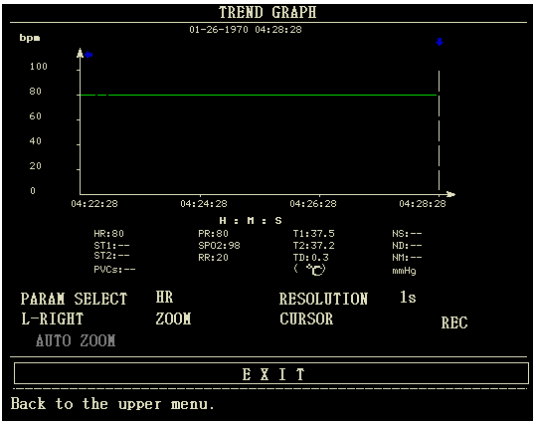
Chapter 8 Recall

The monitor provides 480-hour trend data of all parameters, storage of 4800 groups of NIBP measurement results and 72 alarm events. All these data can be output through recorder. By using SD card, the trend data and 72-hour ECG waveform can be reviewed. This chapter gives detailed instruction for reviewing these data.

8.1 Trend Graph

- The latest 1-hour trend is displayed in a resolution of every 1 or 5 seconds;
- The latest 480-hour trend is displayed in a resolution of every 1, 5 or 10 minutes;

Pick "TREND GRAPH" in the SYSTEM MENU to call up the following menu:



The y-axis stands for measured value and x-axis stands for time. The symbol " ▼ " in above figure is the cursor of trend graph. The value that the cursor points to, is displayed under the trend graph, and its corresponding time is displayed above the trend. Other trends except NIBP trend are displayed in continuous curves. In NIBP trend graph, the symbol "*" represents the coordinate of the NIBP value.

To select trend graph of a specific parameter:

Pick PARAM SELECT item by using the cursor, and select a requested parameter name by turning the knob, then the trend graph of this parameter will be displayed.

To select 1-hour or 480-hour trend graph:

Pick RESOLUTION item by using the cursor, choose 1 s/5 s for 1-hour trend graph and 1min/5 min/10 min for 480-hour trend graph.

To view earlier or later trend curves:

When " ▶ " appears on the right part of the screen, pick "L-RIGHT" button, turn the knob

clockwise to view later trend curves. When " ◄ " appears on the left part of the screen, select the "L-RIGHT" button, turn the knob counterclockwise to view earlier trend curve.

To change the display scale

Pick the "ZOOM" button to adjust the y-axis scale and thus change the trend curve in proportion. The value beyond maximum value will be represented by the maximum value.

To obtain trend data of a specific time

Select "CURSOR" button, and turn the knob to left/right, then the cursor will move accordingly, and the time to which the cursor points will change too. Parameter at this time is displayed below the x-axis. When " ► " appears on the right part of the screen, the trend graph pages down for later trend curve as the cursor moves here. When " ◄ " appears on the left part of the screen, the trend graph pages up for earlier trend curve as the cursor moves here.

To print out the trend curve

Press REC button to print out the trend curve of current selected parameter through the recorder.

Auto Zoom

The AUTO ZOOM is available only when the PARAM SELECT is set as "NIBP". If the current measured value exceeds the scale range, click "ATUO ZOOM" button, the scale will automatically adjust to proper range for current measurement.

Event marks on the trend graph

If an event is marked A, B, C, or D, then on the trend graph, the event type (A, B, C, or D) will be displayed at the point corresponding to the moment of marking.

Operation example

To view the NIBP trend graph of the lastest 1 hour:

- Select the "MENU" button on the front panel, the "SYSTEM MENU" will pop up.
- Pick TREND GRAPH item.
- Select the "PARAM SELECT" item, switch to "NIBP" by turning the knob.
- Adjust the "RESOLUTION" to 1s or 5 s.
- Select the "L-RIGHT" button, turn the knob to view the changes of trend graph time and trend curve.
- Stop at requested trend time section for careful review. Pick the ZOOM button to adjust the display scale if necessary.
- For measurement result of a specific time, pick CURSOR to move the cursor to this point, corresponding time and value will be displayed above and below the curve respectively.
- For printout of trend graph, pick REC to print the NIBP trend currently displayed.
- Pick EXIT to finish the reviewing.

8.2 Trend Table

- The latest 480-trend table data can be displayed at every 1 min, 5 min, 10 min, 30 min, or 60 min.

Pick TREND TABLE in the SYSTEM MENU to call up the following menu:

Time corresponding to each group of trend data is displayed at the leftmost list with date in brackets. Marked events are listed under the "EVENT" corresponding to the time of marking. Trend data of all parameter is divided into 6 groups.

HR ，PVCs

ST1，ST2

RR

T1，T2，TD

SpO_2，PR

NIBP (S/M/D)

To select trend table of a specific resolution:

Select the "RESOLUTION" item by using the cursor, turn the knob to change the options under resolution, then the time interval of trend data will be changed.

To view earlier or later trend data:

When a "up arrow" appears on the upper part of the screen, pick "UP/DOWN" button, turn the knob clockwise to view later trend data. When a "down arrow" appears on the upper part of the screen, select the same item, turn the knob counterclockwise to view earlier trend data.

To view trend data of different parameter

Pick L-RIGHT to select one from the 6 groups of parameters. A ">" by the rightmost item indicates following page available. And "<" by the leftmost item indicates previous page available.

To print out the trend table

Press REC button to print out the trend data of all parameters currently displayed through the recorder.

Event marks on the trend data

If an event is marked A, B, C, or D, the event type (A, B, C, or D) will be displayed at corresponding

time in the trend table.

Operation example

To view the NIBP trend table:

- Select the "MENU" button on the front panel, the "SYSTEM MENU" will pop up.
- Pick TREND TABLE item.
- Select the "L-RIGHT" item, switch to "NIBP" by turning the knob.
- Adjust the "RESOLUTION" to the option that you need.
- Select the "UP/DOWN" button, turn the knob to view the NIBP trend data at different time.
- If you need to print the NIBP trend table, pick REC button, the recorder will print the NIBP trend data.
- If you need to print all trend tables, select "REC ALL" button, the recorder will print all trend data of all parameters.
- Pick EXIT to finish the reviewing.

8.3 NIBP recall

The monitor can review the latest 4800 groups of NIBP measurement data.

Pick NIBP RECALL in the SYSTEM MENU to invoke the result and time of the latest 9 measurements. Data is listed chronologically from the latest to the earliest. Nine measurements can be displayed in one screen. Pick UP/DOWN to view the earlier or later data. Pick REC to print out all measurement data of NIBP RECALL.

8.4 Alarm recall

The alarm recall includes physiological alarm recall and technical alarm recall.

- Physiological alarm recall

Select "ALARM RECALL" in the SYSTEM MENU, then select "PHYSIOLOGICAL ALM RECALL" item. In this menu, user may set the conditions for alarm review, including:

1） Start and End time of review

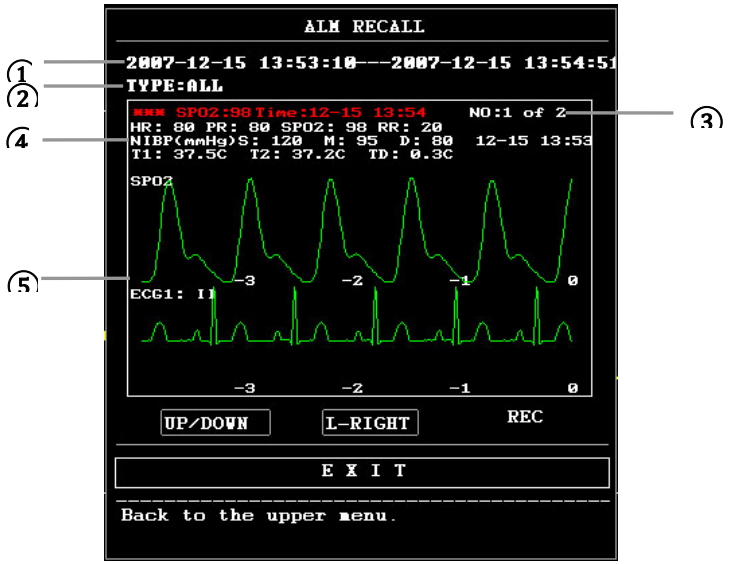
User may select the start time of review in the "BEGIN TIME" item, and the end time in the "END TIME". The end time can be set as the current time or the user-defined time.

2） Alarm recall event

In the pull-down list of ALARM RECALL EVENT, user can select the parameter that need to be reviewed. The selections include ALL (alarm events of all parameters), ECG, RESP, SpO_2, NIBP, TEMP.

After finishing the setup of all review conditions, press the "ALARM RECALL" button to access "ALARM RECALL" menu.

The PHYSIOLOGICAL ALARM RECALL interface is shown as below:



① Time span (Format: year/month/day/hour/minute/second---year/month/day/hour/minute/second).

② Event type.

③ Serial number (Format: NO. xx of XX).

④ The value at the moment of alarming. NIBP result is excluded.

⑤ Two channels waveforms, stored for 8 s/16 s/32 s.

To view all waveforms during the alarming process

Pick L-RIGHT and turn the knob to view all 8/16/32 seconds waveforms stored.

Recording

Select "REC" button, all review data currently displayed will be output by the recorder.

■ Technical alarm recall

1) Select "ALARM RECALL" in the SYSTEM MENU, then select "TECHNICAL ALM RECALL" item.

2) Technical alarm events are arranged chronologically from the latest to the earliest. When the number of alarm events exceeds storage range, the latest events will be displayed. Pick UP/DOWN button, and turn the knob to view the earlier or later events.

8.5 SD recall

User can review patient data stored in the SD card on the monitor, or on the PC by using the sync software.

An empty SD card with at least 2G capacity is needed. The SD card mounted on the monitor could memory trend data (parameters including: HR, PVCs, ST1, SpO_2, PR, RR, T1, T2, TD, NIBP) and 72-hour ECG waveform. The trend data is stored per 1 minute.

NOTE

- **For the review on PC by using the sync software, only ECG and SpO_2 related waveforms and parameter values can be reviewed. Refer to the instructions of sync software for details. This chapter only introduces the reviewing method on the monitor.**
- **Please first set the patient's information correctly before inserting SD card.**
- **If different patient's data need to be saved in one SD card, you should unmount the SD card first, and then modify patient's information. Make sure that the patient number is different.**

1. Enter SD OPERATE menu:

Select "MENU"→"SYSTEM SETUP"→"SD OPERATE", then you could enter the SD OPERATE menu.

2. Insert SD card

If SD card has been inserted and works normally, the prompt "SD device was found, please mount it by the button above." appears.

NOTE

- **If information "SD device wasn't found, please enter SD card" appears, you should exit "SD OPERATE" menu, check if SD card or USB interface is normal. If the problem still exists, reboot the monitor.**

3. Mount SD card

If the monitor has found the SD card, select "MOUNT DEVICE" item, the system will display messages to indicate whether the SD card has been mounted successfully.

NOTE

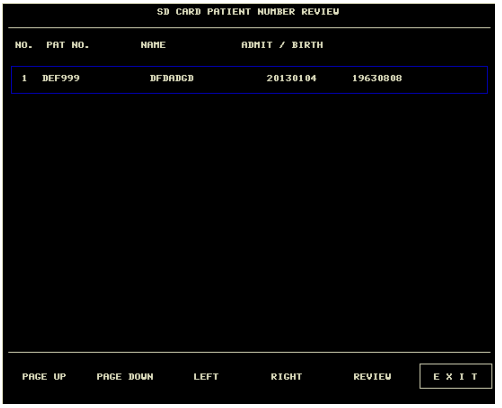
- **Data can be reviewed only after SD card has been mounted successfully for 90 seconds . Otherwise the two buttons "REVIEW TREND" and "REVIEW ECGWAVE" are invalid.**

4. Review trend

■ **Review trend**

① Select "REVIEW TREND" item in SD OPERATE menu.

The following menu will pop up. In this menu, you can select any patient you want to review.



The items from left to right in this menu are No., patient No., patient name, admission date and birth date. The information is displayed according to the content set in patient setup. The buttons at the bottom of menu includes:

- PAGE UP/PAGE DOWN: observe patient lists of other page.
- UP/DOWN: move the cursor to select a specified patient.
- REVIEW: press this button to call up the patient trend information.

② Reading trend data's information

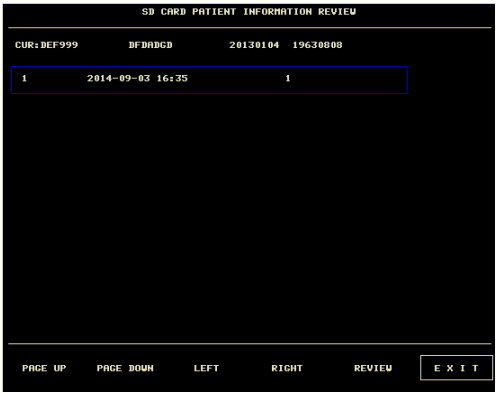
The menu displays the trend data's information according to the selected patient.

The header, from left to right is:

- Patient No.
- Patient's name
- Admission date
- Birth date

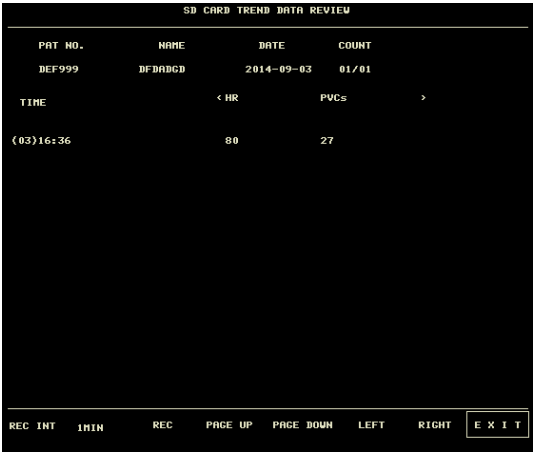
The content of list, from left to right is:

- The list number
- The time that the patient data was reviewed.
- The size of data having been saved to the time that the patient data was reviewed.



③ **Review trend data**

Select an item in above menu by using the cursor, then press "REVIEW" button, the trend data will be displayed in a list. The resolution is 1 minute.

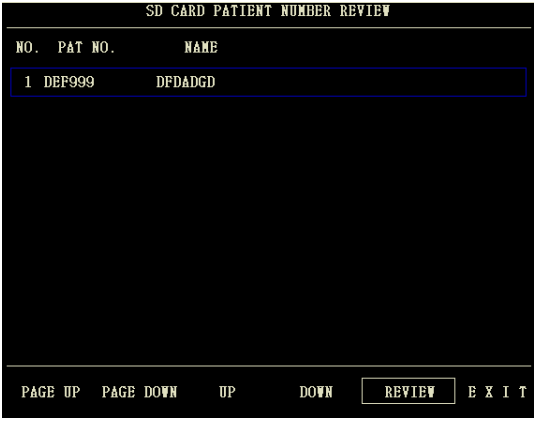


The buttons are:

- Page UP/ PAGE DOWN: to view trend data of different time.
- LIGHT/ RIGHT: to view trend data of different parameter.
- REC: to print current list.

■ **Review ECG waveform**

① Select the "REVIEW ECG WAVE" button in SD OPERATE menu, then choose a specific patient to review.

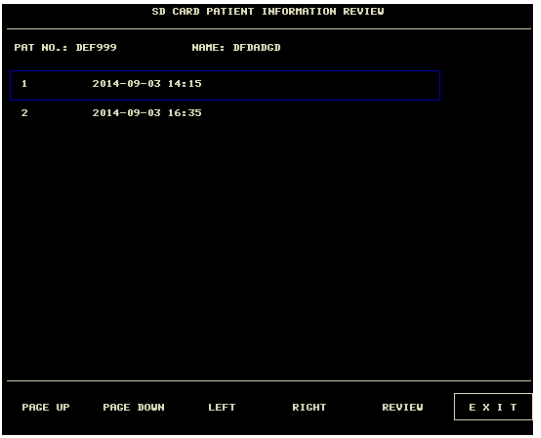


② **Select time span you want to review**

ECG data is saved in many different files. It need save ECG data in a new file per half an hour. For example, "2014-09-03 14:15" represents ECG file name, it also indicates the starting time that the file is saved.

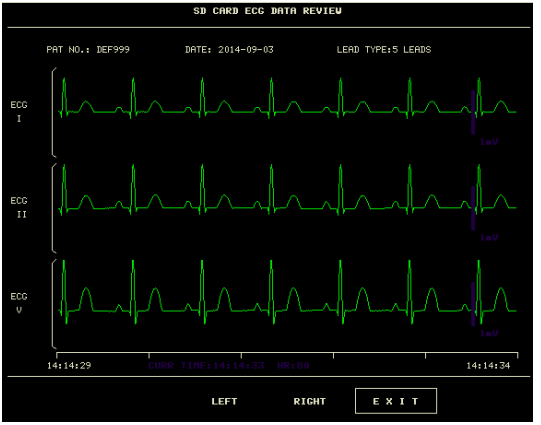
Select the time span:

- To review the ECG waveform about "2014-09-03 14:15"
- By pressing cursor, select the item "1 2014-09-03 14:15"
- Press "REVIEW" button.



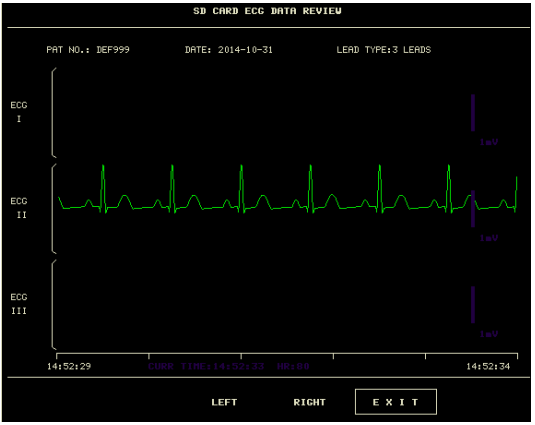
③ Review ECG waveform

- The time span of one window is 5s.
- The window can display 3 channels ECG waveform. When the lead type is "5 LEADS", it displays ECG I, ECG II and ECG V.



5-Lead

- When the lead type is "3 LEADS", it can displays only one channel waveform. The ECG lead is the same with the one displayed on the monitor.



5. Unmount SD card

Enter "SD OPERATE" menu, press "UMOUNT DEVICE". You can take out SD card only when the system displays the prompt "UMOUNT SD CARD SUCCESSFULLY, YOU CAN TAKE OUT THE CARD NOW."

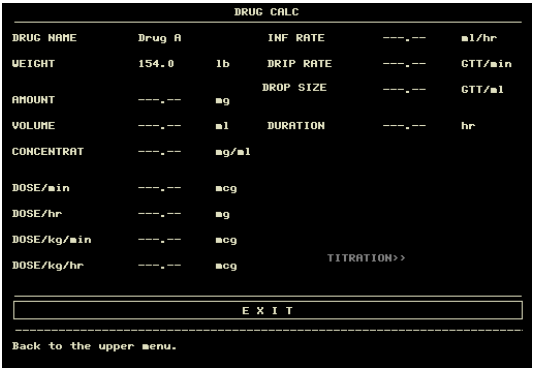
Chapter 9 Drug Calculation and Titration Table

This Portable Patient Monitor provides drug calculation and titration table display functions for fifteen drugs and outputs the content of titration table on the recorder.

9.1 Drug Calculation

The drug calculations that can be performed by the system are AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN and PITOCIN. Besides DRUG A, DRUG B, DRUG C, DRUG D and DRUG E are also provided to flexibly replace any of the drugs.

Select "DRUG CALC" in SYSTEM MENU, the following interface will appear:



The following formulas are applied for dose calculation:

Concentration= Amount / Volume

INF Rate= Dose/Concentration

Duration= Amount / Dose

Dose= Rate × Concentration

Operating method:

In the Drug Calculation window, the operator should first select the name of the drug to be calculated, and then confirm the patient weight. Afterwards, the operator should also enter other known values.

Turn the knob to move the cursor to each calculation item in the formula, press the knob and turn it to select a value. When the calculated value is selected, the result of other items will be displayed correspondingly. Each calculation item has a range limit, and if the result is out of range, the system will display "---.--".

NOTE

- **For the drug calculation, the prerequisite is that the operator must first of all enter the patient weight and drug name. Values given by the system at the beginning are a group of random initial values, which cannot be used as the calculation reference. Instead, a new group of values suitable for the patient should be entered according to doctor's advice.**

- **Each drug has its fixed unit or unit series. Operator must select the proper unit following the doctor's instruction. The unit will automatically adjust itself in its unit series according to the input value. If the result expressed by this unit exceeds the range, the system will display "---".**
- **After entering a value, a conspicuous prompt will appear in the menu warning the operator to confirm the correctness of the entered value. The correctness of input value is the guarantee for the reliability and safety of the calculated results.**
- **In neonate mode, Drip Rate and Drop Size items are disabled.**
- **For each entered value, the system will always give a dialog box asking for user's confirmation. You must be careful when answering each box. The calculated result is reliable only when the entered values are correct.**

■ Select the drug name: Turn the knob to pick the DRUG NAME item. You may select the drug name in the pull-down list, including AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN, PITOCIN, Drug A, Drug B, Drug C, Drug D and Drug E. Calculation for only one type can be generated each time.

NOTE

- **Drug A/B/C/D/E are only codes for drugs instead of their real names. The units for these five drugs are fixed. The operator may select the appropriate units according to the convention of using these drugs. The rules for expressing the units are:**

  "mg" series units are fixedly used for drug A, B and C: g, mg, mcg.

  "unit" series units are fixedly used for drug D: unit, k unit, m unit.

  "mEq" is fixedly used for drug E.

■ Patient weight: After accessing the DRUG CALC window, the operator should enter the patient weight into the first or the second item. The entered weight will be used as the independent data only for the calculation of drug concentration.

NOTE

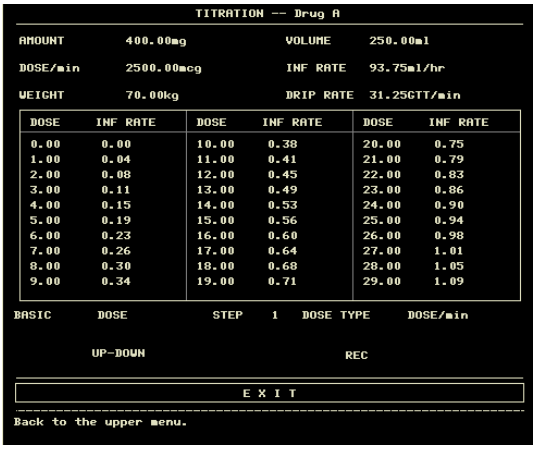
- **This drug calculation function acts only as a calculator. Information in this interface may not related to the patient being currently monitored. That means the patient weight in Drug Calculation menu and the data in Patient Information menu are independent from each other. Therefore, if the Weight in Patient Information changes, the value in Drug Calculation will not be affected.**

9.2 Titration Table

Access titration table:

Select "DRUG NAME" item in DRUG CALC menu, confirm your selection, then select "TITRATION≫" to enter the titration table interface.

The interface of titration table is as following:



■ Method to operate the titration table:

1) In the TITRATION table, turn the knob to pick BASIC item. Press and turn the knob to select either INF RATE or DOSE or DRIP RATE.

2) Move the cursor to STEP item. Press the knob to select step. The selectable range is 1 ~ 10.

3) Move the cursor to DOSE TYPE item. Press the knob to select the unit.

4) Move the cursor to UP-DOWN item, press and turn the knob to view the data in previous or following pages.

5) Move the cursor to REC item. After pressing the knob, the recorder prints out the data displayed in the current titration table.

6) Move the cursor to EXIT item, press the knob to return to DRUG CALC menu.

Chapter 10 ECG Monitoring

10.1 Introduction

The ECG monitoring produces a continuous waveform of the patient's cardiac electric activity to enable an accurate assessment of patient's current physiological state. Only proper connection of the ECG cables can ensure satisfactory measurement. The monitor displays 2-channel ECG waveforms at the same time in normal working, and provides 3/5-lead monitoring, ST segment analysis and arrhythmia analysis.

- The patient cable consists of 2 parts;
  The cable that connects to the monitor;
  The lead set that connects to the patient.
- For 5-lead monitoring, the ECG can derive two waveforms from two different leads. It is available to choose a specified lead to monitor from the left side of ECG waveform by using the knob.
- The monitor displays the Heart Rate (HR), ST segment and Arrhythmia analysis.
- All parameters above can be set as alarm parameters.

NOTE

- **In the default settings of the monitor, the ECG waveforms are the top two waveforms displayed in the waveform area.**

10.2 Safety information

WARNING

- **Do not touch the patient, table nearby, or the equipment during defibrillation.**
- **Use only the ECG cables and electrodes provided by our company for monitoring.**
- **When connecting the cables and electrodes, please do make sure that the cables and electrodes are not in contact with any conductive part or the earth, especially all the ECG electrodes, including neutral electrodes are securely attached to the patient. Do not let them contact with any conductive part or the ground.**
- **Check the skin attached with ECG electrode patches for irritation everyday. If there is a sign of allergies, replace the electrodes every 24 hours or change the sites.**
- **Before starting the monitoring, inspect whether the lead works normally. Unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm will be activated.**
- **To achieve a successful defibrillation, it is required that all patches related to electrodes should be correctly attached.**
- **Electrodes should not be made of different metal materials.**
- **When placing eletrodes or connecting cables,ensure that there is no comtact with other conductive parts or ground.In particular,make sure that all electrodes are connected to the patient.**

NOTE

- **Please use defibrillation proof ECG cable during defibrillation.**
- **Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.**
- **When a ECG device is unable to work, such as "ECG module communication stopped", "ECG module communication error" or "ECG module initialization error" appears, the monitor will stop monitoring automatically, and the prompt system alarm, which is a high-level alarm.**
- **For protecting environment, used electrodes must be recycled or disposed properly.**

10.3 Monitoring Procedure

10.3.1 Preparation

1. Prepare the patient's skin prior to placing the electrodes.
   - The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good contact between electrodes and skin.
   - Shave hair from the sites where electrode patches attach to, if necessary.
   - Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).
   - Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.
   - Before installing the electrodes, let the skin dry completely.
2. Attach clip or snap to electrodes prior to placement.
3. Install the electrodes on the patient. Before attaching, apply some conductive paste on the skin if the electrode does not contain conductive paste itself.
4. Connect the electrode lead to the patient cable.
5. Make sure the monitor is ready with power supply.

10.3.2 Choose Lead Type

1. Select the ECG parameter area, enter the ECG setup menu.
2. Set the "LESD TYPE" to "3 LEADS" or "5 LEADS" according to the lead type you applied.

10.3.3 Installing ECG lead

The following description takes America standards as examples.

NOTE

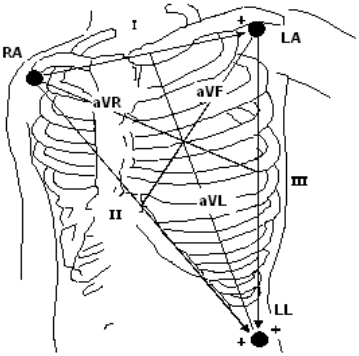
- **The following table gives the corresponding lead names used in Europe and America Standards. (Lead name is represented by R, L, N, F, C and C1~C6 respectively in Europe Standard, while corresponding lead name in America Standard is RA, LA, RL, LL, V and V1~V6.)**

America Stand		Europe Standard	
Lead name	Color	Lead name	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/Red	C1	White/Red
V2	Brown/Yellow	C2	White/Yellow
V3	Brown/Green	C3	White/Green
V4	Brown/Blue	C4	White/Brown
V5	Brown/Orange	C5	White/Black
V6	Brown/Purple	C6	White/Purple

The 3-lead

The placement of 3-lead electrodes is shown as below:

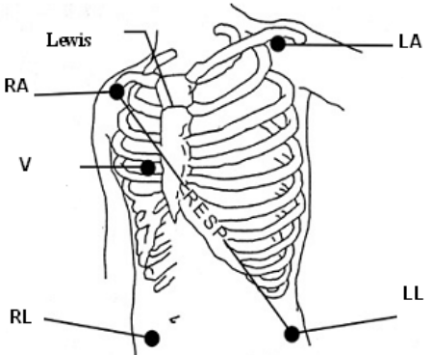
- RA (right arm): under the clavicle, near the right shoulder
- LA (left arm): under the clavicle, near the left shoulder
- LL (left leg): left lower quadrant



The 5-lead

The placement of 5-lead electrodes is shown as below:

- RA (right arm): under the clavicle, near the right shoulder
- LA (left arm): under the clavicle, near the left shoulder
- RL (right leg): right lower quadrant
- LL (left leg): left lower quadrant
- V (chest): on the chest

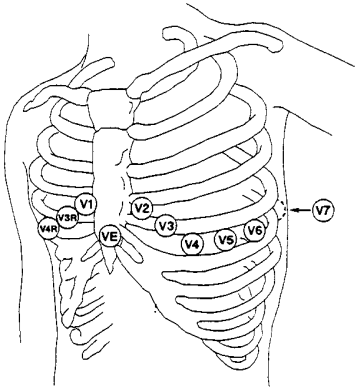


NOTE

- **To ensure patient safety, all leads must be attached to the patient.**

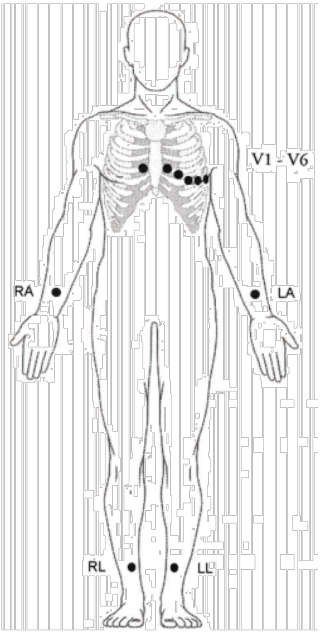
  For 5-lead set, attach the chest electrode (V) to one of the indicated positions as below:

  - V1: On the 4th intercostal space at the right sterna margin.
  - V2: On the 4th intercostal space at the left sterna margin.
  - V3: Midway between V2 and V4 electrodes.
  - V4: On the 5th intercostal space at the left clavicular line.
  - V5: On the left anterior axillary line, horizontal with V4 electrode.
  - V6: On the left middle axillary line, horizontal with V4 electrode.
  - V3R-V7R: On the right side of the chest in positions corresponding to those on the left.
  - VE: Over the xiphoid position. For the placement of V-leads on the back, it should be attached on one of the following sites.
  - V7 : On the 5th intercostal space at the left posterior axillary line of back.
  - V7R: On the 5th intercostal space at the right posterior axillary line of back.



The 12-lead

In American Standards, the 12-lead (10 lead cables) electrodes should be placed on limbs and chests. Limbs electrodes should be placed on the soft skin of both hands and feet, and the chest electrode should be placed according to the doctor's needs. As shown below:



Recommended ECG Lead Placement for Surgical Patients

The placing of the ECG leads will depend on the type of surgery that is being performed. For example, with open chest surgery the electrodes may be placed laterally on 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 of mid-chest. Avoid placing the electrodes on the upper arms, otherwise the ECG waveform will be too small.

WARNING

- **When using electrosurgery equipment, leads should be placed in a position in equal distance from electrotome and the grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.**
- **When using Electrosurgery equipment, never place an electrode near the grounding of the electrosurgery device, otherwise there will be a great interference with the ECG signal.**
- **When the monitor is connected to a defibrillator and other high-frequency devices, it is recommended to use anti-defibrillation ECG leads, otherwise it may cause burns to**

the patient.

- **When using an electrosurgical device (ESU), the monitor may be affected by the effects of the electrosurgical device, which can return to its previous mode of operation within 10s of the elimination of high frequency signals and high frequency electromagnetic fields, without losing any data that has been permanently stored.**
- **When the monitor is used with a defibrillator, the operator should avoid contact with the patient or bed, and the defibrillation electrode should not touch the electrode of the monitor directly, for doing so may generate sparks then causing device damage or patient injury.**

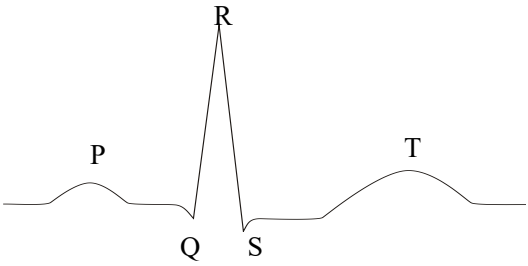
NOTE

- **If a ECG waveform is not accurate, while the electrodes are correctly attached, try to change the lead.**
- **Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.**

A good signal should be:

- Tall and narrow with no notches.
- With tall R-wave completely above or below the baseline.
- With pacemaker signal 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.

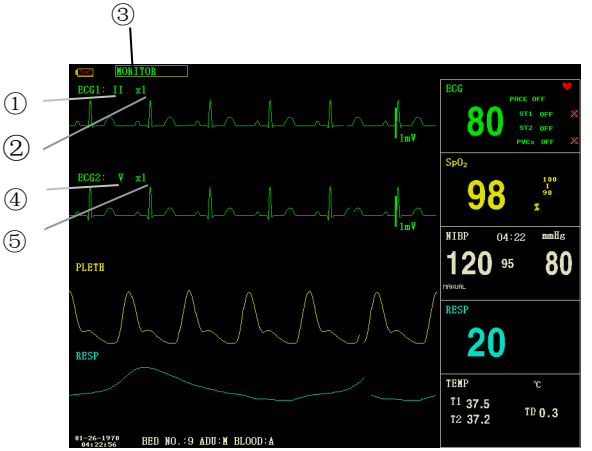
To obtain a 1 mv calibrated ECG wave, the ECG should be calibrated. A message "when CAL, can't monitor!" prompts on the screen.



Stand ECG Waveform

10.4 ECG Screen Hot Keys

The following figure is an interface of 5-lead monitoring, only for reference.



ECG Hot Key

① Leads of channel 1:

1) The selectable leads are I, II, III, aVR, aVL, aVF, V.

2) When the ECG is 5-lead, the selectable leads are: I, II, III, aVR, aVL, aVF; V. When ECG is 3-lead, theselectable leads are: I, II, III.

3) Leads on the ECG waveform must not use the same name. Otherwise, the system will automatically change the ECG waveform name that has been used to another one.

② Waveform gain of channel 1: to adjust the amplitude of ECG waveforms

Select gain value for each channel from ×0.25, ×0.5, ×1, ×2 and ×4. A 1mV scale displays on each ECG channel's one side. The height of the scale is directly proportional to the waveform amplitude.

③ Filter method: to display clearer and more detailed waveform

There are three filter modes for selection. In DIAGNOSTIC mode, the ECG waveform is displayed without filter. In MONITOR mode, the artifact that may cause false alarm is filtered. And the SURGERY mode could reduce artifacts and interferences from electrosurgery equipment. The filter mode is applicable for both channels, and it is displayed at the top of screen.

④ Leads of channel 2: refer to ① for detailed information.

⑤ Waveform gain of channel 2: refer to ② for detailed information.

WARNING

- **Only in Diagnostic mode, the system can provide non-processed real signals. In Monitor or Surgery mode, ECG waveforms may have distortion of different extent. In either of the latter two modes, the system can only show the basic ECG, the results of ST analysis may also be greatly affected. In Surgery mode, results of ARR analysis**

may be somewhat affected. Therefore, it is suggested that in the environment having relative small interference, you'd better monitor a patient in Diagnostic mode.

NOTE

- **When the input signals are too large, the peak of the waveform may not able to be displayed. In this case user could manually change the gain setup of ECG waveform according to the actual waveform so as to avoid the occurrence of the unfavorable phenomena.**

10.5 ECG setup

Turn the knob to move the cursor to the ECG hot key in parameter area, and press the knob to enter ECG setup menu.

- ALM REC: if set to "ON", HR alarm will be recorded once alarm happens.
- HR FROM

ECG: Heart rate will be detected by ECG wave.

SpO_2: Heart rate will be detected through PLETH, the monitor prompts "PULSE" at the right side of ECG hot key with pulse sound. Only pulse alarm is available. When the HR FROM is set to "PLETH", the system only carry on the alarm judgement of pulse rate, while the heart rate alarm will not be judged.

AUTO: The monitor distinguishes heart rate source according to the quality of signal. ECG source priority is higher than SpO_2 source. Only when the ECG signal is poor, which can not be analyzed, the system will choose SpO_2 source, and when the ECG signal quality returns to normal, the heart rate source automatically switch to the ECG. As long as the presence of ECG module, the heart rate value will be displayed, only when the ECG module does not exist, the pulse rate value will be displayed.

BOTH: The monitor displays HR and PR simultaneously. The PR value is displayed at the right side of SpO_2 hot key. Both HR alarm and PR alarm are available. As for the sound of HR or PR in BOTH mode, HR is given the priority, i.e., if HR is available, the system prompts the sound of heart rate, but if HR is not available, then it will prompt the sound of pulse rate.

- SWEEP

  Available options for ECG SWEEP are 12.5 mm/s, 25.0 mm/s, and 50.0 mm/s.
- LEAD TYPE: to select either 5 LEADS or 3 LEADS.
- HR CHANNEL

  "CH1" : to count the heart rate by channel-1 waveform

  "CH2": to count the heart rate by channel-2 waveform

  "AUTO": the monitor selects a channel automatically for HR calculation
- ECG ALM SETUP
  - HR ALM: pick "ON" to enable alarm prompt and data record during the heart rate alarm; pick "OFF" to disable the alarm function, and there will be a  in parameter area.
  - ALM LEV: selectable from "HI" and "MED". Level HIGH represents the

most serious alarm.

◆ ALM HI: to set the upper limit of HR alarm.

◆ ALM LO: to set the lower limit of HR alarm.

◆ ST ALM SETUP: refer to the section *ST Segment Monitoring* in the following for details.

◆ ARR ALM SETUP: refer to the section *ARR Monitoring* in the following for details.

NOTE

- **ECG alarm is activated when the heart rate exceeds ALM HI value or falls below ALM LO value.**
- **Please set the alarm limits according to clinical condition of individual patient.**
- **The setup of HR alarm limits is very important in monitoring process. The upper limit should not too high. Considering the factors of variability, the upper limit of HR alarm should 20 beats/min higher than the patient's heart rate at most.**

■ DEF POINT: refer to the section *ST Segment Monitoring* in the following for details.

■ ARR RECALL: refer to the section *ARR Monitoring* in the following for details.

OTHER SET: Pick this item to access ECG SETUP menu.

■ BEAT VOL: 8 selections are available: OFF, 1~7. 7 indicates maximum volume. OFF indicates no sound.

In ECG monitoring, the patient monitor makes “beep-beep-beep” prompt with patient’s heart beating, this kind of prompt is the heart sound.

■ PACE: "ON" means the detected signal will be marked by a "↑" above the ECG waveform. "OFF" means no pacemaker analysis.

■ KEYVOL: 8 options, 0~7. 1: the minimum volume, 7: the maximum volume, 0: turn off the volume. Key button sound refers to the “beep” prompt when pressing the Key button.

WARNING

- **For a patient using pacemaker, the heart rate meter may count the pacemaker pulse when patient appears cardiac arrest or arrhythmia. Therefore, do not entirely rely on the alarms of heart rate meter. Patient with pacemaker should be closely monitored.**
- **If monitoring a patient with pacemaker, set "PACE" to On. If monitoring a patient without pacemaker, set "PACE" to Off. If "PACE" is on, the system will not perform some types of ARR analysis. For detailed information, please refer to the section about arrhythmia analysis.**
- **When the "PACCE" is on, the arrhythmia events related to ventricular premature beat (including PVCs count) will not be detected, neither the ST segment analysis.**

- NOTCH: ON/OFF.
- EMG: ON/OFF.
- PITCH TONE: ON/OFF
- ECG CAL: pick this item to start calibrating ECG. The method to end calibrating: re-select this button in the menu or change the lead name on the screen.
- ADJUST WAVE POS:
  1. CHANNEL: CHANNEL I/CHANNEL II
  2. UP-DOWN: to adjust the up and down of channel-1/channel-2 ECG waveform
  3. DEF POS: return to the original position
- DEFAULT: pick this item to access the ECG DEFAULT CONFIG dialog box, in which user may select either the FACTORY DEFAULT CONFIG or the USER DEFAULT CONFIG. After selecting one item and exiting the dialog box, the system will pop up a dialog box asking for user's confirmation.

10.6 ECG Alarm and Prompt Message

11.6.1 Alarms

Alarms occurring in the process of ECG measurement contain two types: physiological alarm and technical alarm. Prompt messages may also appear in the mean time. For the audio and visual features during the appearance of these alarms and prompt messages, please refer to the related description in *Chapter 5 Alarm*. In the screen, physiological alarms and prompt messages (general alarms) are displayed in the physiological alarm area of the monitor, while technical alarms, and prompt messages that unable to trigger alarms are displayed in the technical alarm area. This section does not describe the alarm part about arrhythmia 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 related menu is On.

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

Physiological alarms:

Message	Cause	Alarm level
ECG SIGNAL WEAK	No ECG signal of the patient is detected.	HIGH
HR HI	Measured HR value is higher than the upper alarm limit.	User-selectable
HR LOW	Measured HR value is lower than the lower alarm limit.	User-selectable

Technical alarms:

Message	Cause	Alarm level	Solution
ECG LEAD OFF or RESP LEAD OFF	ECG electrodes fall off the skin or ECG cables fall off the	LOW	Make sure that all electrodes, leads and patient cables are properly connected.

V LEAD OFF	monitor.		
LL LEAD OFF			
LA LEAD OFF			
RA LEAD OFF			
MODULE ERROR	Occasional communication failure	HIGH	If the fault persists, stop using the measurement function provided by this ECG module, and inform the biomedical engineer or maintenance personnel of our company.
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.

10.7 ST Segment Monitoring

■ The default setting for ST segment monitoring is "OFF", so the monitor will not process ST analysis.

You can switch it to ON when necessary.

■ The ST segment algorithm can measure the elevation or depression of the ST segment on the user-specified lead. The relevant ST measurement results are displayed numerically at the parameter areas ST1 and ST2. View the trend data displayed graphically and in tables under "TREND GRAPH" and "TREND TABLE" menu.

■ Unit: mV

■ Measurement range: -2.0～+2.0 mV

■ Meaning of the value: positive means elevating, negative means depressing.

NOTE

- **When setting ST ANALYSIS on, the monitor will select "DIAGNOSTIC" mode. You can set it to "MONITOR" mode or "SURGERY" mode as required. However at this time ST value has been severely distorted.**

10.7.1 ST ON/OFF

To set the display of ST parameter on or off:

1. Select "ECG ALM SETUP" item in the "ECG SETUP" menu, refer to the "ECG SETUP" for details;
2. Then select "ST ALM SETUP" to enter its interface, set the "ST ANALYSIS" to on or off.

10.7.2 ST alarm setup

Select "ECG ALM SETUP" item in the "ECG SETUP" menu, click "ST ALM SETUP"to modify the following items:

■ ST ANAL: the switch for ST analysis. Set it to ON to activate the ST analysis or

OFF to disable the ST analysis.

■ ST ALM: pick "ON" to enable prompt message and data record during the ST analysis alarm; pick "OFF" to disable the alarm function, and there will be a  beside parameter area ST1. ST alarm is activated when the result exceeds the upper limit of ST value or falls below the lower limit of ST value.

■ ALM LEV: to set the ST alarm level. There are three selections: "HI", "MED" and "LO".

■ ALM REC: "ON" means that the system will enable the recorder for alarm recording.

■ ALM HI: to set the upper limit of ST alarm. The maximum setting is +2.0. The minimum high limit should be 0.1 larger than the set low limit.

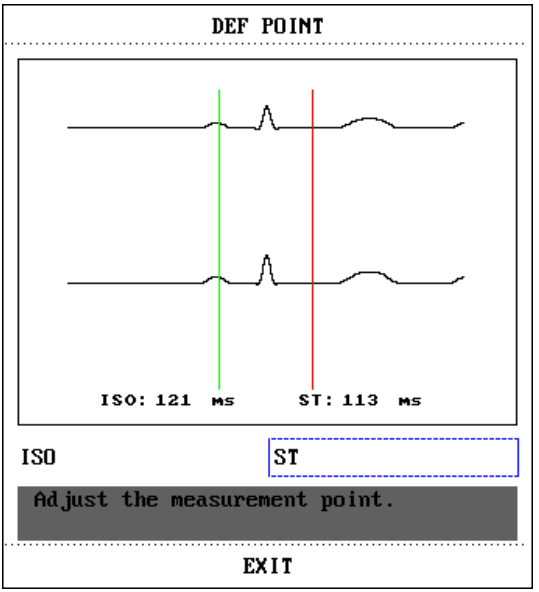
■ ALM LO: to set the lower limit of ST alarm. The minimum setting is –2.0. The maximum low limit should be 0.1 lower than the set high limit.

10.7.3 DEF point setup

Identify the analysis point for ST segment.

Select the "DEF POINT" item in "ECG SETUP" menu, in which the value of ISO and ST point can be set.

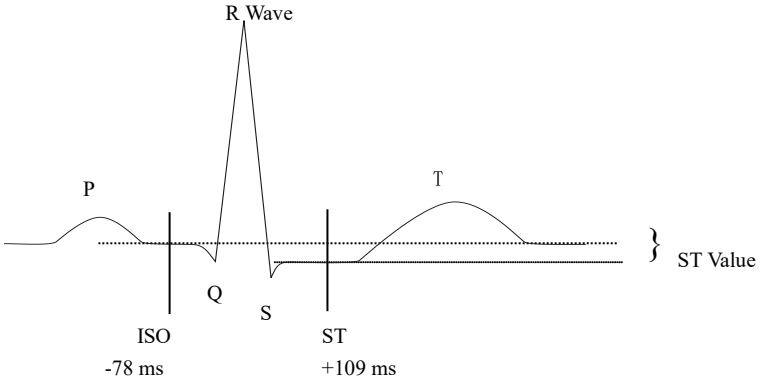
1. ISO (Base point): to set the baseline point.
2. ST (Starting point): to set the measurement point.



The ISO and ST are the two measurement points in ST segment, both of them can be adjusted.

The reference point is the position where the peak of R-wave locates (as figure below). The ST measurement value for each heartbeat complex wave is the difference between the two

measurement points.



The position of measurement points (ISO and ST) should be adjusted at the beginning of monitoring, or the patient's HR or ECG waveform changes significantly. Abnormal QRS complex is not considered in ST segment analysis.

NOTE

- **Abnormal QRS complex is not considered in ST segment analysis.**
- **The measurement points should be adjusted if the patient's HR or ECG waveform changes significantly, detailed instructions are described in the following.**

10.7.4 Adjust ISO/ST point

These two points can be adjusted by turning the knob.

For ST measurement points setting, enter the "DEF POINT" window. The QRS complex template displays in the window (If the channel is switched off, the system prompts "ST ANALYSIS KEY IS OFF!".). It is adjustable of the highlight lines in the window. You may select ISO or ST, then switch the knob left or right to move the line, then to decide the baseline point and the measurement point.

NOTE

- **The alarm limits for two ST measurements are identical. The setting of alarm limits can not be made only for one channel.**

10.7.5 ST alarms and Prompt messages

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 related menu is On.

Possible physiological alarms during ST measurement are listed as below.

Physiological alarms:

Message	Cause	Alarm Level
ST1 HI	ST measuring value of channel 1 is above the upper alarm limit.	User-selectable
STI LOW	ST measuring value of channel 1 is below the lower alarm limit.	User-selectable
ST2 HI	ST measuring value of channel 2 is above the upper alarm limit.	User-selectable
ST2 LOW	ST measuring value of channel 2 is below the lower alarm limit.	User-selectable

10.8 ARR Monitoring

Arrhythmia analysis

The arrhythmia analysis is used to monitor ECG of neonate and adult patient in clinical, detect the changing of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarming information. Arrhythmia analysis can monitor the patient with or without pacemaker. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and abnormal heartbeat) and decide the treatment accordingly. Besides detecting the changing of ECG, arrhythmia analysis can also monitor patients and give proper alarm for arrhythmia.

- The arrhythmia monitoring is shutoff by default. You can enable it when necessary.
- This function can call up the doctor's attention to the patient's heart rate by measuring and classifying the arrhythmia and abnormal heart beat, and triggering the alarm.
- The monitor can conduct up to 13 different arrhythmia analysis.
- The monitor can store the latest 60 alarm events (a single-channel ECG waveform 4 seconds before and after the alarm) during the arrhythmia analysis process. The operator can edit these arrhythmia events through this menu.

10.8.1 ARR Analysis ON/OFF

To set the ARR analysis on or off:

1. Select "ECG ALM SETUP" item in the "ECG SETUP" menu, refer to the "ECG SETUP" for details;

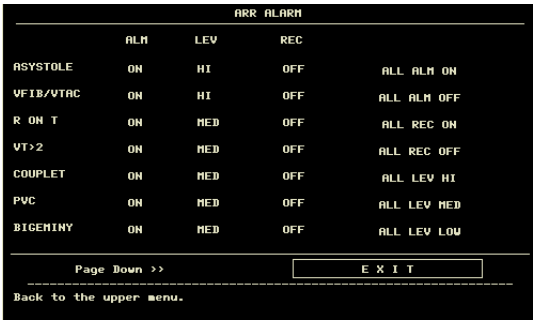
2. Then select "ARR ALARM" to enter its interface, set the "ARR ANAL" to on or off.

10.8.2 ARR alarm setup

Select "ECG ALM SETUP" item in the "ECG SETUP" menu, click "ARR ALM SETUP"to modify the following items:

- ARR ANAL: Pick "ON" during monitoring. Default set is "OFF".
- PVCS ALM: pick "ON" to enable prompt message and data record when alarm occurs; pick "OFF" to disable the alarm function, and there will be a  beside PVCs parameter area.

- ALM LEV: selectable from HI, MED, LO. Level HIGH represents the most serious PVCs alarm.
- ALM REC: pick "ON" to enable the recording when PVCs alarm occurs.
- ALM HI: PVCs alarm is activated when the PVCs exceeds the set ALM HI value.
- ARR RELEARN: press this button to start a learning procedure.
- ARR ALM SETUP: to set the arrhythmia alarm. In this menu, "ALM" is the alarm switch, "LEV" is alarm level, "REC" is the switch of alarm recording.



Arrhythmia Alarm Setup

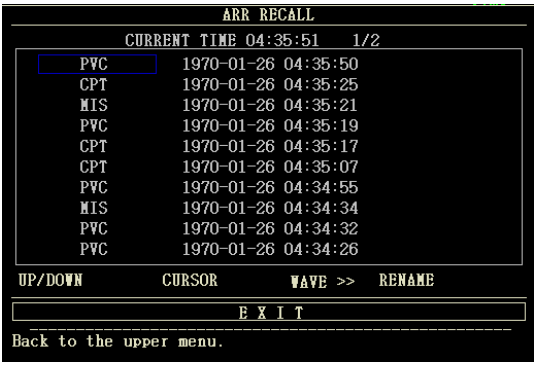
Select "Page Down" to enter the interface for following setup.

Arrhythmia Alarm Setup

You can pick ALL ALM ON to enable alarm function of all arrhythmia types and pick ALL ALM OFF to disable this function. Likewise, you can pick ALL REC ON to enable recording function for all arrhythmia types and pick ALL REC OFF to disable this function. Changing the ALM LEV can reset alarm level of all arrhythmia types.

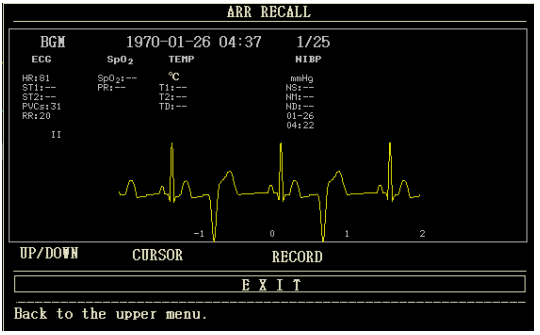
10.8.3 ARR Recall

1. Pick this item to review and edit the ARR analysis result.
2. Select "ARR RECALL" item in the "ECG SETUP" menu, the following interface will pop up.



The recent stored ARR events are listed in this interface:

- ✧ UP/DOWN: Observe event lists of other pages.
- ✧ CURSOR: Move the cursor to select an event in the list.
- ✧ RENAME: Rename the selected Arr. event. Turn the knob until your necessary name appears, then press the knob.
- ✧ WAVE: Press this button to display the waveform of the selected arrhythmia event, time of occurrence and the parameters at this time in the window.



In the arrhythmia waveform recall interface:

- ✧ UP/DOWN: To observe waveforms of other Arrhythmia events.
- ✧ CURSOR: To observe the whole 8s waveform of Arrhythmia event.
- ✧ RECORD: To print out displayed waveform of Arrhythmia event.
- ✧ EXIT: To return to ARR RECALL menu listing Arrhythmia events.

NOTE

- **If there are more than 60 Arrhythmia events, the latest ones will be retained.**

10.8.4 PVCs Alarms and Prompt messages

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 related menu

is On.

Possible physiological alarms and technical alarms during PVCs measurement are listed as below.

Physiological alarm:

Message	Cause	Alarm Level
PVCS ALM	PVCs measuring value is above the upper alarm limit.	User-selectable

Arrhythmia alarm

The alarm is triggered when an Arrhythmia occurs. If the ALM is ON, the alarm sounds and the alarm indicator flashes. If the REC is ON, the alarm record will be printed out (the ECG waveform of the channel being analysed 4 seconds prior to and after the alarm).

Alarms and prompt messages related to arrhythmia analysis are listed as below:

Physiological alarm:

Message	Applicable Patient Type	Occurring Condition	Alarm Level
ASYSTOLE	All patients	No QRS complex is detected for consecutive 6 seconds.	User-selectable
VFIB /VTAC	Without pacemaker	Fibrillation wave for consecutive 4 seconds, or the number of continuous ventricular beats is larger than the upper limit of cluster ventricular beats (≥5). The RR interval is less than 600ms.	User-selectable
VT>2	Without pacemaker	3 ≤ the number of cluster PVCs < 5	User-selectable
COUPLET	Without pacemaker	2 consecutive PVCs	User-selectable
BIGEMINY	Without pacemaker	Vent Bigeminy	User-selectable
TRIGEMINY	Without pacemaker	Vent Trigeminy	User-selectable
R ON T	Without pacemaker	HR is less than 100, R-R interval is less than 1/3 of the average interval, followed by a compensatory pause of 1.25 times of the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
PVC	Without pacemaker	Single PVC not belonging to the type of above mentioned PVCs.	User-selectable
TACHY	All patients	5 consecutive QRS complex , RR interval is less than 0.5s.	User-selectable

BRADY	All patients	5 consecutive QRS complex, RR interval is longer than 1.5s.	User-selectable
MISSED BEATS	Without pacemaker	When HR is less than 100 beats/min, no heart beat is tested during the period 1.75 times of the average RR interval; or When HR is larger than 100 beats/min, no beat is tested with 1 second.	User-selectable
PNP	With pacemaker	No QRS complex and pacing pulse are available during the period 1.75 times of the average R-R interval (only considering patients with pacemaker.)	User-selectable
PNC	With pacemaker	When pacing pulse is available, no QRS complex exists during the period 1.75 times of the average RR interval (only considering patients with pacemaker.)	User-selectable

Applicable patient type: "All patients" refers to perform Arr.analysis on patients either with pacemakers or without pacemakers.

"Without pacemaker": refers to perform Arr. Analysis only on the patients without pacemakers.

"With pacemaker": refers to perform Arr. Analysis only on the patients with pacemakers.

Prompt message:

Message	Cause	Alarm Level
ARR LEARNING	The QRS template building required for Arr. Analysis is in process.	No alarm

NOTE

- **Arrhythmia name displays in the alarm area.**

Chapter 11 RESP Monitoring

11.1 Introduction

Measurement method: chest impedance. When the patient breathes, the thoracic activity causes a change in the thoracic impedance between the two ECG electrodes. The monitor produces a respiratory wave on the screen by measuring the impedance change (due to the movement of the thorax), then it calculates the respiration rate based on the waveform cycle.

11.2 Safety information

WARNING

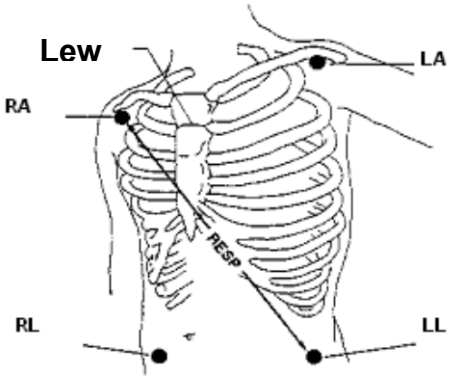
- **Respiratory measurement does not recognize the reason of suffocation, it will only give alarm if no next respiration is checked within the predetermined time after the last breath, so it can not be used for diagnostic purposes.**

11.3 Placement for RESP electrode

As the skin is a bad conductor, in order to get a good respiration signal, process the skin where the electrode is placed is necessary. See "ECG Monitoring" chapter for skin processing method.
For RESP monitoring, it is not necessary for additional electrodes, however, the electrode placement 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

- **The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.**



Electrodes Placement (5-lead)

NOTE

- **Placing the red and white electrodes diagonally to obtain the optimal respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.**

11.4 RESP SETUP

Press RESP hot key on the screen to "RESP SETUP" interface:

- ALM REC: select "ON" to enable report printing upon RESP alarm.
- SWEEP: 6.25 mm/s, 12.5 mm/s, 25.0 mm/s
- WAVE AMP: RESP waveform can be amplified for displaying, amplification factor: ×0.25, ×0.5, ×1, ×2, ×4.
- Measurement mode: LL-RA or LA-RA
- RESP alarm setup:
  - ALM: when RESP alarm occurs, the system will prompt and store the alarm information after selecting "ON", it will not alarm when selecting "OFF", and "  " will appear in parameter area.
  - ALM LEV: HIGH, MED and LOW, high represents the most serious alarm.
  - ALM HI: set the upper alarm limit.
  - ALM LO: set the lower alarm limit.
  - APNEA ALM: set the time of judging an apnea case. Range: 10 ~ 40 s, increase / decrease 5 s after every rotating.When the patient suffocates，after the set time is exceeded，the monitor triggers a suffocation alarm.
- DEFAULT: select it to "RESP DEFAULT CONFIG" menu, in which the user may select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for confirmation

11.5 RESP 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 RESP measurement.

Physiological alarms:

Message	Cause	Alarm Level
RR HI	RESP measurement value is higher than upper alarm limit.	User-selectable
RR LOW	RESP measuring value is lower than lower alarm limit.	User-selectable
RESP APNEA	RESP can not be measured within specific time interval.	HIGH

Technical alarms:

Message	Cause	Alarm Level	Remedy
RESP LEAD OFF	RA, RL or LL falls off.	MED	Make sure all electrodes, leads and cables are connected normally.

Chapter 12 SpO2 Monitoring

12.1 Introduction

SpO_2 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 SpO_2 oxygen saturation of 97%. The SpO_2 numeric on the monitor will read 97%. The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

How the SpO_2 / PLETH Parameter Works

- Arterial oxygen saturation is measured by a method called pulse oximeter. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (for example, a finger), to a receiver on the other side.The sensor measurement wavelengths are nominally 660nm for the Red LED and 905nm for Infrared LED. Maximum optical power output for the Red LED is 6.65 mW and the Infrared LED is 6.75 mW. Optical sensors as the light-emitting components, will bring influence to other medical devices applied the wavelength range. This information may be useful for clinicians who carry out optical therapy.
- 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 get the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.
- The SpO_2 value and the PLETH waveform can be displayed on the main screen.

12.2 Safety information

WARNING

- **Only the SpO_2 sensor specified in this manual can be used, please use it following the Use Manual, and obey all warnings and precautions.**
- **Check if the sensor cable is in normal condition before monitoring. After unplugging the SpO_2 sensor cable from the socket, the system shall display the error message "SpO_2 SENSOR OFF" and give the audible alarm.**
- **Do not use the SpO_2 sensor once the package or the sensor is found damaged. Instead, you shall return it to the vendor.**
- **ES (Electrosurgery) equipment cable and SpO_2 cable must not be tangled up.**
- **Prolonged and continuous monitoring may increase the risk of unexpected change of skin condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. Check the sensor placement**

periodically and move it when the skin deteriorates. More frequent examinations may be required for different patients.

- **The person who is allergic to silicone or ABS can not use this device.**
- **The SpO_2 probe accompanying with the monitor is only intended for use in this monitor. The monitor can only use the SpO_2 probe supplied in this manual. It is the operator's responsibility to check the compatibility of the monitor, probe and extension cord before use, to avoid the patient's injury.**

NOTE

- **SpO_2 waveform is not proportional to the pulse volume.**
- **Some models of functional tester or patient simulator can measure the accuracy of the device that reproduces the calibration curve, but it can not be used to evaluate the accuracy of this device.**
- **SpO_2 function is calibrated to show functional oxygen saturation.**
- **The accuracy of pulse rate has been verified by using a patient simulator.**
- **The PLETH waveforms are not normalized, so the accuracy of the measured values may decrease when the waveform does not tend to be smooth and stable. When the waveform tends to be smooth and stable, the measured value is the best value, and the waveform is the most standard.**
- **The update time of measurement data is less than 10 seconds, which depends on the PR value. Data averaging and other signal processing have no effect on SpO_2 displaying and data values transmitted.**
- **The device does not need to be calibrated during maintenance.**

12.3 SpO_2 Measurement

1. During measuring, make sure that the wearing parts meet the following conditions:

◆ Pulsating blood flow, and circulation perfusion is well.

◆ The thickness does not change, the thickness change will cause the mismatch for the sensor and wear parts.

2. PR will be displayed only under the following situations:

■ Select "HR FROM" as "SpO_2" or “BOTH” in the ECG SETUP menu.

■ Select "HR FROM" as “AUTO” in the ECG SETUP menu and there is no ECG signal.

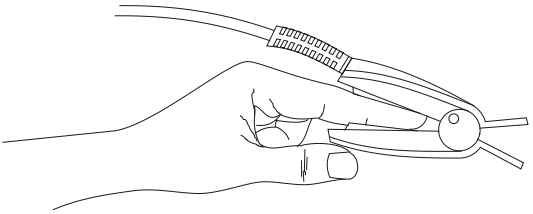
NOTE

- **Make sure the fingernail covers the light.**
- **The SpO_2 value is always displayed in a fixed place.**
- **The declaration for SpO_2 accuracy is supported by a clinical study covering the entire range.**
- **The clinic report contains 32 healthy volunteers’ data, including 18 females and 14 males. Volunteers are aged 18-45 years old, among them, there are 3 people with dark black skin, 2 people with black skin, 22 people with light skin, and 5 people with white skin.**

- **Do not perform SpO_2 measuring and NIBP measuring on the same arm, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO_2 value.**

12.4 Monitoring steps

1. Switch on the monitor.
2. Insert the sensor plug into the SpO_2 jack.
3. Attach the sensor to the appropriate site of the patient finger.



WARNING

- **Check the wearing parts once per 2 to 3 hours to ensure the good skin texture and proper light alignment. If the skin texture changes, move the sensor to another location. It is best to change the wearing parts once per 4 hours.**

NOTE

- **Do not use photoelectric oximeters and SpO_2 sensors during magnetic resonance imaging (MRI) scanning, as the induced current may cause burns.**

12.5 Measurement Limitations

During measuring, the measurement accuracy can be affected by:

- High-frequency electrical interference, such as the interference created by the host system, or interference from external sources, for example electrosurgical apparatus connected to the system.
- Diagnostic test.
- Electrosurgery unit.
- Intravascular dye injections
- Electromagnetic field effects, such as nuclear magnetic resonance equipment.
- Excessive patient movement(patient moves actively or passively).
- Improper sensor installation or incorrect contact position of the patient
- Place the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line.
- Significant concentrations of non-functional hemoglobin, such as carboxyhemoglobin(COHb) and methemoglobin(MetHb).
- Bad circular perfusion of the part being measured

- For some special patients, it should be a more prudent inspecting in the measurement part. The sensor can not be clipped on the edema and tender tissue.
- When the device is carried from cold environment to warm or humid environment, please do not use it immediately.
- As to the fingers which are too thin or too cold, it would probably affect the normal measurement of the patients' SpO_2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- Make sure the optical path is free from any optical obstacles like rubberized fabric, to avoid inaccurate measurement.
- Excessive ambient light may affect the measurement result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight, etc.
- The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
- Testee can not use enamel or other makeup.
- Testee's fingernail can not be too long.

12.6 SpO_2 SETUP

Turn the knob to move the cursor onto the SpO_2 hot key in the Parameter area, push the knob to "SpO_2 SETUP" menu.

- ALM REC: pick "ON", the system will output alarm information when SpO_2 alarm occurs.
- SWEEP: 12.5mm/s, 25.0 mm/s
- SpO_2 alarm setting
  - ◆ SpO_2 ALM: pick "ON", the system will give alarm prompt and store alarm information when SpO_2 alarm occurs; pick "OFF", the system will not give alarm and instead display a  beside "SpO_2".
  - ◆ ALM LEV: set the alarm level, selectable from HI, MED and LO. HIGH represents the most serious case.
  - ◆ SpO_2 ALM HI and SpO_2 ALM LO: SpO_2 alarm is activated when the result exceeds set SpO_2 ALM HI value or falls below SpO_2 ALM LO value.
  - ◆ PR ALM: pick "ON", the system will give alarm prompt and store alarm information when PR alarm occurs.
  - ◆ PR ALM HI: PR alarm is activated when the pulse rate exceeds set PR ALM HI value.
  - ◆ PR ALM LO: PR alarm is activated when the PR falls below PR ALM LO value.

To further detect alarms for individual measurement parameters, perform a measurement check on yourself or by using the simulator, adjust the alarm limits setting and check if the correct alarm response is triggered.

WARNING

- **Set the upper limit of SpO_2 alarm to completely equal to off-state upper limit alarm.**

High-oxygen level will cause fibrous fibrosis for preterm infants. Therefore, the upper limit of the SpO_2 alarm must be carefully chosen according to accepted clinical practice.

NOTE

- **The upper and lower limit of SpO_2 alarm will be displayed continuously in the SpO_2 parameter area.**

- DEFAULT: select it to "SpO_2 DEFAULT CONFIG" menu, in which you can select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting one item and exiting the interface, the system will pop up the dialog box asking for your confirmation.

12.7 SpO_2 Alarm message

NOTE

- **There is no alarm delay for SpO_2.**

SpO_2 alarm information

When the alarm switches are set to "ON" in relevant menus, the physiological alarms caused by the parameter exceeding the alarm limit may possibly trigger the recorder to automatically output the alarm parameter value and corresponding waveforms.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during SpO_2 measurement.

Physiological alarm:

Message	Cause	Alarm Level
SpO_2 HI	SpO_2 measurement value is higher than the upper limit of alarm.	User-selectable
SpO_2 LOW	SpO_2 measurement value is lower than the lower limit of alarm.	User-selectable
PR HI	PR measurement value is higher than the upper limit of alarm.	User-selectable
PR LOW	PR measurement value is lower than the lower limit of alarm.	User-selectable

Technical alarms:

Message	Cause	Alarm Level	Remedy
SpO_2 SENSOR OFF	SpO_2 sensor may be disconnected from the patient or the monitor.	LOW	Make sure the sensor is placed in patient's finger or other parts, and the connection between the monitor and the cables is well.
SpO_2	SpO_2 module failure	HIGH	Stop using the measuring function of

COMM ERR	or communication error.		SpO_2 module, notify biomedical engineer or our service staff.
SpO_2 SENSOR FAULT	Inserting the probe falsely will cause the short circuit for SpO2 circuit or SpO2 probe cable.	HIGH	Check the type of SpO2 probe or replace the SpO2 probe.

Prompt message:

Message	Cause	Alarm Level
SpO_2 SEARCHING PR	SpO_2 module is searching for pulse.	No alarm
SpO_2 SEARCH TIMEOUT	SpO_2 module cannot detect SpO_2 signal for a long time.	HIGH

Chapter 13 NIBP Monitoring

13.1 Introduction

Measurement method: Oscillometry. It is applicable for adult, pediatric and neonate.

In order to know how the Oscillometry works, we compare it with auscultatory method:

- Auscultatory method: the doctor listens the blood pressure by the stethoscope, to obtain the systolic pressure and diastolic pressure. When the artery pressure curve is normal, the mean pressure can be calculated by the systolic pressure and diastolic pressure.
- Oscillometry: the blood pressure can not be listened by the monitor, it measures the vibration amplitude of cuff pressure. Cuff vibration appears when the blood pressure changes, the cuff pressure corresponding to the maximum amplitude is the mean pressure, the systolic and diastolic pressure can be calculated by the mean pressure.

In a word, the auscultatory method measures the systolic and diastolic pressure, then calculates the mean pressure. And the Oscillometry measures the mean pressure, then calculates systolic and diastolic pressure.

The clinical meaning for NIBP measurement must be determined by the physician.

When measuring during in representative patients group, compare the blood pressure values measured by the device and auscultatory method, its accuracy meets the requirements specified in IEC 80601-2-30:2009.

13.2 Safety information

WARNING

- **Before measuring, make sure that the monitoring mode and cuff type you selected are appropriate for your patient(adult, pediatric or neonate). As false settings may imperil patient's safety, higher adult settings are not suitable for pediatric and neonate.**
- **You must not perform NIBP measurement on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.**
- **For the patients with severe clotting mechanism abnormality, please determine whether automatically measure the blood pressure according to the clinical evaluation, as the rub position between the limb and cuff will have the risk of producing hematoma.**
- **Do not apply the cuff to a limb that has an intravenous infusion or catheter. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.**
- **NIBP measurement can be performed during electrosurgery and defibrillator discharge, as the device has the function of protecting burn patients.**
- **The device can be used in existence of electrosurgical equipment, but when using them together, user(doctor or nurse) should guarantee the patient's safety.**
- **Don’t put the cuff on the wound, otherwise it will further hurt the patient.**
- **The clinical use of Sphygmomanometer should follow the requirements of standard**

ISO 81060-2: 2013.

- **Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.**
- **Do not use the cuff on the side of the mastectomy or lymph node clearance.**
- **The pressure by cuff may cause temporary weakness of some functions of the body. So do not use monitoring medical electrical equipment on corresponding arm.**
- **If liquid is inadvertently splashed on the device or its accessories, or may enter the conduit or inside the monitor, please contact with the maintenance department in hospital.**
- **The effectiveness of this sphygmomanometer has not been established in pregnant women, including pre-eclamptic patients.**
- **Do not Place the cuff under persistent over-inflated transition,otherwise there may be risk management.**

NOTE

- **If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by an alternative method before checking the functioning of the monitor.**
- **When the alarm prompt information for low battery appears, it is not recommended to start NIBP measurement. As in this circumstance, it may cause device shutdown.**

13.3 Measurement Limitations

NIBP measurement can not be done on the patients with extreme heart rate(lower than 40 bpm or higher than 240 bpm) or connecting with heart-lung machine.

The measurement may be inaccurate or can not be done in the following conditions:

■ Patient Movement

Measurement will be unreliable or may be impossible if the patient is moving, shivering or having convulsions. As these conditions may interfere the detection of the arterial pressure pulsation, and the measurement time will be prolonged.

■ Cardiac Arrhythmia's

Measurement will be unreliable and may be impossible if the patient has irregular heartbeat arisen from cardiac arrhythmia, and the measurement time will be prolonged.

■ Heart-lung Machine

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

■ Pressure Change

Measurement will be unreliable and may be impossible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulsation are being analyzed to obtain the measurement values.

■ Severe Shock

If the patient is in severe shock or hypothermia, measurements will be unreliable since the decrease for the blood flowed to the peripheries will cause the reduction of artery pulsation.

■ Fat patient

The thick fat layer under the limb will decrease the measurement accuracy, as the vibration from artery can not arrive to the cuff which is arisen from the fat damping.

13.4 Measurement steps

1) Preparing the Patient for NIBP Measurements.

In normal use, perform NIBP measurement on a patient who is in the following position:

■ Comfortably seated

■ Legs uncrossed

■ Feet flat on the floor

■ Back, arm and feet supported

■ Middle of the cuff at the level of the right atrium, of the heart

2) A recommendationthat the PATIENT relax as much as possible and not talk during the measurement PROCUEDURE.

3) It is recommended to take 5 minutes rest at least before measurement.

4) Confirm the patient type, if it is false, please change "Patient type" in "PATIENT SETUP" of "SYSTEM MENU".

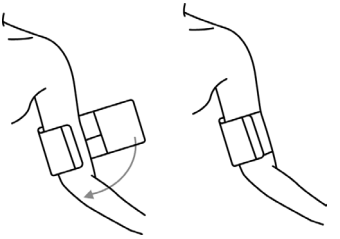
5) Connect the airway tube with the NIBP interface of the device, then switch on thedevice.

6) Select the cuff, make sure the cuff is completely deflated, then apply the cuff to the patient's arm or leg following the instructions below.

■ Confirm the limb perimeter of the patient.

■ Apply the cuff to the patient's arm or leg, and make sure that the symbol "φ" exactly locates to the artery. Ensure that the cuff is not wrapped too tightly around the limb, otherwise it will cause discoloration or ischemia of the limb. Check the cuff edge is in the range marked <->, otherwise please change an appropriate cuff.

■ The width of the cuff should be either 40% of the limb circumference (50% for neonates) 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 has problem, then use a larger cuff.



7) Connect the cuff to the airway tube. Make sure that the airway tube is neither blocked nor tangled.

8) Select a measurement mode in "NIBP SETUP" interface. Refer to the following paragraphs "Operation Hints" for Details

9) Press "NIBP" button on the front panel to start a measurement.

NOTE

- **When measuring NIBP, keep subject and subject's limbs still, not move and talk.**
- **An explanation that any blood pressure reading can be affected by the measurement site, the position of the patient(standing, sitting, lying down), exercise,or the patient's physiologic condition.**

13.5 Operation hints

1. Manual operation

- Select "MANUAL" in "INTERVAL" item of "NIBP SETUP" interface, then press "NIBP" button on the front panel to start a manual measurement.
- During the idle time of auto measuring process, press "NIBP" button on the front panel to start a manual measurement. Press "NIBP" button again to stop manual measurement and the system continues auto measuring.

2. Auto measuring

Select a interval value in "INTERVAL" item of "NIBP SETUP" interface to perform auto measurement., then press "NIBP" button on the front panel to start the first measurement, after finishing, the system will automatically measure according to the interval time.

3. Continuous measuring

Select "CONTINUAL" item in "NIBP SETUP" interface to start a continuous measurement. The precess will continue 5 minutes.

4. Stop measuring

During measuring, press "NIBP" button on the front panel to stop measuring.

WARNING

- **In auto or continuous mode, if the time is too long, then the limb rubbed with the cuff may appear purpura, ischemia and nerve injury. So when monitoring the patient, patient's limb color, warmth and sensitivity should be checked frequently. Once any abnormality appears, please replace the cuff location or stop the NIBP measurement.**

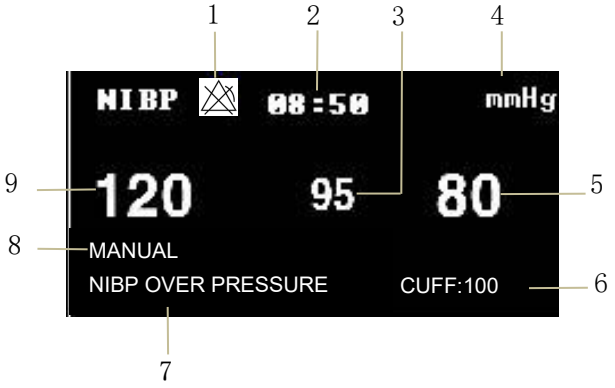
13.6 Amend results

Keep the limb to be measured and the patient's heart on one horizontal position. Otherwise amend the measurement results by the following methods:

- If the cuff is higher than the horizontal position of the heart, then the value should add 0.75 mmHg(0.10 kPa) after the displayed value.
- If the cuff is lower than the horizontal position of the heart, then the value should subtract 0.75 mmHg(0.10 kPa) after the displayed value.

13.7 NIBP display

There is no waveform for NIBP measurement, it only displays the NIBP measurement results. The following figure is only used for reference, your device may display a different interface.



1. Alarm is off
2. Measurement time
3. Mean pressure
4. Unit: mmHg or kPa
5. Diastolic pressure
6. Current cuff presure
7. Prompt information area: display the prompt information related to the NIBP.
8. Measurement mode
9. Systolic pressure

13.8 NIBP SETUP

Move the cursor to the NIBP hot key, press it to enter the "NIBP SETUP" interface.

- ALM REC: select "ON" to enable report printing upon NIBP alarm.
- Unit: mmHg or kPa
- INTERVAL

Interval time in AUTO mode: 1/2/3/4/5/10/15/30/60/90/120/240/480/960 minutes. After selecting the interval time, the information "Please start" will appear in the NIBP prompt area, then press "NIBP" button to start the first auto measurement. Select "MANUAL" in interval time to stop auto measuring and enter to manual measurement.

- INFLATION

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

Default configurations	Default inflation value (mmHg/kPa)	Selectable inflation value in manual mode in NIBP menu(mmHg/kPa)
FACTORY DEFAULT ADU CONFIG	150	80/100/120/140/150/160/180/200/220/240
FACTORY DEFAULT PED CONFIG	100	80/100/120/140/150/160/180/200

FACTORY DEFAULT NEO CONFIG	70	60/70/80/100/120
USER DEFAULT ADU CONFIG	150	80/100/120/140/150/160/180/200/220/240
USER DEFAULT PED CONFIG	100	80/100/120/140/150/160/180/200
USER DEFAULT NEO CONFIG	70	60/70/80/100/120

Press "MENU" button to enter "SYSTEM MENU" menu, then select a factory or user configuration in "DEFAULT" menu, after configuration, return to the main interface to select NIBP hot key to enter "NIBP SETUP" menu. Here the initial value for "Inflation" is the initial inflation pressure value corresponding to default configuration, as shown in the above table. Move the cursor to the "Inflation" item and press it, inflation value range(as shown in the above table) in MANUAL mode can be seen.

NOTE

- **"Inflation" is used to help user select the cuff inflation pressure next time, but the subsequent inflation is the measurement value of last systolic pressure based on the same patient. The system momorizes the value, which can shorten the measurement time of the same patient and increase the measurement accuracy.**
- **If user only sets the "Patient type" in "PATIENT SETUP" interface, does not perform any selection in "DEFAULT", the system will operate according to the initial setting of relative module parameter in "Patient type". The change of default type setting in "DEFAULT" will alter the "Patient type" in "PATIENT SETUP" interface.**

■ NIBP alarm setting

◆ AlM: when pressure alarm occurs, the system will prompt and store the alarm information after selecting "ON", it will not alarm when selecting "OFF", and "  " will appear in parameter area.

◆ ALM LEV: HIGH and MED, "HIGH" represents the most serious alarm.

◆ Pressure alarm is set according to the HIGH and LOW limits, alarm is activated when the pressure is higher than the HIGH limit or lower than the LOW limit. Alarm for systolic pressure, mean pressure and diastolic pressure can be set separately.

■ RESET

Restore measurement status of the pressure pump. Press this button to restore the initial settings of the pressure pump. When the pressure pump does not work properly and the system fails to give prompt information for the problem, press this button to activate self-test procedure, thus restore the system from abnormal performance.

■ CONTINUAL

Start a continuous measurement, after selecting it, the menu will automatically disappears and

measure continuously.

■ PNEUMATIC:

It is mainly used to check whether the airtight condition of the air circuit is good. If the test passes, the system will not prompt any information. Otherwise it will prompt corresponding information in NIBP information area. NIBP air leakage test should be performed once per two years at least or once when you thought that the reading is inaccurate.

Prepared materials:

- ◆ Adult cuff: one
- ◆ Airway tube: one
- ◆ Cylinder: one

Procedure of the air leakage test:

1. Set the "Patient type" to "Adult".
2. Connect the cuff with the NIBP cuff jack.
3. Wrap the cuff around the cylinder of an appropriate size.

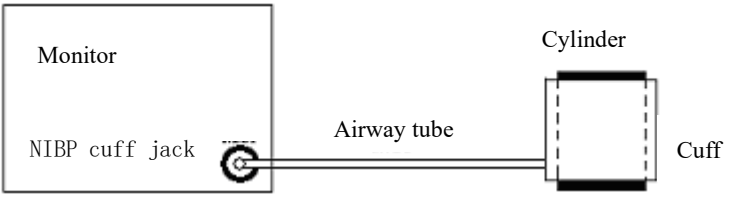


Diagram of NIBP Air Leakage Test

4. Select "PNEUMATIC" in NIBP menu, then the information "Pneum testing..." will display in the NIBP parameter area.
5. The system will automatically inflate to 180 mmHg.
6. The system will automatically deflate after about 20s, it indicates that the air leakage test has finished.
7. If no prompt information appears in NIBP parameter area, it indicates that the airway is in good situation and no air leaks exist. However if the prompt information “NIBP PNEUMATIC LEAK” appears, it indicates that the airway may have air leaks. In this case, the user should check whether the connection is loose. After confirming properconnections, the user should re-perform the pneumatic test.

If the failure prompt still appears, please contact the manufacturer for maintenance.

WARNING

- **This pneumatic test other than being specified in the EN 1060-1 standard is 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 prompts that the NIBP airway has air leaks, please contact the manufacturer for maintenance.**

■ DEFAULT: Select "DEFAULT" to enter "NIBP DEFAULT CONFIG" interface, the user may

select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting, the system will prompt for your confirmation.

13.9 NIBP Alarm Message

Physiological alarm belongs to the alarm which triggers by the parameters exceeding the limits, which 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 NIBP measurement.

Physiological alarms:

Message	Cause	Alarm Level
SYS HI	NIBP SYS measuring value is above upper alarm limit.	User-selectable
SYS LOW	NIBP SYS measuring value is below lower alarm limit.	User-selectable
DIA HI	NIBP DIA measuring value is above upper alarm limit.	User-selectable
DIA LOW	NIBP DIA measuring value is below lower alarm limit.	User-selectable
MEAN HI	NIBP MAP measuring value is above upper alarm limit.	User-selectable
MEAN LOW	NIBP MAP measuring value is below lower alarm limit.	User-selectable

Technical alarms(display in the prompt area below NIBP value):

Message	Cause	Alarm Level	Remedy
NIBP SELF TEST ERROR	Transducer or other hardware of NIBP module is incorrect.	HIGH	Stop using measuring function of NIBP module, notify biomedical engineer or Our service staff.
NIBP COMM ERR	Communication with NIBP module is failed.	HIGH	If failure persists, stop using measuring function of NIBP module, notify biomedical engineer or Our service staff.
NIBP LOOSE CUFF	Cuff is no properly wrapped or no cuff exists.	LOW	Properly wrap the cuff.
NIBP AIR LEAK	Cuff, hose or connector is damaged.	LOW	Check and replace the leaking parts, if required, notify biomedical engineer or Our service staff.
NIBP AIR	Stable pressure value	LOW	Check if the hoses are tangled, if

PRESSURE ERROR	is not available. e.g. hoses are tangled.		failure persists, notify biomedical engineer or Our service staff.
NIBP WEAK SIGNAL	Cuff is too loose or patient pulse is too weak.	LOW	Use other methods to measure blood pressure.
NIBP RANGE EXCEEDED	Measurement range exceeds the specified upper limit.	HIGH	Reset NIBP module, if failure persists, stop using measuring function of NIBP module, notify biomedical engineer or Our service staff.
NIBP EXCESSIVE MOTION	Affected by arm motion, signal noise is too large or pulse rate is not regular.	LOW	Make sure that the patient under monitoring is motionless.
NIBP OVER PRESSURE	Pressure has exceeded the specified upper safety limit.	HIGH	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or Our service staff.
NIBP SIGNAL SATURATED	Excessive motion	LOW	Stop the patient from moving.
NIBP PNEUMATIC LEAK	During pneumatic test, leak is detected.	LOW	Check and replace the leaking parts, if required, notify biomedical engineer or Our service staff.
NIBP SYSTEM FAILURE	Operation of blood pressure pump system is failed.	HIGH	Stop using measuring function of NIBP module, notify biomedical engineer or Our service staff.
NIBP CUFF TYPE ERROR	Cuff type does not comply with the patient type.	LOW	Select an appropriate cuff type
NIBP TIME OUT	Measurement time has exceeded the spcified time.	LOW	Measure again or use other measurement methods.
NIBP ILLEGALLY RESET	Abnormal module reset	HIGH	Reset again.
MEASURE FAIL	The system cannot perform measurement, analysis or calculation during measuring.	HIGH	Check the cuff. Make sure that the patient under monitoring is motionless. Measure again.

Prompt message: (display in the prompt area below NIBP value)

Message	Cause	Alarm Level
Manual measure…	During manual measuring mode.	No alarm
Cont measuring…	During continuous measuring mode.	
Auto measuring…	During automatic measuring mode.	
Please start	After selecting interval time in MENU	
Measurement over	Press NIBP key during measuring to stop measuring.	
Calibrating…	During calibrating	
Calibration over	Calibration over	
Pneum testing…	During pneumatic test	
Pneum test over	pneumatic test over	
Resetting...	NIBP module in resetting	
Reset failed	NIBP module reset failed	

Chapter 14 TEMP Monitoring

14.1 Introduction

Two TEMP probes can be used together to obtain 2 temperature data, via comparing, the temperature difference can be obtained.

14.2 Safety information

WARNING

- **Verify whether the probe cable is normal before monitoring. Unplug the temperature probe cable from the socket, the screen will display the error message "T1/T2 TEMP OFF" and the audible alarm is activated.**
- **Take and place the temperature and cable carefully, and they should be rolled to loose loop when not used. If internal electric wires are pulled too tight, the mechanical damage will appear.**
- **The calibration of the temperature measurement is necessary for every two years (or as frequently as dictated by your Hospital Procedures Policy). When you need calibrate the temperature measurement, contact the manufacture please.**

14.3 Measurement

Measurement steps:

1. Select an appropriate TEMP probe according to patient type and measurement requirement.
2. Insert the probe cable into the TEMP jack directly.
3. Attach the TEMP probe to the patient properly.
4. Confirm that the alarm settings are suitable for the patient.

NOTE

- **Disposable TEMP probe can only be used once for one patient.**
- **The clinical thermometer is a direct mode clinical thermometer.**
- **The self-test of the temperature measurement is performed automatically once per 30s during the monitoring. The test procedure lasts about 1s, which does not affect the normal measurement of the temperature monitoring.**

14.4 TEMP SETUP

Move the cursor to the TEMP hot key, then press the button to enter to "TEMP SETUP" menu.

- ALM REC: Select "ON" to enable report printing upon TEMP alarm.
- TEMP unit: ℃ or °F
- TEMP alarm setting
  - ALM: pick "ON" to enable prompt message and data record during the TEMP alarm; pick "OFF" to disable the alarm function, and prompt the  symbol beside

TEMP area.

- ALM LEV: set the alarm level, three options: HIGH, MED or LOW.
- Alarm for T1, T2 and TD occurs when the measured temperature exceeds set alarm high limit or falls below alarm low limit.

■ DEFAULT: select "DEFAULT" to enter "TEMP DEFAULT CONFIG" interface, the user may select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting, the system will prompt the user to confirm, then exit.

14.5 TEMP Alarm message

The alarm which triggers by the parameters exceeding the limits, which 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 HI	Measuring value of channel 1 is above upper alarm limit.	User-selectable
TI LOW	Measuring value of channel 1 is below lower alarm limit.	User-selectable
T2 HI	Measuring value of channel 2 is above upper alarm limit.	User-selectable
T2 LOW	Measuring value of channel 2 is below lower alarm limit.	User-selectable
TD HI	Difference between two channels is larger than upper limit.	User-selectable

Technical alarms:

Alarm Message	Cause	Alarm Level	Remedy
T1 SENSOR OFF	Temperature cable of channel 1 may be disconnected from the monitor.	LOW	Make sure that the cable is properly connected.
T2 SENSOR OFF	Temperature cable of channel 2 may be disconnected from the monitor.	LOW	Make sure that the cable is properly connected.

Chapter 15 IBP Monitoring

15.1 Introduction

The monitor can provide 2-channel IBP measurement, generate and display real-time waveform, systolic pressure, mean pressure and diastolic pressure for each channel.

15.2 Safety information

WARNING

- **When applying the accessories, make sure the accessories selected comply with medical device safety requirements.**
- **Disposable IBP transducer should not be reused.**
- **The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.**
- **When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.**
- **If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.**

NOTE

- **Use only the pressure transducer listed in the User Manual.**
- **Whether it is a new sensor or a sensor used, it should be calibrated in accordance with hospital procedures.**

15.3 Monitoring Procedure

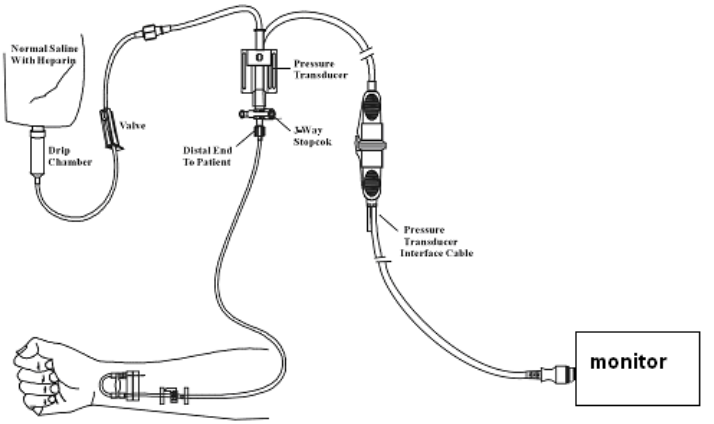
1. Insert the pressure sensor cable into the IBP interface.
2. Prepare the rinse solution.
3. Rinse the system, exhaust all air in the pipeline. Make sure there are no air bubbles in the sensor or the value.

WARNING

- **If there are air bubbles in the pipeline, you should rinse the system with the solution. As air bubble may cause false pressure reading.**

4. Connect the patient catheter to the pressure pipe.
5. Place the sensor at the same level as the heart, about the middle-axillary line.
6. Select a correct label name.
7. Zero the transducer.
8. After zeroing successfully, turn off the valve from the transducer to atmospheric pressure,

and turn on the valve to the patient.



15.4 Setting for label name

1. Select the IBP hot key by the cursor.
2. Select an appropriate label name.

Waveform name	Definition
ART	Arterial Blood Pressure
PA	Pulmonary Arterial Pressure
CVP	Center Venous Pressure
RAP	Right Atrial Pressure
LAP	Left Atrial Pressure
ICP	Intracranium Pressure
P1-P2	Expand Pressure

15.5 IBP Menu

Select the IBP hot key on the screen to enter the" IBP(1,2) SETUP" menu shown as following:

The items to be set in the menu include:

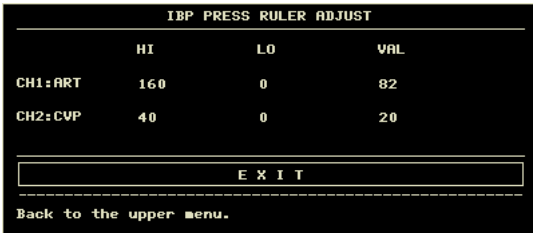
- ALM REC: select “ON” to enable alarm prompt and data storage during IBP alarm.
- SWEEP: set the scanning speed of the IBP waveform. Two selections: 12.5 mm/s or 25

mm/s.

- UNIT: mmHg / kPa / cmH2O
- FILTER:non filter, smooth, normal.
- SCALE ADJUST: select it to enter "IBP PRESS RULER ADJUST" menu, in which the user may adjust the position of upper scale, lower scale and middle scale displayed on the screen.
- EXPAND PRESSURE: select it to enter "IBP EXPAND PRESS SET" menu, in which the user can set the pressure type of P1 and P2.
- DEFAULT: select it to enter "IBP DEFAULT CONFIG" menu, in which the user may select "FACTORY DEFAULT CONFIG" or "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.
- IBP Alarm SETUP:
  - ALM: when IBP alarm occurs, the system will prompt and store the alarm information after selecting "ON", it will not alarm when selecting "OFF", and "  " will appear in parameter area.
  - ALM LEV: HIGH, MED.
  - ALM LIMIT SET: select it to enter "IBP Alarm Limit Settings" menu. In this sub-menu, the user canrespectively adjust the upper and lower limits of systolic, diastolic and average pressure of channel 1 and channel 2.

In the case of the alarm switch is open, when the systolic blood pressure, mean pressure or diastolic blood pressure is higher than the upper limit or less than the lower limit, the corresponding physiological alarm occurs. Alarm limit can be adjusted (the step is 1), first select the name to be set, then set the systolic pressure alarm / diastolic pressure alarm / mean pressure alarm.

15.6 IBP Scale Setup



The waveform scale displays in the IBP waveform area, the three dotted lines from top to bottom respectively represent the upper scale, reference scale and lower scale of the waveform, which can be set, the steps are as followings:

1. Select "SCALE ADJUST" in "IBP SETUP" interface.
2. Select "HI", "VAL" and "LO" to set the appropriate scale.

NOTE

- **IBP1 and IBP2 pressure name can be selected from IBP waveform hotkey area.**

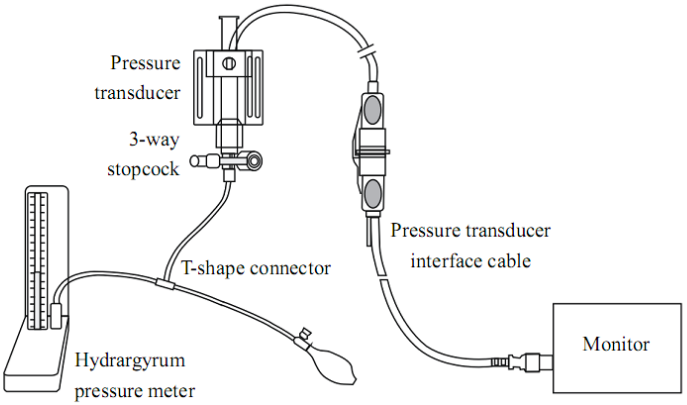
15.7 IBP Pressure Zero

The monitor requires a valid zero point to obtain an accurate pressure reading. Please calibrate the sensor according to the requirements of the hospital (at least once a day). The zero operations must be performed in following conditions:

- When using a new sensor or sensor cable.
- When re-connecting the sensor cable and the monitor.
- When the monitor is restarted.
- When you doubt that the monitor pressure reading is inaccurate.

Calibration steps are as followings:

1. Turn off the valve from the 3-way stopcock to the patient.



2. The transducer must be vented to atmospheric pressure via the 3-way stopcock.
3. Take the channel 1 as an example, select "IBP SETUP" → "IBP PRESSURE ZERO" → "CH1 ZERO", then select it to calibrate.
4. When the information "CH1 SUCCESSFUL ZERO." apears, close the valve to the atmospheric pressure and open the valve to the patient.

NOTE

- **The user should ensure that the sensor has been calibrated before zeroing, otherwise the device hasn't a valid zero value, which will lead to an inaccurate result.**

Troubleshooting for pressure zeroing

Cause	Remedy
IBP1 SENSOR OFF, FAIL.	Make sure that the channel 1 has not the prompt of sensor off, then zero again, if the problem exists still, please contact the service personnel.

DEMO, FAIL.	Make sure that the monitor is not in DEMO mode, then zero again, if the problem exists still, please contact the service personnel.
PRESSURE OVER RANGE, FAIL	Make sure the valve is vented to atmospheric pressure, then zero again, if the problem exists still, please contact the service personnel.
PULSATILE PRESSURE, FAIL	Make sure that the sensor is not connected to the patient, the valve is vented to atmospheric pressure, then zero again, if the problem exists still, please contact the service personnel.

15.8 IBP Calibration

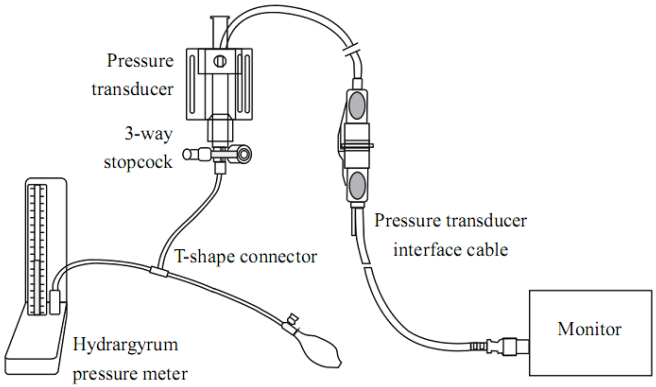
Calibration points for mercury pressure gauge:

Mercury pressure gauge calibration should be carried out when a new sensor is used or in accordance with the period specified by the hospital procedure.

The purpose of the calibration is to ensure that the system provides an accurate measurement. Before starting a calibration by the mercury pressure gauge, a zero procedure must be performed. If you need to perform this procedure by yourself, you need the following equipment:

- Standard sphygmomanometer
- T-shape connector
- Tubing(approximately 25 cm)

The calibration procedure for mercury pressure gauge:



IBP Calibration

WARNING

- **You must never perform this procedure while the patient is being monitored.**

1. Zeroing must be performed before starting the mercury pressure gauge calibration.
2. Connect the tubing to the sphygmomanometer.

3. Ensure that the connection to patient is off.
4. Connect one end of the T-shape connector to the 3-way stopcock, the other end to the gasbag, the third end to the sphygmomanometer.
5. Open the port of the 3-way stopcock to the sphygmomanometer.
6. Select the channel to be calibrated in"IBP PRESSURE CALIBRATE" menu, then select the pressure value.
7. Inflate to make that the sphygmomanometer pressure is close to the pressure value set.
8. Adjust repeatedly until the value in the menu is equal to the pressure value shown by the mercury calibration.
9. Press "CALIBRATE" button, the device will begin calibrating.
10. Wait for the calibrated result. You should take corresponding measures based on the prompt information.
11. After calibrating, disassemble the blood pressure tubing and the attached T-shape connector.

15.9 Troubleshooting for Pressure Calibration

The possible reasons for unsuccessful calibration are listed below:

Cause	Remedy
IBP1 SENSOR OFF, FAIL!	Check the connection condition of channel 1 to make sure that it has not the prompt of sensor off, then cabibrate again, if the problem exists still, please contact the service personnel.
DEMO, FAIL.	Make sure that the monitor is not in DEMO mode, then calibrate again, if the problem exists still, please contact the service personnel.
PRESSURE OVER RANGE, FAIL	Make sure the calibration value selected is reasonable, then calibrate again, if the problem exists still, please contact the service personnel.
PULSATILE PRESSURE, FAIL	Make sure the current pressure value displayed on the Sphygmomanometer is constant, then calibrate again, if the problem exists still, please contact the service personnel.

15.10 Alarm Information and Prompts

Alarm Messages

When the alarm switches are set to "ON" in relevant menus, the physiological alarms caused by the parameter exceeding the alarm limit may possibly trigger the recorder to automatically output the alarm parameter value and corresponding waveforms.

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

Physiological alarms:

Message	Cause	Alarm Level
IS1 HI	SYS measuring value of channel 1 is above upper alarm limit.	User-selectable
IS1 LOW	SYS measuring value of channel 1 is below lower alarm limit.	User-selectable
ID1 HI	DIA measuring value of channel 1 is above upper alarm limit.	User-selectable
ID1 LOW	DIA measuring value of channel 1 is below lower alarm limit.	User-selectable
IM1 HI	MAP measuring value of channel 1 is above upper alarm limit.	User-selectable
IM1 LOW	MAP measuring value of channel 1 is below lower alarm limit.	User-selectable
IS2 HI	SYS measuring value of channel 2 is above upper alarm limit.	User-selectable
IS2 LOW	SYS measuring value of channel 2 is below lower alarm limit.	User-selectable
ID2 HI	DIA measuring value of channel 2 is above upper alarm limit.	User-selectable
ID2 LOW	DIA measuring value of channel 2 is below lower alarm limit.	User-selectable
IM2 HI	MAP measuring value of channel 2 is above upper alarm limit.	User-selectable
IM2 LOW	MAP measuring value of channel 2 is below lower alarm limit.	User-selectable

Technical alarms:

Message	Cause	Alarm Level	Remedy
IBP1 SENSOR OFF	IBP cable of channel 1 falls off from monitor.	MED	Make sure that the cable is properly connected.
IBP2 SENSOR OFF	IBP cable of channel 2 falls off from monitor.	MED	Make sure that the cable is properly connected.
IBP1SENSOR FAULT	IBP sensor has failed,replace the sensor.	MED	Stop using the measurement function of IBP module, notify biomedical engineer or Our service staff.

IBP2SENSOR FAULT	IBP sensor has failed,replace the sensor.	MED	Stop using the measurement function of IBP module, notify biomedical engineer or Our service staff.
IBP(1,2) COMM ERR	IBP module failure or communication failure	MED	Stop using the measurement function of IBP module, notify biomedical engineer or Our service staff.

Prompt message:

Message	Cause	Alarm Level
IBP1 MEASUREMENT EXCEED	IBP measuring value of channel 1 is beyond measurement range.	HIGH
IBP2 MEASUREMENT EXCEED	IBP measuring value of channel 2 is beyond measurement range.	HIGH
IBP1 NEED ZERO-CAL	IBP1 is not performed the zero calibration.	LOW
IBP2 NEED ZERO-CAL	IBP2 is not performed the zero calibration.	LOW

Chapter 16 CO2 Measuring

16.1 Introduction

The device adopts infrared absorption technology to measure the CO_2 concentration in the patient's breathing airway. The principle is that the CO_2 molecules can absorb the infrared energy with specific wavelength, and the amount of energy absorbed is directly related to the CO_2 concentration. When the infrared light emitted by the infrared light source penetrates the CO_2 sample, part of the energy will be absorbed by the CO_2 in the gas. On the other side of the infrared light source, use a photodetector to measure the residual infrared light energy which will be converted into the electrical signal. Comparing and adjusting the electrical signal and infrared light energy to accurately reflect the CO_2 concentration in the gas sample.

CO_2 measurement methods:

1. Mainstream

   Install the CO_2 sensor to the airway joint of respiratory system connected to the patient directly.

2. Sidestream

   The respiratory gas in the patient's respiratory airway was sampled using a constant sampling flow rate and analyzed by a built-in CO_2 sensor.

CO_2 measurement can provide:

1. One-channel CO_2 waveform.
2. $EtCO_2$: End Tidal carbon dioxide, CO_2 value measured in the end of respiratory phase
3. $InsCO_2$: Inspired Minimum CO_2
4. AwRR: Air Way Respiratory Rate, respiratory times per minute.

16.2 Safety information

WARNING

- **Don't use the device in the environment with flammable anesthetic gas.**
- **The device can only be operated by personnel having taken professional training and familiar with this manual.**
- **Notice and prevent the electrostatic discharge (ESD) and electromagnetic interference (EMI) with other instruments.**
- **When placing sensor cables or tubes, avoid intertwining or squeezing each other.**
- **When the CO_2 module is wet or condensed, do not use it.**
- **Do not connect the exhaust pipe to the ventilation duct.**
- **The device and its accessories are free of latex.**
- **If the patient can not tolerate the sampling rate of 50 ml / min ± 10 ml / min, please stop using it.**

NOTE

- **When you do not use CO2 monitoring function, it is suggested to set " WORK MODE" to "STANDBY".**

16.3 Monitoring steps

16.3.1 Sensor zeroing

When you use a new airway joint, you must calibrate as the following procedures:

1. Connect the sensor to the CO_2 module.
2. Select the CO_2 parameter area, set the "WORK MODE" to "MEASUREMENT" in "CO_2 SETUP"→"OTHER SET", then the information "CO_2 SENSOR WARM UP" will display on the screen.
3. After warm up, install the sensor on a clean and dry air-way adapter. The adapter should be connected to the atmosphere and isolated from all CO_2 sources, including ventilators, patient breathing and your own breathing.
4. Select "ZERO" in "CO_2 SETUP" interface, then the information "To initiate a CO_2 sensor zero" will display on the screen.
5. Typical zeroing time is 6~10 s, the prompt information will disappear after zeroing.

WARNING

- **When calibrating the sensor during the measurement, please disconnect it from the patient's airway.**

NOTE

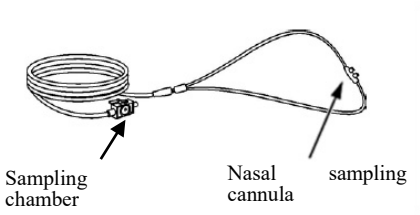
- **When using a new airway adapter, it must be zeroed as described in this section.**

16.3.2 Measurement setting for sidestream CO_2 module

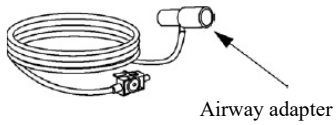
16.3.2.1 Measurement steps

1. Connect the sensor to the CO_2 module.
2. Set the "WORK MODE" to "MEASUREMENT" in "CO_2 SETUP"→"OTHER SET".
3. After start-up, the information "CO_2 SENSOR WARM UP" will display on the screen, the module locates in quasi-precision measurement state. Now the measurement can be performed, but the accuracy is low.
4. After warn up, the module will enter full-precision measurement state.

Sidestream sampling cannula

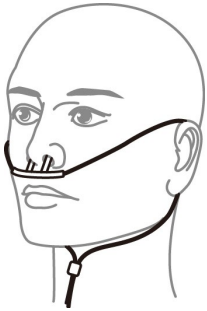


Non-intubated sampling cannula



Intubated sampling cannula

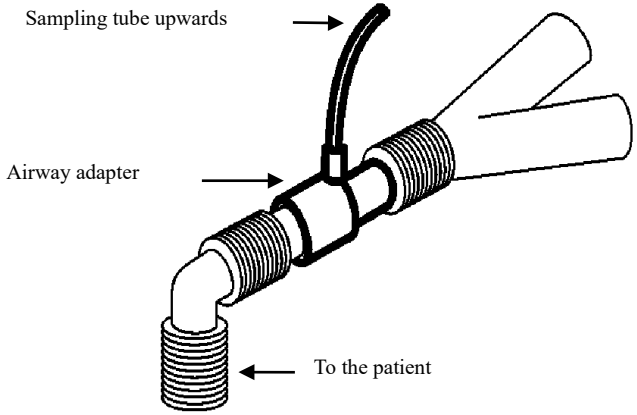
Connection for sidestream and non-intubated patient



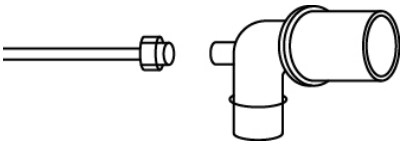
We aring for Nasal sampling cannula

Connection for sidestream and intubated patient

1. For the intubated patient, when using the airway adapter, install the adapter to the near-end of the loop, between the elbow bend and ventilator Y tube, as shown below.



2. For intubated patients with an integrated airway respiration adapter in the breathing circuit: connect the luer male head on the sampling tube to the concave port of the airway adapter.



NOTE

- **Disconnect the cannula, airway adapter, or sampling tube from the sensor when it is not used.**
- **Before connecting the 3-way stopcock to the breathing circuit, make sure to properly connect the airway adapter and the sensor. Conversely, before removing the sensor, be sure to remove the airway adapter from the breathing circuit.**
- **Check the airway adapter before using it. If the airway adapter is already damaged or destroyed, do not use it.**

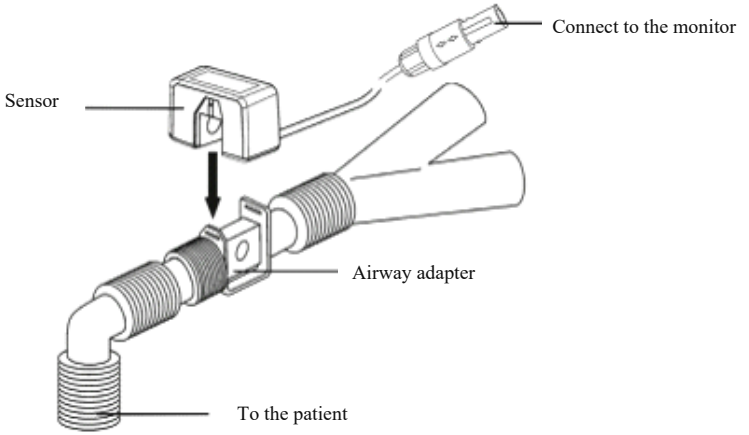
During measuring, if the tube falls off, it is necessary to re-calibrate after connecting well for further measurement.

16.3.3 Measurement setting for mainstream CO_2 module

NOTE

- **When using a new airway adapter, it must be zeroed as described in this section.**

1. Connect the sensor to the CO_2 module.
2. The information "CO_2 SENSOR WARM UP" will display on the screen.
3. After warm up, connect the sensor to the airway adapter.
4. Refer to relative chapter for zeroing the sensor.
5. After zeroing, connect the gas circuit as the following figure.



NOTE

- **Install the sensor above the adapter to prevent the liquid from gathering on the adapter window. The high concentration of liquid at this location will hinder the gas analysis.**
- **Use only sterile airway adapter or disposable airway adapter to avoid**

cross-contamination.

- **Check the airway adapter before using it. If the airway adapter is already damaged or destroyed, do not use it.**
- **Regularly check flow sensor and sampling tube to prevent excessive moisture or secretions gathering.**

16.4 CO_2 Menu

Turn the knob to CO_2 hot key on the screen to activate "CO_2 Setup" menu as shown below:

- ALM REC: pick "ON", the system will output alarm information when CO_2 alarm occurs, the default is "OFF".
- SWEEP: adjust the display speed of CO_2 waveform, three options: "6.25 mm/s", "12.5 mm/s", or "25.0 mm/s".
- UNIT: change the display units of CO_2 and $InsCO_2$ parameters. Two options: "mmHg" and "kPa".
- CO_2 ALM SETUP:
  - ALM: when CO_2 alarm occurs, the system will prompt and store the alarm information after selecting "ON", it will not alarm when selecting "OFF", and "  " will appear in parameter area.
  - ALM LEV: two options: HI and MED. "HI" is the most serious alarm, the second serious alarm is "MED". The change of "ALM LEV" only effects the physiological alarm level of CO_2 parameters(including $EtCO_2$ upper limit, $EtCO_2$ lower limit, $InsCO_2$ upper limit, AwRR upper limit and AwRR lower limit). The default level is "MED".
  - CO_2 ALM HI: adjust the upper limit of $EtCO_2$ alarm. If the measurement value is higher than CO_2 upper alarm limit, the information "CO_2 TOO HIGH" appears on the screen. After the measurement value returns to the normal one, the information disappears.
  - CO_2 ALM LO: adjust the lower limit of $EtCO_2$ alarm. If the measurement value is lower than CO_2 lower alarm limit, the information "CO_2 TOO LOW" appears on the screen. After the measurement value returns to the normal one, the information disappears.
  - INS ALM HI: adjust the upper limit of $InsCO_2$ alarm. If the measurement value is higher than $InsCO_2$ upper alarm limit, the information "INS TOO HIGH" appears on the screen. After the measurement value returns to the normal one, the information disappears.
  - AWRR ALM HI: adjust the upper limit of AwRR alarm. If the measurement value is higher than the upper alarm limit of AwRR, the information "AWRR TOO HIGH" appears on the screen. After the measurement value returns to the normal one, the information disappears.
  - AWRR ALM LO: adjust the lower limit of AwRR alarm. If the measurement value is lower than the lower alarm limit of AwRR, the information "AWRR TOO LOW" appears on the screen. After the measurement value returns to the normal one, the information disappears.
  - APNEA ALM: after selecting the alarm time for APNEA alarm (7 options: 10 s, 15 s, 20 s, 25 s, 30 s, 35 s, and 40 s), the information "CO_2 APNEA" will appear on the screen

after the corresponding time selected. The alarm level is "HI".

OTHER SET: select it to enter "CO_2 SETUP" interface.

- WAVE SCALE: adjust the amplitude of CO_2 waveform display area, two options: “LO” or “HI”, the default value is "LO".
- WORK MODE: change the work mode of CO_2, two options: MEASUREMENT or STANDBY, the default is "STANDBY". When you need to perform CO_2 monitoring, select "MEASUREMENT".
- ATMOS (mmHg): adjust current atmospheric pressure, range: 400 mmHg~850 mmHg, Resolution: 1 mmHg, default:760 mmHg.
- O_2 COMPENSATE: set the gas compensation, which is used with "BALANCE GAS" and "ANEA" together. Adjustable range: 0~100%, accuracy: 1%, default: 16%.
- BALANCE GAS: set the gas compensation, which is used with "O2 COMPENSATE" and "ANEA" together. Three options: room air, N2O and Helium. The default is "room air".
- ANEA: set the gas compensation, which is used with "O2 COMPENSATE" and "BALANCE GAS" together. Adjustable range: 0.0~20.0 %, accuracy: 0.1%, default: 0.0 %.

NOTE

- **Anesthetic gas will ignore it when the balance gas is set to "Helium".**

- Zero: “Sample Cell Zero “is a quick process that allows the module to accommodate the optical characteristics of the different adapter types. "Sample Cell Zero" should be performed whenever the type of adapter being used with the module is changed. For optimal accuracy, "Sample Cell Zero "should also be performed whenever the module is connected to the host system.
- DEFAULT: select it to enter "CO_2 DEFAULT CONFIG" menu, in which the user may select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting one item and exiting the menu, the system will pop up the dialog box asking for your confirmation.

16.5 Influence factors

The following factors may affect the measurement accuracy:

- Leakage or internal leakage of sampling gas.
- Mechanical shock.
- Other interference sources of interference.

16.6 Alarm Information and Prompts

When the alarm switches are set to "ON" in relevant menus, the physiological alarms caused by the parameter exceeding the alarm limit may possibly trigger the recorder to automatically output the alarm parameter value and corresponding waveforms.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during CO_2 measurement.

Physiological alarms:

Message	Cause	Alarm Level
CO_2 HI	EtCO_2 measuring value is above upper alarm limit.	User-selectable
CO_2 LOW	EtCO_2 measuring value is below lower alarm limit.	User-selectable
INS HI	InsCO_2 measuring value is above alarm limits.	User-selectable
AWRR HI	AwRR measuring value is above upper alarm limit.	User-selectable
AWRR LOW	AwRR measuring value is below lower alarm limit.	User-selectable
CO_2 APNEA	RESP stops(in specific time interval, no RESP can be detected using CO_2 module.).	HIGH

Technical alarms:

Message	Cause	Alarm Level	Remedy
CO_2 SENSOR FAULT	The sensor error.	HIGH	Check that the sensor is properly plugged in. Reinsert or reset the sensor if necessary. If error persists, return sensor to factory for servicing.
CO_2 SENSOR OVER TEMP	The sensor temperature is greater than 40℃	LOW	Make sure the sensor is not exposed to extreme heat. If error persists, return sensor to factory for servicing.
CO_2 CHECK SAMPLING LINE	The atmospheric pressure exceeds the specified range.	LOW	Check whether the sampling cannula is occluded or twined.
CO_2 ZERO ERROR	An error was found during Zeroing	LOW	Check and clean the air adapter, if the error is not corrected, please calibrate zero.
CO_2 OUT OF RANGE	The value being calculated is greater than the upper CO_2 limit.	LOW	Calibrate zero.
CO_2 CHECK AIRWAY ADAPTER	It is usually caused when the airway adapter is removed from the sensor or when there is an optical blockage on the	LOW	If there is obvious sticky material or moisture on the air adapter, please clean it before calibrating zero.

	windows of the airway adapter. It may also be caused by performing false Zero When adapter type is changed.		
CO_2 NOT INITIALIZED	Barometric Pressure or gas compensations have not been set after power on.	LOW	Set the Barometric Pressure and gas compensations to clear this error.

Prompt message:

Message	Cause	Alarm Level
CO_2 ZERO IN PROGRESS	A Zero is currently in progress	No alarm
CO_2 SENSOR WARM UP	It shows that the sensor is in warming-up stage.	No alarm
CO_2 CHECK ADAPTER		No alarm
CO_2 ZERO REQUIRED		No alarm
CO_2 Sample Line Disconnected	This is no sidestream sampling set connected to the CO_2 sensor	No alarm

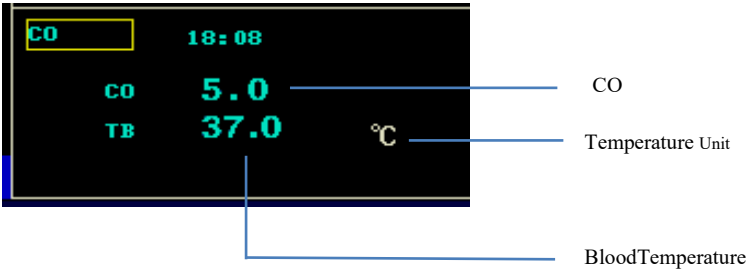
Chapter 17 CO Measurement

17.1 Introduction

The CO (cardiac output) measurement adapts right atrial thermodilution method to invasively measure cardiac output and other hemodynamic parameters. The thermodilution method is to inject a certain kind of solution (colder than body temperature) into human blood circulation system, and then measure the reduction of blood temperature at certain lower end. At the CO measurement window, the change of temperature will be indicated by a curve. The area below the curve is inversely proportional to the CO value. Basing the cure, the monitor will calculate the CO value. Because CO value is a continuous changing value, to obtain a reliable average CO value, multiple measurements must be taken. This monitor will save the latest 6 measurement results, so the user may select the required measurement results for average calculation. The CO measurement function can only be used on adults.

17.2 CO Display

At the main interface, there is no CO measurement waveform displayed. Instead,the CO value and TB (temperature of blood) value are displayed at the parameter area. By selecting CO parameter area, you can open the **[CO Selection]** sub-menu.



17.3 Influencing Factors

Factors that may influence the accuracy of CO measurement results include:

- Temperature of the injection
- Volume of the injection
- The baseline of patient blood temperature
- The inhale and exhale cycle of the patient
- The distance between the end of the floating catheter and the lung
- The catheter
- The heart rate and hemodynamic status of the patient
- Injection of any kind of fast IV solution during CO measurement

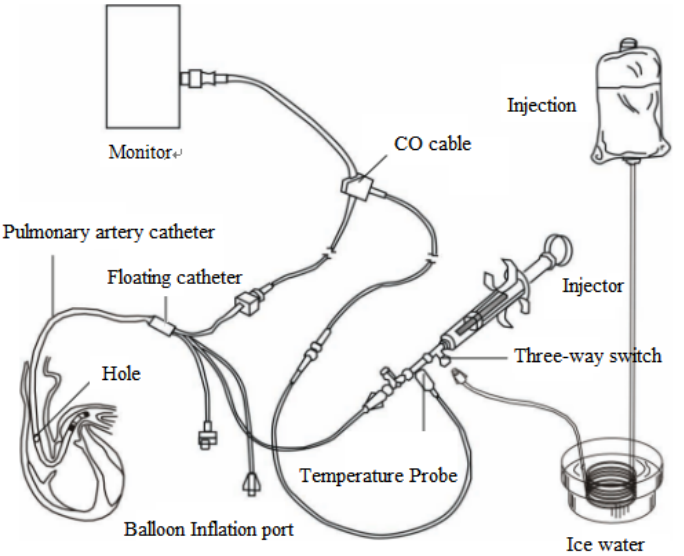
- In order to obtain accurate CO value, it is suggested that:
- The temperature of injection shall be lower than that of the patient's blood.
- The injection shall be steadily and fast.
- The injection shall be performed at the end of exhaling.
- Leave 1 minute interval between two injections, allowing the baseline of blood temperature to recover.

17.4 CO Measurement

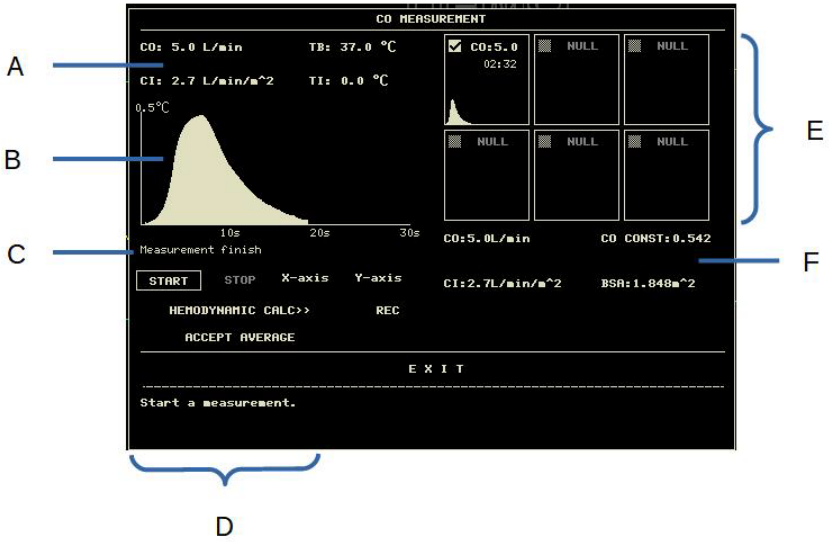
Warning

- **Please use the accessories stipulated by this instruction, and avoid the contact between accessories and electricity conductive metals.**
- **Do not reuse single-use product.**
- **When perform defibrillation while CO monitoring, please do not touch or contact the CO measurement connection cable. Otherwise, it will cause electrical damage, electrical breakdown and other damages.**
- **Do not immerse the CO measurement connection cable into alcohol. Otherwise, the cable will harden or be damaged.**
- **Do not disinfect the cable under high pressure.**

1. Connect the CO cable to the corresponding socket on the patient monitor.
2. As guided by the following picture, connect the monitor with floating catheter, injector and other parts .



3. Locate at the module setting, and adjust the working parameters.
4. Select [CO Measurement] to open CO measurement window, and you may choose to perform multi-measurements according to your need.



A. The value of current measurement

CO: Cardiac output measurement result; CI: Cardiac index ; TB: blood temperature; TI: injection temperature

B. The CO curve of current CO measurement

C. Prompt information area

D. Function button

E. Measurement history window

F. CO constant, the average value of CO, CI and BSA; BSA: body surface area

5. Select [Start] button and start injection (no more than 4 seconds) to the patient, the CO measurement window will display real-time thermodilution curve. After each measurement, the result will be displayed in the measurement history window. Please wait for a while before repeating the above procedure and start the next measurement.
6. Repeat the procedures for 5 times to finish all required measurements. The monitor can save up to 6 measurement results. If you perform more than 6 measurements, the first measurement result will be automatically deleted, to save the latest result. After finishing

multiple measurements and selecting several measurement curves at the history window, the system will calculate and display the average CO and CI value according to the user's selection.

While injecting, open the port (of three-way switch) to the floating catheter and close the port to the injection end. After measurement, close the port to the floating catheter, open the port to the injection end, and absorb the injection into the injector.

In addition, you may also perform the following actions at the CO measurement window:

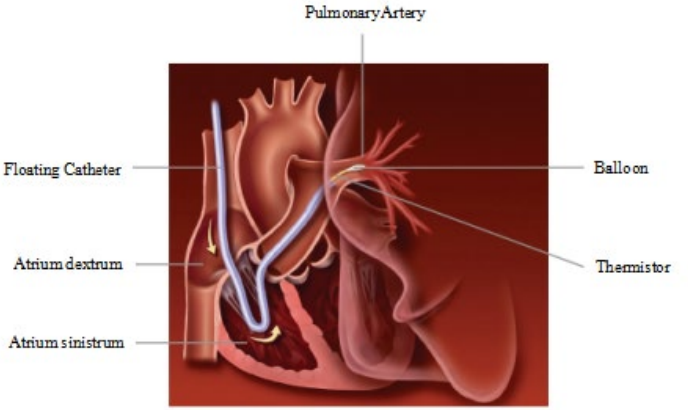
1. **[Start]:** start a CO measurement.
2. **[Stop]:** if the measurement lasts for too long and is unable to stop, pressing this button could stop the ongoing measurement.
3. **[X axis]:** adjust the abscissa scale amplitude, choose the maximum length between 30 seconds or 60 seconds.
4. **[Y axis]:** adjust the ordinate scale amplitude, choose the maximum length among 0.5ºC, 1ºC and 2.0ºC.
5. **[Hemodynamic calculation]:** open **[Hemodynamic calculation]** menu.
6. **[Record]:** record the latest measurement curve and result.
7. **[Accept average value]:** accept the average CO value and display it on the parameter area.

Attention:

- **□During CO measurement, blood temperature alarm will be disabled.**

17.5 Blood Temperature Measurement

As shown in the following picture, it is the thermistor at the end of the pulmonary artery floating catheter measuring the blood temperature. During CO measurement, the blood temperature alarm will be shielded, to prevent mistaken-alarm. After the measurement, the blood temperature alarm will be activated automatically.



17.6 CO Setting

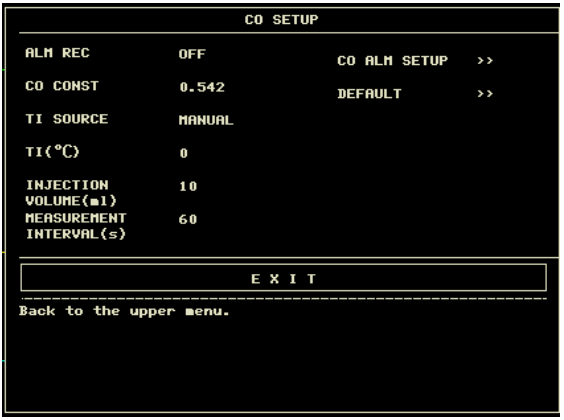
Open **[CO Setting]** menu at the CO parameter area, and start the following settings:

- **[Alarm History]**: [ON]/[OFF]
- **[CO CONST]**: Input the constant coefficients related to the calculations of the floating catheter and the volume and temperature of the injection. When replacing a different floating catheter, please adjust the constant according to the instruction of the catheter manufacturer.
- **[Source of injection temperature]**: if **[Auto]** mode is selected, the probe will be used to obtain the temperature of the injection.
- **[Injection temperature]**: when **[Source of injection temperature]** is set as **[Manual]**, please input the temperature of the injection at this interface.
- **[Injection volume (ml)]**: the selectable range is 1ml~200ml, interval is 1ml.
- **[Measurement interval (s)]**: the smallest time between two measurements, the unit is second; the selectable intervals include: 30s, 45s, 60s and 90s. To ensure the accuracy of measurement, the blood temperature must recover to normal value, therefore, it is necessary to set an interval between two measurements.
- **[CO alarm setting]**: alarm ON/OFF, alarm level, TB upper limit alarm and TB lower limit alarm.

■ **[Default setting]**: after selecting this option, the [CO default setting] dialogue box will appear, the user may select [Default Manufacturer Setting] or [Default User Setting]. After selection and exit from the dialogue box, the system will pop out another dialogue box asking the user for confirmation.

Attention:

● **The CO constant can not be edited without sound reason.**



17.7 Alarm Information and Prompts

When the alarm switches are set to "ON" in relevant menus, the physiological alarms caused by the parameter exceeding the alarm limit possibly trigger the recorder to automatically output the alarm parameter value and corresponding waveforms.

The table below describes the possible physiological alarms, technical alarms and prompt messages occurring during CO measurement.

Message	Cause	Alarm Level	Remedy
CO MODULE ERROR	CO module cannot communicate with the main system	HIGH	Restart the device, if the error still appears, contact the manufacturer.
TI LEAD OFF	The TI temperature sensor cable is not connected properly.	LOW	Check the connection of TI temperature sensor cable.
TB LEAD OFF	The TB temperature sensor cable is not connected properly.	LOW	Check the connection of TB temperature sensor cable.

Chapter 18 Battery

18.1 Introduction

The device can configure the rechargeable battery(lithium battery), which can ensure that the device can be used normally when the patient is moving in hospital or in the condition of power failure. The battery can be charged once connecting to the AC, no matter whether the the device is powered on. When sudden power interruption appears, the system will operate by the battery.

18.2 Battery status information

The battery status information displays the battery condition, which can be used to estimate the monitoring time.


The battery works normally, and the solid represents the battery power.

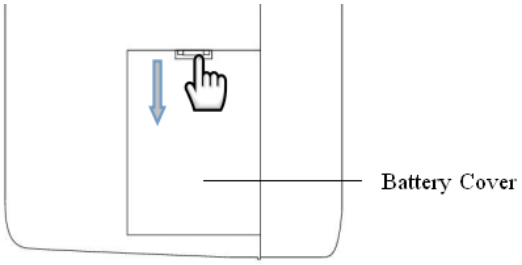

The battery power is low and low-battery alarm appears, it indicates that the battery needs to be charged immediately.

Working by the battery can only maintain a period of time. Too low voltage will trigger high-level technical alarm "Low battery", then you should charge to the battery, otherwise it will shut down after the first alarm (about 5 minutes).

18.3 Battery installation

Refer to the following contents to install or replace the battery:

1. Open the battery compartment cover.



2. Connect the new battery to the connector, place the battery into the slot, then fix the battery compartment
3. Install the battery compartment baffle.

18.4 Check for battery performance

The battery performance may decrease with the increasing of use time. Please refer to the following steps to check the battery performance.

1. Disconnect the connection between the device and the patient to stop all monitoring and measurement.
2. Connect the device to AC to continuously charge the battery for above 10 hours.
3. Disconnect the AC, use the battery to supply power for the device till shutdown.

4. Battery-powered time reflects the battery performance.

If the battery-powered time is obviously lower than the time claimed in the Specification, please replace the battery or contact the service personnel.

WARNING

- **Please read the manual and safety information carefully before using the rechargeable lithium battery(hereinafter referred to as "battery").**
- **Keep the battery out of children's reaching.**
- **Don't take out the battery during monitoring.**
- **Don't connect the anode and cathode falsely to avoid explosive hazard.**
- **Don't heat the battery or throw it into the fire.**
- **Don't use the battery near the fire source or in the environment of temperature over +60℃.**
- **Don't throw the battery into the water, nor wet the battery.**
- **Don't destroy the battery: don't chisel the metal into the battery, or hammer or knock the battery, or use other methods to destroy the battery, to avoid the the battery heating, smoking, deformation or burning, even producing risks.**
- **Only the battery specified by the manufacturer can be used.**
- **The battery can only be used in the device. Necessary maintenance must be performed by qualified and trained service engineers ONLY.**
- **If the electrolyte exudes and enters your eye, please don't knead your eye, use clean water to rinse immediately and go to the doctor.**
- **If there is the sign of battery damage or leakage, please replace it immediately. Don't use the faulted battery.**

NOTE

- **In order to protect the environment, please recycle the scrap battery as the regulations.**
- **When the device is turned off arisen from power failure, the system will save the latest settings before power failure when it is turned on again.**

18.5 Battery maintenance

The battery should be maintained periodically to prolong its use life, pay attention to the following instructions:

- During storing the battery, please charge to it once per 3 months at least.
- Battery performance must be checked once per 2 years. And it also should be checked when the device is maintained or you doubt the battery is the fault source.
- Please take out the battery before transporting the device or the device is not used over 3 months.
- If the device is not used for a long time, and the battery is not taken out, please charge to the battery once per 3 months, to avoid shortening the battery life.

18.6 Battery recycle

The battery should be replaced and recycled properly if it has obvious damage or it can not store the power normally. The disposal of scrap battery should follow the relevant laws and regulations.

WARNING

- **Don't disassembly the battery, or throw it into the fire, or make it short circuit. As battery burn, explosion or leakage may injury to the human.**

Chapter 19 Maintenance and Cleaning

Only use the material and method listed in this chapter to clean or maintain the device. Otherwise we do not provide any guarantee.

Our company has verified the cleaning and disinfection methods described in the manual. Professional personnel in hospital should obey the manual to ensure sufficient cleaning and disinfection.

19.1 Introduction

Keep the device and accessories out of dust. In order to prevent damage, please obey the following rules:

- Please dilute the detergent and disinfectant according to the manufacturer's instructions, or adopt the lower concentration as soon as possible.
- Don't immerse the device into the liquid.
- Don't pour the liquid into the device or accessories.
- Don't allow liquid to enter into the enclosures.
- Don't use abrasion material(such as steel wool or silver polishing agent) and any strong solvent(such as acetone or the detergent contained acetone).

19.2 Cleaning

The device should be cleaned periodically, in the area of seriously polluted or greater sand wind, cleaning frequency should be increased. Before cleaning, please consult or understand the regulations about device cleaning in advance.

Selectable detergents:

- water
- soap-suds/mild detergent
- 1% saline lolution
- 2%glutaric dialdehyde solution
- 10%sodium hypochlorite aqueous solution

When cleaning the device with the adsorption detergent, or wipe the residual detergent after cleaning, please use the clean and non-corrosive soft cloth or paper towel.

19.2.1 Cleaning for host

Clean the device surface according to the following steps:

1．Turn off the power and unplug the power cord.

2．Use the soft cloth adsorbed proper detergent to completely wipe the external surface(including the LCD) of the

device until that there is no obvious dirt.

3．After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.

4．Place the device in ventilation and shady environment for air drying.

WARNING

- **Before cleaning, make sure that the device is switched off and disconnected from the**

power cord.

CAUTION

- **If the liquid is poured into the device or the accessories carelessly, please contact with our company or our service personnel immediately.**

Note

- **Do not use alcohol or alcohol-based cleaning solution.**

19.2.2 Cleaning for the reusable accessories

19.2.2.1 Cleaning for the ECG lead cables

1. Use the soft cloth adsorbed proper detergent to completely wipe the lead cable surface until that there is no obvious dirt.
2. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
3. Use a dry soft to wipe the residual water.
4. Place the lead cable in ventilation and shady environment for air drying.

19.2.2.2 Cleaning for NIBP cuff

Clean the cuff:

1. Take out the gasbag before cleaning.
2. The cuff should not be dry-cleaned, but it can be machine-washed or hand-washed, and the latter method may prolong the service life of the cuff. .
3. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
4. Use a dry soft to wipe the residual water.
5. Place the cuff in ventilation and shady environment for air drying.

Replace the gasbag:

After cleaning, install the gasbag into the cuff according to the following steps:

1. Roll up the gasbag lengthwise, place it into the cuff from the cuff side of the big opening.
2. Thread the leather hose of airbag from the small hole on the cuff, from inside to outside.
3. Adjust the gasbag location in cuff.

19.2.2.3 Cleaning for SpO_2 probe

8. Use the soft cloth adsorbed proper detergent to wipe the probe and lead cable surface until that there is no obvious dirt.
9. Use the cotton swab adsorbed proper detergent to completely wipe the contact position between the probe and the patient until that there is no obvious dirt.
10. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
11. Use a dry soft to wipe the residual water.
12. Place the probe in ventilation and shady environment for air drying.

19.2.2.4 Cleaning for TEMP probe

1. Use the soft cloth adsorbed proper detergent to wipe the contact position between the probe and the patient
   until that there is no obvious dirt.
2. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual
   detergent until that there is no obvious dirt.
3. Use a dry soft to wipe the residual water.
4. Place the probe in ventilation and shady environment for air drying.

19.2.2.5 Cleaning for IBP cable

1. Use the soft cloth adsorbed proper detergent to completely wipe the lead cable surface until that there is no obvious dirt.
2. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
3. Use a dry soft to wipe the residual water.
4. Place the cable in a ventilation and shady environment for air drying.

19.2.2.6 Cleaning for CO cable

1. Refer to the cleaning method for ECG cable.

19.3 Disinfection

To avoid extended damage to the device, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. The device should be cleaned firstly before disinfection.

Disinfectant recommended: isopropanol(70%),2％glutaric dialdehyde solution，10％ sodium hypochlorite aqueous solution.

19.4 Sterilizing

Sterilization is not recommended for this monitor, related products, accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies.

Chapter 20 Maintenance

WARNING

- **The hospital or medical institution using the device should establish a perfect maintenance plan, otherwise it may result in device failure and unpredictable consequences, even endanger personal safety.**
- **All safety inspections or maintenance works to the components to be disassembled should be carried out by professional service personnel, otherwise it may result in device failure, even endanger personal safety.**
- **If any problem has been found, please contact the service person or our company.**
- **Parts cannot be maintained while equipment is in use.**

20.1 Check

The device should be completely checked before using, or after continuous use of 6 to 12 months, maintenance or upgrading, to ensure normal operation and working.

The items to be checked should include:

- Environment and power meet the requirements.
- No abrasion and good insulation performance for the power cord.
- No mechanical damage for the device and accessories.
- The accessories specified are used.
- Alarm functions are normal.
- The recorder works normally, the recording paper conforms with specified requirements.
- Battery performance.
- Each monitoring function is in good working state.
- Ground impedance and leakage current conform requirements.

If any signs of damage to the instrument can be found, please don't use the monitor to perform any monitoring on the patient. And contact the medical engineer of the hospital or the maintenance engineer of the company.

All inspections that require to open the device must be carried out by qualified service personnel. Safety and maintenance inspections may also be carried out by personnel of the Company.

20.2 Troubleshooting

■ Power failure

Install the battery when using the device. As if the mains is disconnected, the device supplied power by the battery, which only sustains a period of time, and it will be automatically switched to mains when it is connected. A low battery voltage will trigger a high-tech alarm "Low battery", and it will shut down after the first alarm (about 5 minutes), then all trend data will be lost.

■ **Troubleshooting**

Other problems related to ECG measurement

Symptoms	Possible reasons and solutions
Noisy ECG signal or no QRS waveform is checked.	• Make sure that the patient does not tremble. Incorrect ECG filter. • The electrode is poor in quality or placed in a wrong position. Check the electrodes, cables and their placement. Refer to "ECG Monitoring" for details. • Replace a lead. Remove the ECG cable from the interface and insert it again.
Thick ECG baseline.	ECG cable is looped. Other power cables are close to ECG lead cables. Inappropriate power frequency.

Other problems related to RESP measurement

Symptoms	Possible reasons and solutions
Failure in RESP measurement.	• Check electrode quality and placement. • Other electrical equipment may interfere the measurement.

Other problems related to NIBP measurement

Symptoms	Possible reasons and solutions
NIBP measurement can not be performed.	• Check whether the cuff is bent, stretched, squeezed, or loose. • Use a cuff in proper size.

Other problems related to TEMP measurement

Symptoms	Possible reasons and solutions
Failure in TEMP measurement.	• Check whether a appropriate probe is used. • Try the other one.

Other problems related to SpO_2 measurement

Symptoms	Possible reasons and solutions
The signal is weak.	• Check the probe and its placement. • Note that skin pigmentation can cause deviations. • Make sure the patient is not trembling.

Other problems related to CO measurement

Symptoms	Possible reasons and solutions
TI LEAD OFF	Check the connection of TI temperature sensor cable.
TB LEAD OFF	Check the connection of TB temperature sensor cable.

Other problems related to battery

Symptoms	Possible reasons and solutions

Battery working time significantly shortens.	• Maintain the battery according to the descriptions in the manual

Other conditions

Other possible conditions and reasons are listed in the table.

Other operation problems

Symptoms	Possible reasons and solutions
The device can not print.	• The battery power is low and the host is not connected to AC.
The measurement value does not display.	• Check if you have selected the required parameters for the waveform or digital area.
The device can not turn on.	• Check whether the power cord is connected correctly. • Check the fuses and replace them if necessary.
The screen stop in LOGO interface.	• Replace the mainrboard, or contact the engineer to re-brush the mainboard program.

20.3 Maintenance plan

The following tasks can only be performed by the professional maintenance staff authorized by our company. Please contact the service personnel when you need the following maintenance. Before test or maintenance, the device must be cleaned and disinfected.

Check/maintenance items	Frequency
Safety check according to IEC60601-1.	When replacing the power supply or after the device falls off.
NIBP air leakage check.	At least once per two years, or check according to the provisions of the hospital.
NIBP pressure check.	At least once per two years, or check according to the provisions of the hospital.
NIBP calibration.	At least once per two years, or check according to the provisions of the hospital.
TEMP calibration.	At least once per two years, or check according to the provisions of the hospital.
CO check	At least once per two years, or check according to the provisions of the hospital.

20.4 NIBP VERIFY

NIBP pressure verification should be performed once per two years at least or once when you thought that the reading is inaccurate.

Prepared materials:

- Standard manometer

- Metal container(500 ml)
- Spheroidal air pump
- Airway tube
- T-shape connector

Procedures of the Pressure Transducer Verification:

Replace the cuff with a metal container with a capacity of 500 ml ± 5%. Connect a calibrated standard manometer, spheroidal air pump(error less than 0.8 mmHg) and airway tube to the NIBP cuff jack of the module by a T-shape connector. Set the monitor in "VERIFY" mode. Inflate the pressure in the metal container to 50 and 200 mmHg by spheroidal air pump separately. The difference between the indicated pressure of the standard manometer and the monitor will not exceed 3 mmHg. Otherwise, please contact our customer service.

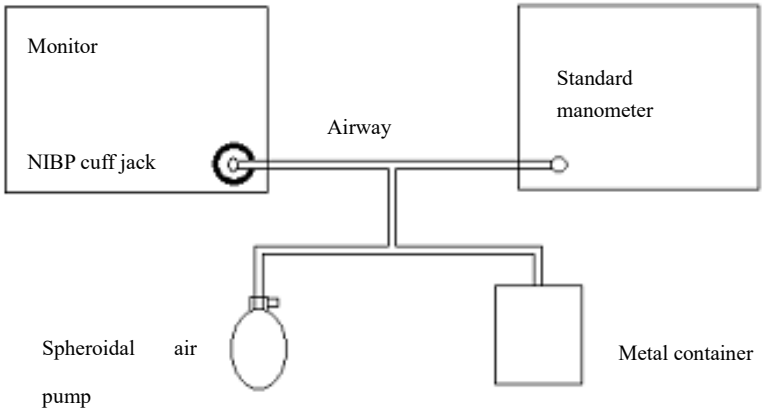


Diagram of NIBP Verification

20.5 ECG Calibration

The ECG signal may be inaccurate due to hardware or software problems when you use the monitor. The main manifestation is that the amplitude of waveform becomes larger or smaller. In this case, you need to calibrate the ECG.

- Select ECG Parameter area.
- Select" ECG SETUP"→ "OTHER SETUP" → "ECG CAL". A square wave signal will appear on the screen.
- Compare the amplitude of the square wave with the scale, generally the square wave should be flush with the top and bottom of the ruler,and the error range should be within 5%.
- After calibration, select "STOP ECG CAL".

Chapter 21 Accessories

WARNING

- **Use only the accessories specified in this chapter, as other accessories may damage the monitor or fail to meet the specifications stated in this manual.**
- **Disposable accessories can only be used once, repeated use may lead to performance degradation or cross infection.**
- **If you find any damage to the accessories packing or accessories, please do not use the accessories.**

21.1 ECG Accessories

ECG electrodes

Specification	Accessory name	Description	Remark
Adult use	ECG electrode, adult, one packet(20 pcs)	Disposable	/
Child use	ECG electrode, child, one packet(20 pcs)		

ECG cable

Specification	Accessory name	Description	Remark
AAT0005	5-lead, American Standard, TPU, gold-plated button-type	Repeatable	/
AIT0006	5-lead, European standard, TPU, gold-plated button-type		
AAT0007	5-lead, American Standard, TPU, children's gold-plated clip-type		
AIT0008	5-lead, European Standard, TPU, children's gold-plated clip-type		
AAT0013	3-lead, American Standard, TPU, gold-plated button-type		
AIT0014	3-lead, European standard, TPU, gold-plated button-type		
AAT0021	5-lead,AmericanStandard,Defibrillation ,TPU, gold-plated button-type		
AAT0015	3-lead, American Standard, TPU, children's gold-plated clip-type		
AIT0016	3-lead, European Standard, TPU, children's gold-plated clip-type		
AAT0023	5-lead, American Standard, ,TPU, children's gold-plated clip-type		

21.2 SpO_2 Accessories

SpO_2 probe

Specification	Accessory name	Applicable Population	Description	Remark
ESA0061	Digital fingertip SpO2 probe for adult (CMS-N-SPO2 6P, 3m, yellow)	Adult(>40 Kg)	Repeatable	Integrated SpO_2 probe
ESB0062	Digital fingerstall SpO2 probe for adult(CMS-N-SPO2 6P, 3m, yellow)	Adult(>40 Kg)		
ESA0063	Digital fingertip SpO2 probe for children (CMS-N-SPO2 6P, 3m, yellow)	Children(10~40 Kg)		
ESC0064	Digital integrated SpO2 probe (CMS-N-SPO2 6P, 3m, yellow)	Adult or children(> 10 Kg)		
FST0014	Common digital blood oxygen probe extension line (CMS-N-SpO_2 6P, 2M, yellow)	——		Split extension line
ESA0016	Digital DB7 finger clip blood oxygen probe for children (1m)	children(10 ～ 40 Kg)		Split blood oxygen probe
ESB0017	Digital DB7 fingertip blood oxygen probe for adult (1m)	adult(＞ 40 Kg)		
ESC0029	Digital DB7 integrated binding blood oxygen probe (1m)	Adult or children (＞10 Kg)		
ESA0003	Digital DB7 finger clip blood oxygen probe for adult (1m)	adult(＞ 40 Kg)		

21.3 NIBP Accessories

Airway tube

Specification	Accessory name	Description	Remark
IGN0064	NIBP extension tube, L = 3 m (direct-plug connector and fast connector(female))	Repeatable	/

Cuff

Specification	Accessory name	Description	Remark
IGN0001	Neonatal cuff, repeatable	Limb perimeter(6~11 cm)	/
IGN0002	Infants cuff, repeatable	Limb perimeter(10~19 cm)	
IGN0003	Children cuff, repeatable	Limb perimeter(18~26 cm)	
IGN0004	Adult cuff, repeatable	Limb perimeter(25~35 cm)	
IGN0005	Adult cuff, repeatable, large size	Limb perimeter(33~47 cm)	
IGN0006	Leg cuff for adult, repeatable	Limb perimeter(46~66 cm)	

21.4 TEMP Accessories

TEMP probe

Specification	Accessory name	Description	Remark
CGP0013	R25=2.252K temperature probe, body surface type, CMS-N-TEMP 2P, PVC, L = 3 m	Repeatable	/
CGP0014	R25=2.252K temperature probe, body cavity type, CMS-N-TEMP 2P, PVC, L = 3 m		

21.5 IBP accessories

Specification	Accessory name	Description	Remark
IBP-100, new plug , new cable	IBP module	/	Ancillary use
DGT0002	CMS and ABBOTT transducer Adapter Cable	Reusable	
PT-01	IBP sensor	Disposable	

21.6 CO_2 Accessories

Sidestream module

Specification	Accessory name	Description	Remark
CO2-M01, self-produced sidestream, XC,TTL	CO2 module	/	/

scheme			
Sampling cannula and adapter			
MGN0006	Nasal sampling cannula (including drying tube and filter cotton)	Disposable	/
MGN0007	Nasal sampling cannula (including filter cotton)		
MGN0008	Sampling cannula, intubation patient(including drying tube and filter cotton)		
MGN0009	Sampling cannula, intubation patient(including filter cotton)		

Mainstream module

Specification	**Accessory name**	**Description**	**Remark**
CO2-M02, self-produced mainstream, TTL scheme	CO2 module	/	/
Airway adapter			
MGN0011	Adult/child CA10M airway adapter/ MGN0011	Disposable	Mainstream
MGN0012	Neonatal CA10M airway adapter/ MGN0012		

21.7 CO Accessories

CO cable

Specification	**Accessory name**	**Description**	**Remark**
DGT0003	CO cable	Reusable	/

Chapter 22 Default Settings

This appendix documents the most important default settings of your monitor as it is delivered from the factory. For a comprehensive list and explanation of default settings, see the Configuration Guide supplied with your monitor. The monitor's default settings can be permanently changed in Configuration Mode.

NOTE

- **If your monitor has been ordered preconfigured to your requirements, the settings at delivery will be different from those listed here.**

22.1 Country-Specific Default Settings

Certain default settings are specific to a particular country. These are listed here for all countries alphabetically.

Country-Description	Line Frequency	Units Weight	Units Height	ECG Cable Color
	50/60 [Hz]	kg, lb	in, cm	IEC, AAMI
Afghanistan	50	kg	cm	AAMI
Åland Islands	50	kg	cm	IEC
Albania	50	kg	cm	IEC
Algeria	50	kg	cm	IEC
American Samoa	60	lb	in	AAMI
Andorra	60	lb	in	AAMI
Angola	50	kg	cm	IEC
Anguilla	60	lb	in	AAMI
Antarctica	60	lb	in	AAMI
Antigua and Barbuda	50	kg	cm	AAMI
Argentina	50	kg	cm	AAMI
Armenia	50	kg	cm	IEC
Aruba	60	kg	cm	AAMI
Australia	50	kg	cm	AAMI
Austria	50	kg	cm	IEC
Azerbaijan	50	kg	cm	IEC
Bahamas, The	60	kg	cm	AAMI
Bahrain	50	kg	cm	AAMI
Bangladesh	60	lb	in	AAMI
Barbados	50	kg	cm	AAMI
Belarus	50	kg	cm	IEC
Belgium	50	kg	cm	IEC
Belize	60	lb	in	AAMI

Benin	60	lb	in	AAMI
Bermuda	60	kg	cm	AAMI
Bhutan	60	lb	in	AAMI
Bolivia	50	kg	cm	AAMI
Bosnia and Herzegovina	50	kg	cm	IEC
Botswana	50	kg	cm	IEC
Bouvet Island	60	lb	in	AAMI
Brazil	60	kg	cm	AAMI
British Indian Ocean Territory	60	lb	in	AAMI
Brunei Darussalam	50	kg	cm	AAMI
Brunei	50	kg	cm	IEC
Bulgaria	50	kg	cm	IEC
Burkina Faso	50	kg	cm	IEC
Burundi	50	kg	cm	IEC
Cambodia	50	kg	cm	IEC
Cameroon	50	kg	cm	IEC
Canada	60	kg	cm	AAMI
Cape Verde	60	lb	in	AAMI
Cayman Islands	60	kg	cm	AAMI
Central African Republic	50	kg	cm	IEC
Chad	60	lb	in	AAMI
Chile	50	kg	cm	AAMI
China	50	kg	cm	IEC
Christmas Islands	60	lb	in	AAMI
Cocos Keeling Islands	60	lb	in	AAMI
Colombia	60	kg	cm	AAMI
Comoros	60	lb	in	AAMI
Congo	50	kg	cm	IEC
Congo, Democratic Republic of the	50	kg	cm	IEC
Cook Islands	60	lb	in	AAMI
Costa Rica	60	kg	cm	AAMI
Côte d'Ivoire	50	kg	cm	IEC
Croatia	50	kg	cm	IEC
Cuba	60	kg	cm	IEC
Cyprus	50	kg	cm	IEC
Czech Republic	50	kg	cm	IEC
Denmark	60	lb	in	AAMI

Djibouti	50	kg	cm	IEC
Dominica	50	kg	cm	AAMI
Dominican Republic	60	kg	cm	AAMI
Ecuador	60	kg	cm	AAMI
Egypt	50	kg	cm	IEC
El Salvador	60	kg	cm	AAMI
Equatorial Guinea	50	kg	cm	IEC
Eritrea	50	kg	cm	IEC
Estonia	50	kg	cm	IEC
Ethiopia	50	kg	cm	IEC
Falkland Islands, Malvinas	60	lb	in	AAMI
Faroe Islands	60	lb	in	AAMI
Fiji	60	lb	in	AAMI
Finland	50	kg	cm	IEC
France	50	kg	cm	IEC
French Guiana	50	kg	cm	IEC
French Polynesia	60	lb	in	AAMI
French Southern Territories	60	lb	in	AAMI
Gabon	50	kg	cm	IEC
Gambia, The	50	kg	cm	IEC
Georgia	60	lb	in	AAMI
Germany	50	kg	cm	IEC
Ghana	50	kg	cm	IEC
Gibraltar	60	lb	in	AAMI
Greece	50	kg	cm	IEC
Greenland	60	lb	in	AAMI
Grenada	50	kg	cm	AAMI
Guadeloupe	50	kg	cm	IEC
Guam	60	lb	in	AAMI
Guatemala	60	kg	cm	AAMI
Guernsey	50	kg	cm	IEC
Guinea	60	lb	in	AAMI
Guinea-Bissau	60	lb	in	AAMI
Guyana	60	kg	cm	AAMI
Haiti	60	kg	cm	AAMI
Heard Island and McDonald Islands	60	lb	in	AAMI
Holy See, Vatican City State	60	lb	in	AAMI

Honduras	60	kg	cm	AAMI
Hong Kong	50	kg	cm	IEC
Hungary	50	kg	cm	IEC
Iceland	50	kg	cm	IEC
India	50	kg	cm	IEC
Indonesia	50	kg	cm	IEC
Iran, Islamic Republic of	50	kg	cm	AAMI
Iraq	50	kg	cm	AAMI
Ireland	50	kg	cm	IEC
Isle of Man	50	kg	cm	IEC
Israel	50	kg	cm	IEC
Italy	50	kg	cm	IEC
Jamaica	50	kg	cm	AAMI
Japan	60	kg	cm	IEC
Jersey	50	kg	cm	IEC
Jordan	50	kg	cm	AAMI
Kazakhstan	50	kg	cm	IEC
Kenya	50	kg	cm	IEC
Kiribati	60	lb	in	AAMI
Korea, Democratic People's Republic of	60	lb	in	AAMI
Korea, Republic of	60	kg	cm	AAMI
Kuweit	50	kg	cm	AAMI
Kyrgyzstan	60	lb	in	AAMI
Lao People's Democratic Republics	50	kg	cm	IEC
Latvia	50	kg	cm	IEC
Lebanon	50	kg	cm	AAMI
Lesotho	50	kg	cm	IEC
Liberia	50	kg	cm	IEC
Libyan Arab. Jamahiriya	60	lb	in	AAMI
Liechtenstein	60	lb	in	AAMI
Lithuania	50	kg	cm	IEC
Luxembourg	50	kg	cm	IEC
Macao	60	lb	in	AAMI
Macedonia, The former Yugoslav. Rep. of	50	kg	cm	IEC
Madagascar	50	kg	cm	IEC

Malawi	50	kg	cm	IEC
Malaysia	50	kg	cm	IEC
Maldives	60	lb	in	AAMI
Mali	50	kg	cm	IEC
Malta	50	kg	cm	IEC
Marshall Islands	60	lb	in	AAMI
Martinique	60	kg	cm	IEC
Mauritania	50	kg	cm	IEC
Mauritius	60	lb	in	AAMI
Mayotte	60	lb	in	AAMI
Mexico	60	kg	cm	AAMI
Micronesia, Fed. States of	60	lb	in	AAMI
Moldova, Republic of	60	lb	in	AAMI
Monaco	60	lb	in	AAMI
Mongolia	60	lb	in	AAMI
Montenegro	50	kg	cm	IEC
Montserrat	50	kg	cm	AAMI
Morocco	50	kg	cm	IEC
Mozambique	50	kg	cm	IEC
Myanmar	60	lb	in	AAMI
Namibia	50	kg	cm	IEC
Nauru	60	lb	in	AAMI
Nepal	60	lb	in	AAMI
Netherlands	50	kg	cm	IEC
Netherlands Antilles	50	kg	cm	AAMI
New Caledonia	60	lb	in	AAMI
New Zealand	50	kg	cm	AAMI
Nicaragua	60	kg	in	AAMI
Niger	50	kg	cm	IEC
Nigeria	50	kg	cm	IEC
Niue	60	lb	in	AAMI
Norfolk Islands	60	lb	in	AAMI
Northern Mariana Islands	60	lb	in	AAMI
Norway	50	kg	cm	IEC
Oman	50	kg	cm	AAMI
Pakistan	50	kg	cm	IEC
Palau	60	lb	in	AAMI
Palestinian Territory	50	kg	cm	AAMI

Panama	60	lb	in	AAMI
Papua New Guinea	60	lb	in	AAMI
Paraguay	50	kg	cm	AAMI
Peru	60	kg	cm	AAMI
Philippines	60	kg	cm	AAMI
Pitcairn	60	lb	in	AAMI
Poland	50	kg	cm	IEC
Portugal	50	kg	cm	IEC
Puerto Rico	60	lb	in	AAMI
Qatar	50	kg	cm	AAMI
Reunion	60	lb	in	AAMI
Romania	50	kg	cm	IEC
Russian Federation	50	kg	cm	IEC
Rwanda	50	kg	cm	IEC
Saint Helena	60	lb	in	AAMI
Saint Kitts and Nevis	60	kg	cm	AAMI
Saint Lucia	50	kg	cm	AAMI
Saint Pierre and Miquelon	60	lb	in	AAMI
Saint Vincent and the Grenadines	50	kg	cm	AAMI
Samoa	60	lb	in	AAMI
San Marino	60	lb	in	AAMI
Sao Tome and Principe	60	lb	in	AAMI
Saudi Arabia	50	kg	cm	AAMI
Senegal	50	kg	cm	IEC
Serbia	50	kg	cm	IEC
Serbia & Montenegro	50	kg	cm	IEC
Seychelles	60	lb	in	AAMI
Sierra Leone	50	kg	cm	IEC
Singapore	50	kg	cm	IEC
Slovakia	50	kg	cm	IEC
Slovenia	50	kg	cm	IEC
Solomon Islands	60	lb	in	AAMI
Somalia	50	kg	cm	IEC
South Africa	50	kg	cm	IEC
South Georgia and the South Sandwich Islands	60	lb	in	AAMI
Spain	50	kg	cm	IEC
Sri Lanka	60	lb	in	AAMI

Sudan	50	kg	cm	IEC
Suriname	60	kg	cm	AAMI
Svalbard and Jan Mayen	60	lb	in	AAMI
Swaziland	60	lb	in	AAMI
Sweden	50	kg	cm	IEC
Switzerland	50	kg	cm	IEC
Syrian Arab Rep	50	kg	cm	AAMI
Taiwan, Province of China	60	kg	cm	AAMI
Tajikistan	60	lb	in	AAMI
Tanzania, United Republic of	60	lb	in	AAMI
Thailand	50	kg	cm	AAMI
Timor-Leste	60	lb	in	AAMI
Togo	60	lb	in	AAMI
Tokelau	60	lb	in	AAMI
Tonga	60	lb	in	AAMI
Trinidad and Tobago	60	lb	in	AAMI
Tunisia	50	kg	cm	IEC
Turkey	50	kg	cm	IEC
Turkmenistan	60	lb	in	AAMI
Turks and Caicos Islands	60	kg	cm	AAMI
Tuvalu	60	lb	in	AAMI
Uganda	60	lb	in	AAMI
Ukraine	60	lb	in	AAMI
UK	50	kg	cm	IEC
United Arab Emirates	50	kg	cm	AAMI
United Kingdom	50	kg	cm	IEC
United States	60	lb	in	AAMI
United States Minor Outlying Islands	60	lb	in	AAMI
Uruguay	50	kg	cm	AAMI
Uzbekistan	60	lb	in	AAMI
Vanuatu	60	lb	in	AAMI
Venezuela	60	lb	in	AAMI
Viet Nam	50	kg	cm	IEC
Virgin Islands (British)	50	kg	cm	AAMI
Virgin Islands (US)	60	lb	in	AAMI
Wallis and Futuna Islands	60	lb	in	AAMI
Western Sahara	50	kg	cm	IEC

Yemen	50	kg	cm	AAMI
Zambia	60	lb	in	AAMI
Zimbabwe	60	lb	in	AAMI

22.2 Alarm and Measurement Default Settings

Settings are only entered once per table row if they are the same for all patient categories.

22.2.1 Alarm

Name	Factory Default
ALARM VOL	1
ALM REC TIME	32 s
ALM PAUSE TIME	2 min
ALM TYPE	UNLATCH
KEYVOL	1
ALM SOUND	ON

22.2.2 ECG

Name	Factory Default		
	Adult	Pedi	Neo
FILTER	Monitor		
HR ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
ALM HI	120 bpm	160 bpm	200 bpm
ALM LO	50 bpm	75 bpm	100 bpm
HR FROM	AUTO		
HR CHANNEL	CH1		
LEAD TYPE	5 LEAD		
SWEEP	25.0 mm/s		

Arrhythmia analysis

Name	Factory Default		
	Adult	Pedi	Neo
ARR ANAL	OFF		
PVCS ALM	OFF		
ALM LEV	MED		

ALM REC	OFF
ALM HI	10

ST-segment analysis

Name	Factory Default		
	Adult	Pedi	Neo
ST ANAL	OFF		
ST ALM	OFF		
ST ALM LEV	MED		
ST ALM SEC	OFF		
ST ALM HI	0.20		
ST ALM LO	-0.20		

22.2.3 RESP

Name	Factory Default		
	Adult	Pedi	Neo
ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
ALM HI	30 rpm		100 rpm
ALM LO	8 rpm		30 rpm
SWEEP	25 mm/s		
APENA ALM	20 s		
WAVE AMP	X1		
RESP FROM	LL-RA		

22.2.4 SpO_2

Name	Factory Default		
	Adult	Pedi	Neo
SpO_2 ALM	ON		
ALM LEV	Hi		
ALM REC	OFF		
SpO_2 ALM HI	100	100	95
SpO_2 ALM LOW	90	90	90

SWEEP	25 mm/s		
PR ALM	ON		
PR ALM HI	120 bpm	160 bpm	200 bpm
PR ALM LO	50 bpm	75 bpm	100 bpm

22.2.5 NIBP

Name	Factory Default		
	Adult	Pedi	Neo
ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
SYS ALM HI	160 mmHg	120 mmHg	90 mmHg
SYS ALM LO	90 mmHg	70 mmHg	40 mmHg
MEAN ALM HI	110 mmHg	90 mmHg	70 mmHg
MEAN ALM LO	60 mmHg	50 mmHg	25 mmHg
DIA ALM HI	90 mmHg	70 mmHg	60 mmHg
DIA ALM LO	50 mmHg	40 mmHg	20 mmHg
UNIT	mmHg		
INTERVAL	MANUAL		
INFLATION	150 mmHg	100 mmHg	70 mmHg

22.2.6 TEMP

Name	Factory Default		
	Adult	Pedi	Neo
ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
T1 HI	39.0		
T1 LO	36.0		
T2 HI	39.0		
T2 LO	36.0		
TD HI	2.0		
UNIT	℃		

22.2.7 IBP

Name		Factory Default		
		Adult	Pedi	Neo
ALM		ON		
ALM LEV		MED		
ALM REC		OFF		
SWEEP		25.0 mm/s		
IBP1 UNIT		mmHg		
IBP2 UNIT		mmHg		
FILTER		No filter		
Alarm limit		Systolic/diastolic(mean) pressure(mmHg)		
		Adult	Pedi	Neo
ART, P1, P2	ALM HI	160/90(110)	120/70(90)	90/60(70)
	LM LO	90/50(70)	70/40(50)	55/20(35)
PA	ALM HI	35/16(20)	60/4(26)	60/4(26)
	LM LO	10/0(0)	24/-4(12)	24/-4(12)
Alarm limit		Adult	Pedi	Neo
CVP, RAP, LAP, ICP	ALM HI	10	4	4
	LM LO	0	0	0

22.2.8 CO_2

Name	Factory Default		
	Adult	Pedi	Neo
ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
CO_2 ALM HI	45		
CO_2 ALM LO	30		
NS ALM HI	4		
AWRR ALM HI	30	30	100
AWRR ALM LO	8	8	30
APNEA ALM	20 s		

SWEEP	25.0 mm/s
Unit	mmHg
WAVE SCALE	LOW
WORK MODE	Standby
ATMOS(mmHg)	760
O2 COMPENSATE	16
BALANCE GAS	Air
ANEA	0.0

22.2.9 CO

Name	Factory default
	Adult
ALM	ON
ALM LEV	MED
TB ALM HI	39.0
TB ALM LO	36.0
ALM REC	OFF
CO CONST	0.542
TI SOURCE	MANUAL
TI(℃)	0
INJECTION VOLUME(ml)	10
INTERVAL(s)	60

Appendix A Product Specification

A.1 Classification

Anti-electroshock type	Class I, internal and external powered equipment
Anti-electroshock degree	Type CF defibrillation-proof applied part
Harmful liquid proof degree	IPX0(protected against harmful effects of 15°tilted falling water drops)
Working mode	Continuous working

A.2 Physical characteristic

Device model	Dimension(L×W×H)	Weight
CMS7000	319 mm×161 mm×269 mm	< 3.0 kg (standard configuration, excluding accessories)
CMS8000	314 mm×145 mm×264 mm	< 3.0 kg (standard configuration, excluding accessories)
CMS9000	319 mm×167 mm×268 mm	< 3.0 kg (standard configuration, excluding accessories)

A.3 Working environment

If used or stored outside the specified temperature and humidity range, the device may not meet the performance specifications listed here.

Working environment	
Temperature	+5~+40 ℃
Humidity	15~85 %
Atmospheric pressure	700~1060 hPa
Storage environment	
Temperature	-20~+55 ℃
Humidity	≤95 %(no coagulation)
Atmospheric pressure	500~1060 hPa

A.4 Power supply

Input voltage	100-240 V ～
Frequency	50/60 Hz
Input power	≤150 VA
Fuse	FUSE T1.6AL250V
Internal battery	
Battery type	Li-ion battery

Battery voltage	7.4 VDC
Battery capacity	5000 mAh
Minimum power supply time	180 min Working conditions: use a new fully charged battery, ambient temperature: 25 ℃. Device configuration: continuous measurement for ECG and SpO_2; NIBP measurement in AUTO mode, measurement interval: 15 minutes
Charging time	90%: about 4 hours,fully charged: 5 hours

A.5 Display

Dimension(diagonal)	12.1 inch, color TFT display
Resolution	800×600
Display information	Up to 8-channel waveform

A.6 LED on host

Alarm indicator	One alarm indicator(yellow/red)
Battery indicator	One
AC power indicator	One

A.7 Recorder

Recorder type	Thermal dot-matrix
Waveform	2-channel
Recording width	48 mm
Paper length	20 m
Paper speed	25 mm/s, 50 mm/s
Recording type	Continuous real-time recording 8-second real-time recording Auto 8-second recording Parameter alarm recording Waveform freeze recording Trend graph/table recording ARR events review recording Alarm event review recording NIBP review recording SD card review recording Drug calculation and titration table recording

A.8 Data storage

Trend recall	Short: 1 hour, resolution: 1 second
	Long: 480 hours, resolution: 1 minute
Alarm event recall	Physiological alarm: review for 72 alarm events of all parameters and 8/16/32-second of corresponding waveform. Technical alarm: 500 technical alarm events
Arrhythmia alarm event review	Review for 60 arrhythmia alarm events and 8-second of corresponding waveform.
NIBP measurement review	Review for the latest 4800 groups of NIBP data
SD card review	Trend data review: resolution: 1 minute 72-hour ECG waveform

A.9 ECG

Lead mode	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V
Waveform	3-lead: 1-channel waveform 5-lead: 2-channel waveform, up to 7-channel waveform can be displayed on one display.
Lead style	AHA(American standard), IEC(European standard)
Sensitivity	2.5 mm/mV(×0.25),5 mm/mV(×0.5),10 mm/mV(×1),20 mm/mV(×2),40 mm/mV(×4)
Scan speed	12.5 mm/s, 25 mm/s, 50 mm/s
Frequency response(bandwidth)	Diagnosis: 0.05~75 Hz(+0.4 dB, -3 dB); 76~150 Hz(+0.4 dB,-4.5 dB) Monitoring: 0.67~40 Hz(+0.4 dB, -3 dB) Surgery: 1~20 Hz(+0.4 dB, -3 dB)
CMRR	Monitoring: ≥100 dB Surgery: ≥100 dB Diagnosis: ≥90 dB
NOTCH	50/60 Hz(NOTCH filter can be turned on or off manually)
Electrode polarization voltage range	±500mV
Lead-off check	DC for active lead: ≤0.1 μA(Drive lead≤1 μA)
Baseline recovery time	After defibrillation ≤5 s(under monitoring and surgery)
Calibration signal	1 mV(peak-to-peak value), accuracy: ±5 %
Pacing pulse	
Pulse display	II lead
Pulse indicator	Pulse is marked if the requirements of ANSI/AAMI EC13:2002, Sect. 4.1.4.1 are met:

	Amplitude: ±2~±700 mV Width: 0.1~2 ms Rise time: 10~100 μs	
Pulse Rejection	Pulse is rejected if the requirements of ANSI/AAMI EC13-2002: Sect. 4.1.4.1 are met: Amplitude: ±2~±700 mV Width: 0.1~2 ms Rise time: 10~100 μs	
Minimum input slew rate	>3.5V/s RTI	
Alarm limit	**Range(bpm)**	**Step(bpm)**
HR high limit	Adult: (low limit+1)~300 Pediatric and neonate: (low limit+1)~350	1
HR low limit	15~(high limit-1)	
HR		
Measurement limit	Adult: 15~300 bpm Pediatric and neonate: 15~350 bpm	
Accuracy	±1 % or ±1 bpm, whichever is greater	
Resolution	1 bpm	
Alarm accuracy	±2 bpm	
Maximum suppression ability for T wave	1.2 mV	
HR mean	In the RR interval within the latest 6 seconds, take the average value after removing the maximum and minimum values. The heart rate displayed on the screen is refreshed in every second.	
Response time for heart rate meter to HR change	80 to 120 bpm: < 8 s 80 to 40 bpm: < 8 s	
Heart rate meter accuracy and response to irregular rhythm	After stable phase(20s), the HR values are: Bigeminy ventricular: 80 bpm±1 bpm Bigeminy ventricular alternative lente: 60 bpm±1 bpm Bigeminy ventricular alternative rapid: 120 bpm ±1 bpm Systoles bidirectional: 95 bpm±1 bpm	
Time to ALARM for tachycardia		
Tachycardia	Gain 1.0: 8 s	

ventricular: amplitude =1 mV(p-v), heart rate =206 bpm	Gain 0.5: 8 s	
	Gain 2.0: 8 s	
Tachycardia ventricular : amplitude =2 mV(p-v), heart rate =195 bpm	Gain 1.0: 8 s	
	Gain 0.5: 8 s	
	Gain 2.0: 8 s	
Arrhythmia type	ASYSTOLE, BIGEMINY, VFIB/VTAC, TRIGEMINY, PVC, R ON T, COUPLET, MISSED BEATS, VT>2, PNC, TACHY, PNP, BRADY	
ST-segment measurement		
Measurement range	-2.0 mV~+2.0 mV	
Accuracy	-0.8 mV~+0.8 mV: ±0.04 mV or ±10 %, whichever is greater. Other range: unspecified	

A.10 RESP

Measurement method	Impedance	
Waveform gain	2.5 mm/mV(×0.25),5 mm/mV(×0.5),10 mm/mV(×1),20 mm/mV(×2), 40 mm/mv(×4)	
Measurement impedance range	0.3~5 Ω	
Base line impedance range	500~2500 Ω	
Differential input impedance	>2.5 MΩ	
Bandwidth	0.2~2.5 Hz	
Scan speed	6.25 mm/s, 12.5 mm/s, 25 mm/s	
RR		
Measurement range	0~150 rpm	
Resolution	1 rpm	
Accuracy	0rpm～6rpm:unspecified; 7rpm～150rpm:±2 rpm or±2％.	
Apnea alarm	10~40 s	
Alarm limit	**range(rpm)**	**Step(rpm)**
Alarm high limit	(low limit+1)~150	1
Alarm low limit	Adult: 0~(high limit-1) Pediatric and neonate: 0~(high limit-1)	

A.11 NIBP

<table>
<tr><td>Measurement method</td><td colspan="4">Oscillometric</td></tr>
<tr><td>Working mode</td><td colspan="4">Manual, Auto, STAT</td></tr>
<tr><td>Measurement Interval in AUTO Mode</td><td colspan="4">1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 240, 480, 960 min</td></tr>
<tr><td>Measuring Period in STAT Mode</td><td colspan="4">5 min</td></tr>
<tr><td>Measurement parameters</td><td colspan="4">SYS, DIA, MEAN</td></tr>
<tr><td rowspan="7">NIBP measurement range</td><td></td><td>Adult</td><td>Pediatric</td><td>Neonatal</td></tr>
<tr><td>Systolic pressure(mmHg)</td><td>30~270</td><td>30~235</td><td>30~135</td></tr>
<tr><td>Systolic pressure(kPa)</td><td>4~36.0</td><td>4~31.3</td><td>4~18.0</td></tr>
<tr><td>Diastolic pressure(mmHg)</td><td>10~220</td><td>10~195</td><td>10~100</td></tr>
<tr><td>Diastolic pressure(kPa)</td><td>1.3~29.3</td><td>1.3~26.0</td><td>1.3~13.3</td></tr>
<tr><td>Mean pressure(mmHg)</td><td>20~235</td><td>20~210</td><td>20~110</td></tr>
<tr><td>Mean pressure(kPa)</td><td>2.7~31.3</td><td>2.7~28.0</td><td>2.7~14.7</td></tr>
<tr><td>Accuracy</td><td colspan="4">Maximum mean error: ±5 mmHg
Maximum Standard deviation: 8 mmHg</td></tr>
<tr><td>Pressure resolution</td><td colspan="4">1 mmHg</td></tr>
<tr><td>Cuff pressure accuracy</td><td colspan="4">±3 mmHg</td></tr>
<tr><td>Over-pressure protection</td><td colspan="4">Adult: 297 mmHg±3 mmHg
Pediatric: 240 mmHg±3 mmHg
Neonate: 147 mmHg±3 mmHg</td></tr>
<tr><td>Alarm limit</td><td colspan="3">Range(mmHg)</td><td>Step(mmHg)</td></tr>
<tr><td>High limit of systolic pressure</td><td colspan="3">Adult: (low limit+1)~270
Pediatric: (low limit+1)~235
Neonate: (low limit+1)~135</td><td rowspan="2">1</td></tr>
<tr><td>Low limit of systolic pressure</td><td colspan="3">30~(high limit-1)</td></tr>
</table>

High limit of diastolic pressure	Adult: (low limit+1)~220 Pediatric: (low limit+1)~195 Neonate: (low limit+1)~100	
Low limit of diastolic pressure	10~(high limit-1)	
High limit of mean pressure	Adult: (low limit+1)~235 Pediatric: (low limit+1)~210 Neonate: (low limit+1)~110	
Low limit of mean pressure	20~(high limit-1)	

A.12 SpO_2

Note:The claims of SpO_2 accuracy shall be supported by clinical study measurements taken over the full range. By artificially inducing to different oxygen levels, in the range of 70% to 100% SaO_2, compare the SpO_2 values collected by the secondary standard pulse oximeter equipment and the tested equipment at the same time to form data pairs, which are used as an accuracy analysis. Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.		
Measurement and display range	0~100 %	
Resolution	1 %	
Accuracy	70~100 %: ±2 %; 0~69 %: unspecified;	
Updating cycle	About 1 s	
Mean time	4 s,8 s,16 s	
Alarm limit	**Range(%)**	**Step(%)**
SpO_2 high limit	(low limit+1)~100	1
SpO_2 low limit	0~(high limit-1)	
PR		
Measurement and display	25~250 bpm	
Resolution	1 bpm	
Accuracy	±2 bpm or ±2%, whichever is greater	
Updating cycle	1 s	
Alarm limit	**Range(bpm)**	**Step(bpm)**
PR high limit	(low limit+1)~250	1
PR low limit	25~(high limit-1)	

A.13 TEMP

Measurement method	Thermistor method
Channel	Dual-channel

Probe type	YSI-2.252 K	
Measurement site	Body surface probe: armpit Body cavity probe: oral, rectum	
Measurement range	0~50 ℃	
Resolution	0.1 ℃	
Accuracy	±0.1 ℃	
Updating cycle	About 1 s	
Minimum time for accurate measurement	Body surface: <100 s Body cavity: <80 s	
Minimum time between measurements	Body surface probe: <100 s Body cavity probe: <80 s	
Response mean time	<10 s	
Alarm response time	≤2 min	
Unit	℃ or ℉	
Alarm limit	**Range(℃)**	**Step(℃)**
T1/T2 high limit	(low limit +0.1)~50	0.1
T1/T2 low limit	0~(high limit-0.1)	
TD high limit	0~50	

A.14 IBP

Measurement method	Invasive and direct measurement	
Channel	Dual-channel	
Measurement range	-50~300 mmHg	
Resolution	1 mmHg	
Accuracy	±2 % or 1 mmHg, whichever is greater.	
Update time	About 1 s	
Pressure sensor		
Sensitivity	5 uV/V/mmHg	
Impedance range	300~3000 Ω	
Volume displacement	<0.04 mm^3 /100 mmHg	
Unit	mmHg, kPa, cmH2O	
Alarm limit	**Range(mmHg)**	**Step(mmHg)**
SYS ALM HI	(low limit+1)~350	1
MEAN ALM HI		
DIA ALM HI		
SYS ALM LO	-50~(high limit-1)	
MEAN ALM LO		
DIA ALM LO		

A.15 CO_2

Measurement mode	Infrared radiation absorption technology		
Sample Rate	50ml/min ± 10ml/min		
Measurement parameters	$EtCO_2$, $InsCO_2$, AwRR		
Measurement range	CO_2	0~150 mmHg	
	$InsCO_2$	0~150 mmHg	
	AwRR	2~150 rpm	
Resolution	CO_2	0.1 mmHg(0~69 mmHg) 0.25 mmHg(70~150 mmHg)	
	$InsCO_2$	0.1 mmHg(0~69 mmHg) 0.25 mmHg(70~150 mmHg)	
Measurement accuracy	CO_2	±2 mmHg, 0~40 mmHg Reading ±5%, 41~70 mmHg Reading ±8%, 71~100 mmHg Reading ±10%, 101~150 mmHg	
	AwRR	±1 rpm	
Initialization time	Mainstream	At 25 ℃, inspiration/expiration CO_2 curve can be displayed within 15s, which meets all specification within 2 minutes.	
	Sidestream	At 25 ℃, inspiration/expiration CO_2 curve can be displayed within 20s, which meets all specification within 2 minutes.	
Rise time for Main-stream	<60 ms——repeatable or disposable airway interface for adult		
	<60 ms——repeatable or disposable airway interface for pediatric		
Accuracy drift	meet accuracy requirements within 6 h		
Update time	1 s		
Delay time for sidestream	2~3 s		
AwRR apnea alarm delay	10~40 s		
Alarm limit	**Range**		**Step**
CO_2 ALM HI	(low limit +1) ~150 mmHg		1
CO_2 ALM LO	0~(high limit -1)mmHg		
INS ALM HI	0~100 mmHg		
AWRR ALM HI	(low limit +1) ~150 rpm		
AWRR ALM LO	0~(high limit -1) rpm		

A.16 CO

Measurement method	thermodilution	
Measurement	CO	0.2～20 L/min

range	TB	23～45°C
	TI	0～27°C
Resolution	CO	0.1 L/min
	TB, TI	0.1°C
Accuracy	CO	±5% of readings or ±0.2 L /min, whichever is greater
	TB, TI	±0.5°C(without sensor)
Alarm range	TB	23~45°C
Alarm limit	**Range(℃)**	**Step**
TB high limit	(low limit+0.1)～45°C	0.1°C
TB low limit	23～(high limit-0.1)°C	

Appendix B EMC Test Level Declaration - Guidance and Manufacture's Declaration

Table 1: Electromagnetic emission

<table>
<tr><td colspan="3">Guidance and manufacture's declaration –electromagnetic emission</td></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.</td></tr>
<tr><td>Emission test</td><td>compliance</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The Patient Monitor is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emission IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 2: Electromagnetic immunity 1

Guidance and manufacture's declaration-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines; ±1 kV for input/output signal;	±0.5 kV for power supply lines; ±1 kV for input/ output signal;	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Line to Line ±2 kV Line to Earth	±1 kV Line to Line ±2 kV Line to Earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips,short interruptions and voltage vatiations on power supply input lines IEC 61000-4-11	<5%U_T(>95%dip in U_T) for 0.5 cycle 40% U_T(60%dip in U_T) for 5 cycle 70%U_T(30%dip in U_T) for 25 cycle <5%U_T(>95%dip in U_T) for 5 sec	<5%U_T(>95%dip in U_T) for 0.5 cycle 40% U_T(60%dip in U_T) for 5 cycle 70%U_T(30%dip in U_T) for 25 cycle <5%U_T(>95%dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3: Electromagnetic immunity 2

Guidance and manufacture's declaration-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC61000-4-6	$3V_{rms}$ 150KHz to 80MHz	$3V_{rms}$	Portable and mobile RF communications equipment should be used no closer to any part of the *Patient Monitor,* including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 3.5\sqrt{P}$ $d = 3.5\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (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: 
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	
NOTE 1 At 80MHz 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 *Patient Monitor* is used exceeds the applicable RF compliance level above, the *Patient Monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Patient Monitor* .

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 1V/m(80-800MHz)&3V/m(800-2500MHz).

Table 4: Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the Patient Monitor			
The *Patient Monitor* is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Patient Monitor* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Patient 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)**		
	150KHz to 80MHz $d = 3.5\sqrt{P}$	80MHz to 800MHz $d = 3.5\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.3500	0.3500	0.2334
0.1	1.1068	1.1068	0.7378
1	3.5000	3.5000	2.3334
10	11.0860	11.0860	7.3786
100	35.0000	35.0000	23.3334
For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix C System Alarm Prompt

PROMPT	CAUSE	Alarm Level	MEASURE
"XX HIGH"	XX value exceeds the higher alarm limit.	User-selectable	Check if the alarm limits are appropriate and the current situation of the patient.
"XX LOW"	XX value is below the lower alarm limit.	User-selectable	
XX represents the value of parameter such as HR, ST1, ST2, RR, SpO_2, NIBP, etc. in the system.			
"ECG saturation, the signal is invalid"	ECG signal exceeds the measurement range.	LOW	Check the connection between the electrode and lead cable; Check the patient' condition.
"ECG WEAK SIGNAL"	The ECG signal of the patient is too small so that the system can not perform ECG analysis.	HIGH	Check the connection between the electrode and lead cable; Check the patient' condition.
"RESP APNEA"	The respiration signal of the patient is too small so that the system cannot perform RESP analysis.	HIGH	Check the connection of the linking wire and the current situation of the patient.
"ASYSTOLE"	Patient suffers from Arr. Of ASYSTOLE.	HIGH	Check the patient' condition; Check the connection between the electrode and lead cable.
"VFIB/VTAC"	Patient suffers from Arr. of VFIB/VTAC.	HIGH	Check the patient' condition; Check the connection between the electrode and lead cable.
"COUPLET"	Patient suffers from Arr. of COUPLET.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"BIGEMINY"	Patient suffers from Arr. Of BIGEMINY.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"TRIGEMINY"	Patient suffers from Arr. of TRIGEMINY.	User-selectable	Check the patient' condition; Check the connection between the electrode and

			lead cable.
“R ON T ”	Patient suffers from Arr. of R ON T.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"TACHY"	Patient suffers from TACHY.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"BRADY"	Patient suffers from BRADY.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"VT>2"	Patient suffers from Arr. of VT>2.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
“MISSED BEATS”	Patient suffers from Arr. of MISSED BEATS.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"PNP"	The pacemaker is not paced.	User-selectable	Check the connection of the pacemaker; check the connection between the electrode and lead cable; check the patient' condition.
"PNC"	No pacemaker signal is captured.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"ECG LEAD OFF or RESP LEAD OFF"	RL lead of ECG is not connected correctly or ECG lead is not connected correctly.	LOW	Check the connection of RL lead or ECG lead cable.
"V LEAD OFF"	The V lead of ECG is not connected correctly.	LOW	Check the connection of V lead.
"LL LEAD OFF"	The LL lead of ECG is not connected correctly.	LOW	Check the connection of LL lead.

"LA LEAD OFF"	The LA lead of ECG is not connected correctly.	LOW	Check the connection of LA lead.
"RA LEAD OFF"	The RA lead of ECG is not connected correctly.	LOW	Check the connection of RA lead.
"RESP LEAD OFF"	At least one lead among RA, RL and LL is not connected correctly.	LOW	Check the connection of RA, RL or LL lead.
"SpO_2 SENSOR OFF"	SpO_2 sensor is not connected correctly.	LOW	Check the connection of SpO_2 sensor.
"SpO_2 SEARCH TIMEOUT"	The pulse signal of the patient is too small so that the system cannot perform pulse signal analysis.	HIGH	Check the connection of sensor; Check the patient' condition.
"T1 SENSOR OFF"	T1 sensor is not connected correctly.	LOW	Check the connection of T1 sensor.
"T2 SENSOR OFF"	T2 sensor is not connected correctly.	LOW	Check the connection of T2 sensor.
"ECG NOISE"	larger interference signals appear in the ECG signals.	LOW	Check the connection of ECG lead cable; Check the current situation of the patient. Check if the patient moves a lot.
"XX COMM ERR"	XX module can't communicate normally with the host.	HIGH	Re-start up the monitor, if the error still exists, contact the manufacturer.
XX represents all the parameter modules in the system such as ECG, NIBP, SpO_2, etc.			
"KEYBOARD COMM ERR"	The keyboard has failures, which cannot be used.	HIGH	Contact the manufacturer for repair.
"WIRELESS CONNECT	The network part in the system appear	MED	Contact the manufacturer for repair.

ERROR"	problems, so the system can't achieve network function.		
"CAN'T FIND WIRELESS DEVICE"			
"LOW POWER"	Low battery.	HIGH	Charge the battery by connecting the AC cord.
"RECORDER OUT OF PAPER"	No recording paper	LOW	Install the recording paper.
"RECORDER ERROR"	The recorder communicates abnormally.	LOW	Turn off the device and restart it.
"NIBP INIT ERR"	NIBP initialization error	LOW	Execute the reset program in the NIBP menu. If the failure still exists, contact the manufacturer for repair.
"NIBP SELFTEST ERR"			
"NIBP ILLEGALLY RESET"	During NIBP measurement, illegal reset occurs.	LOW	Check the airway of NIBP to check if there are clogs. Then measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP COMM ERR"	The NIBP communication part has problem.	HIGH	Execute the reset program in the NIBP menu. If the failure still exists, contact the manufacturer for repair.
"NIBP LOOSE CUFF"	The NIBP cuff is not connected correctly.	LOW	Re-connect the NIBP cuff.
"NIBP AIR LEAK"	The NIBP cuff is not connected correctly or there are leaks in the airway.	LOW	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"NIBP AIR PRESSURE ERROR"	Problem happens when measuring the curve. The system can't perform	LOW	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for

	measurement, analysis or calculation.		repair.
"NIBP WEAK SIGNAL"	Problem happens when measuring the curve. The system can't perform measurement, analysis or calculation.	LOW	Check if the setup of patient type is correct. Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair
"NIBP RANGE EXCEEDED"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	LOW	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"NIBP EXCESSIVE MOTION"	The patient's arm moves.	LOW	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP OVER PRESSURE"	Perhaps folds exist in the airway.	LOW	Check for the smoothness in the airway and patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP SIGNAL SATURATED"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	LOW	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP TIME OUT"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	LOW	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP CUFF TYPE ERR"	Perhaps the used cuff does not fit the patient type sey.	LOW	Check if the patient type is set up correctly. Check whether the cuff conforms to the patient's type.
"NIBP PNEUMATIC	NIBP airway has leaks.	LOW	Check the connection of each part or replace with a new

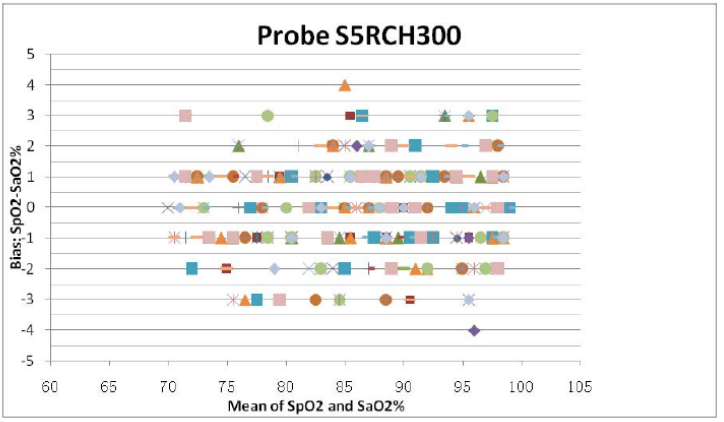
LEAK"			cuff. If the failure still exists, contact the manufacturer for repair.
"NIBP SYSTEM FAILURE"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	LOW	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
CO MODULE ERROR	CO module cannot communicate with the main system	HIGH	Restart the device, if the error still appears, contact the manufacturer.
TI LEAD OFF	The TI temperature sensor cable is not connected properly.	LOW	Check the connection of TI temperature sensor cable.
TB LEAD OFF	The TB temperature sensor cable is not connected properly.	LOW	Check the connection of TB temperature sensor cable.

Appendix D SpO_2 Clinical Information

Clinical Result information for each sensor

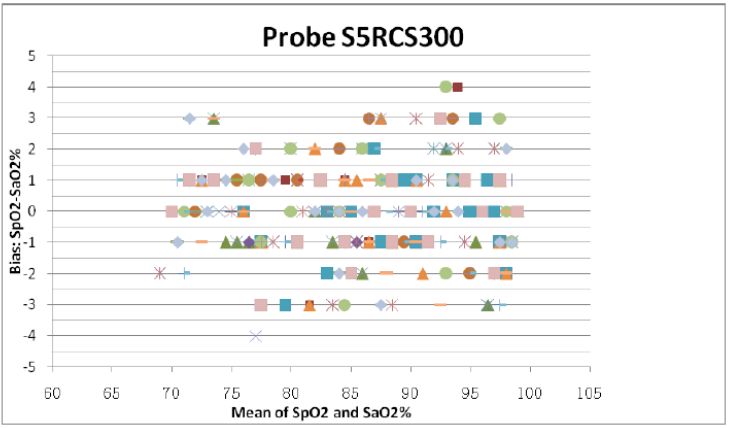
The table below shows ARMS values measured using SpO_2 sensor (S5RCH300) with Patient Monitor in a clinical study.

Hemoximeter SaO2 Range	70-80	80-90	90-95	95-100	Total
Effective Data Point Count	85	149	82	84	400
Exclusion Data Point Count	89	156	91	97	433
Mean	0.01	0.19	0.17	-0.07	0.10
Standard Deviation	1.27	1.35	1.55	1.40	1.39
Upper/lower 95% limit	2.50/-4.27	2.85/-2.50	3.22/-2.88	2.68/-2.82	2.82/-2.63
Root Mean Square (RMS)	1.26	1.36	1.55	1.40	1.39



The table below shows ARMS values measured using SpO_2 sensor (S5RCS300) with Patient Monitor in a clinical study.

Hemoximeter SaO2 Range	70-80	80-90	90-95	95-100	Total
Effective Data Point Count	83	151	84	82	400
Exclusion Data Point Count	92	159	86	87	424
Mean	0.29	0.07	0.57	-0.28	0.15
Standard Deviation	1.38	1.39	1.37	1.34	1.40
Upper/lower 95% limit	3.00/-2.42	2.80/-2.67	3.26/-2.12	2.34/-2.90	2.89/-2.60
Root Mean Square (RMS)	1.41	1.39	1.48	1.36	1.41



Appendix E Abbreviations

E.1 Unit list

Abbreviation	Description
µA	microampere
µV	microvolt
A	ampere
Ah	ampere hour
bpm	beat per minute
ºC	centigrade
cm	centimeter
dB	decibel
ºF	fahrenheit
g	gram
h	hour

Hz	hertz
inch	inch
k	kilo
kg	kilogram
kPa	kilopascal
L	litre
lb	pound
m	meter
mAh	milliampere hour
mcg	microgram
mEq	milli-equivalents
mg	milligram
min	minute
ml	milliliter
mm	millimeter
mmHg	millimeters of mercury
cmH_2O	centimeters of water
ms	millisecond
mV	millivolt
mW	milliwatt
MΩ	megaohm
nm	nanometer
rpm	breaths per minute
s	second
V	volt
VA	volt ampere
Ω	ohm
W	watt

E.2 Terminology list

Abbreviation	Description
AC	alternating current
Adu	adult
AHA	American Heart Association
Art	arterial
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead
AwRR	airway respiratory rate
BP	blood pressure

CO	cardiac output
CCU	cardiac (coronary) care unit
CI	cardiac index
CISPR	International Special Committee on Radio Interference
CMS	central monitoring system
CO_2	carbon dioxide
COHb	carboxyhemoglobin
CVP	central venous pressure
DC	direct current
Dia	diastolic
DPI	dot per inch
ECG	electrocardiograph
EMC	electromagnetic compatibility
EMI	electromagnetic interference
ESD	electro-static discharge
ESU	electrosurgical unit
Et	end-tidal
$EtCO_2$	end-tidal carbon dioxide
EtO	ethylene oxide
HR	heart rate
ICG	Impedance cardiography
ICT/B	intracranial catheter tip pressure transducer
ICU	intensive care unit
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
IBP	Invasive brood pressure
IP	internet protocol
LA	left arm
LAP	left atrial pressure
LCD	liquid crystal display
LED	light emitting diode
LL	left leg(electrode)
MAP	mean arterial pressure
MetHb	methemoglobin
MRI	magnetic resonance imaging
N/A	not applied
Neo	neonate
NIBP	noninvasive blood pressure
oxyCRG	oxygen cardio-respirogram

Ped	pediatric
Pleth	plethysmogram
PR	pulse rate
PVC	premature ventricular contraction
RA	right arm
Rec	record, recording
Resp	respiration
RL	right leg(electrode)
RR	respiration rate
SpO_2	arterial oxygen saturation from pulse oximetry
SV	stroke volume
SYS	systolic pressure
TB	Blood temperature
TBW	Total body water
TD	temperature difference
TI	Injectate temperature
TPR	total peripheral resistance
Temp	temperature
USB	universal serial bus

Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.