Multi-parameter Patient Monitor

User Manual

PROPERTY STATEMENT

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All information contained in this manual is believed to be correct. XXX shall not be liable for errors contained herein nor for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Our Company is responsible for safety, reliability and performance of this product only in the condition that:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Our Company authorized personnel; and,
- the electrical installation of the relevant room complies with the applicable national and local requirements; and,
- this product is operated under strict observance of this manual.

⚠ **Note** ⚠

This equipment cannot be used at home.

⚠ **Warning** ⚠

Warning in order to safely use this device, you must follow the instructions listed. This manual lists indicates that are not a substitute for the medical procedure.

- **Do not rely only on audible alarm system to monitor patient. When monitoring adjusting the volume to very low or completely muting the sound may result in the disaster to the patient. The most reliable way of monitoring the patient is at the same time of using monitoring equipment correctly, manual monitoring should be carried out.**
- **This multi-parameter patient monitor is intended for use only by medical professionals in health care institutions.**
- **To avoid electrical shock, you shall not open any cover by yourself. Service must be carried out by qualified personnel.**
- **Use of this device may affect ultrasonic imaging system in the presence of the interfering signal on the screen of ultrasonic imaging system. Keep the distance between the monitor and the ultrasonic imaging system as far as possible.**
- **It is dangerous to expose electrical contact or applicant coupler to normal saline, other liquid or conductive adhesive. Electrical contact and coupler such as cable connector, power supply and parameter module socket-inlet and frame must be kept clean and dry. Once being polluted by liquid, they must be thoroughly dried. If to further remove the pollution, please contact your biomedical department or Factory.**

⚠ **Warning** ⚠

This is not a treatment device.

If the hospitals or institutions who has the responsibility to use this instrument can not achieve a satisfactory maintenance program may cause abnormal equipment failure, and may endanger human health.

For the component of the equipment that identified by this manual that user can repair, Our Company **will provide circuit diagrams, calibration method and other information as the user request, to help users to repair by the appropriate qualified technical personnel.**

Warranty

This warranty is exclusive and is in lieu of all other warranties, expressed or implied, including warranties of merchantability or fitness for any particular purpose.

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 the product or the use of parts or accessories not approved by Our Company or repairs by people other than Our Company authorized personnel.

This warranty shall not extend to

any Our Company product which has been subjected to misuse, negligence or accident; or

any Our Company product 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.

Return Policy

In the event that it becomes necessary to return a unit to Our Company, follow the instructions below.

Obtain a return authorization.

Contact the Our Company Service Department and obtain a Our Company Customer Service Authorization Number. The Our Company Customer Service Authorization Number must appear on the outside of the shipping container. Return shipments will not be accepted if the Our Company Customer Service Authorization 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 this product is shipped to Our Company for service (including any relevant customs fees or other freight related charges).

Return address

Please send the part(s) or equipment to the address offered by Customer Service Department.

⚠ **Note** ⚠

- **Demo mode password is “999”.**
- **User Setting password is “999”.**
- **Factory service password is “999”.**

CONTENTS

Chapter 1 Overview

1.1 Overview

This monitor is suitable for adult, pediatric and neonate patient, may monitor the physical parameters, such as electrocardiograph (ECG), noninvasive blood pressure (NIBP), oxygen saturation (SpO_2), respiration rate (Resp), body temperature (Temp), invasive blood pressure (IBP), CO_2 monitoring(CO_2) and so on, can display maximum 8 waveforms and all information of the parameters monitored in the same screen.

Below shows the monitoring functions of this monitor:

1) electrocardiograph (ECG), including: heart rate, 6 channels ECG waveforms;

2) oxygen saturation (SpO_2), including: oxygen saturation, pulse rate, perfusion index, pulse wave;

3) noninvasive blood pressure (NIBP), including: Systolic pressure, diastolic pressure, mean pressure;

4) body temperature (Temp): 2 channels body temperature data;

5) respiration (Resp): Breath rate, breath waveform;

6) CO_2 monitoring(CO_2): Fi/EtCO_2, AwRR, CO_2 waveform;

7) invasive blood pressure (IBP): 2 channels IBP waves and Systolic pressure, diastolic pressure, mean pressure;

1.2 Safety information

⚠ NOTE⚠	**Points to be noted.**
⚠ CAUTION ⚠	**Points to be noted to avoid damage to the equipment.**
⚠ WARNING ⚠	**Points to be noted to avoid injury to the patient and the operator.**

⚠ WARNING ⚠

- **Do not rely only on audible alarm system to monitor patient. When monitoring adjusting the volume to very low or completely muting the sound may result in the disaster to the patient. The most reliable way of monitoring the patient is at the same time of using monitoring equipment correctly, manual monitoring should be carried out.**
- **This multi-parameter patient monitor is intended for use only by medical professionals in health care institutions.**
- **To avoid electrical shock, you shall not open any cover by yourself. Service must be carried out by qualified personnel.**
- **Use of this device may affect ultrasonic imaging system in the presence of the interfering signal on the screen of ultrasonic imaging system. Keep the distance between the monitor and the ultrasonic imaging system as far as possible.**
- **It is dangerous to expose electrical contact or applicant coupler to normal saline, other liquid or conductive adhesive. Electrical contact and coupler such as cable connector, power supply and parameter module socket-inlet and frame must be kept clean and dry. Once being polluted by liquid, they must be thoroughly dried. If to further remove the pollution, please contact your biomedical department or Factory.**

⚠ Warning ⚠

Monitor can only monitoring one patient at a time.

⚠ Warning ⚠

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 Factory.

⚠ **Warning** ⚠

You must verify if the device and accessories can function safely and normally before use.

⚠ **Warning** ⚠

Possible explosion hazard if used in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

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⚠ **Warning** ⚠

You must customize the alarm setups according to individual patient situation and make sure that alarm sound can be activated when alarm occurs.

⚠ **Warning** ⚠

Do not touch the patient, table, or the device during defibrillation.

⚠ **Warning** ⚠

Do not use cellular phone in the vicinity of this device. High level electromagnetic radiation emitted from such devices may greatly affect the monitor performance.

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

When used with Electro-surgery equipment, you (doctor or nurse) must give top priority to the patient safety.

⚠ **Warning** ⚠

Do not place the monitor or external power supply in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient cable, use only the handle on the monitor.

⚠ **Warning** ⚠

Consult IEC-601-1-1 for system interconnection guidance. The specific requirements for system interconnection are dependent upon the device connected to the monitor and the relative locations of each device from the patient, and the relative location of the connected device to the medically used room containing the monitor. In all circumstance the monitor must be connected to a grounded AC power supply. The monitor is referred to as an IEC 601/F device in the summary of situations table contained in IEC 601-1-1.

⚠ **Warning** ⚠

Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.

⚠ **Warning** ⚠

Grounding:
Connect the monitor only to a three-wire, grounded, hospital-grade receptacle. The three-conductor plug must be inserted into a properly wired three-wire receptacle; if a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing

electrical code.
Do not under any circumstances remove the grounding conductor from the power plug.
Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.
If there is any doubt about the integrity of the protective earth conductor arrangement, operate the monitor on internal battery power until the AC power supply protective conductor is fully functional.

⚠ **Warning** ⚠

For continued safe use of this equipment, it is necessary that the listed instructions be followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

⚠ **Warning** ⚠

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.

⚠ **Caution** ⚠

If you have any doubt to the grounding layout and its performance, you must use the built-in battery to power the monitor.

1.3 Device Label

CE 0123	This mark means that this device is fully in conformance with the Council Directive Concerning Medical Devices 93/42/EEC. The number adjacent to the CE marking (0123) is the number of the EU-notified body that certified meeting the requirements of Annex II of the Directive.
	This symbol means ”BE CAREFUL“. Refer to the manual.
	Caution: alert users, if you do not follow the instructions, may cause damage to equipment or to affect the test results.
	Note: to illustrate the procedure for important information is also used to describe some special techniques.
	Warning: warned user attention of potential danger, if you do not follow the instructions may result in personal injury.
	Equipotential grounding system.
	Protective earth ground.
	Power On/Off
	AC power

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

1.4 Intended Usage

The monitor is intended to be used for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in health care facilities. The devices are to be used in health care facilities by trained health care professionals. They are not intended for home use. This device is restricted to be used by or on the order of a physician.

⚠ Warning ⚠

This is not a therapeutic device.

1.5 Screen layouts introduction

The screen is divided into four sections: 1st information section; 2nd waveform section; 3rd parameters section; 4th menu section (as chart 1-1 shows).

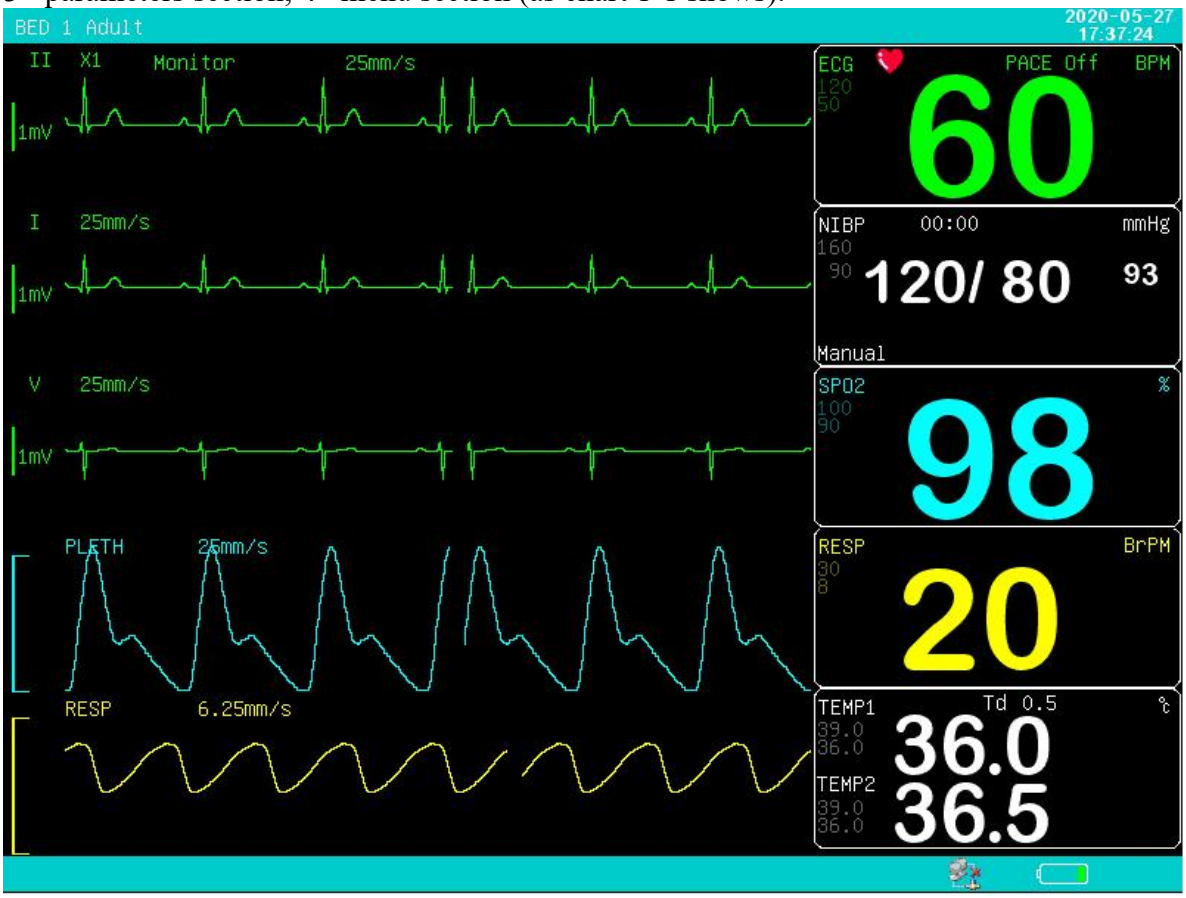


Chart 1-1 monitor demo interface

1.5.1 Information section

The information section is on top of the screen, displays current conditions of monitor and patient. The information in turn from left to right on the top is “patient information”, “technical alarm information”, “physiological alarm information”, “date and time” ,

“network state” and “battery state”.

1) Patient information:

Bed number (refers to the hospital bed number of patient monitored);

Type of patient (“Adult”, “Pediatric” or “Neonate”);

Name of patient (if operator doesn’t input patient’s name, this position will displays “NO NAME”);

2) Technical alarm information: Reporting current condition of monitor or sensors, this section will display alarm information;

3) Physiological alarm information: If patient's physiological parameters exceed the alarm limit, this section will display alarm information;

4) Date and time: Updating current date and time every second;

5) Network connection state;

6) Battery state: current battery capacity or its condition.

1.5.2 Parameters section

Heart rate: heart rate (unit: beats per minute bpm)

NIBP: From right to left is: systolic pressure, diastolic pressure, mean pressure (unit: millimeter mercury column- mmHg or kilopascal- kPa)

SpO_2: oxygen saturation SpO_2 (unit: %), Pulse rate (unit: pulses /minute), Perfusion Index(Unit %)

Respiration rate: respiration rate (unit: Breaths/Minute BrPM)

Temperature: body temperature (unit: centigrade -℃ or Fahrenheit- ℉)

invasive blood pressure (IBP): Systolic pressure, diastolic pressure, mean pressure;

carbon dioxide (CO_2): Breath rate, Et CO_2 and $FiCO_2$.

The user may change the settings of above monitored parameters which will be introduced in later chapters in detail.

1.5.3 Waveform section

The waveform section displays 9 waveforms in standard screen layout, which from top to bottom respectively are: ECG1 waveform, ECG2 waveform, pulse wave, respiration waveform, 2 channels of IBP waveforms, CO_2 waveform,. Total 13 waveforms can be displayed if in “ECG Full Lead” screen layout.

The name appears in upper left side of each waveform. The ECG waveform gain and filter mode will be also displayed besides the ECG wave name. On the right side of the ECG waveform stands a mark with the unit of 1 mV. The gain of breathing waveform is displayed on the right side of the name of breathing wave.. The ruler mark of IBP waveform is displayed on the right side of the name of IBP wave. The ruler mark of CO_2 waveform is displayed on the right side of the name of CO_2 wave.

When user push the keys of patient monitor, a window may pop-up in the waveform section. The waveform section will restore demo after the window is retreated.

1.5.4 Menu section

On the bottom of the screen there are 5 menu item: “Patient”, “Review”, “Setting”, “Alarm Limit” and “Service”. When no window displays on the screen, the user may visit these menus by rotating the knobs. When the cursor chooses anyone of the items, sublevel menus will popup. When the user presses down the knob once again, the corresponding dialog will pop-up and the user can change the settings in the dialog.

1.6 Alarm

When the alarm occurs, the warning light will glitter or bright, the color represents certain level of the alarm. The detailed contents please refer to chapter2 “Alarm”.

1.7 Control panel

The control panel is on the front panel. The total keys from left to right are listed below:

1) Power key: key to turning on and turning off of the power;

2) Silence key: With this key pressed down, sound of the alarm will shut down, also the "ALARM SILENCE" will be displayed in the information section, and other sounds (key sound, palpitation sound and so on) will not be affected. Pressing down the key again will restore all the alarms.

3) Pause key: With this key pressed down, the alarm may hang up for 2 minutes ("1 minute", "2 minutes" and "3 minutes" are optional), and the "ALARM PAUSE" will be displayed in the information section. All the alarm will be restored after this key is pressed again.

4) Freeze key: In the normal mode, all the waveforms on the screen will be frozen with this key pressed down. Pressing down this key once again will release the frozen waveforms;

5) NIBP key: Pressing down this key will start to charge the cuff with gas, and to measure the blood pressure. Pressing down the key once again can cancel the measurement;

6) Record/Stop key: If the monitor has a recorder, pressing down this key will start recording the real-time waveforms. Pressing the key again may stop recording;

7) Main menu key: press this key to returning to the main menu;

8) Knob key: With this key, the user may enter the menus and windows and change the monitor settings.

1.8 Menu

1.8.1 Main Menu

By pushing the main menu key, the user may choose to enter the main menu.

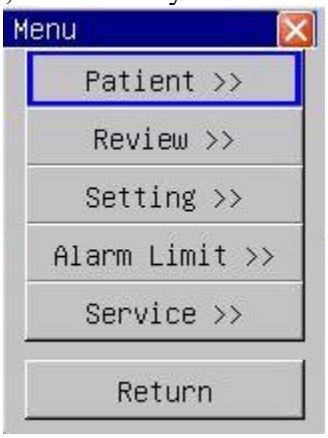


Chart 1- 2 main menu

1.8.2 Patients management

By pushing the "patient" button, the user may choose to enter the window of "Admit new patients", "Discharge Current Patient" or "Dose Calculation" the detailed introductions may refer to chapter4 "Admit and Discharge Patient".

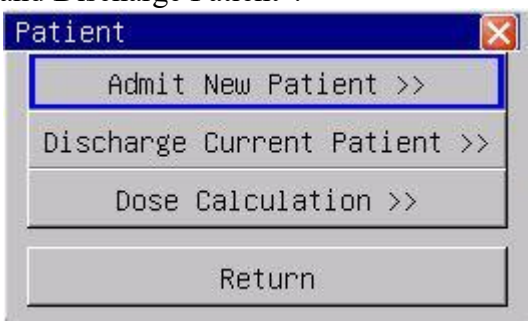


Chart 1-3 patient management

1.8.3 History review

By selecting the “Review” button, the user may choose to enter the window of “Trend Graph”, “Trend Table”, “Alarm Review”,“NIBP review” or “Wave review”. The detailed introductions may refer to chapter12 “History Review”.

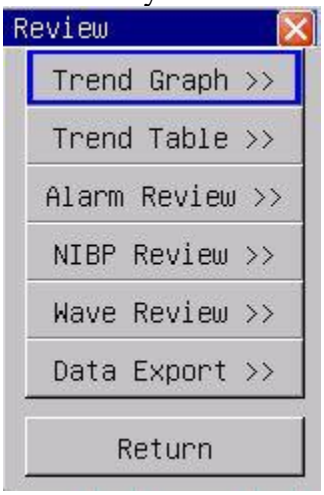


Chart 1-4 history review

1.8.4 Setting

By selecting the “Setting” button, the user may choose to enter the window of “Color setting”, “Alarm setting”, “Record setting”, “Screen layout”, “Adjust time”, “Miscellaneous”, “ECG setting”, “SpO_2 setting”, “NIBP setting”, “Resp setting”, “Temp setting” , “IBP Setting”, “CO_2 Setting”or “Load Default “.

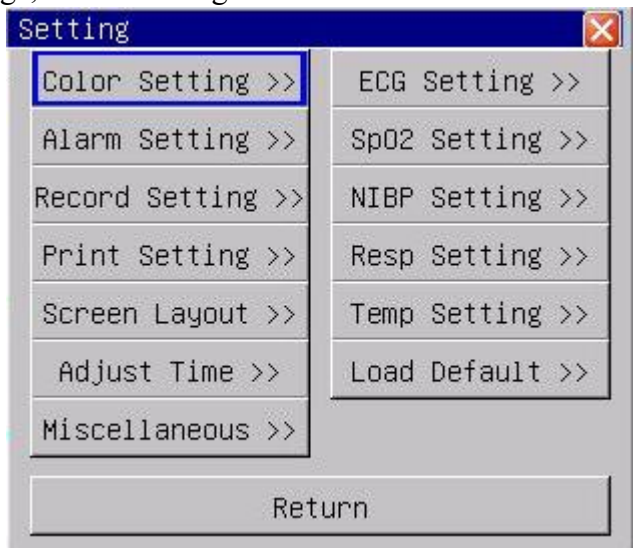


Chart 1-5 setting

1.8.4.1 Alarm setting

Detailed introductions can refer to Chapter2 “Alarm”.

1.8.4.2 Recording setting

Detailed introductions can refer to Chapter3 “Recording”.

1.8.4.3 Screens layout

After entering the screen layouts window, the user may change the current display interface by selecting the interfaces of 6 types of “Standard”, “ECG Full Lead”, “Big Font”, “OxyCRG”, “NIBP Trend”, “Trend Table”, and choose to turn on or turn off parameter or waveform in the “parameter switch” and “waveform switch”.

The user can change trend resolution from “1 min” to “60 min” by setting “Trend Time” if the screen layout is set to “Trend Table”.

The following chart shows the menu of screen layouts:

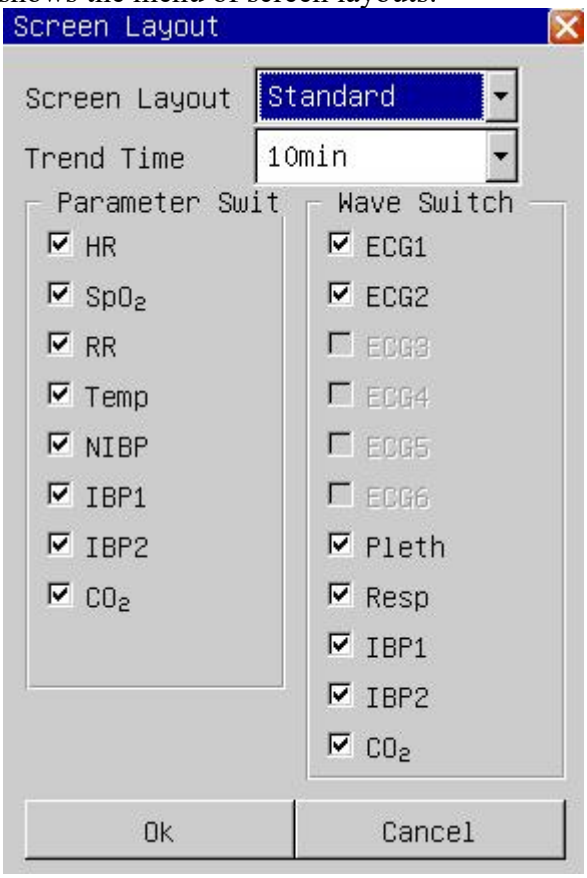
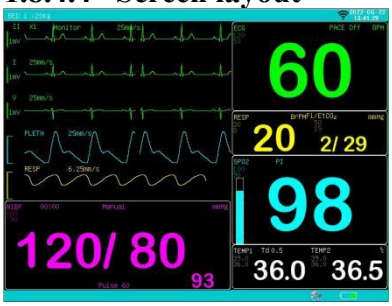


Chart 1- 6 screen layouts

1.8.4.4 Screen layout

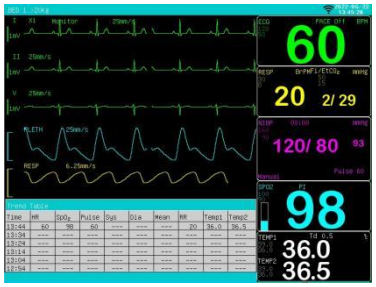


Big font

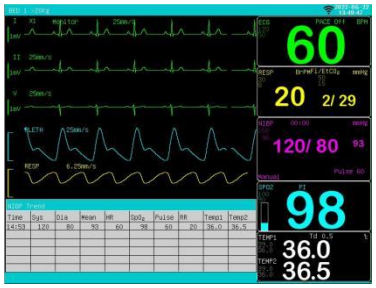
Standard

ECG Full Lead

OxyCRG



Trend table



NIBP trrend

1.8.4.5 Adjust Time

By entering the adjust time window, the user may choose the date format and adjust the current date and time, as the following chart shows:

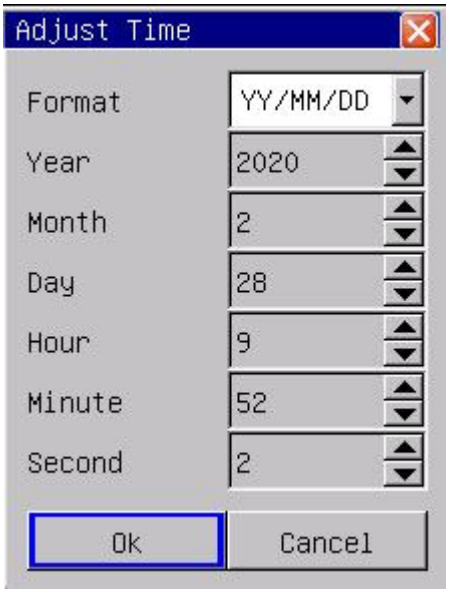


Chart 1- 7 adjust time

1.8.4.6 Miscellaneous

By entering the miscellaneous windows, the user may change the key volume and the screen brightness. The adjusting scope of key volume is 0~10 (0 means volume closure); The adjusting scope of screen brightness is 1~10 (10 means the highest brightness). If "Wave Smooth" switch is "On", the wave will be displayed as smooth mode.

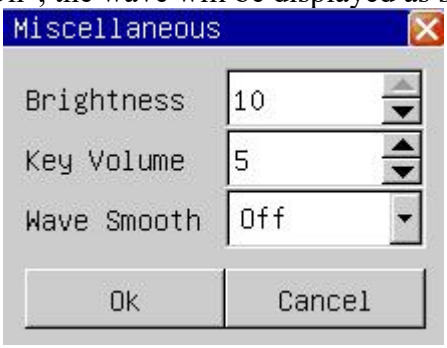


Chart 1- 8 miscellaneous setting

1.8.4.7 ECG setting

Detailed introductions of ECG settings can refer to Chapter5 "ECG monitoring".

1.8.4.8 Resp setting

Detailed introductions of RESP settings can refer to Chapter8 "RESP monitoring".

1.8.4.9 SpO_2 setting

Detailed introductions of oxygen saturation settings can refer to Chapter9 "SpO_2 monitoring".

1.8.4.10 NIBP setting

Detailed introductions of noninvasive blood pressure settings can refer to Chapter10 "NIBP monitoring".

1.8.4.11 Temperature setting

Detailed introductions of body temperature settings can refer to chapter11 "temperature monitoring".

1.8.4.12 Load default setting

The following chart shows the window of Apply default setting**s**:

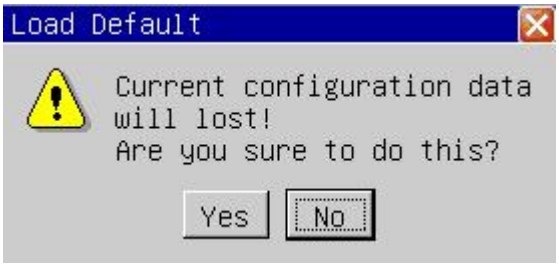


Chart 1- 9 Load default settings

If “Yes” is chosen, then the current settings will be replaced with default settings

1.8.5 Alarm limit

By selecting the “limits of alarm” button, the user may choose to enter the windows of “ECG Alarm Limit”, “ SpO_2 Alarm Limit”, “NIBP Alarm Limit”, “Resp Alarm Limit”, “Temp Alarm Limit”, “IBP Alarm Limit”, “CO_2 Alarm Limit” or “Load default Alarm Limit”, the detailed introductions refer to chapter2 “alarms”.

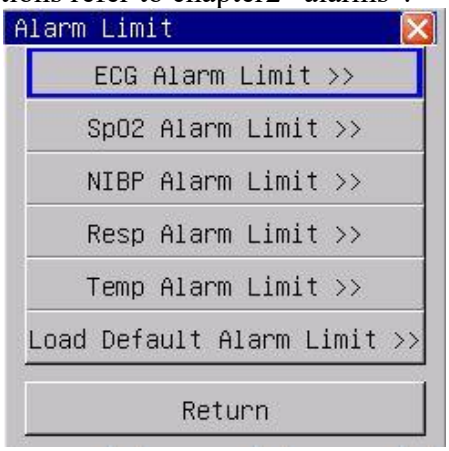


Chart 1- 10 Alarm Limit

1.8.6 Maintenance

By selecting the “Service” button, the user may choose to enter the windows of “ECG calibration”, “ Temp Sensor Type”, “NIBP Pneumatic Test”, “NIBP calibration”, “NIBP Reset”, “IBP Zero”, “IBP Calibration”, “CO_2 Calibration”, “Demo mode”, “Version info”, “User setting”, “Factory Service” and so on.

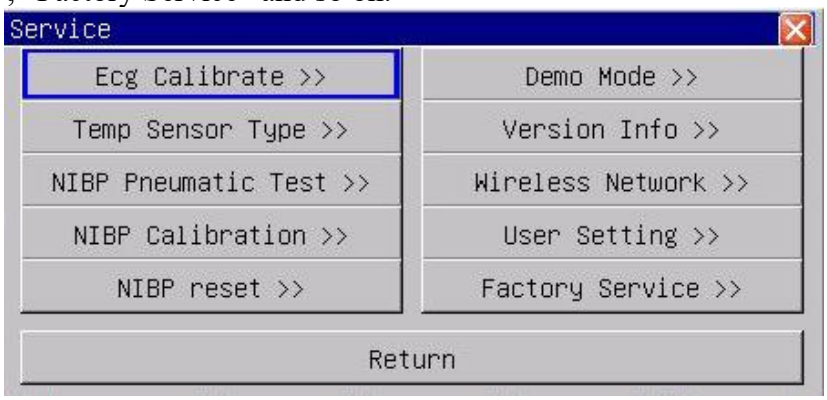


Chart 1- 11 Service

1.8.6.1 ECG calibration

Entering the ECG calibration window, the user may turning on or turning off of the ECG calibration signal, as the following chart shows:

Chart 1- 12 ECG calibration

1.8.6.2 Temp Sensor Type

Entering the Temp Sensor Type window, the user may initialize the type of body temperature sensor: 10K or 2.25K, as the following chart shows:

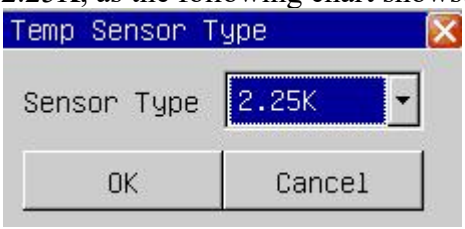


Chart 1- 13 Temp Sensor Type

1.8.6.3 NIBP Pneumatic test

Selecting the “NIBP Pneumatic test”, the user may examine whether the entire air way of blood pressure measurement leaks air or not.

When the blood pressure cuff is connected, the user may start the air leakage test with this key, thus discover whether the airtight condition of gas route is good or not. The examination result is:

If air leakage examination is passed, the system will not make any prompt;

If isn’t, the corresponding failure prompts will be displayed in the noninvasive blood pressure information section.

The detailed introductions refer to 10.5 the air leakage examination.

1.8.6.4 NIBP calibration

After selecting the noninvasive blood pressure calibration, the user enters the calibration mode, and at this time the user may calibrate, using a pressure gauge (or mercury sphygmomanometer) with a calibration precision higher than 1 mmHg after calibrated. If the “measure blood pressure” key is presses down during the calibration, the system will stop calibrating. The detailed introductions refer to 10.4 the blood pressure calibrations.

1.8.6.5 NIBP reset

After choosing the noninvasive blood pressure reset, the user may restore the blood pressure module to the initial settings.

When the blood pressure measurement is abnormal, yet the monitor cannot prompt reasons of the problem, using this key is suggested. Because this causes the blood pressure module to reset, the blood pressure module may commit self-recovery when the abnormity of work is caused by accidental reasons.

1.8.6.6 Demo mode

The user input the correct password, the monitor will enter demo mode, and in the centre of the screen a big “DEMO” label will be shown. The demo mode is a particular state just for demonstrating performance of the machine, helping user carry out trainings. In the actual clinical use, this function is forbidden, because it can possibly cause the medical staffs to take demo waveforms as the patient waveforms and parameters by mistake, to affect patient monitoring.

1.8.6.7 Version information

Choosing the “version information”, the user may look over the version information of

the software installed in the monitor.

1.8.6.8 User settings

The user may carry out user maintenance in the user settings menu, by inputting the password. This item is merely open to the serviceman appointed by the factory.

1.8.6.9 Factory service

The user cannot implement functions of maintenance. This item is merely open to the serviceman appointed by the factory.

⚠Warning⚠

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

1.9 Networks

The network port of the monitor is the standard RJ45 network interface, may communicate with the central station through the ethernet cable, to achieve the function of remote monitoring. In the top right corner of the screen there is a network icon representing current network status. If the network electric cable is disconnected, the network condition icon shows as "  "; After the monitor has established connection with the central station, the icon shows as "  "; If the monitor communicates normally with the central monitoring system, the icon shows as "  ".

1.10 Rechargeable built-in battery

The monitor is equipped with a rechargeable built-in battery. In the top right corner of the screen exists one symbol "  ", indicating the state of the battery capacity, of which the green part denoting electric quantity of the battery. When the battery is charged, the charging condition is expressed with animation. After the battery is full-charged, the symbol will show as "  ". When this monitor has not been installed the built-in battery, the symbol shows as "  " indicating no battery.

When running with power supply from battery, the monitor detects the volume of the battery, and alarms when the battery is insufficient, and prompts in the information section: "BAT LOW". At this time, the AC power should be plug in, and immediately charge battery in time. If battery is still used for power supply, the monitor will power off automatically when the battery exhausted.

⚠Warning⚠

If you have any doubt to the grounding layout and its performance, you must use the built-in battery to power the monitor.

1.11 Installation

1.11.1 Open the Package and Check

Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list.

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

If there is any problem, contact the distributor immediately.

1.11.2 Connect the Power Cables

Connection procedure of the AC power line:

- Make sure the AC power supply complies with following specification: 100~240 VAC, 50/60 Hz.

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

⚠ Note ⚠

Connect the power line to the jack special for hospital usage.

- Connect to the ground line if necessary. Refer to **Chapter Patient Safety** for details.

1.12 Power on the Monitor

Press **power switch** to power on the monitor. Then the company logo will show on the screen, After 15 seconds or so, the system will enter monitoring screen after self-test, and you can perform normal monitoring now.

During self-test, the Model Code will display.

⚠ **Note** ⚠

If the monitor finds any fatal error during self-test, it will alarm.

⚠ **Note** ⚠

Check all the functions that may be used to monitor and make sure that the monitor is in good status.

⚠ **Note** ⚠

The battery must be recharged to the full electricity after each use to ensure adequate electricity reserve.

⚠ **Warning** ⚠

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

⚠ **Note** ⚠

The interval between twice press of POWER should be more than 1 minute.

1.13 Connect Patient Sensors

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

⚠ **Note** ⚠

For information on correct connection, refer to related chapter 5-11.

1.14 Check the Recorder

If your monitor is equipped with a recorder, open the recorder door to check if paper is properly installed in the output slot. If no paper present, refer to **Chapter Recording** for details.

Chapter 2Alarms

2.1 Alarms overview

2.1.1 Types of the alarms

The alarms can be divided into two types: physiology alarms and technical alarms.

Physiology alarms: triggered by some of patient's physiological parameters exceed the limits, taking the body temperature exceeding temperature alarm limit as an example.

Technical alarms: triggered by the abnormality of certain monitoring function or distortion of monitoring results caused by failure of system or sensors, taking ECG lead off as an example.

2.1.2 Level of alarms

The alarms have three levels: high, medium and low.

The monitor has set levels for technical alarms and physiology alarms.

2.1.3 Modes of the alarms

When alarming, the monitor gives alarm prompts by three ways: sound alarm, light alarm, and alarm message description.

The prompts of sound and light come from the speaker, the alarm indicator light and alarm message description. The alarm message description is displayed on the screen. The physiology alarm is displayed in the patient alarm information section, while the technical alarm displayed in the monitor alarm information section.

When the physiology alarm occurs, which is caused by the measurement parameters exceeding the alarm limit, the color of high limit and low limit would change from dark to bright, besides the three means of alarm prompting mentioned above.

When there is “*” before technical or the physiology information section, it means low level alarm. “**” means medium level alarm and the information bottom color will turn yellow. “***” means high level alarm and information bottom color will turn red. For example: The “** HR TOO HIGH” is the expression of medium alarm.

Physical alarm has 2 kind of alarm mode: LATCH or Unlatch. LATCH means that once alarm occurs, the system will give alarm all the time until manual intervention (such as push the “SILENCE” button on the panel). UNLATCH means that the system will stop giving alarm once the alarm condition does not exist.

There are three levels of the alarm: high, midium, low, by using the different light and the sound. The following table shows in order:

Alarm level	alarm light	sound characteristic of the alarm
High	alarm light glitters red, the flicker frequency is quick	The pattern as “honk - honk - honk------honk - honk, honk - honk - honk------honk - honk”, each 8 seconds occur once
medium	alarm light glitters yellow, the flicker frequency is slow	The pattern as “honk - honk - honk”, each 25 seconds emit sound once
Low	alarm light is bright and always show yellow	The pattern as “honk -”, each 25 seconds emit sound once

2.2 Alarms pausing

Presses “PAUSE” key on the control panel, all alarm sound and light and the alarm message are closed. Then the system enters alarm suspend state. The suspension countdown time is displayed in the area of the technical alarm.

The alarm suspension time is 2 minutes for fixation.

2.3 Alarms SILENCE

Presses “SILENCE” key on the control panel, then may close the sound and the light alarm; when presses down “SILENCE” key again, will quit from alarm silence condition and reactivated correspondingly sound alarm, returns to normal alarm condition.

If the alarm still exists under the condition of the silence state, then the information section display this alarm information.

If there is no alarm exists under the condition of the silence state, then all the alarm will be eliminated.

⚠ **Attention** ⚠

When the system is under the “SILENCE” condition, any newly triggered alarm will terminate the silence condition, and then makes the system to restore to the normal alarm condition.

2.4 Alarm Setting

Enter the alarm setting window, the options below may be set.

1) Alarm Volume: The scope is 1~10 (10 is the highest volume).

2) Flash: if “On” is selected and there is physical alarm, corresponding parameter digit will flash to indicate that the parameter has alarm.

3) Para Alarm: 2 items: LATCH or Unlatch. LATCH means that once alarm occurs, the system will give alarm all the time until manual intervention (such as push the “SILENCE” button on the panel). UNLATCH means that the system will stop giving alarm once the alarm condition does not exist.

4) Alarm Record: If “On” is selected, the recorder will record the alarm event when physical alarm occurs, otherwise it will not record.

5) Voice Alarm: If “On” is selected and alarm event occurs, a human voice alarm will continuously notify the user, otherwise it will not notify by human voice.

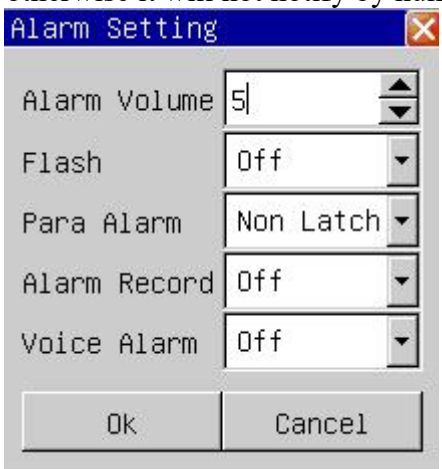


Chart 2- 1 alarm setting

2.5 Limits of the alarms

Physiology alarm is triggered according to the settings limits. Various parameters limits are showed by the dark color in the parameter area of the upper corner on the left side. If the parameter exceeds the limits, then triggers the physiology alarm at this parameter by the bright color. For example: the low limit of the heart rate is 80, if at this time the heart rate is 60 pieces, then triggers “HR TOO LOW”, the low limit of the heart rate “80” will be a bright color, the following chart will show:

Chart 2-2 Alarm Limit

2.5.1 ECG Alarm Limit

Choosing “ECG Alarm Limit” may enter “ECG Alarm Limit” window:

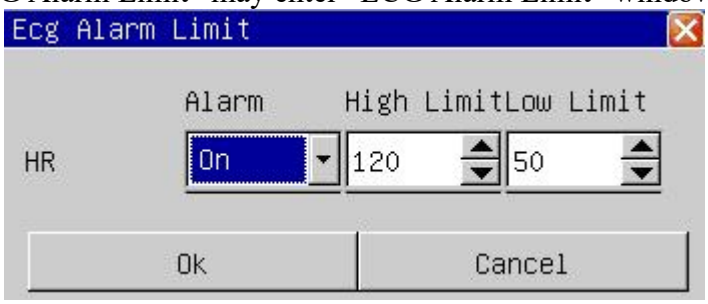


Chart 2-3 Ecg Alarm Limit

Following is the adjustment scope of the heart rate:

Patient type	Adult	Pediatric	Neonate
HR high limit	300	350	350
HR low limit	15	15	15

2.5.2 SpO_2 Alarm Limit

Choosing “SpO_2 Alarm limit” may enter “SpO_2 Alarm Limit” window:

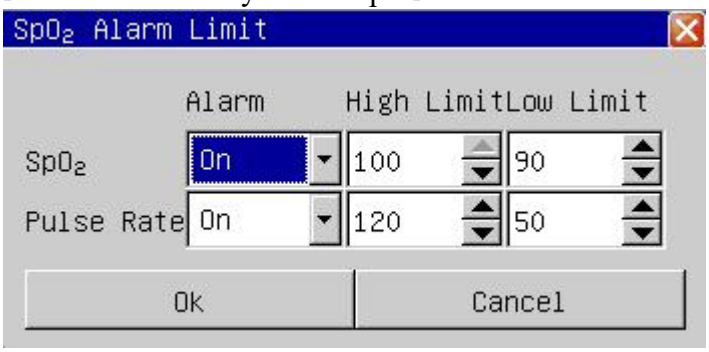


Chart 2-4 SpO_2 Alarm Limit

The SpO_2 limit adjustment scope is 1～100% for upper limit and 0～99% for lower limit;

The Pulse rate alarm limit adjustment scope are 20～300.

2.5.3 NIBP Alarm Limit

Choosing “NIBP Alarm Limit” may enter “NIBP Alarm Limit” window:

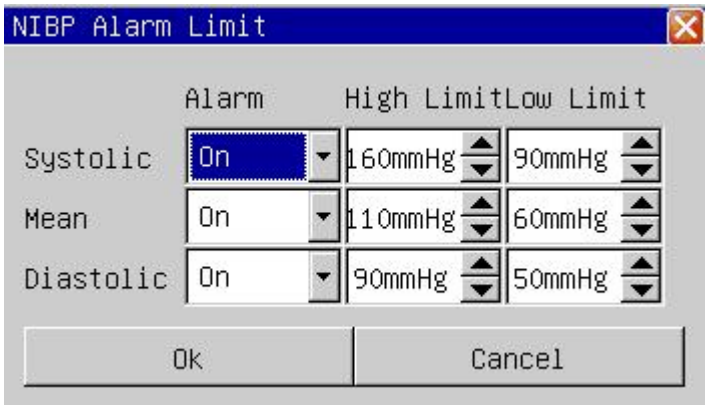


Chart 2- 5 NIBP Alarm Limit

The NIBP Alarm Limit adjustment scope as follows:

Patient type	Adult	Pediatric	Neonate
Systolic pressure high limit	280	220	135
Systolic pressure low limit	40	40	40
Diastolic pressure high limit	220	160	100
Diastolic pressure low limit	10	10	10
mean pressure high limit	240	170	110
mean pressure low limit	20	20	20

2.5.4 Resp Alarm Limit

Choosing “Resp Alarm Limit” may enter “Resp Alarm Limit” window:

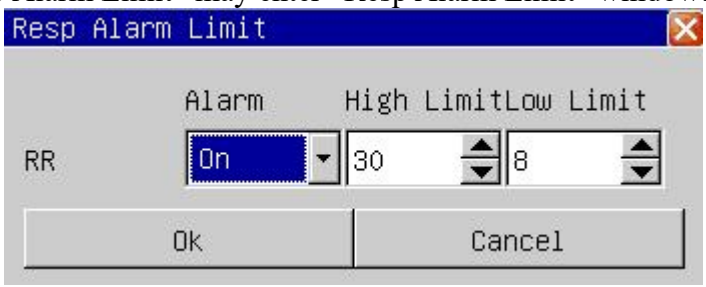


Chart 2- 6 Resp Alarm Limit

The Resp rate alarm limit adjustment scope is:7~120.

Patient type	Adult	Pediatric	Neonate
RR high limit	120	150	150
RR low limit	7	7	7

2.5.5 Temp Alarm Limit

Choosing “Temp Alarm Limit” may enter “Temp Alarm Limit” window:

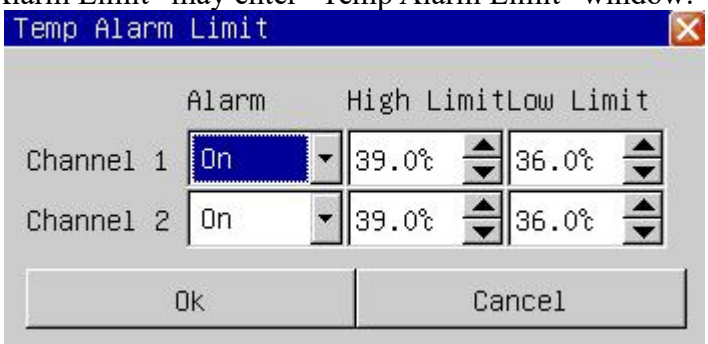


chart 2- 7 Temp Alarm Limit

The Temp alarm limit adjustment scope is:0~50℃ (32～122℉).

2.5.6 CO_2 Alarm Limit

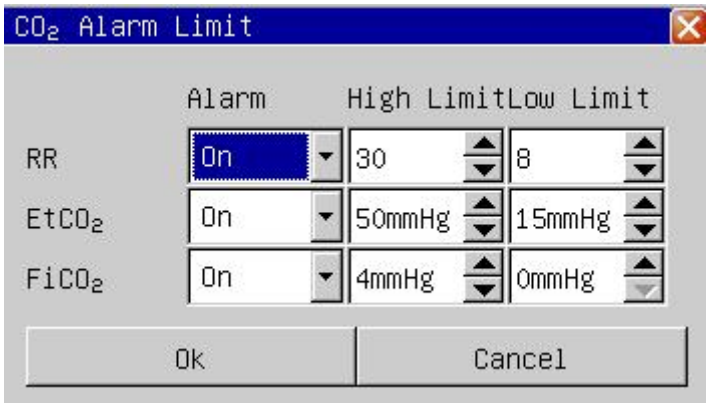


Chart 2- 9 CO_2 Alarm Limit

The Resp rate alarm limit adjustment scope is: 7~120;

The $EtCO_2$ alarm limit adjustment scope is: 0～100mmHg;

The $FiCO_2$alarm limit adjustment scope is: 0～100mmHg.

2.5.7 IBP Alarm Limit

Choosing “IBP Alarm Limit” may enter “IBP Alarm Limit” window:

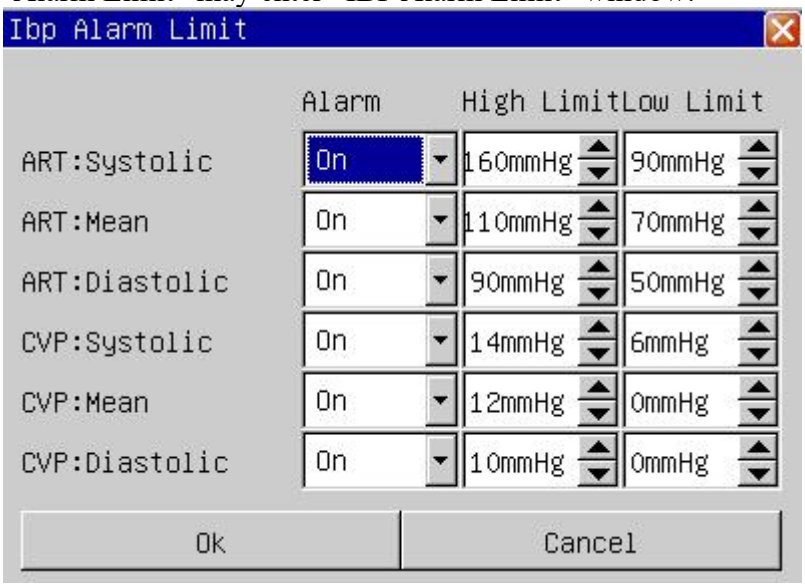
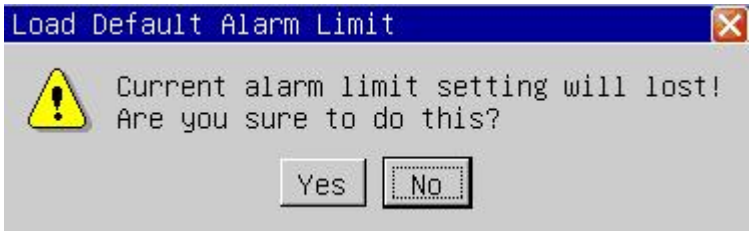


chart 2- 8 IBP Alarm Limit

The IBP alarm limit adjustment scope is: -50～300mmHg.

2.5.8 Load Default Alarm Limit

Choosing “Load Default Alarm Limit” can enter “load default Alarm limit” window:



The chart 2- 11 Load default Alarm Limit

If chooses “Yes”, then the current alarm limit settings will be able to substituted by the default alarm limit settings.

2.6 Physiology alarm information

Below is all physiologies alarm tabulates:

Alarm Information	Trigger Condition
***ASYSTOLE	Over 4 seconds non- palpitations signals
*** APNEA	In a setting time without breath signal
*** NO PULSE	Over 15 seconds without pulse signals
** HR TOO HIGH	The heart rate exceeds the alarm high limit
** HR TOO LOW	The heart rate is lower than the alarm low limit
** SPO_2 TOO HIGH	The oxygen saturation exceeds the alarm high limit
** SPO_2 TOO LOW	The oxygen saturation is lower than the alarm low limit
** Pulse rate TOO HIGH	The Pulse rate surpass the alarm high limit
** Pulse rate TOO LOW	The Pulse rate are lower than the alarm low limit
**NIBP SYS TOO HIGH	NIBP systolic pressure exceeds the alarm high limit
**NIBP SYS TOO LOW	NIBP systolic pressure is lower than the lower alarm limit
**NIBP MEAN TOO HIGH	NIBP mean pressure exceeds the alarm high limit
**NIBP MEAN TOO LOW	NIBP mean pressure is lower than the alarm low limit
**NIBP DIA TOO HIGH	NIBP diastolic pressure exceeds the alarm high limit
**NIBP DIA TOO HIGH	NIBP diastolic pressure is lower than the alarm low limit
** RR TOO HIGH	The Breath rate exceeds the alarm high limit
** RR TOO LOW	The Breath rate is lower than the alarm low limit
** TEMP1 TOO HIGH	The body temperature channel 1 exceeds the alarm high limit
** TEMP1 TOO LOW	The body temperature channel 1 is lower than the alarm low limit
** TEMP2 TOO HIGH	The body temperature channel 2 exceeds the alarm high limit
** TEMP2 TOO LOW	The body temperature channel 2 is lower than the alarm low limit
**$EtCO_2$ TOO HIGH	$EtCO_2$ exceeds the high limit
**$EtCO_2$ TOO LOW	$EtCO_2$ is lower than the low limit
**$FiCO_2$ TOO HIGH	$FiCO_2$ exceeds the high limit
**$FiCO_2$ TOO LOW	$FiCO_2$ is lower than the low limit
**ART SYS TOO HIGH	ART systolic pressure exceeds the alarm high limit
**ART SYS TOO LOW	ART systolic pressure is lower than the low limit
**ART MEAN TOO HIGH	ART mean pressure exceeds the high limit
**ART MEAN TOO LOW	ART mean pressure is lower than the low limit
**ART DIA TOO HIGH	ART diastolic pressure exceeds the high limit
**PA DIA TOO LOW	PA diastolic pressure is lower than the low limit
**PA SYS TOO HIGH	PA systolic pressure exceeds the alarm high limit
**PA SYS TOO LOW	PA systolic pressure is lower than the low limit
**PA MEAN TOO HIGH	PA mean pressure exceeds the high limit
**PA MEAN TOO LOW	PA mean pressure is lower than the low limit
**PA DIA TOO HIGH	PA diastolic pressure exceeds the high limit

**PA DIA TOO LOW	PA diastolic pressure is lower than the low limit
**PA DIA TOO LOW	PA diastolic pressure is lower than the low limit
**CVP SYS TOO HIGH	CVP systolic pressure exceeds the alarm high limit
**CVP SYS TOO LOW	CVP systolic pressure is lower than the low limit
**CVP MEAN TOO HIGH	CVP mean pressure exceeds the high limit
**CVP MEAN TOO LOW	CVP mean pressure is lower than the low limit
**CVP DIA TOO HIGH	CVP diastolic pressure exceeds the high limit
**CVP DIA TOO LOW	CVP diastolic pressure is lower than the low limit
**LAP SYS TOO HIGH	LAP systolic pressure exceeds the alarm high limit
**LAP SYS TOO LOW	LAP systolic pressure is lower than the low limit
**LAP MEAN TOO HIGH	LAP mean pressure exceeds the high limit
**LAP MEAN TOO LOW	LAP mean pressure is lower than the low limit
**LAP DIA TOO HIGH	LAP diastolic pressure exceeds the high limit
**LAP DIA TOO LOW	LAP diastolic pressure is lower than the low limit
**RAP SYS TOO HIGH	RAP systolic pressure exceeds the alarm high limit
**RAP SYS TOO LOW	RAP systolic pressure is lower than the low limit
**RAP MEAN TOO HIGH	RAP mean pressure exceeds the high limit
**RAP MEAN TOO LOW	RAP mean pressure is lower than the low limit
**RAP DIA TOO HIGH	RAP diastolic pressure exceeds the high limit
**RAP DIA TOO LOW	RAP diastolic pressure is lower than the low limit
**ICP SYS TOO HIGH	ICP systolic pressure exceeds the alarm high limit
**ICP SYS TOO LOW	ICP systolic pressure is lower than the low limit
**ICP MEAN TOO HIGH	ICP mean pressure exceeds the high limit
**ICP MEAN TOO LOW	ICP mean pressure is lower than the low limit
**ICP DIA TOO HIGH	ICP diastolic pressure exceeds the high limit
**ICP DIA TOO LOW	ICP diastolic pressure is lower than the low limit
**P1 SYS TOO HIGH	P1 systolic pressure exceeds the alarm high limit
**P1 SYS TOO LOW	P1 systolic pressure is lower than the low limit
**P1 MEAN TOO HIGH	P1 mean pressure exceeds the high limit
**P1 MEAN TOO LOW	P1 mean pressure is lower than the low limit
**P1 DIA TOO HIGH	P1 diastolic pressure exceeds the high limit
**P1 DIA TOO LOW	P1 diastolic pressure is lower than the low limit
**P2 SYS TOO HIGH	P2 systolic pressure exceeds the alarm high limit
**P2 SYS TOO LOW	P2systolic pressure is lower than the low limit
**P2 MEAN TOO HIGH	P2mean pressure exceeds the high limit
**P2 MEAN TOO LOW	P2mean pressure is lower than the low limit
**P2 DIA TOO HIGH	P2diastolic pressure exceeds the high limit
**P2 DIA TOO LOW	P2diastolic pressure is lower than the low limit

2.7 **Technical alarm information**

Below is all technical alarm tabulates:

Alarm Information	**Trigger Condition**	**Process Method**
** ECG LEAD OFF	RL or more than 2 ECG leads falls off	check the ECG lead connection

** ECG LEAD RA OFF	RA lead fall off	check the ECG lead connection
** ECG LEAD LA OFF	LA lead fall off	check the ECG lead connection
** ECG LEAD LL OFF	LL lead fall off	check the ECG lead connection
** ECG LEAD V OFF	V lead fall off	check the ECG lead connection
** MODULE INIT ERR	Module self-checking mistake	Restart the machine, if error still existed, contact the factory service
***MODULE COMM STOP	The module and the main engine communication have the problem	Restart the machine, if error still existed, contact the factory service
** MODULE COMM ERR	The module and the main engine communication have the problem	Restart the machine, if error still existed, contact the factory service
** PARA ALARM LMT ERR	The parameter of the alarm limit is modified by the accident	contact the factory service
** RANGE EXEED	The parameter observed value has exceed the measurement scope which the system can carry on	contact the factory service
** SpO_2 SENSOR OFF	SpO_2 sensor does not connected	Check SpO_2 sensor connection
** SpO_2 FINGER OFF	The finger fall off from SpO_2 sensor	Check SpO_2 sensor connect with the finger
SEARCHING PULSE...	SpO_2 sensor connect bad or the patient move the arm	Check SpO_2 sensor connection situation and patient's current condition
** Temp1 SENSOR OFF	The body temperature channel 1 sensor do not connect	Check temperature sensor connection
** Temp2 SENSOR OFF	The body temperature channel 2 sensor do not connect	Check temperature sensor connection
** WATCHDOG ERR	Main engine watch-dog self-checking defeat	Restart the machine, if wrong still existed, contact the factory service
** SYSTEM TIME LOST	The system clock has not set	Change the system time as the current time, if error still existed, related the factory to carry on the service
** 12V HIGH	The 12V voltage examination exceeds the normal voltage scope	Restart the machine, if error still existed, contact the factory service
** 12V LOW	The 12V voltage examination is lower than the normal voltage scope	Restart the machine, if error still existed, contact the factory service
** 3.3V HIGH	The 3.3V voltage examination exceeds the normal voltage scope	Restart the machine, if error still existed, contact the factory service
** 3.3V LOW	The 3.3V voltage examination is lower than the normal voltage scope	Restart the machine, if error still existed, contact the factory service
**BAT HIGH	The battery voltage	Restart the machine, if error

	examination exceeds the normal voltage scope	still existed, contact the factory service
**BAT LOW	The battery capacity is insufficient	Meets the alternating current to carry on the charge immediately to the battery
* NIBP LOOSE CUFF	The cuff has not connected	Reconnects the blood pressure cuff
* NIBP AIR LEAK	The cuff has not connected good or the air course leaks air	check the pipe connection situation or replace cuff, if the breakdown still existed, please contact the factory service
* NIBP DEFLATE ERR	When blood pressure measurement deflates has the problem	check the tube connection or replace cuff, if the error still existed, please contact the factory service
* NIBP WEAK SIGNAL	When blood pressure measurement the pulse signal too weak, is unable to calculate the blood pressure	Examined the patient type set whether correctly, check the tube connection or replace cuff, if the error still existed, please contact the factory service
* NIBP OUT OF RANGE	When blood pressure measurement the blood pressure or the pulse signal exceeds the normal range, is unable to carry on the measurement	check he tube connection or replace cuff, if the error still existed, please contact the factory service
* NIBP MOVEMENT	Patient arm move	Check the patient situation or replace cuff, if the error still existed, please contact the factory service
** NIBP OVER PRESSURE	The pressure value exceeds the measurement scope	check the pipe connection situation or replace cuff, if the error still existed, please contact the factory service
* NIBP SATURATE	When blood pressure measurement the pulse signal exceeds the normal range, is unable to carry on the measurement	Check the patient situation or replace cuff, if the error still existed, please contact the factory service
* NIBP PNEUMATIC FAIL	The cuff has not connected good or the air course leaks air	check the pipe connection situation or replace cuff, if the error still existed, please contact the factory service
** NIBP SYSTEM ERR	Blood pressure system self-check defeat	Restart the machine, if the error still existed, please contact the factory service
** NIBP TIME OUT	Blood pressure measurement overtime	Restart the machine, if the error still existed, please contact the factory service
** NIBP CUFF TYPE WRONG	Patient type for adult when has used the neonate cuff	Check the patient type or replace cuff, if the error still existed, please contact the factory service
** NIBP MEASURE FAIL	This blood pressure measurement has not been	Check the patient situation or replace cuff, if the error

	able to calculate the blood pressure	still existed, please contact the factory service
** NIBP RESET ERR	When blood pressure measurement exceptionally reset	Restart the machine, if the error still existed, please contact the factory service
**CO_2 STANDBY	CO_2 is on standby mode	Set CO_2 to run mode
***CO_2 COMM STOP	CO_2 module and the main engine communication have the problem	Restart the machine, if error still existed, contact the factory service
**IBP1 SENSOR OFF	IBP sensor does not connected	Check IBP sensor connection
**IBP2 SENSOR OFF	IBP sensor does not connected	Check IBP sensor connection
**IBP1 NEED ZERO	IBP1 has not been zeroed	Zero IBP channel 1 sensor
** IBP1 NEED ZERO	IBP2 has not been zeroed	Zero IBP channel 2 sensor

⚠Attention ⚠

1. When different level of alarm simultaneously exists, the sound of the alarm is the highest level alarm.

2. In alarm suspend condition, Monitoring will not process any alarm information.

Chapter 3 Record

3.1 Record setting

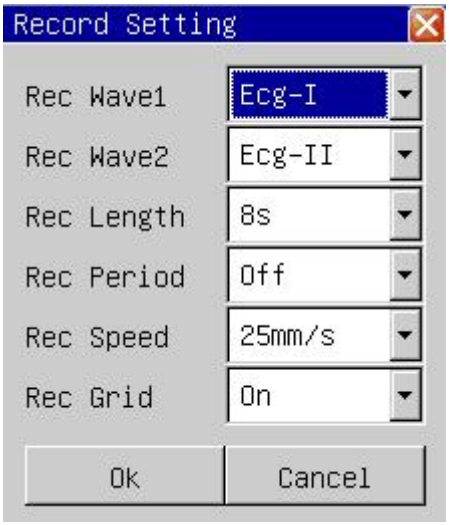


Chart 3- 1 recording settings

1) record waveform 1, record waveform 2: there are five options of the waveform to be choose: off, ECG1, ECG2,ECG3, pulse wave, respiratory wave, IBP1 wave, IBP2 wave,. The user may choose simultaneously two waveforms to record, or choose one waveform to record while close another record wave.

2) record length: there are two options, which are “continuous”, “8 seconds”. “continuous” means that the record can continuously output the wave until presses down the “RECORD” key again.

3) record period: the time interval of two record outputs. There are 10 options which are: off, 10 minutes, 20 minutes, 30 minutes, 40 minutes, 50 minutes, 1 hour, 2 hours, 3 hour and 4 hours. The recording length is 8 seconds.

4) record speed: There are two options, which are “25.0mm/s” and “50.0mm/s”.

5) record grid: “Off” means non- grid output. “On” means grid output.

3.2 Record type

The monitor can carry on several kinds of types record: the continuously real-time records; 8 seconds real-time records; Automatic 8 second records.

3.2.1 Real-time record

This means that it starts the real-time recording waveform when presses down the recording key , and stops the record when press down the recording key again in the recording process .

3.2.2 Auto record

The monitor can trigger the record output according to the time interval. the recording length is 8 seconds.

3.3 Record content

The record outputs contents: The recording type, the patient information, the parameter table, the record time, the waveform name, the waveform amplitude and waveforms.

Chapter 4 Admit/Discharge Patient

4.1 Admit patient

The step of receiving new patient is as follows:

enter “Patient info” window by choosing the “Admit new patient” menu, and input the patient information (the following chart to show).

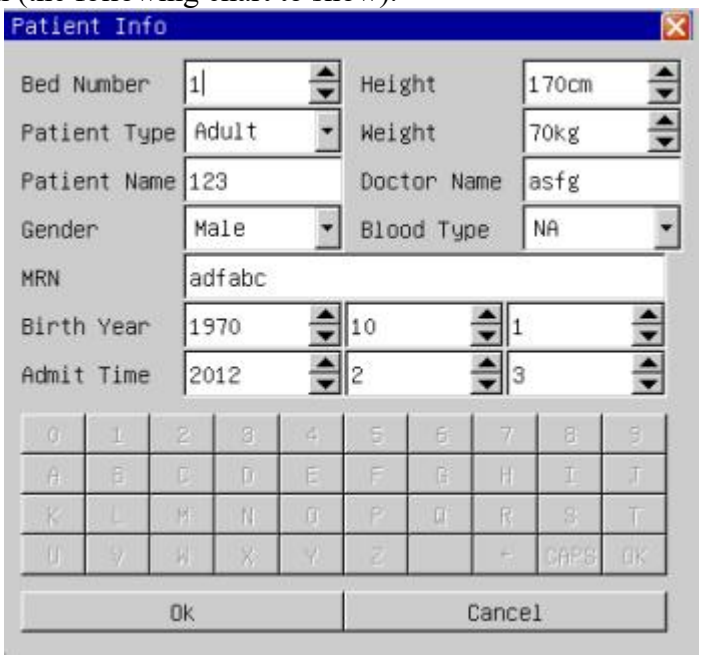


Chart 4- 1 admit new patient

choose the”yes” button to quit, the patient’s informations is accepted.

4.2 Discharge patient

Enter the “Discharge Patient” window by choosing ”Discharge Patient” menu, as the following chart to show.

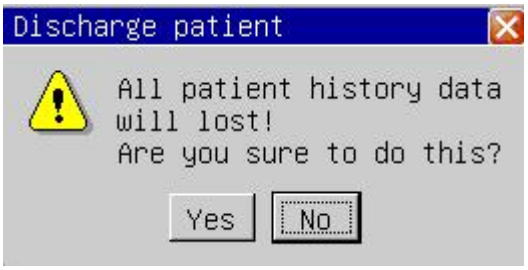


Chart 4- 2 Discharge patient

Carry on the following operations to relieve the patient:

1) Discharge all patients information;

2) Discharge all historical data (including trend graph, trend table, blood pressure review, waveform review data);

⚠Attention ⚠

If do not relieve the patient firstly before receive new patient, new patient’s measurement data would be save in the preceding patient's data. The monitor can not distinguish the new patient data from the old one.

Chapter 5 ECG Monitoring

The ECG monitors the heat electricity activity of the body, and shows the heart electricity waveform and the heart rate on the monitor.

5.1 Connecting ECG electrodes

1) make the patient's skin preparation at first before place the electrode. A good signal at the electrode provides the monitor with valid information for ECG data processing.

Clean the skin with the soap and the water (don't use aether and pure alcohol, because this can increase skin impedance) or scratches the skin dry to increase the blood stream capillary of the organization, and remove skin filings and fat. If necessary, shave the hairs in which the electrode is placed.

2) place the electrode on the patient's body.

3) Connect the ECG-lead with the patient cable.

5.2 ECG electrode placement

The position of the ECG electrode is as follows:

The RA (right arm) electrode — place under the subclavian, approaching the right shoulder.

The LA (left arm) electrode — places under the subclavian, approaching the left shoulder.

The LL (left leg) electrode — places under the left abdomen.

The RL (right leg) electrode — places under the right abdomen.

The V (chest) electrode — places on the chest.

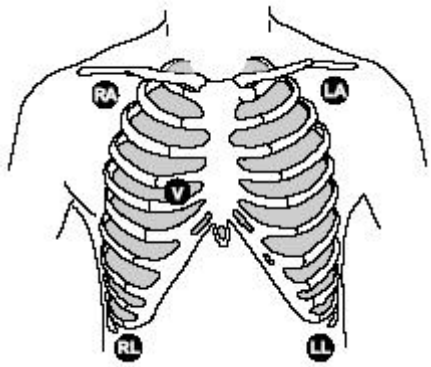


Chart 5- 1 The position of electrode

⚠ Warning ⚠

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

⚠ Warning ⚠

Verify lead fault detection before start of monitoring. Unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm is activated.

⚠ Warning ⚠

Use five lead wires. Use only silver - silver chloride (Ag-AgCl) ECG electrodes and cables that meets AAMI standards.

⚠ Warning ⚠

Set out the following table are standard in Europe and the United States the name of the lead.

United states		europe	
Name of the lead	**Colour**	**Name of the lead**	**colour**
RA	White	R	red
LA	Black	L	yellow
LL	Red	F	green
RL	Red	N or RF	black
V	Brown	C	white

5.3 Connecting ECG leads recommended for surgical patients

The position of ECG electrode is decided by the type of the operation. For example, regarding the chest operation, the electrode may be put on the chest side or the back. Sometimes in the operating room, because of using surgical equipment, the artifact possibly can affect the ECG waveform. In order to reduce the artifact, place the electrode on the left or right shoulder, approaching the left or right side of the abdomen, however, the chest leads can be placed on the center of the chest left side. Avoid to place the electrode on the upper arm, otherwise ECG signal can be very weak.

A good characteristic of the ECG-waveform:

the QRS wave height is great and narrow with no notchs.

The R wave height is big and located completely above the baseline or under.

The amplitude of the P wave and the T wave is smaller than 0.2mV.

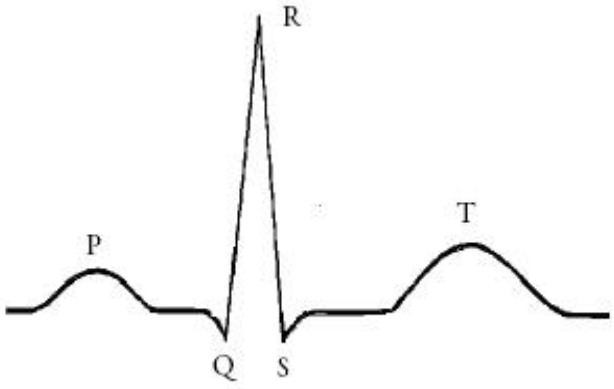


Chart 5- 2 standard ECG-waveform

⚠ Warning ⚠

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

⚠ Warning ⚠

When apply the ECG cable with no resistances to patient monitor or other patient monitors which themselves with no current limit resistance, it can't be applied to defibrillation.

⚠ Note ⚠

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

⚠ Warning ⚠

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

5.4 ECG setting

enter the" ECG setting" window by choosing the "ECG setting" menu, as can be seen from the following chart:

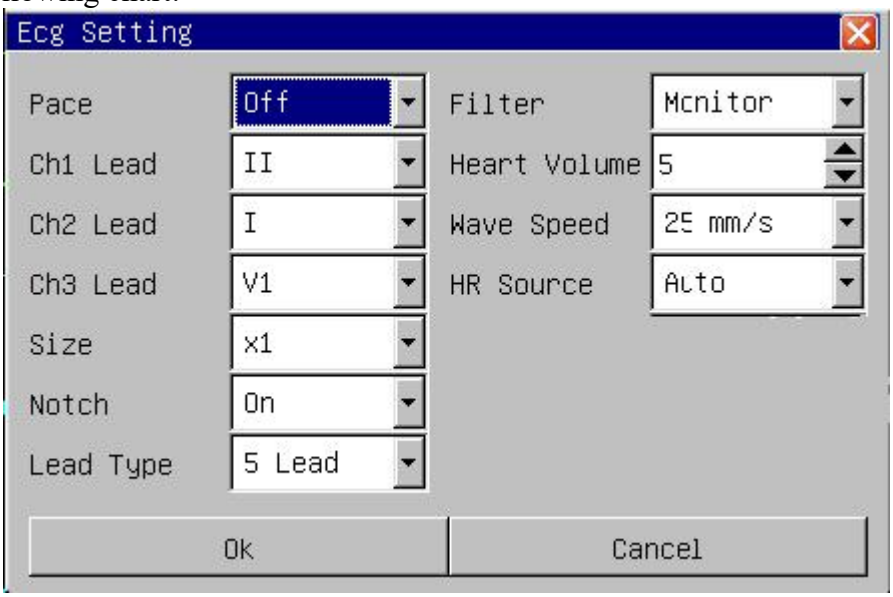


Chart 5-3 ECG settings menu

1) Pacemaker: When it is turned on, the pacing signal, which is considered as the pacing symbol, is shown as a vertical line above the ECG waveform l; When it is turned off, the pace maker will not be detected.

2) channel 1 lead, channel 2 lead: There are 7 leads: I, II, III, AVR, AVL, AVF, V.

3) channel 1 gain, channel 2 gain: There are four gains: "×0.25", "×0.5", "×1", "×2". 1 millivolt ruler mark is displayed on the right of the ECG waveform, the height of which make a direct ratio with the wave amplitude.

4) Notch: work frequency suppression switch, when it is "On" will filter the AC disturbance of ECG signal.

5) filter mode: There are 3 filter modes, diagnostic, monitor and surgery.

In "diagnostic" mode, The ECG wave without filtering is displayed;

In "monitor" mode, the artifact which causes the false alarm, is filtered out;

In "surgery" mode, the artifact and the disturbance caused by the electricity surgical equipment can be reduced.

The filter modes can be displayed above the heart electricity waveform.

6) heart volume: the range is from 0 to10, "0" means that the sound of heartbeat is shuted, "10" means it is on the maximum volume.

7) wave speed: There are three levels of the ECG waveform tracing speed to be chosen, 12.5, 25.0 and 50.0 mm/s.

8) HR source：there are "Auto", "ECG", "SpO_2". When "ECG" is selected, HR and heart sound are from ECG; when "SpO_2"is selected, HR and heart sound are from SpO_2;when "Auto" is selected, patient monitor will auto detect the ECG and SpO_2 signal, HR will from ECG when ECG signal exist, otherwise is from SpO_2;

⚠ Warning ⚠

Don't touch the patient or the monitor in the period of defibrillating.

In order to ensure the patient safety, all leads must be connected to the patient

When the electricity surgical (ES) equipment is used, lay the ECG-lead in the middle of both the ES ground plate and ES to avoid burning. The cable of the electricity surgical equipment cannot twist with the ECG-cable.

When the electricity surgical (ES) equipment is used, don't place the electrode on

the ground plate near the electricity surgical equipment. Otherwise, the ECG-signal will be disturbed.

If monitoring a patient with the pacemaker, set "PACE" to On. If monitoring a patient without pacemaker, set "PACE" to Off.

Regarding the pacemaker patient, the pacing switch must be "On", otherwise, it is possibly to consider the pacing pulse as the normal QRS.

Chapter 6 Resp Monitoring

6.1 Principles of Respiration measurement

When the human body breathes, the chest impedance will change along with the breath, the monitor gets the breath signal through the chest impedance value from the RA and the LL electrodes at the chest. After amplify the signal of the impedance between the electrodes (as a result of the thorax activity), the breath wave will be displayed on the screen.

6.2 Placing the electrodes

Connect the electrodes like the way that connect the heart electrodes at 5.1.

6.3 Resp settings

Choose the "Resp settings" menu and enters "Resp setting" window.

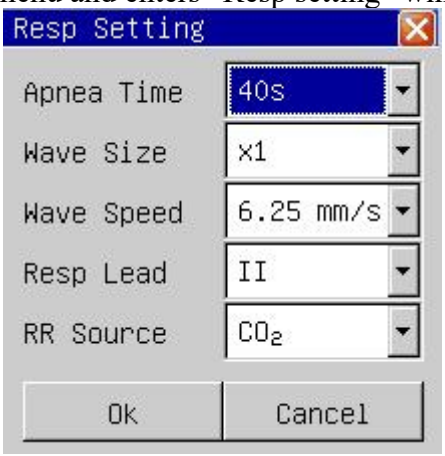


Chart 8- 1 RESP settings

1) Apnea alarm: Setting the judgment time while the patient is asphyxiating, between 10 seconds and 40 seconds, if switch the settings off, indicate the asphyxiation alarm is closed.

2) Waveform speed: you can choose the waveform speed at 6.25mm/s, 12.5mm/s,25.0 mm/s.

3) Amplitude: The user may setting the amplitude's enlargement factor, has ×0.25, ×0.5, ×1, ×2, ×4 altogether 5 levels.

4) RR Source: when "Ecg" is selected, RR is from ECG leads; when "CO_2" is selected, RR is from CO_2 module and AwRR is displayed on parameter area.

5) Resp Lead: when "II" is selected, Resp source is ECG lead II; when "I" is selected, Resp source is ECG lead I.

⚠ Attention ⚠

Resp monitoring is not recommended on patient who moves a lot, because this possibly causes wrong alarm.

⚠ Attention ⚠

Place the RA and the LL electrode in the patient opposite angle of the body in order to obtain the best breath wave. Should avoid the liver area and the ventricle at the breath electrode's lines, this may avoid the false difference to be caused by the heart beat or pulsing blood stream, this is specially important to the neonate.

Chapter 7 SpO_2 Monitoring

The Oxygen Saturation (SpO_2) parameter measurement the artery blood oxygen saturation, it is the percentage of the oxygen gathers hemoglobin .For example, if in the artery blood red blood cell, 97% hemoglobin combine with the oxygen, then this blood has 97% oxygen saturation, the value reading on the monitor should be 97%, this value demonstrated the percent of the carry oxygen hemoglobin molecule which forms the oxygen gathers hemoglobin.

7.1 Monitoring Procedure

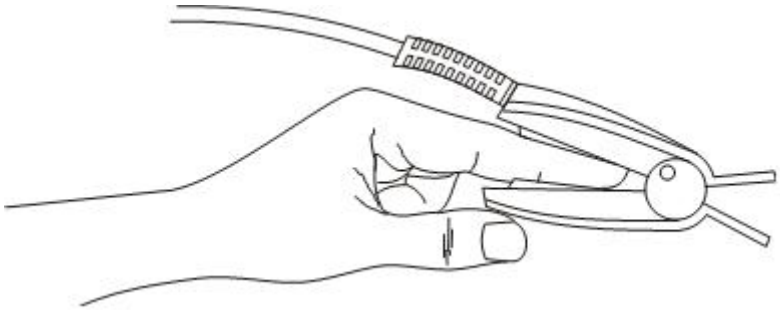


Figure 7-1 Finger sensor placement

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

⚠ **Note** ⚠

Place the SpO_2 sensor cable at the backside of the patient hand. Make sure the fingernail is just opposite to the light emitted from the sensor.

7.1.1 Neonatal SpO2 plethysmography measurements

Neonate SpO_2 sensor consists of a Y-shape SpO_2 sensor and its sheath. Insert t he LED and PD ends of the Y-shape SpO_2 sensor respectively into the upper and lower grooves on the sheath (Figure 7-2). The Figure 7-3 shows us the neonate SpO_2 sensor after insertion.

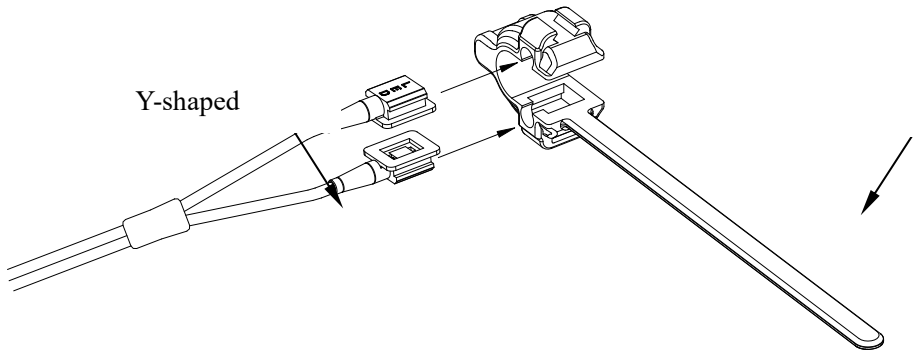


Figure 7-2 neonatal arterial oxygen probe (1)

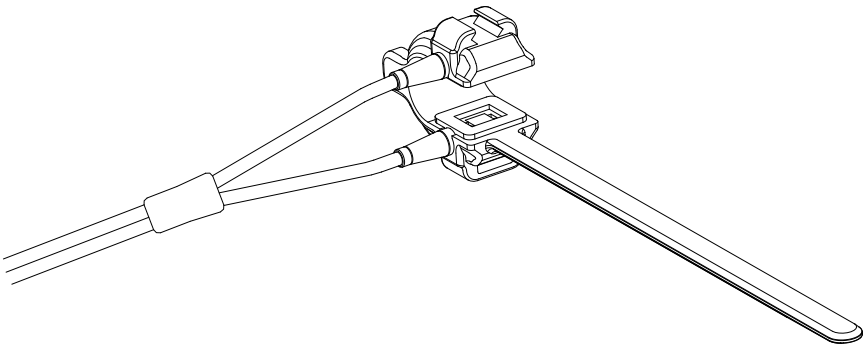


Figure 7-3 neonatal arterial oxygen probe (2)

7.1.2 Neonatal oxygen probe placed

Wind the SpO_2 sensor around a hand or foot of a neonate patient. Hold the sensor, pull the belt and fit one of its sides with “V” edge into the “V” groove on the corresponding side of the sheath. Appropriately elongate the belt to about 20mm, and fit the “V” edge of the other side of the belt into the “V” groove of the other side of the sheath. Then, loosen the belt. After the “V” edges of the two sides of the belt fit well into the “V” grooves on the two sides of the sheath, put the belt into the first lock bar to fasten the belt. If the belt is too long, you may put it into the second lock bar. You must position the SpO_2 sensor in this way so as to make the photoelectric component face the correct position. Besides, note not to elongate the belt too much, which may lead to inaccurate measurement and block the blood circulation severely.

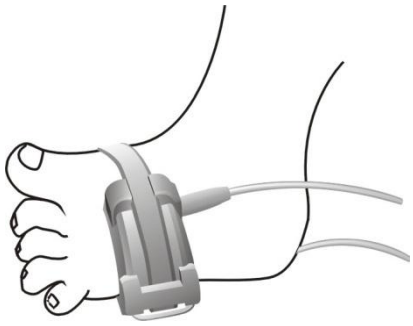


Figure 7-4 neonate oxygen probe placed

⚠ **Note** ⚠

No calibration curve for the pulse oximeter.
No normalization for the waveform.
If the sensor cannot be positioned accurately to the part to be measured, it may result in inaccurate SpO2 reading, or even that the SpO2 cannot be measured because no pulse is detected. If this is true, you must position the sensor again.
The excessive patient movement may result in inaccurate reading. In this situation, you must keep the patient quiet or change the part for monitoring to reduce the adverse influence of excessive movement.
Function tester cannot evaluate the accuracy of the probe and the patient monitor.
Special use for the probe:

Patient Type	Adult	Pediatric	Neonate
Age	≧18years	1month-12years	≦28days
Weight	>30 kg	10-50 kg	2.5-4 kg
Type of the probe	Finger type for adult	Finger type for Pediatric	Tied type for neonate
Sensor position	Finger	Finger	Palm or leg
Application condition	Normal temperature，check the peripheral circulation and the skin every 2 hours, keep the patient quiet.	Normal temperature，check the peripheral circulation and the skin every 2 hours, keep the patient quiet.	Normal temperature，check the peripheral circulation and the skin every 2 hours, keep the patient quiet.

⚠ **Warning** ⚠

The probe should be non-poisonous.

In the process of extended and continuous monitoring, you should check the peripheral circulation and the skin every 2 hours. If any unfavorable changes take place, you should change the measured position in time.

In the process of extended and continuous monitoring, you should periodically check the position of the sensor. In case that the position of the sensor moves during monitoring, the measurement accuracy may be affected.

The temperature of the probe should be less than 41℃, otherwise the patient will be burned.

7.2 Measurement restrictions

In the operating process, following factors may affect the accuracy of the oxygen saturation measurement:

1) High-frequency electrical jam, such as the disturbance which is produced by monitor system oneself or comes from such as the electricity surgery instrument disturbance which connected with the system;

2) In magnetic resonance image formation scanning (MRI) period do not use the blood oxymeter and the blood oxygen sensor, the induced current possibly can cause the burn;

3) In vein dye;

4) Patient too frequently migration;

5) Outside ray radiation;

6) Sensor installment inappropriate or contact the improper position with the object;

7) Body temperature (best body temperature should in 28℃- 42℃);

8) Lay aside the sensor in the body has the blood pressure cuff, in the ductus

9) arteriosus or the cavity on the pipeline body;

10) The density of the non- function hemoglobin like carbon oxygen hemoglobin (COHb) and blood and iron hemoglobin (MetHb) and so on;

11) Oxygen saturation lowly;

To be circular poured is not good at the test part;

Shock, anemia, the low temperature and applies the vasoconstriction medicine and so on all possibly cause the artery blood stream to be reduced to the level which was unable to measurement;

12) Measurement is also decided on the oxygen gathers hemoglobin and the absorption situation of the return oxygen gathers hemoglobin to the special wave length light. If other substances which absorb the same wave length light exist, they can cause the measurement

to appear pseudo or the low oxygen saturation value. For example: Carbonizes the hemoglobin, the blood and iron hemoglobin, the methylene blue, indigo carmine.

7.3 SpO_2 setting

Chooses "SpO_2 settings" menu and enters "SpO_2 setting" window.

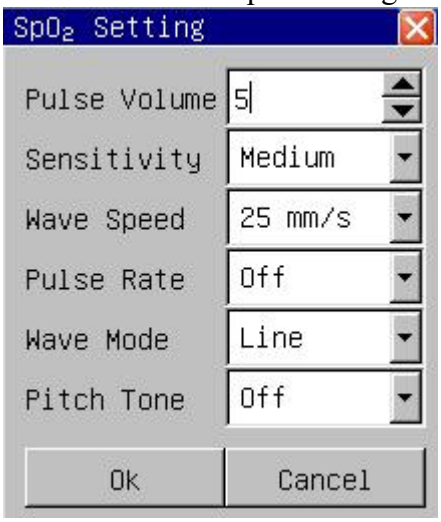


Chart 9- 1 SpO_2 settings

1) Pulse volume: the volume choice scope is the 0~10,0 denotes closure pulse sound, 10 denotes maximum volumes.

2) Sensitivity: the sensitivity for computing oxygen saturation value, has "high", "medium", "low" three options.

3) Data refresh cycle is one second and three kinds of data average, 8 seconds for high sensitivity, 16 seconds for medium sensitivity and 32 seconds for low sensitivity.

4) Wave speed: the waveform scanning velocity has 12.5 and 25mm/s, two levels may choose.

5) Pulse rate: setting as "On", in parameter area will show Pulse rate; otherwise the Pulse rate will not be displayed.

6) Wave Mode: when "Line" is selected, will use line mode to draw pleth wave; when "Fill" is selected, will use fill mode to draw pleth wave;

7) Pitch Tone: setting as "On", we can hear the beat of the pulse rate; otherwise we can't hear the beat of the pulse rate.

⚠ Warning ⚠

1) If it has the carbon oxygen hemoglobin, metahemoglobin or dye dilution chemicals, then the oxygen saturation value can have the deviation;

2) Electricity surgical department equipment electric cable cannot twine with the sensor cable in the same place;

3) Do not place the sensor at the body has the ductus arteriosus or the vein syringe ;

4) Guarantees the nail to block the lights. Sensor should at the back of hand;

5) Do not place SpO_2 or the blood pressure oversleeve blood pressure measurement on the same body, because in the blood pressure measurement process the blood stream unenlightened can affect the oxygen saturation reading.

6) Continually, the excessively long time monitor possibly can increase do not hope danger that the skin characteristic change occurs, for example exceptionally sensitive, changes red, bubbles or pressure necrosis, specially in the neonate or has pour barrier as well as the change or juvenility skin kind sickness person;

7) In the long time continuous monitoring process, about every 2 hours inspects the

measurement SpO_2 the end circulation situation and the skin situation, if discovered changes not good, should change the measurement SpO_2 promptly, simultaneously should periodical inspection the sensor fastness situation, avoids the sensor fastness situation change caused by the moving and so on the factors affect the accuracy of the measurement;

8) If the test SpO_2 and the sensor cannot locate accurately, possibly causes the oxygen saturation reading inaccurate, even unable to search the pulse wave result in unable to carry on the blood oxygen monitor, this time should relocate;

9) Measurement SpO_2 move excessively possibly creates measurements inaccurate, this time should cause the patient peaceful or the replacement measurement SpO_2, reduces the influence of moves excessively to the measurement

Chapter 8 NIBP monitoring

8.1 NIBP measurement procedure

⚠Warning⚠

Use accessories specified by XXX only, otherwise; the device may not function normally.

⚠ Warning ⚠

- **Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, pediatric or neonate.)**
- **Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.**

⚠ Warning ⚠

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

⚠ Notes ⚠

The blood pressure of the patient as the basis for establishing therapy may be obtained by using other method such as the cuff/stethoscope auscultation method. Accordingly, the clinical doctor must note that the values obtained by using other method and may be different.

⚠ Notes ⚠

NIBP monitoring uses the oscillometric method of measurement. Blood pressure determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method and an intra-arterial blood pressure measurement device, within the limits prescribed by the ANSI/AAMI SP10.

The initial air inflation is 160mmHg for adult, 120 mmHg for pediatric and 70 mmHg for neonate.

⚠ Notes ⚠

This equipment is suitable for use in the presence of electro-surgery.

1) Insert the gas tube into the blood pressure socket of the monitor;

2) Tie the blood pressure cuff on the patient upper arm or the thigh;

3) Use the suitable size cuff for the patient, guaranteed the symbol Φ is located above to the suitable artery. Guarantee the cuff to twine the body is not too tight, otherwise possibly causes the body far-end to change color even lacks the blood;

4) Inspects the edge of the cuff to fall in the range signed <->.If it is not this, exchange a more appropriate cuff;

5) Confirm the cuff deflated completely;

6) Cuff and gaseous tube coupling. The body which will be measured should put in the same horizontal position with the patient heart. If it is unable to achieve, must use the following adjustment method to make the revision to the measurement result

If the cuff is higher than the heart horizontal position, each centimeter disparity should add 0.75mmHg(0.10kPa) in the value.

If the cuff is lower than the heart horizontal position, each centimeter disparity should reduce 0.75mmHg(0.10kPa) in the value.

7) Confirm the patient type whether correct (patient type shows in the block of information on the monitor, the right side of bed number), if needs to change the patient type, please enter “the patient information” window, change “the patient type”;

8) Press down the blood pressure measurement button on the front panel, start to measures the blood pressure.

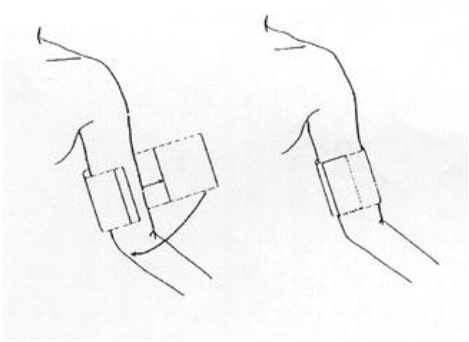


Figure 8- 1 Applying Cuff

⚠ **Note** ⚠

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 is in question, then use a larger cuff.

⚠ **Note** ⚠

For Neonate measurement, the maximum pressure of the cuff is 147mmHg. The maximum pressure is 140mmHg when the cuff is used normally. The initial inflating pressure of the cuff is 70mmHg during measurement.

Size of reusable cuff for neonate/children/adult

Patient Type	Limb perimeter	Cuff width	Hose
Neonate	10 ~19 cm	8 cm	1.5 m or 3 m
Pediatric	18 ~ 26 cm	10.6 cm	
Adult 1	25 ~ 35 cm	14 cm	
Adult 2	33 ~ 47 cm	17 cm	
Thigh	46 ~ 66 cm	21 cm	

Size of disposable cuff for neonate/children/adult

Size No.	Limb perimeter	Cuff width	Hose
1	3.1 ~ 5.7 cm	2.5 cm	1.5 m or 3 m
2	4.3 ~ 8.0 cm	3.2 cm	
3	5.8 ~ 10.9 cm	4.3 cm	
4	7.1 ~ 13.1 cm	5.1 cm	

8.2 NIBP measurement limits

This machine NIBP measuring technique is the vibration mothod, this kind of measuring technique basis has the certain limit according to difference metrical object. The user should realize at following several situations, the observed value changes unreliable, or the time measured press increases or the measurement is unable to carry on.

1) Patient movement: If the patient is moving, trembles or the convulsion;

2) Arrhythmia: the irregular heart beat caused by the arrhythmia;

3) Heart-lung machine: such as the patient uses the heart-lung machine connection;

4) Pressure variation: such as while in blood pressure measurement the patient blood pressure rapid change;

5) Serious shock: such as the patient is being in the serious shock or the hypothermia;

6) The heart rate exorbitant or lower: The heart rate is lower than 40bpm (heart

beat/minute) and is higher than 240bpm (heart beat/minute), cannot carry on the blood pressure measurement;

7) Obese patient: The excessively thick fat stratum can reduce the accuracy of the measurement, because the fat can cause the artery pulse signal cannot arrive the cuff.

8.3 NIBP settings

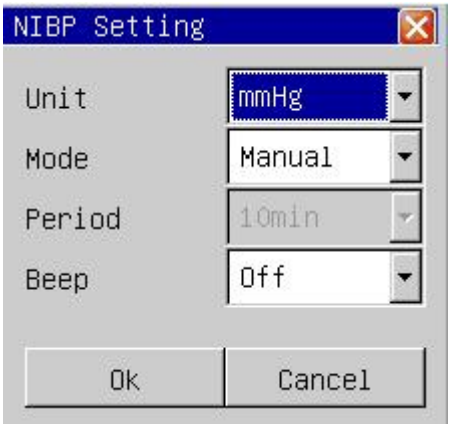


Chart 10- 1 NIBP settings

1) Pressure unit: mmHg or kPa is optional.

2) Measurements mode: have 3 kinds of mode: manual, automatic, STAT.

Under the manual measurement way, presses down the blood pressure measurement button on the control panel, then starts the manual measurement once;

Under the automatic measurement way, presses down the blood pressure measurement button on the control panel, then starts the automatic measurement once, afterwards the monitor can automatic start blood pressure measurement defer to the period;

Under the STAT measurement way, presses down the blood pressure measurement button on the control panel, then starts to continuously measure for 5 minutes.

While the blood pressure measuring, the user presses down the blood pressure measurement button on the control panel anytime, can stop the current blood pressure measurement.

3) The automatic sampling interval: If the measurement pattern setting as “automatically”, then the automatic sampling interval button will be available.

The automatic sampling interval time can be chosen in 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 60 minutes, 90 minutes, 2 hours, 3 hours, 4 hours, 8 hours.

4) There are two choices for the beep: On or Off.

After choose the time interval, presses down the blood pressure measurement button will start the first automatic measurement charge, in order to finish the automatic measurement should choose the “manually” returns to the manual pattern while in sampling interval period.

8.4 Blood pressure calibrations

Using the precision of the pressure gauge (or mercury sphygmomanometer) is higher than 1 mmHg after the calibration carries to carry on the calibration, choose “noninvasive blood pressure calibration” in the “the maintenance” menu to start to carry on the calibration, if presses down the blood pressure measurement button while calibrating , then the system will stop calibrating.

Connect the pressure gauge, the cuff through a 3-way tube to the blood pressure trachea jack on the monitor, setting the monitor as “the calibration” pattern, then charge the cuff using a air pump, first make the pressure to 250 mmHg, then slowly deflates, when the monitor display 200, 150 and 50 mmHg, the disparity between the standard pressure gauge

value and the monitor pressure value should in 3 mmHg. If the value exceeds 3 mmHg, please contact our company's attendant.

Attention: The cuff must entangle in the suitable big and small pillars.

⚠ **Warning** ⚠

You shall calibrate NIBP measurement once every two years (or as required in your hospital's maintenance regulation). You shall check the performance according to following information.

8.5 leakage examination

When the cuff is connected may use this function to start air course charge process, thus to discover whether the air way's airtight condition is good or not. If the test passes, the system will not make any prompt; If do not passed, then in the noninvasive blood pressure parameter area will have the corresponding wrong prompt.

The air leakage examination process:

1) Connect the cuff and the blood pressure socket on the monitor;

2) Wrap the cuff around a suitable cylinder;

3) Choose "NIBP Pneumatic Test" in "Service" menu, the noninvasive blood pressure parameter area diplays "Pneumatic test.....", indicated the system starting to carry out leak air examination;

5) After about 20 seconds, the system will turn on the valve automatically, marking leaks air examination is completed;

6) If in the noninvasive blood pressure parameter area does not prompt the information, indicate the system does not leak air. If "Pneumatic leak!" is displayed, indicate the air course possibly leaks air. The operator should check loose conditions and carry on the leaks air examination again after confirming all connections are ok.

⚠ **Warning** ⚠

1) Can't carry on the noninvasive blood pressure on the patient who have the sickle cell anemia or have the skin disrepair or will have damage.

2) To the patient who has the serious hemoglutination machine-made barrier, must according to the clinically appraise decided whether carries on the automatic blood pressure measurement, because the place where the body and the cuff friction will has have the haematoma danger.

3) Before start the measurement, you must confirm the patient type is correct(adult, pediatric, neonate).

4) Do not enwind the cuff to the body have the venous transfusion or inserted the drive pipe, while cuff charging period, when the transfusion reduces speed or stops up, possibly causes damage around the drive pipe.

5) If the time of the automatic pattern noninvasive blood pressure measurement pull too long, then the body connected with the cuff possibly have the purpura, lack the blood and the neuralgia. When guarding patient, must inspect the luster, the warmth and the sensitivity of the body far-end frequently. Once observes any exception, please immediately stop the blood pressure measurement.

6) The calibration of the noninvasive blood pressure measurement is supposed to be carried on one time every year. (Or according to the maintenance regulation of your hospital).

7) The cuff width should be 40% size of the body perimeter. (Neonate is 50%), or the 2/3 of the upper arm length. The length of the cuff charging part should long enough surround 50~80% of the body, the inappropriate size cuff can have the wrong reading. If the cuff size has the question, should use the bigger cuff to reduce the mistake.

Chapter 9 Temperature Monitoring

9.1 Steps of temperature measurement

1) Insert temperature sensor directly into the socket.
2) Power on patient monitor.

9.2 Temperatures settings menu

Chooses “Temperature setting” menu and enters “Temp setting” window:

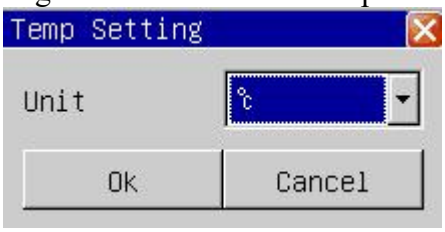


Chart 11-1 Temperature settings

Temperature unit: Choose ℃ or ℉.

⚠ Note ⚠

The battery and single-use temperature probe should be recycled or destroyed according to regular rules.

The measurement range is 0 to 50℃, the maximum permissible errors is ±0.1℃ (not including the probe) and ±0.2℃ (including the probe).

The minimum time to get an accurate data is 150 seconds.

⚠ Warning ⚠

Before start to use the temperature measuring , please examine whether the sensor cable is normal. Unplug the temperature sensor cable from the socket, the screen will display the error message “Temp sensor off” and sends out the sound alarm.

Chapter 10IBP Monitoring

10.1 Steps of IBP measurement

1) Plug the pressure cable into the IBP connector on the monitor and power on the monitor;
2) Prepare the flush solution.
3) Flush the system to exhaust all air from the tubing. Make sure that the transducer and stopcocks are free of air bubbles.
4) Connect the pressure line to the patient catheter.
5) Position the transducer so that it is level with the heart, approximately at the level of the midaxillary line.
6) Select IBP channel name.
7) Zeroing IBP transducer.

Following is IBP sensor connection chart：

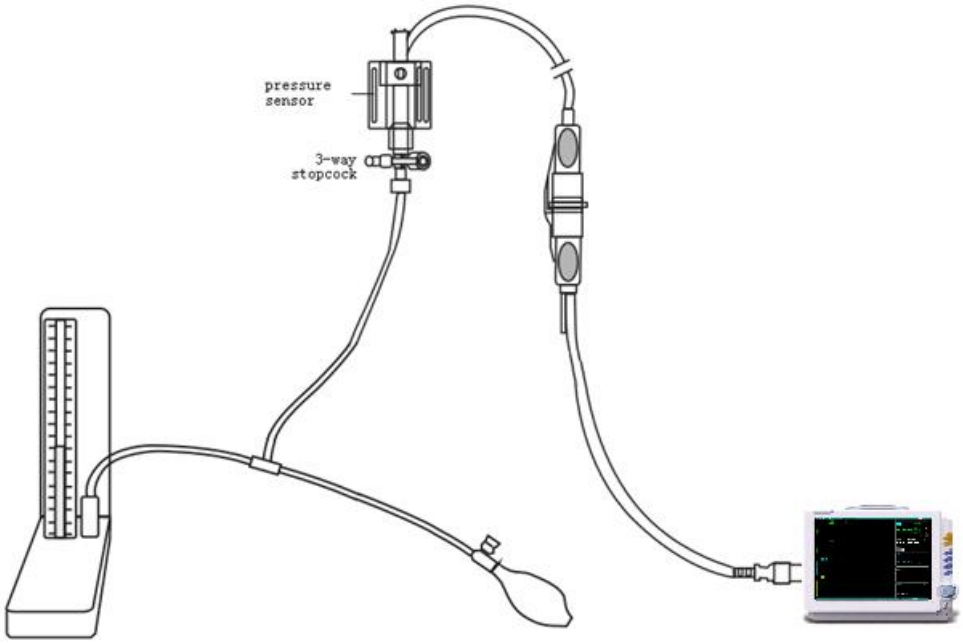


Chart 10- 1 IBP sensor connection

10.2 IBP Setting

Select “IBP Setting”menu will enter “IBP Setting” dialog:

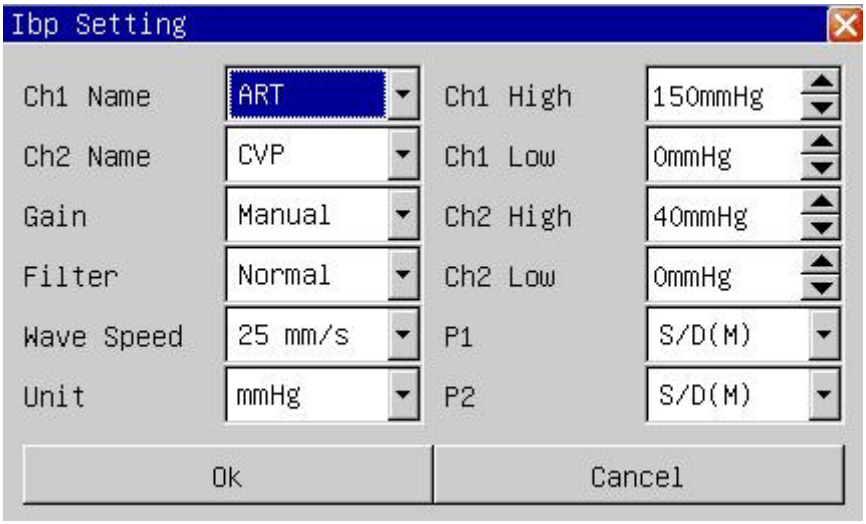


Chart 10-2 IBP Setting

1) Ch1 Name, Ch2 Name：set name of IBP channel 1 and 2: ART, PA, CVP, LAP , RAP , ICP , P1, P2.
2) Gain: when “Manual” is selected, the measure range is set by channel high or low gain mark ; when “Auto” is selected, when name is P1 or P2, the measure range is auto adjusted, otherwise is set by channel high or low gain mark.
3) Filter: when “normal” is selected, the IBP wave bandwidth is 40Hz; when “Smooth” is selected, the IBP wave bandwidth is 12.5Hz.
4) Wave Speed: 12.5mm/s or 25mm/s can be selected;
5) Unit：mmHg or kPa.
6) Ch1 High, Ch1 Low, Ch2 High, Ch2 Low：set channel 1 or channel 2 wave display range;
7) P1, P2：if “S/D(M)” is selected, systolic, mean and diastolic pressure are measured; if “MEAN” is selected, only mean pressure is measured.

10.3 IBP Zeroing

Steps of IBP zeroing:

1) Turn off the stopcock to the patient;
2) Vent the transducer to the atmospheric, to compensate for the static and atmospheric pressure exceed on the transducer;
3) Enter “IBP Zero” dialog, push “IBP1 Zero” or “IBP2 Zero” button to start zeroing;
4) When zeroing finished, turn the stopcock to the patient.

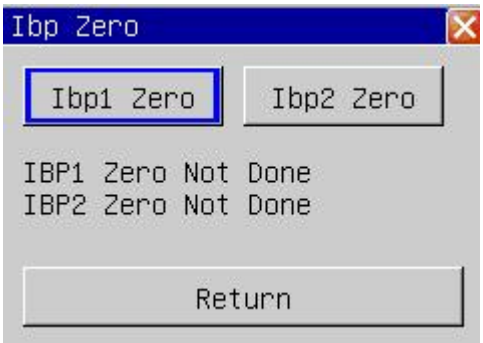


Chart 10-3 IBP Zero Dialog

Prompt information of IBP zeroing:

Prompt	Cause	Process Method
IBP Zero Fail: Lead Off	IBP sensor not connected	Verify the transducer is connected to the monitor, and then perform zeroing again. If the monitor continues to give this prompt information, contact Customer Service.
IBP Zero Fail: Over Range	Pressure is not zero	Verify the transducer is connected to the monitor and the 3-way stopcock is open to the atmosphere, then perform zeroing again. If the monitor continues to give this prompt information, contact Customer Service.
IBP Zero Fail: Pulsatile	Pressure is not stable	Verify the transducer is connected to the monitor and the 3-way stopcock is open to the atmosphere, then perform zeroing again. If the monitor continues to give this prompt information, contact Customer Service.

⚠ Warning ⚠

1、 Ensure zero the transducer before it is used to zero the monitor, otherwise will cause uncorrect measurement.

2、 Position the transducer at the same level with the patient's heart, approximately mid-axillary line.

3、 Perform zeroing before monitoring and between monitoring (at least once per day). The zeroing should also be conducted once the transducer cable is changed.

10.4 IBP Calibration

Steps of IBP Calibration:

1) Disconnect the pressure transducer from the patient. Using a T connector to connect the 3-way stopcock, the sphygmomanometer and the inflation orb as Chart 12-5 shown below;
2) Perform the pressure transducer zeroing. If the zeroing succeeds, open the stopcock to the sphygmomanometer;
3) Inflate using the inflation orb, until the mercury volume of the sphygmomanometer rises to 100~250mmHg;
4) In the "IBP Calibrate" menu, set the value for calibration which should be the same with the sphygmomanometer;
5) Press "IBP1 Calibrate" or "IBP2 Calibrate" to start calibrate;
6) After calibration, disconnect the blood pressure tubing and the T-shape connector. Then, connect the pressure transducer with the patient for normal monitoring;

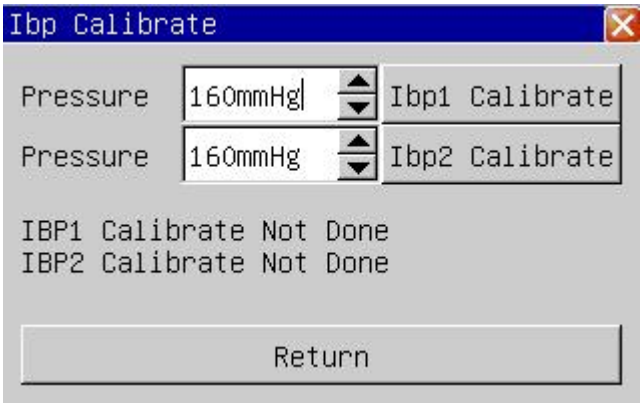


Chart 10-4 IBP Calibrate Dialog

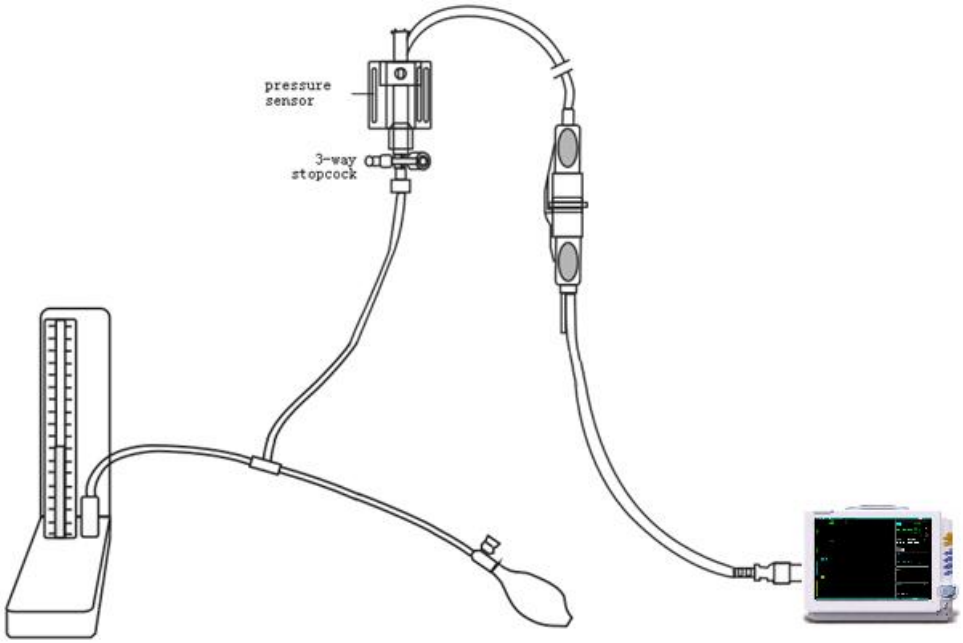


Chart 10-5 IBP Calibrate

IBP calibrate prompt message：

Prompt	Cause	Process Method
IBP need zero	IBP have not zeroed	Start zeroing IBP then calibrate again, if the message still exist, contact Customer Service.
IBP calibrate fail: Lead off	IBP sensor is not connected to the monitor	Verify the transducer is connected to the monitor, and then perform calibrate again. If the monitor continues to give this prompt information, contact Customer Service.
IBP calibrate fail: Over Range	IBP pressure is too high	Verify the transducer is connected to the monitor and the 3-way stopcock is open to the atmosphere, then perform zeroing again. If the monitor continues to give this prompt information, contact Customer Service.
IBP calibrate Fail: Pulsatile	IBP pressure is not stable	Verify the transducer is connected to the monitor and the 3-way stopcock is open to the atmosphere, then perform zeroing again. If the monitor continues to give this prompt information, contact Customer Service.

⚠ Warning ⚠

1、Ensure zero the transducer and perform zeroing before it is used to calibrate the monitor.

2、Calibration should be performed before using a new pressure transducer.

Chapter 11CO_2 Monitoring

11.1 Introduction

The monitor can measure CO_2 of patient's air way, displays 1 channel CO_2 wave form and $EtCO_2$(End Tidal CO_2), $FiCO_2$（Fraction of Inspired CO_2）, AwRR（AwRR：Air Way Respiration Rate）.

11.2 CO_2 Measurement

1) Connect the water trap to the socket and power up the monitor;
2) If prompt "CO_2 STANDBY", enter "CO_2 Setting" and change work mode to "RUN";
3) After monitor is power up, CO_2 waveform and values will be displayed.

11.3 CO_2 Setting

Choose "CO_2 setting" menu to enter "CO_2 Setting" dialog：

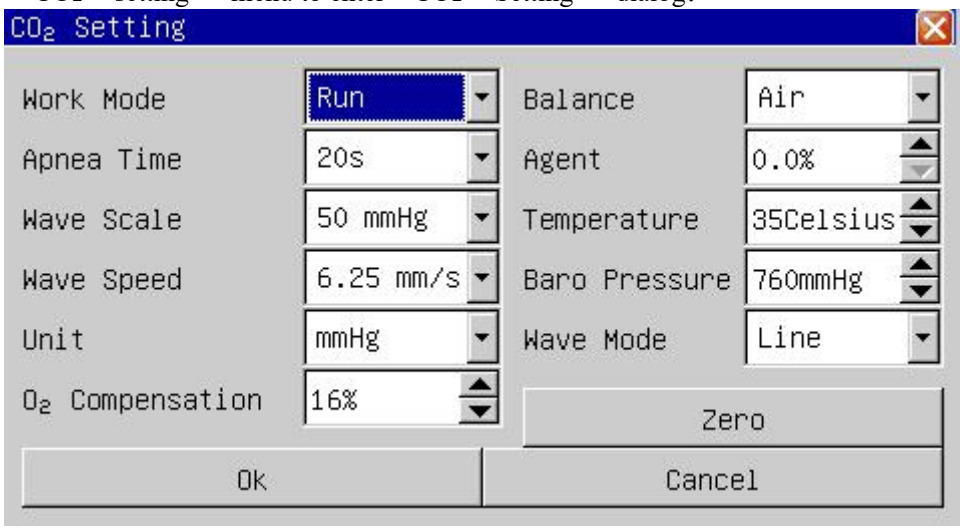


Chart 11-1 CO_2 Setting

1) Work Mode： when "Standby" is selected, CO_2 pump will be closed to lower the power consumption and extend the lifetime of CO_2 module;
2) Apnea Time： set delay time of apnea detection, from 10 seconds to 40 seconds. If the settings off, indicate the apnea alarm is closed.
3) Wave Scale：wave scale is 30~100mmHg;
4) Wave Speed：6.25mm/s,12.5mm/s,25.0mm/s;
5) Unit：mmHg, kPa, %, the formula of unit list below：
   CO_2（mmHg）= CO_2（%）×Pbaro（mmHg）/100
   CO_2（kPa）= CO_2（mmHg）/7.5
   PCO_2 : CO_2 pressure; Pbaro: barometer pressure,standard barometer is 760mmHg.
6) Rate：set CO_2 pump flow rate:50ml/min, 100ml/min, 150ml/min;
7) BTPS compensation：if "On" is selected, CO_2 module will auto compensate BTPS; if "Off" is selected, CO_2 module will not compensate BTPS. BTPS（Body temperature and pressure, Saturated）means the CO_2 is measured at a temperature of 37℃, a relative humidity of 95% and a 47mmHg (pH2O) partial pressure of moisture.
8) N_2O Compensate：Off, 20%, 40%, 60%;
9) O_2 Compensate：Off, 40%, 60%, 80%;

11.4 CO_2 calibrate

Select "CO_2 Calibrate" menu to enter"CO_2 Calibrate" dialog：

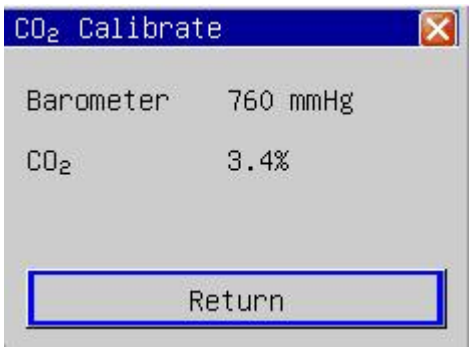


Chart 11-2 CO_2 calibrate

1) CO_2：set CO_2 calibration value to 5%~10%;
2) Barometer：display current atmosphere pressure;
3) Zero：press this button to start zeroing CO_2 module;
4) calibrate：press this button to start calibrating CO_2 module;

11.4.1 CO_2 zero procedure

1) Power on the monitor for 30 minutes;
2) Disconnect the filter line from the patient and make sure that the air in filter line have no CO_2;
3) Press "Zero" button in "CO_2 Zero"dialog;

11.4.2 CO_2 calibrate procedure

1) Power on the monitor for 30 minutes;
2) Connect a gas bottle with a 3-way connector to the monitor as shown below;
3) Set the CO_2 value in "CO_2calibrate" dialog the same with the CO_2 gas bottle;

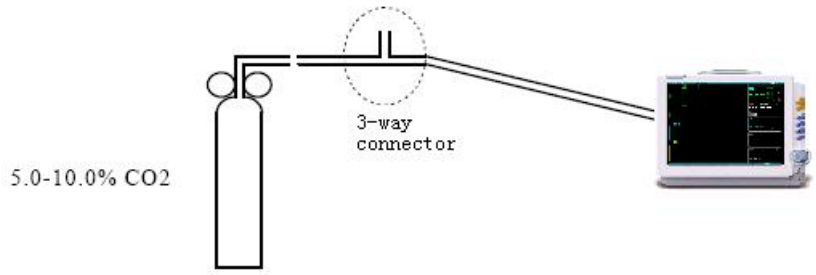


Chart 11-3 CO_2calibrate

Chapter 12Anesthesia Gas Monitoring

12.1 Overview

The anesthesia gas monitoring can be used for measuring the anesthesia gas and respiration gas of the patient in the anesthetic status. This monitor can configure IRMA AX+ gas module. Gas module provides the numerics of the gases mentioned below.

- Carbon dioxide (CO_2): The measured numeric is $EtCO_2$ (Max. exhaling value: Max. exhaling numeric detected during the respiration);
- Nitrous oxide (N_2O): Laughing gas;
- Oxygen (O_2);
- Anesthetic (AA): Refers to the monitored anesthetic (DES, ISO, ENF, SEV or HAL);
- Airway respiration rate (AwRR): respiration per minute (BrPM).

The patient monitor can display simultaneously a maximum of 4 waveforms, including the CO_2 waveform (default waveform), N_2O waveform, O_2 waveform and the anesthetic (ENF: Enflurane) waveform.

In addition, the patient monitor can display parameters, including CO_2, N_2O, O_2 and AA (Which refers to the monitored anesthetic: DES, ISO, ENF, SEV or HAL). It also displays the inhaling and exhaling numerics as well as MAC (Minimum Alveolar Concentration)/MAL (balance gas) and AwRR.

Parameters include: CO_2 (Carbon dioxide), N_2O (Nitrous oxide, laughing gas), O_2 (Oxygen), AwRR (Airway respiration rate, respiration per minute, BrPM), HAL: Halothame, ISO: Isoflurane, ENF: Enflurane, SEV: Sevoflurane, DES : Desflurane.

12.2 Measurement Principles and Procedure

The gas concentration is measured based on the rationale that the gas have the property of absorbing the infrared.

The gas module can measure gases that have various properties of absorbing the infrared. To measure the concentration of a gas, send it to the sampling room, select the infrared of a specific wavelength with an optical infrared filter, and transmit it through the gas. For a given volume of gas, the higher its concentration is, the more the infrared that will be absorbed by the gas is, and the less the infrared that will be transmitted through the gas is. The concentration of the measured gas is in inverse proportion to the volume of the infrared that is transmitted through the gas. Therefore, the gas concentration can be obtained by calculating the infrared. For the gas module that implements the measurements of multiple gases, multiple infrared filters are necessary.

The oxygen (O_2) does not absorb the infrared within the above-mentioned wavebands, so the oxygen is measured based on its paramagnetism. Inside the sensor of the O_2 module, there are two crystal balls full of nitrogen. They are suspended in the symmetrical magnetic field, and they are designed to point to the strongest outgoing part of the magnetic field. Outside the balls is the paramagnetic oxygen. Therefore, the balls are forced, by the relatively stronger paramagnetic oxygen, out of the magnetic field. The moment of the force acting on the balls is proportional to the paramagnetic strength as well as to the concentration of the oxygen.

Figure 12-1 IRMA gas module connection

12.3 Measurement Procedure

1) Plug IRMA gas module into the airway and connect IRMA cable to the “GAS” socket on the patient monitor;
2) If there are “IRMA Stand by” prompt on the screen, set “work mode” to “Run” in the “Gas Setting” dialog;
3) Co2, N2O, O2 and gas waveform and value will be displayed on the screen after gas module starts up.

12.4 Gas Setting

Enter “Gas Setting” dialog by select “Gas setting” menu:

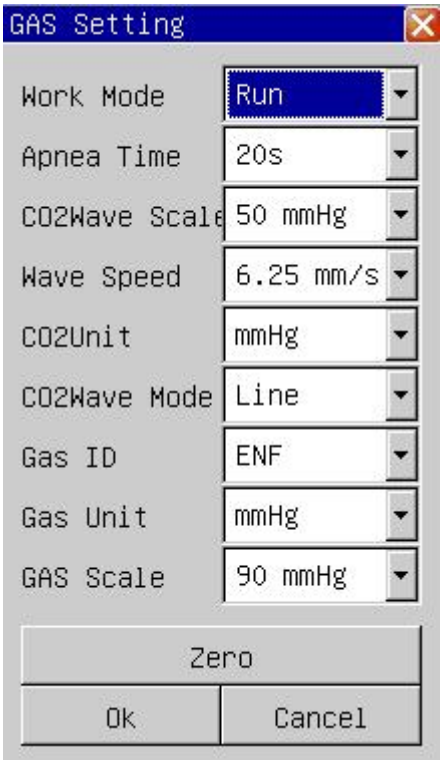


Figure 12-1 Gas Setting

10) Work Mode： when “Standby” is selected, gas IR source will be closed to lower the power consumption and extend the lifetime of gas module;
11) Apnea Time： set delay time of apnea detection, from 10 seconds to 40 seconds. If the settings off, indicate the apnea alarm is closed.
12) Wave Scale：wave scale is 30~100mmHg;

13) Wave Speed：6.25mm/s,12.5mm/s, 25.0mm/s;

14) Unit：mmHg, kPa, %, the formula of unit list below：
CO_2（mmHg）= CO_2（%）×Pbaro（mmHg）/100
CO_2（kPa）= CO_2（mmHg）/7.5

PCO_2 : CO_2 pressure; Pbaro: barometer pressure,standard barometer is 760mmHg.

1) Wave mode： “line” or “fill” mode can be selected；

2) Gas ID：set the anesthesia gas type: (DES, ISO, ENF, SEV or HAL). This selection is only enabled when using manual ID gas module.

3) Gas unit：mmHg、kPa、% can be selected；

4) Gas gain：wave scale is 30mmHg~150mmHg.

12.4.1 Gas zeroing procedure

4) Power on the patient monitor for at least 30 minutes;

5) Input gas without CO_2 and other anesthesia gases ;

6) Select “Zero” in “Gas Setting ” dialog;

7) “Zero OK” will be displayed on the screen when zero done.

Chapter 13History Review

The monitor can storage 72 hours trend data of the whole monitored parameters and 1000 noninvasive blood pressure measurement data. The monitor collects data of parameter every minute and preserves it in trend data, the operator may choose trend graph or trend table to examine the trend data. Every time the noninvasive blood pressure measurement data is obtained, it will be stored in the noninvasive trend data, the operator may choose the noninvasive blood pressure review to look over the noninvasive blood pressure trend data.

13.1 Trend Graph

The trend graph permits operator observing the stored trend data in graph mode. The recent 72 hours trend data is displayed as a trend curve with a resolution of 1 second, 5 second, 1 minute, 2 minutes, 3 minutes, 4 minutes or 5 minutes.

Choosing the “Trend Graph” in the “Review” menu will spring out the following window:

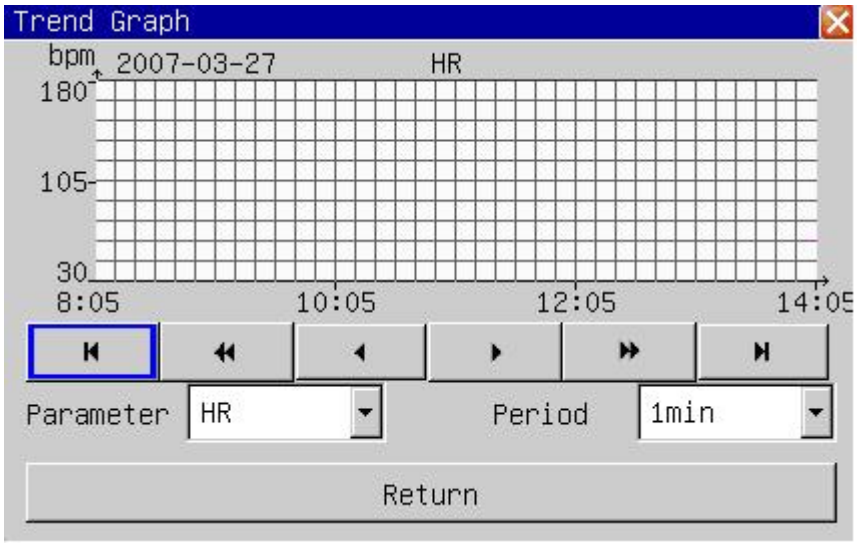


Chart 12- 1 Trend Graph

In trend graph window, time shows underneath the X axis, recent time is displayed on the nearest right side, scope value of parameters is displayed on left side of the Y axis.

13.1.1 Select parameters

By selecting the “parameter” list box with cursor, the operator may choose the parameter trend that is to be displayed. After the anticipant parameter appears, its trend graph will show in the window by pressing down the revolving button.

13.1.2 Set period

By selecting the “period” option, the operator may choose a period of 1 second, 5 seconds, 1 minute, 2 minutes, 3 minutes, 4 minutes or 5 minutes.

13.1.3 Adjust observing time

With the button “ ” and “ ”, the operator may move the time of trend graph a second length forward or backward (current period). With the button “ ” and “ ”, the operator may move the time of trend graph a page forward or backward. By selecting the button “ ” the operator may move the time of trend graph 72 hours forward, and “ ” to current time.

13.2 Trend table

The trend graph permits operator observing the trend data in tabulate mode. The recent 72 hours trend data is displayed as a trend curve with a resolution of 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes or 60 minutes.

Choosing the "Trend Graph" in the "Review" menu will spring out the following window:

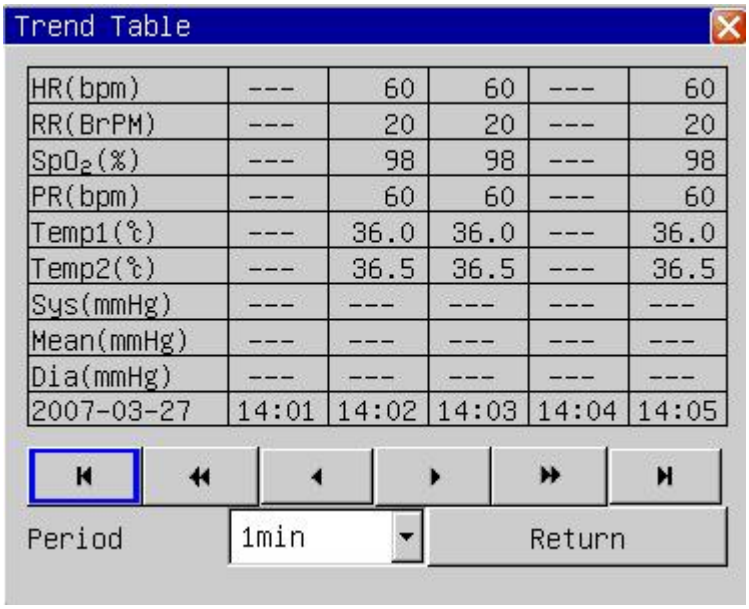


Chart 12-2 trend table menu

In the window of trend table, the time shows underneath the parameter tabulates, the recent time is displayed on the nearest right side, the parameter name and the unit are displayed in the first column.

The alarm events may also be observed in the trend table: The alarm time of parameter is saved in the trend data, if the parameter alarm, the trend data in the correspond alarm time period would be displayed with a yellow background color.

13.2.1 Set period

By selecting the "period" option with cursor, the operator may choose a period of 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes or 60 minutes.

13.2.2 Adjust observing time

With the buttons "◀" and "▶", the operator may move the time of trend graph a step length forward or backward (current period). With the buttons "◀◀" and "▶▶", the operator may move the time of trend graph a page forward or backward. By selecting the button "⏮", the operator may move the time of trend graph 72 hours forward, and "⏭"the current time.

13.3 Alarm Review

When physical alarm occurs, the monitor will save all the parameters and 16 seconds waveforms in the alarm event database. the monitor can display 200 alarm event in the alarm review.

Choosing the "Alarm Review" in the "Review" menu will display recent alarm event information, just as the following chart shows:

- Sequence number: format is I/N which I means the index of alarm event and N means the total alarm event number in the database, as chart 12-4 shown. new alarm has smaller number, eg, No 1 means the closest alarm.

- Alarm event's time;
- Alarm event's type;
- Parameters when alarm occurs;
- 2 channels of waveform, 16 seconds for both channels;

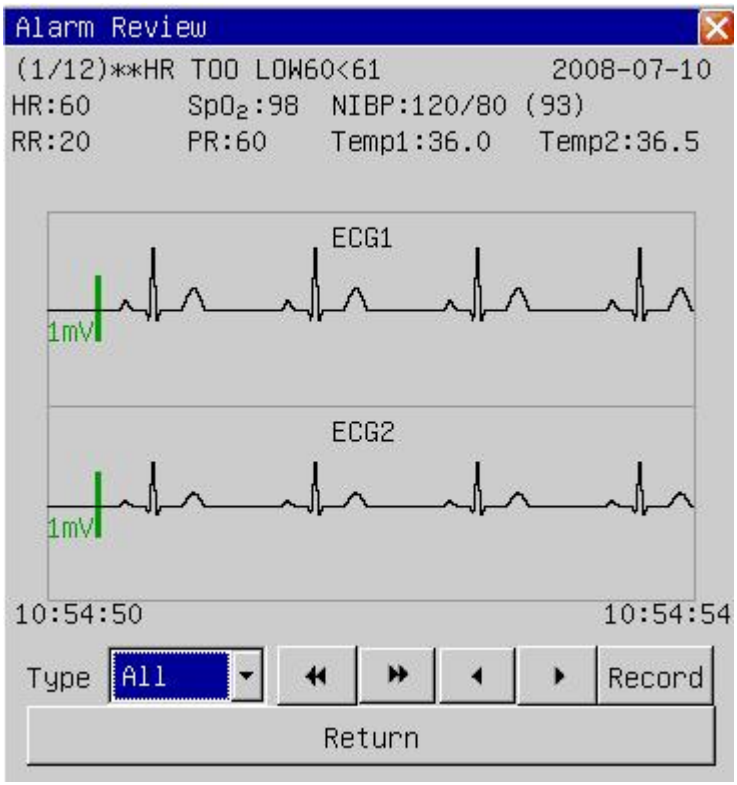


Chart 12- 4 NIBP measurement review

13.3.1 Alarm Type

There are 8 types of alarm event: "All", "ECG", "NIBP", "SpO2", "RESP", "TEMP", "IBP", "CO2", "All" means all parameters. User can select the parameter's alarm event to view.

13.3.2 Choose Alarm

User may use button " " and " " to choose alarm event. By selecting " " button, the previous event will be displayed, selecting " " button, the next event will be displayed,

13.3.3 Select waveform

With the buttons " " and " ", the operator may move the alarm waveform a page forward or backward.

13.3.4 Record

The recorder will output current alarm event if the user pressed button "Record".

13.4 NIBP Review

The monitor may display the recent 1000 pieces of noninvasive blood pressure measurement data in the NIBP review.

Choosing the “NIBP Review” in the “Review” menu will display the results and time of the recent 10 pieces of noninvasive blood pressure measurement, just as the following window shows:

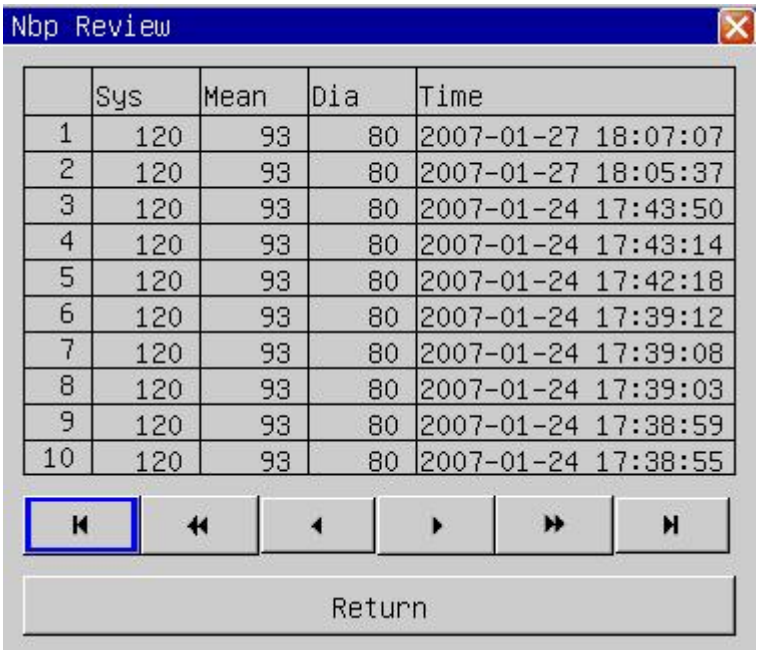


Chart 12- 4 NIBP measurement review

The data is arranged in order according to the time, the recent measurement data is displayed on the topside, 10 measurement data can be displayed on the screen each time. The buttons “ ◀ ” and “ ▶ ”can display the pre or the next measurement data. With the buttons “ ◀◀ ” and “ ▶▶ ”, the operator may move the time of trend graph a page forward or backward. By selecting the button “ ⏮ ”, the operator may see the earliest measurement data, and “ ⏭ ”the most recent.

13.5 Wave review

The monitor can display 1 hour waveform data in the waveform review.

Choosing the “wave review” in the “history review” menu will display the recent measurement waveform, just as the following chart shows:

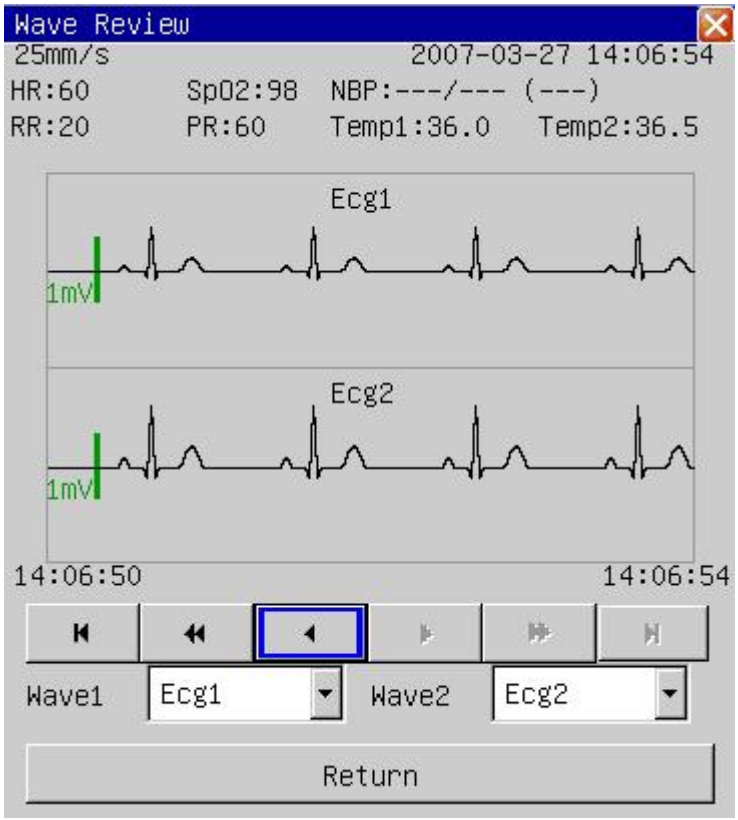


Chart 12- 5 waveform review

Above the waveform shows the interrelated information: waveform scanning velocity, current review time, the currently reviewed parameter measurement tabulate.

13.5.1 Select waveform

By selecting “waveform 1” and “waveform 2” with cursor, the operator may choose the waveform that he wants to observe: ECG1, ECG2, pulse wave and resp wave.

13.5.2 Adjust observing time

With the buttons “ “ and “ “, the operator may move the waveform a page forward or backward. With the buttons “ “ and “ “, the operator may move the waveform one minute forward or backward. By selecting the button “ “, the operator may move the waveform time one hour backward, and “ “the current time.

⚠ Attention ⚠

The trend data can be preserved for 720 hours after the turning off of the monitor. If the monitor is turned on after 720 hours’ power-off, the trend data would be eliminated.

The waveform review data can be preserved for 2 hour after the turning off of the monitor. If the monitor is turned on after 2 hour’s power-off, the waveform review data would be deleted.

Chapter 14 Drug Calculation

This monitor provides the function of computation for 21 kinds of medicines and the titration table.

14.1 Drug Calculation

The kinds of medicine that can be computed include: AMINOPHYLLIN, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, INOCOR, INSULIN, INSUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN, NOREPINEPHRINE, PITOCIN, PROCAINAMIDE, VASOPRESIN. DRUG A, DRUG B, DRUG C, DRUG D, DRUG E have been provided in addition to replace any kind of the medicine nimbly.

Selecting the “Drug Calculate” in the menu will spring out window as the following chart shows:

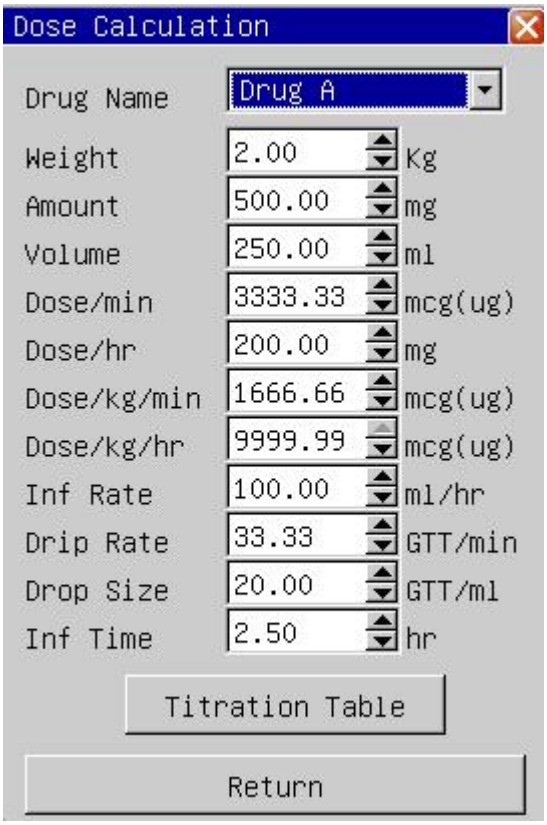


Chart 13- 1 Drug Calculate

The drug calculation can apply the following formulas:

Concentrate = Amount/volume
Inf rate = Dose / Concentrate
Durate = Amount / Dose
Dose = Inf rate × Concentrate

14.2 Operating procedures

In the Drug Calculate window, first the operator should choose the name of the drug that is to be computed, then confirm the patient's weight, and input other values that's already known.

Rotate the knob, move the cursor to each calculated item in the formula separately. Press down and rotate the knob, select the calculated values. After the selection, value of the calculated item will be displayed in the corresponding place.

Drug name selection: move the cursor to the "drug name", rotate the knob, may choose among the 21 kinds of medicines, AMINOPHYLLIN, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, INOCOR, INSULIN, INSUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN, NOREPINEPHRINE, PITOCIN, PROCAINAMIDE, VASOPRESIN, DRUG A, DRUG B, DRUG C, DRUG D, DRUG E. Only one type of medicine can be computed each time.

14.3 Titration table

Select the "Titration Table" in the "Drug Calculate" menu to turn into the interface of titration table.

The following chart shows the interface of the titration table:

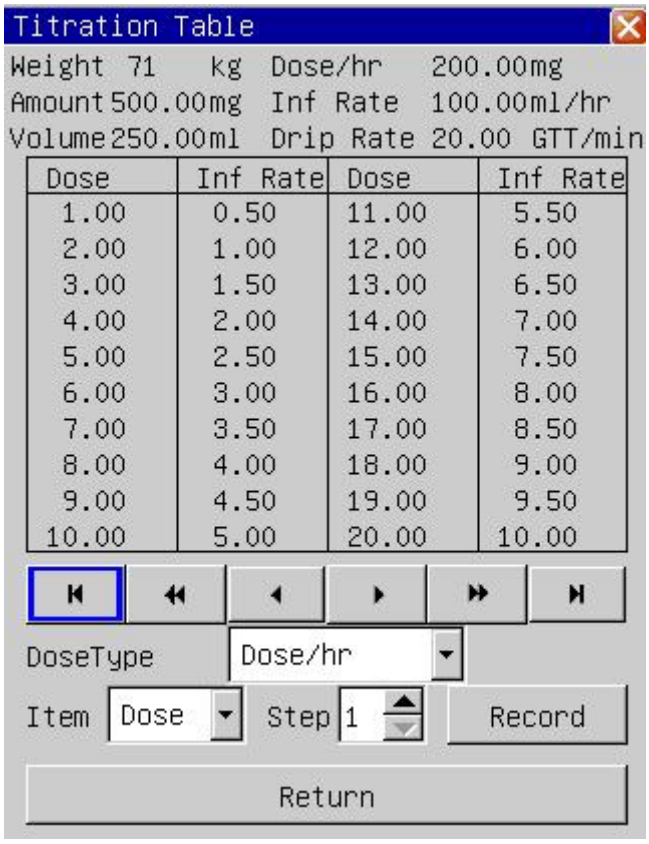


Chart 13-2 titration table

1) Move the cursor to the “DoseType” option, press down the knob to choose dosage unit.

2) Move the cursor to the “Item” option, then press down the knob to choose “Dose”, “Inf Rate”. The selection of “Dose” will calculate the infusion rate taking the dose as the basis of calculation, otherwise the dose taking infusion rate as the basis of calculation.

3) Move the cursor to the “step” option, press down the knob to choose length of step. The optional scope is 1~10.

4) With the buttons “ ” and “ ”, the operator may move the titration table a step backward or forward. With the buttons “ ” and “ ”, the operator may move the table a page forward or backward. By selecting the button “ ”, the operator may display the minimum titration table data, and “ ” the maximum.

5) The recorder will output current titration table if “Record” button is pressed.

6) Move the cursor to the “Return” button, press down the knob to get back to the “Drug Calculate” menu.

Chapter 15 Maintenance and Cleaning

15.1 System Check

Before using the monitor, you shall check:

- Check if there is any mechanical damage;
- Check if all the outer cables, inserted modules and accessories are in good condition;
- Check if all the monitoring functions of the monitor can work normally so as to make sure that the monitor is in good condition.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or XXX Customer Service Department immediately.

The overall check of the monitor, including the functional safety check, must be performed by qualified personnel once every 6 to 12 month or each time after fix up.

All checks that need to open the monitor enclosure must be performed by qualified service personnel. Safety and maintenance check may also be conducted by persons from XXX. You can obtain the material about the customer service contract from the local XXX office.

⚠ Warning ⚠

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

15.2 General Cleaning

⚠ Warning ⚠

Turn off the power and disconnect the line power before cleaning the monitor or the sensor/probe.

The Multi-Parameter Patient Monitor must be kept dust-free.
It is recommended that you should clean the outside surface of the monitor enclosure and the display screen regularly. Only use non-caustic detergents such as soap and water to clean the monitor enclosure.

⚠ Caution ⚠

Pay special attention to avoid damaging monitor:

1. **Avoid using ammonia-based or acetone-based cleaners such as acetone.**
2. **Most cleaning agents must be diluted before use. Dilute the cleaning agent as per the manufacturer's direction.**
3. **Do not use the grinding material, such as steel wool etc.**
4. **Do not let the cleaning agent enter the monitor. Do not immerse any part of the system into liquid.**
5. **Do not leave the cleaning agents at any part of the equipment.**

Cleaning Agents

Except the solutions specified in the above **Caution**, you can use any of the solutions listed below

as the cleaning agent.

- Diluted Ammonia Water
- Diluted Sodium Hyoichlo (Bleaching agent).

⚠ **Note** ⚠

The diluted sodium hyoichlo from 500ppm (1:100 diluted bleaching agent) to 5000ppm (1:10 bleaching agents) is very effective. The concentration of the diluted sodium hyocihlo depends on how many organisms (blood, mucus) are left on the surface of the enclosure.

- Diluted Formaldehyde 35% -- 37%
- Hydrogen Peroxide 3%
- Alcohol
- Isopropanol

⚠ **Note** ⚠

You can use hospital-grade ethanol to clean monitor and its sensor/probe and leave it to dry naturally or use clean cloth to dry it.

⚠ **Note** ⚠

XXX has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

Sterilization

To avoid extended damage to the equipment, sterilization is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Sterilization facilities must be cleaned first.

Recommended sterilization materials: Ethylate, and Acetaldehyde.

Appropriate sterilization materials for ECG lead and blood pressure cuff are introduced **Chapter ECG/RESP Monitoring** and **Chapter NIBP Monitoring** respectively.

⚠ **Caution** ⚠

- **Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible concentration.**
- **Do not let liquid enter the monitor.**
- **Do not immerse any part of the monitor into liquid.**
- **Do not pour liquid onto the monitor during sterilization.**
- **Use a moistened cloth to wipe off any agent remained on the monitor.**

Disinfection

To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.

Appropriate disinfection materials for ECG lead, SpO_2 sensor, blood pressure cuff and TEMP probe are introduced in **relevant chapters.**

⚠ **Caution** ⚠

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

Chapter 16Patient Safety

The Patient Monitor is designed to comply with the International National Safety requirements for medical electrical equipment, IEC60601-1, EN60601-2-27 and EN60601-2-30. This device has floating inputs and is protected against the effects of defibrillation and electrosurgery. If the correct electrodes are used and applied in accordance with the manufacturer instructions (see Chapter ECG/RESP Monitoring), the system can restore screen display within 10 seconds after defibrillation.

This symbol indicates that the instrument is IEC60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.

⚠Warning⚠

Do not come into contact with patients, bed or the monitor during defibrillation.

Environment

Follow the instructions below to ensure complete and safe electrical installation. The environment where the PM-5000 Multi-Parameter Patient Monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

The Patient Monitor operates within specifications at ambient temperatures between 0℃ and 40℃. Ambient temperatures that exceed these limits may affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5cm) clearance around the instrument for proper air circulation.

Power Requirements

See Chapter 14 Appendix - Specifications.

Grounding

To protect the patient and hospital personnel, the enclosure of the Patient Monitor must be grounded. Accordingly, the Patient Monitor is equipped with a detachable 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electrician.

⚠**Warning**⚠

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

The ground equipment and other potential associated to the ground terminal. From the instrument specifications confused whether a particular combination of dangerous equipment, such as leakage current caused by the accumulation of dangerous, the user should consult the manufacturers or other experts in this field to ensure that all instruments which necessary security will not be damaged by the proposed combination.

Equipotent grounding

When other devices used in conjunction with the monitor, you should also use the wire to the rear panel monitors and other potential ground terminal and other equipment such as potential ground terminal connected to different equipment to eliminate potential difference between the grounds and ensure safety.

Condensation

In the work, to ensure no condensation apparatus, when the equipment from one room to another room to go, it may form a condensation. This is because the equipment exposed to humid air and the temperature difference among the reasons.

⚠**Warning**⚠

If there are places where flammable anesthetics used, there will be a risk of explosion.

Chapter 17EMC

The monitor meets the requirements of IEC 60601-1-2:2001

⚠ **Caution** ⚠

The use of unapproved accessories may diminish the monitor performance.

⚠ **Note** ⚠

The monitor should not be used adjacent to or stacked with other equipment. If adjacent or tacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.

⚠ **Note** ⚠

The monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

⚠ **Note** ⚠

Portable and mobile RF communications equipment can affect this monitor. See tables 1,2,3, and 4 below.

TABLE 1

Guidance and declaration — electromagnetic emissions

The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment — guidance**
RF emissions CISPR 11	Group1	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic Emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliance	

TABLE 2

Guidance and declaration — electromagnetic immunity

The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment — guidance**
Electrostatic Discharge(ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast	±2 kV for power	±2 kV for power	Mains power quality should be that

Transient/burst IEC 61000-4-4	supply lines ±1 kV for input/output lines (>3m).	supply lines ±1 kV for input/output lines (>3m).	of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV different mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation 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 of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) 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.

UT is the A.C. mains voltage prior to application of the test level.

TABLE 3

Guidance and declaration — electromagnetic immunity

The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment — guidance
Conduced RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to

Radiated RF IEC 61000-4-3	**3 V/m 80MHz to 2.5 GHz**	3V/m	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:** 

Note — At 80 MHz and 800 MHz, the higher frequency range applies.

Note — 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 monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.

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

TABLE 4

Recommended separation distances between portable and mobile RF communication and the monitor

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

Rated Maximum Output power of Transmitter W (Watts)	**Separation Distance According to Frequency of Transmitter M (Meters)**		
	150kHz -2MHz $d = 1.2\sqrt{P}$	80MHz -800MHz $d = 1.2\sqrt{P}$	800MHz -2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined 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 — At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Chapter 18 Appendix - Product Specifications

⚠ Warning ⚠

The patient monitor may not meet its performance specification if stored or used outside the manufacturer's specified temperature and humidity range.

18.1 Classification

Item	Specification	
MDD classification	Class Iib	
Anti-electroshock degree	Class I equipment with internal power supply	
Anti-electroshock degree	TEMP/SpO_2/NIBP：	BF
	ECG/RESP	CF
Explosion proof level	Ordinary equipment， without explosion proof	
Harmful liquid proof degree	IPX1	
Working system	Continuous running equipment	
Movement grade	portable	

18.2 applicable standards

Medical Device Directive 93/42/EEC

EN60601-1+A1+A2 or IEC60601-1+A1+A2, Medical Electrical Equipment, Part 1: General Requirements for Safety

EN60601-1-1 or IEC60601-1-1, Medical Electrical Equipment- Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems

IEC60601-1-4, Medical Electrical Equipment- Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems

IEC60601-2-49 Medical Electrical Equipment-Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment

IEC 60601-1-2:2007,Electromagnetic Compatibility – Medical Electrical Equipment

18.3 size and weight

Model	Size	Weight
7”	192×148×91 mm	1.2 Kg
8”	212×172×81 mm	1.6Kg
12”	306×287×172 mm	3.4Kg
15”	306×287×172 mm	4.3Kg

18.4 Power Supply

Model	External power required	Input power
7”, 8”	d.c. 16.8V 1.5A	< 25W
12”, 15”	a.c.100V~240 V, 50 Hz /60 Hz	Pmax=90VA FUSE:T1.5AL 250V

18.5 Battery

2200 mAh 14.8V rechargeable battery

Model	Operating time (Hour)
7”	5.5
8”	4
12”	3.5
15”	1.5

Note:Operating time after the first alarm of low battery will be about 5 minutes
Maximum charging time is less than 6 hours.

18.6 Signal Interface

Network interface standard RJ45 Socket

18.7 Storage

Trend	720 hours
NIBP review	1000 NIBP events
Wave review	2 hours
Alarm review	200 alarm events

All storage data are non volatile.

18.8 Environment

Temperature

Working	0 ~ 40 °C
Storage	-20 ~ 50°C

Humidity

Working	15% - 90 %
Storage	15% - 90 % (no coagulation)

Atmospheric pressure

Working	86.0 kPa ~ 106.0kPa;
Storage	86.0 kPa ~ 106.0kPa

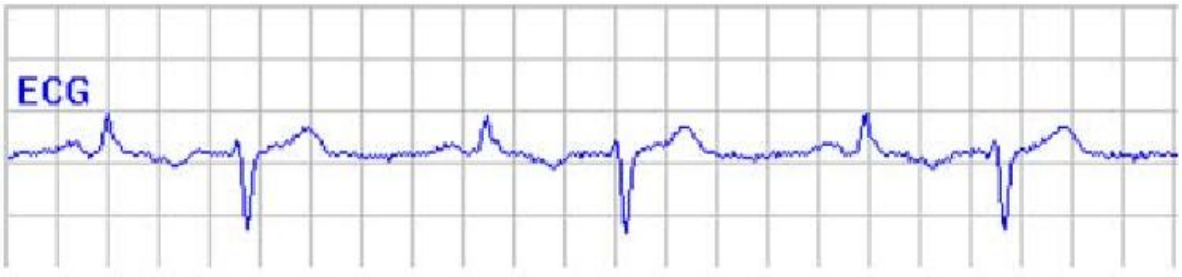
18.9 ECG

18.9.1 Heart rate calculation method

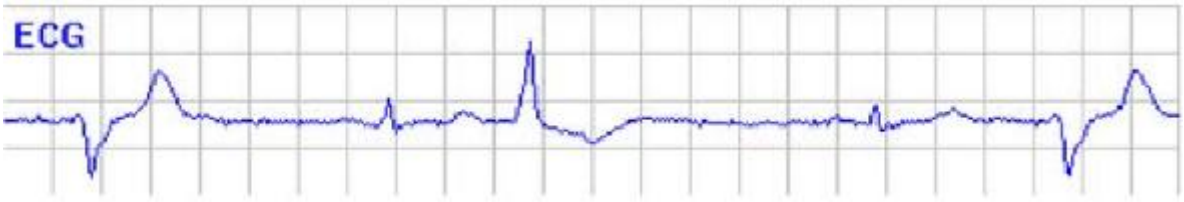
The average of the last 4 R-to-R intervals, when last 3 R-to-R intervals > 1200msec. Otherwise, the average of the last 12 R-to-R intervals, minus the maximum and minimum values. The update rate of the Heart Rate on the display is once per second.

18.9.2 Heart rate meter accuracy and arrhythmia response

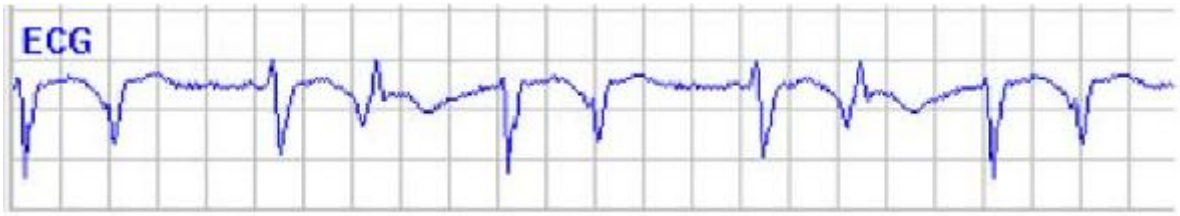
After 20s stable time, the monitor will display a): heart rate display 40bpm ± 5bpm; b): heart rate display 30bpm ±5bpm; c): heart rate display 120bpm±5bpm; d): heart rate display 45bpm±5bpm.



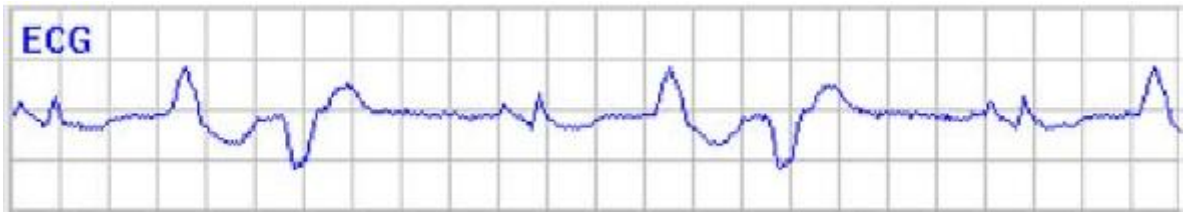
a) Couplet rhythm — two waves of duration is 1500ms; if calculate all the QRS complex, heart rate is 80bpm, if only calculate large R wave or S-wave, the heart rate is 40bpm.



b) Slow change couple rhythm — if calculate all the QRS complex, heart rate is 60bpm, if only calculate large waves, heart rate is 30bpm.



c) Fast couple rhythm — if the calculate all the QRS complex, heart rate is 120bpm.



d) bi-directional contraction — if calculate all the QRS complex, heart rate is 90bpm, if only large waves, heart rate is 45bpm.

18.9.3 Lead mode

5 Leads: RA、LA、LL、RL、V; lead mode: I, II, III, AVR, AVL, AVF, V

18.9.4 Gain

×2.5mm/mV, 5.0mm/mV, 10mm/mV, 20mm/mV

18.9.5 Sweep speed

12.5mm/s, 25mm/s, 50mm/s

18.9.6 Heart rate

Measure range:	
Adult	15 ~ 300 bpm
Neonatal/Pediatric	15 ~ 350 bpm
accuracy	± 1%
resolution	1 bpm

18.9.7 Sensitivity

> 200 μV P-P

18.9.8 Differential Input Impedance

> 5 M ohm

18.9.9 Bandwidth

Surgery	1 ~ 20 Hz
Monitor	0.5 ~ 40 Hz
Diagnostic	0.05 ~ 130 Hz

18.9.10 CMRR

Diagnostic Mode	>90 dB
Monitor Mode	>110 dB
Surgery Mode	>110 dB

18.9.11 Electrode offset potential

±300mV

18.9.12 Input dynamic range

The device shall be capable of responding to and displaying differential voltages of ±5 mV varying at a rate up to 320 mV/s from a dc offset voltage in the range of .300 mV to +300 mV, when applied to any lead. The time-varying output signal amplitude shall not change by more than ±10 percent over the specified range of dc offset.

18.9.13 Pace pulse suppression

when the pace switch is "On", the patient monitor can inhibit pace pulse without affect heart rate calculation: ± 2 mV ~ ± 700mV, width: 0.1ms ~ 2ms, rise time: 10us ~ 100μs normal QRS wave single pulse without overshoot pacing pulse.

when the pace switch is "On", the patient monitor can inhibit pace pulse without affect heart rate calculation: ± 2 mV ~ ± 5mV, width: 0.5ms ~ 2ms, rise time: 10us ~ 100μs single pulse overshoot normal QRS waves of pacing pulses.

Overshoot (a0) range should 0.025ap to 0.25ap range, independent of the choice of time constant, but not more than 2mV;

when the pace switch is "On", pace pulse inhibition of rapid ECG signal to 1V / s RTI minimum input slew rate.

18.9.14 QRS wave amplitude and period range between

The minimum range of QRS amplitude (ar + as) is 0.5 mV to 5 mV, and the duration of the QRS wave is between 70 ms and 120 ms (40 ms and 120 ms for neonatal/pediatric monitors). For monitors set for adult patients, the heart rate meter shall not respond to signals having a QRS amplitude of 0.15 mV or less, or a duration of 10 ms or less with an amplitude of 1 mV. Response to either or both of these types of signals is permitted in monitors set for neonatal/pediatric patients.

18.9.15 Line frequency voltage tolerance

The maximum line frequency peak-to-valley sinusoidal voltage amplitude that can be superimposed on a train of QRS signals without exceeding the error limits of ±10% for indicated heart rate accuracy shall be no less than 100 μV p-v. The QRS signal shall have an amplitude of 0.5 mV, a duration of 100 ms, and a repetition rate of 80 bpm.

18.9.16 Drift tolerance

The monitor shall indicate the heart rate within the error limits of 80bpm ± 8bpm when a 0.1 Hz triangular wave of 4 mV p-v amplitude is superimposed on a train of QRS signals of 0.5 mV amplitude, 100 ms duration, and 80 bpm repetition rate.

18.9.17 Baseline stability

Reset: reset recovery time is not greater than the 3s;

Baseline Stability: After boot, 10s baseline drift in the output rate should not exceed 10μV / s RTI;

After boot, 1h, total drift should not exceed 500μV / s RTI;

Working temperature should not exceed 50μV / ℃

18.9.18 system noise

No more than 30μV (p-v RTI)

18.9.19 Multi-channel crosstalk

Any input signal limited in amplitude and rate of change as per 14.7.12, applied to any one lead of a multi-channel monitor, and with all unused inputs connected to patient reference through a 51 kilohm resistor in parallel with a 47 nF capacitor, shall not produce an unwanted output greater than 5% of the applied signals (multiplied by the gain) in those channels where no signal is applied.

18.9.20 Electro surgery interference suppression

The heart rate shall not change by more than ±10 percent of the rate before electrosurgical interference was activated while the interference is applied for less than 10s.

18.9.21 Pace pulse display capabilities

An indication of the pacemaker pulse shall be visible on the display with an amplitude of no less than 0.2 mV RTI.

18.9.22 heart rate response time

The maximum response time is less than 10 s, for step change of heart rate from 80bpm to 120bpm;

The maximum response time is less than 10 s , for step change of heart rate from 80bpm to 40bpm;

18.9.23 Baseline Recovery

< 3 s After defibrillation.

18.9.24 Signal Range

± 8 mV p-p

18.9.25 Calibration Signal

1 mV p-p, ± 5% accuracy

18.10Respiration

18.10.1 Method

Impedance between RA-LL

18.10.2 Respiration Impedance Range

0.3~3 Ω

18.10.3 Base Impedance Range

200 Ω -4000 Ω

18.10.4 Bandwidth

0.3 ~ 2.5 Hz

18.10.5 Gain

×0.25,×0.500,×1,×2,×4

18.10.6 Respiration Rate

Measurement Range		
	Adult	0 ~ 120 BrPM
	Neonatal / Pediatric	0 ~ 150 BrPM
Resolution		1 BrPM
Accuracy		0～6 BrPM: unspecified
		7～150 BrPM: ±2 BrPM

18.10.7 Apnea Alarm

10 ~ 40 s

18.11NIBP

18.11.1 Method

Oscillometry

18.11.2 Measure mode

Manual, Auto, STAT

18.11.3 Measure Interval in AUTO Mode

1,2,3,4,5,10,15,30,60,90,120,180,240,480 min

18.11.4 Measure Period in STAT Mode

5 min

18.11.5 Pulse Rate Range

40 ~ 240 bpm

18.11.6 Measure and Alarm Range

Adult Mode		
	SYS	40 ~ 280 mmHg
	DIA	10 ~ 220 mmHg
	MEAN	20 ~ 240 mmHg
Pediatric Mode		
	SYS	40 ~ 220 mmHg
	DIA	10 ~ 160 mmHg
	MEAN	20 ~ 170 mmHg
Neonatal Mode		
	SYS	40 ~ 135 mmHg
	DIA	10 ~ 100 mmHg
	MEAN	20 ~ 110 mmHg

18.11.7 Static pressure accuracy

±3mmHg

18.11.8 Resolution

1mmHg

18.11.9 Accuracy

Maximum Mean error	±5mmHg
Maximum Standard deviation	8mmHg

18.11.10 Overpressure Protection

Adult	300 mmHg
Pediatric	240 mmHg
Neonatal	150 mmHg

18.12 SpO_2

18.12.1 Measurement Range

0 ~ 100 %

18.12.2 Resolution

1 %

18.12.3 Accuracy

70% ~ 100%	±2 %
<69%	unspecified

18.12.4 Pulse Rate

Measure and Alarm Range	20~250bpm
Resolution	1bpm
Accuracy	±3bpm

18.12.5 Perfusion Index

Measure and Alarm Range	0.02~20%
Resolution	0.01%

18.13 Temperature

Sensor Type	10K series，2.25K series
Channel	7 inch and 8 inch are one，12.1 and 15 inch are two
Measure and Alarm Range	0 ~ 50 ℃
Resolution	0.1℃
Accuracy(no sensor)	± 0.1℃(0℃ – 50℃)

18.14 IBP(optional)

18.14.1 Sensor

reusable sensors：OHMEDA P23XL or BD, EDWARD compatible

once usage：OHMEDA DT-4812 or BD, EDWARD compatible

excitation voltage：＋5Vdc±2%

sensitivity：5uV/V/mmHg

18.14.2 Channels

2 channels

18.14.3 Measuer Range

-50~ 360（mmHg）

18.14.4 Resolution

1mmHg

18.14.5 Accuracy(no sensor)

±2% or ±1mmHg, use the greater

18.14.6 Band Width

Normal mode: DC～40Hz

Smooth mode: DC～12.5Hz

18.15 CO_2(optional)

18.15.1 Measuer Range

0% ~ 13%

18.15.2 Resolution

1 mmHg

18.15.3 Accuracy

2 mmHg @ < 5.0% CO_2 (at ATPS)

18.15.4 Breath Rate

Breath Rate: 3 - 150 bpm

18.16 IRMA Gas (optional)

18.16.1 Measuer Range

CO2	0 - 15 %
O2	0 - 10 %
N2O	0 - 15 %
HAL, ISO, ENF	0 - 100 %
SEV	0 - 8 %
DES	0 - 18 %

18.16.2 Accuracy

CO2	± (0.2 %ABS + 2 %REL)
O2	± (1 %ABS + 2 %REL)
N2O	± (2 %ABS + 2 %REL)
HAL, ISO, ENF	± (0.15 %ABS + 2 %REL)
SEV	± (0.15 %ABS + 2 %REL)
DES	± (0.15 %ABS + 2 %REL)

18.16.3 Breath Rate

Breath Rate: 0 - 150 bpm， ±1bpm

18.17Recorder(optional)

No recorder for 7 inch and 8 inch.

Paper width	48 mm
speed	25/50 mm/s
wave channel	3 channels

18.18Default Setting

Patient Information

Patient Type .	Adult
Bed number	1
Gender	Male

Alarm Setting

Alarm Volume	5
Flicker	Off
parameter Alarm	None bolt-lock
Alarm Record	Off
Voice Alarm	On

Record Setting

Record Waveform 1	ECG1
Record Waveform 1	ECG2
Record Length	8S
Inter-record Gap	Off
Record Speed	25mm/s
Record Grid	On

ECG Setting

Pacemaker	Off
Channel 1 Lead	II
Channel 1 Amplitude	X1
Channel 2 Lead	I
Channel 2 Amplitude	X1
Notch	On
Filter	Monitor
Heartbeat Volume	5
Waveform Speed	25mm/s
HR Source	Auto

RESP Setting

Apnea Time	40s
Waveform Size	X2

Waveform Speed 6.25 mm/s

SpO2 Setting

Pulse Volume 5
Sensitivity Medium
Waveform Speed 25mm/s
PR Off
Waveform Mode Line

NIBP Setting

Unit mmHg
Mode Auto
Period 10 minutes

Temp Setting

Unit ℃

IBP Setting

Unit mmHg
Mode Normal
Ch1 ART
Ch2 PA

CO2 Setting

Unit mmHg

Alarm Limits Setting

Parameters	Adult	Pediatric	Neonate	Unit
HR High Alarm Limit	120	160	200	bpm
HR Low Alarm Limit	50	75	100	bpm
Resp High Alarm Limit	30	30	100	brpm
Resp Low Alarm Limit	8	8	30	brpm
SpO2 High Alarm Limit	100	100	95	%
SpO2 Low Alarm Limit	90	90	80	%
PR High Alarm Limit	20	160	200	bpm
PR Low Alarm Limit	50	75	100	bpm
Sys High Alarm Limit	160	120	90	mmHg
Sys Low Alarm Limit	90	70	40	mmHg
Mean High Alarm Limit	110	90	70	mmHg
Mean Low Alarm Limit	60	50	25	mmHg
Dia High Alarm Limit	90	70	60	mmHg
Dia Low Alarm Limit	50	40	20	mmHg
Temp High Alarm Limit	39.0	39.0	39.0	℃
Temp Low Alarm Limit	36.0	36.0	36.0	℃
Co2 Et High Alarm Limit	50.0	50.0	50.0	mmHg
Co2 Et Low Alarm Limit	15.0	15.0	15.0	mmHg
Co2 Fi High Alarm Limit	4.0	4.0	4.0	mmHg
Co2 Fi Low Alarm Limit	0.0	0.0	0.0	mmHg