

COMEN

CE 0434

Neonate Patient Monitor

C60

User Manual

Shenzhen ComenMedical Instruments Co., Ltd.

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Edition: B

Date: 2014/09

Part No: 046-000558-01

Product Name: Neonate Patient Monitor

Product Model: C60

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Preface

In this Instruction Manual, the performance, operation method and other safety information of the C60 Neonate Patient Monitor (hereinafter referred to as Monitor or Patient Neonate Monitor) are described in detail. Here is the best starting point for new users to use their monitors.

Performance, Structure and Composition

The monitor is mainly comprised of host machine and corresponding functional accessories (ECG cable, noninvasive blood pressure cuff, blood oxygen sensor, body temperature sensor, IBP sensor, CO2 sensor, Oxygen sensor, neonatal asphyxia wake up etc.).

Applicable Scope

The Neonate Patient Monitor (“the Monitor”) is applicable to the monitoring or measuring of neonate patient physiological sign parameters such as ECG, noninvasive blood pressure, pulse oxygen saturation, body temperature, respiration, pulse frequency / pulse, invasive blood pressure, carbon dioxide of the expiration tip, with the functions of respiratory oxygenation chart analysis, ST segment analysis, arrhythmia analysis and drug calculation.

Applicable Objects of the Product

This instruction manual is applicable to the professional clinical medical staff or the persons who are experienced in using the monitoring equipment for reading. The readers shall have the knowledge and working experience in medical procedure, practice and terms necessary for monitoring the patients.

Figures

All the figures provided in this Instruction Manual shall be for your reference only. The menus, options, values and functions in the figures may be not entirely consistent with what you see from the monitor.

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Revision history

The table below shows major changes and additions in each revision of this manual.

No.	Edition	Date	Description
1	A	2014/04	See edition A of this document
2	B	2014/09	Changed the EC representative and its address as “Lotus Medical Equipment Limited; Add: 26B Cameron Court, Cork Street, Dublin 8, Ireland; Tel: +00353-1-6571034; Email: peter@lotusme.org”

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Chapter 1 General Information

1.1 Safety Information

Warning

- To warn you of the conditions where serious consequence, disadvantageous matters or danger may occur. Failure to comply with the warning will result in severe personal injury or death of the user or the patient.

Caution

- To indicate potential danger or unsafe operation. If not avoided, it may lead to mild personal injury, product malfunction, damages or property loss. It may also give rise to more severe harm.

Attention

- It emphasizes primary warnings or provides descriptions or explanations so that this product can be used in a better way.

Warning

- This monitor is used for monitoring the clinical patients, so only the doctors and nurses who are qualified through training can use this monitor.
- Before use, the user shall check whether this instrument and its accessories can work normally and safely.
- The alarm volume and upper and lower limits for alarm shall be set for different patients. When a patient is monitored, the audible alarm system cannot be merely depended on. If the alarm volume is set too low or is completely turned off, the alarm will fail and the patient safety will be endangered. The most reliable patient monitoring method shall be to closely monitor the actual clinical situation of the patient.
- This instrument can only be connected to a power socket with protective grounding. If the power socket is not connected to a grounding conductor, do not use this socket, but use the

rechargeable batteries for power supply.

- Do not open the shell of this instrument to avoid the possible electric shock hazard. The maintenance and upgrading of this monitor must be conducted by the service personnel trained and authorized by Comencomany.
- The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. The packaging materials must be placed away from the children.
- Do not use this instrument at the place where there are flammable articles such as anesthetic to prevent explosion or fire from happening.
- Please carefully install the power lines and the cables for various accessories to avoid the patient from being constricted or suffocated or the cables from getting entangled and keep the patient free from electrical interference.
- Do not use mobile phone near the monitor, because the mobile phone will generate a very strong radiation field and disturb the functions of the monitor.
- For the patient with pacemaker, cardiometer might measure the heart rate by the pulse of pacemaker when cardiac arrest or arrhythmia. Do not completely rely on the alarm of cardiometer. The patient with pacemaker shall be closely monitored. For the inhibiting capacity of relevant equipment on the pacemaker, refer to the Instruction Manual.
- The operators shall not touch the patients, tables and instruments during the defibrillation period.
- Before reusing these cables, check whether the function is normal.
- The equipment connected with the monitor shall form an equipotential body (the protective grounding wire is effectively connected).
- When the monitor is shared with the electrosurgery unit, the user (doctor or nurse) shall ensure the patients safety.
- The physiological waveforms, physiological parameters and alarm information, etc. displayed by this monitor shall be for the doctors' reference only and cannot be directly used as the clinical treatment basis.
- The electromagnetic field will affect the performance of this instrument, so the use of the other equipment near this instrument must meet corresponding EMC requirements. For example: Mobile phone, X-ray or MRI equipment may be an interference source, because they will transmit high-strength electromagnetic radiation.
- This is not a treatment device.

⚠ Caution

- To avoid damage to this instrument and guarantee patient safety, please use the accessories designated in this instruction manual.
- Please properly install or move this instrument and prevent the instrument from being damaged due to fall, collision, strong vibration or other external mechanical forces.
- Before the instrument is switched on, please confirm whether the power supply used meets the requirements for power supply voltage and frequency designated in the nameplate label or in the instruction manual of this instrument.
- When this instrument and its accessories are about to exceed the service life, they must be disposed of according to local relevant laws and regulations or the rules and regulations of the hospital.

⚠ Attention

- Please install the equipment in a place that is convenient for observation, operation and maintenance.
- This instruction manual introduces the product according to the most complete configurations. The product you have purchased may not possess some configurations or functions.
- The SpO₂ type this monitor equipped is Masimo SpO₂, with options of digital SpO₂ and Nellcor SpO₂. When monitors leaving the factory, the manufacturers have already allocated the specific SpO₂ according to the monitor type users having ordered. Therefore, users should not make any changes without permission of authorized persons by the manufacturer.
- Please place this instruction manual near the instrument for easy and timely reference.
- This instrument can be used for one patient only at the same time.
- The neonate ECG electrode and the disposable cuff can both be used only once. Do not use them repeatedly.
- The instrument configured for newborns is a standard feature.

1.2 Contraindication

Electrodes are prohibited to be used where the skin suffers from inflammation or fester.

People who are alleged to electrode conductive medium are prohibited to use it.

Blood pressure cuffs are forbidden to be used for people whose skin on the upper arm or leg is damaged.

1.3 Overview of the Monitor

The monitor (as the figure below shows) is applicable to bedside monitoring for neonates.

This monitor can monitor following parameters, including electrocardio graph (ECG), respiration (RESP), oxyhemoglobin saturation (SpO₂), non-invasive blood pressure (NIBP), temperature (TEMP), carbon dioxide (CO₂), oxygen concentration (O₂) and asphyxia awakening.

The equipment adopts an 8.4-inch color touch screen and supports two kinds of operational mode—keybuttons and touch screen. The monitor's basic functions are as the following figure 1-1 shows:

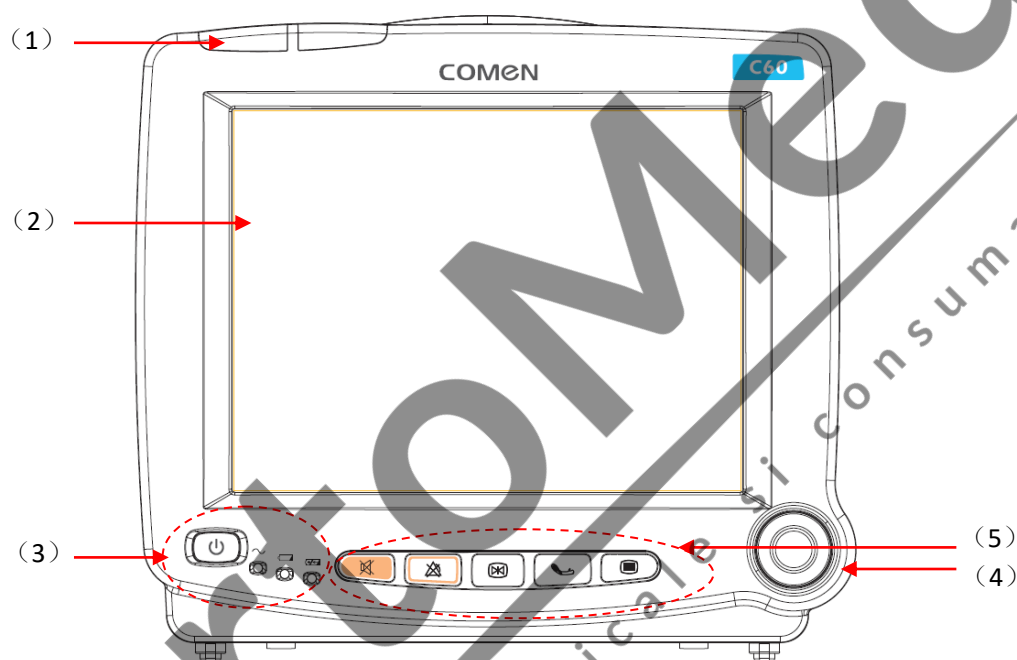


Figure 1-1 Neonate Patient Monitor

(1)	Alarm Indicator(The left one is physical alarm indicator and the right is technical alarm indicator).
(2)	Screen.
(3)	Power switch and indicators (from left to right: power key, AC power indicator, battery status indicator, battery charging indicator).
(4)	Flying knob, which has three working methods as turning left, turning right and pressing, realizing cursor left shift, cursor right shift and confirming operation respectively.
(5)	Keys (from left to right they are in turn: silence button/reset button, alarm pause button/alarm cancel button, freeze/unfreeze button, NIBP measurement start/stop button, pop/exit main menu button. For more details, please refer to contents in “Button Functions and Basic Operations” in this chapter.









This monitor has rich functions, able to provide various functions such as visual/audio alarming, TREND storage& output, NIBP measurement storage and review, medicine calculation, ST analysis, pulse analysis, heart rate turbulence analysis, etc.


This monitor has a friendly operation interface, able to provide all functions with the keys, buttons and touch screen on the front panel as figure 1-1 shows. Refer to Button Functions part for details.

1.4 Button Functions and Basic Operations

1.4.1 Button Functions

The monitor can be operated through use of the buttons and knobs. Here are the functions of the buttons as follows:

	(SILENCE/RESET button): Press down this key for more than one second to shield or turn off all alarm sounds. After the alarm resumes, the monitor will immediately respond to the alarm and the response time will not exceed 3s.
	(ALARM PAUSE/CANCEL button) : Press this button for more than one seconds to pause all alarm sounds, including the physical alarm, and display the pause time in the physical alarm area on the screen, such as “ALM PAUSE ××s”. This can be set in the “ALARM SETUP” menu of the “MONITOR SETUP” under the “MAIN MENU”. Press this button again or the pause time is out, the alarm would immediately respond to the alarm and the response time will not exceed 3s.
	(FREEZE/UNFREEZE button): Press this button and all waveforms on the screen can be frozen in the normal mode. Press this button once again and the frozen waveforms can be freed. After pressing down the freezing key, click the screen to review the waveforms stored within 4 mins.
	(To start/stop NIBP measurement) : Press to inflate the cuff to start a blood pressure measurement. When measuring, press to stop the measurement and deflate the cuff.
	(POP/EXIT the Main Menu button) : Press this button the main menu would pop up or exit the main menu and return to the current interface with all menus closed.
	(ON/OFF button): Press this button to control the startup and shutdown of the monitor.
	a.c. INDICATOR
	Battery status indicator

	Battery charging indicator
Flying Knob	JOG-DIAL to select and change the settings. Operation can be performed by turning it clockwise, counterclockwise or pressing it down. JOG-DIAL is mainly used in menu and window operation.

1.4.2 Basic Operations

(1) Display the desired waveform:

Press "■" pop-up "MAIN MENU", open "MONITOR SETUP(Monitor Settings)" and select "MODULE SETUP(module switch settings)" in the main menu, select the waveform to be displayed. Details can be found in the relevant sections of the screen to set the content of the waveform.

(2) Adjust the waveform speed:

ECG: get into the "ECG SETUP" hotkey setting menu in the waveform area to set the waveform speed by the "SWEEP" option.

Waveform speed of SPO₂, RESP, CO₂ and other parameters can also be set through their corresponding hotkey setting menu "XX SETUP" in the waveform area.

(3) Change the alarm limits :

ECG: get into the "ECG SETUP" hotkey setting menu in the parameter area to set it in the "HR ALM SETUP" option.

Alarm limits of NIBP, SPO₂ (including PR), CO₂, O₂ and other parameters can also be set through their corresponding hotkey setting menu "ALM SETUP" in the parameter area.

RESP, TEMP: get into the "TEMP SETUP" hotkey setting menu in the parameter area to set it in the "×× ALM HI" or "×× ALM LO" options.

(4) Adjust the volume :

Alarm volume: Press the "■" button, pop-up "MAIN MENU" to enter the "SELECTION", select "ALARM VOL" menu, you can set the alarm volume.

Heartbeat, button volume and LCD brightness can also be set through the "SELECTION" menu as the above steps.

(6) System time setting:

Press the "■" button, pop-up "MAIN MENU" to enter the "MONITOR SETUP (Monitor Settings)", select "TIME SETUP (System Time Settings)" menu, you can set the time.

1.5 Screen display

This monitor has a color LED screen, able to concurrently display collected patient parameters, waveforms,

and alarm information provided by the monitor, clocks, monitor status and other reminder information.

The main screen is divided into 4 sub-areas, i.e., Information Area ①, Waveform Area ②, Parameter Area ③ and Menu Area④ (As shown in Figure 1-2).

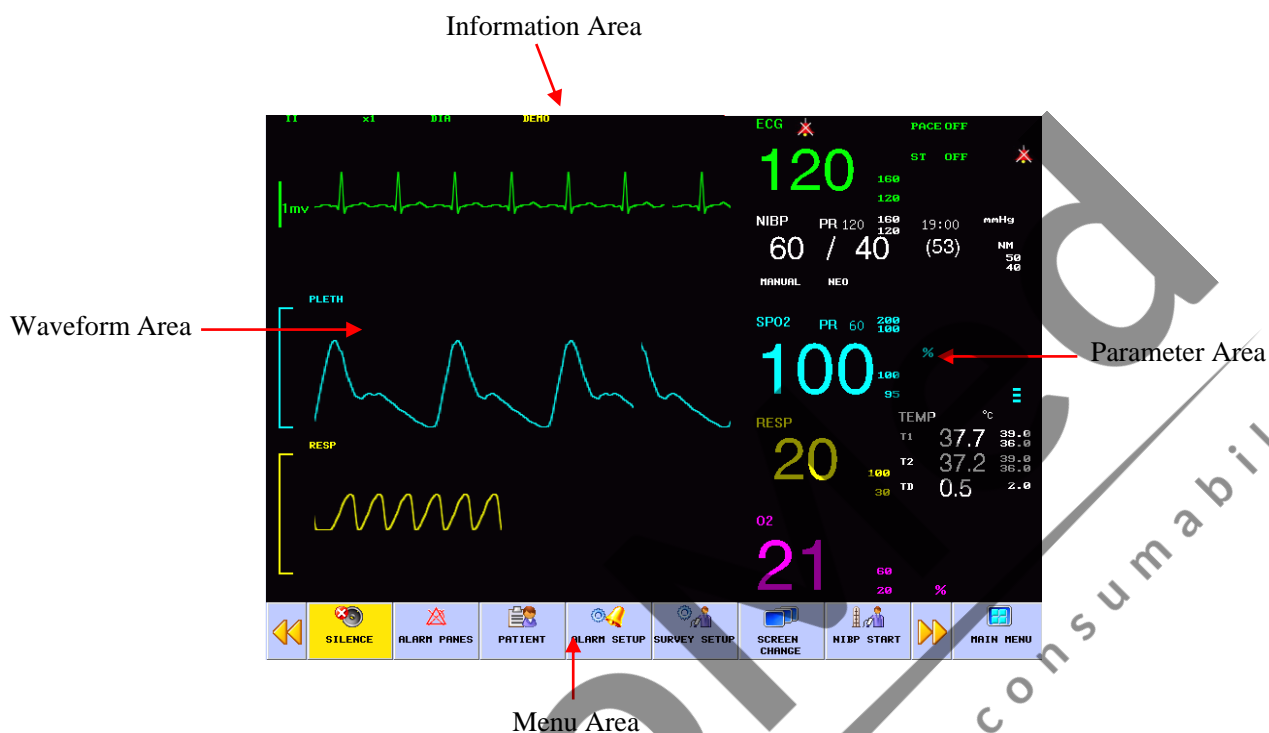


Figure 1-2 Main screen display

1.5.1 The upper menu bar (Information Area)

(1) Network setup: Cursor stops in sign, press to enter “NET BED” menu.

- NET BED: network bed No.in the monitor connected to the central monitoring system
- LOCAL IP(IP Address): IP is 200.200.200.X, (X : from 1 to 254)
- GATE WAY: 200.200.200.1.
- REMOTE IP (SERVER IP):200.200.200.100, mainly the address of the central monitor’s server to which the monitor is connected.



Attention

- **Status of connection to the central monitor system: the indicates no connection; the indicates successful connection.**

The Network bed number must be unique, and can not overlap the bed numbers of any other instruments connected to the central monitoring system, otherwise it will cause instrument signal deadlock because of the preemption of the central monitoring system channel.

If any instrument freezes due to network bed number conflicts, remove the network cable, turn off the monitor and restart. Reset the networks and then reconnect to the network connector.

(2) Patient Information: press to enter the Patient Information menu when cursor is in bed No., name or patient group area.

- PAT NO: support input from 0-999999999.
- BED NO.: Refer to the bed number of the patient being monitored; this area will be blank if there is no input.
- NAME: Patient name, this area will be blank if there is no input.
- SEX: Male and Female.
- PAT TYPE (Patient Type): neonatal.
- PACE: pacer state, pacer detected displaying , otherwise displaying .
- HEIGHT (cm): 0~300, e.g. 180.
- WEIGHT(kg): 0~200, e.g. 100.
- BLOOD:A,B,O,AB,unkown
- DEPT. (department): According to the department's name pop-up keypad input, support English, spelling, and handwriting input function.
- DOCTOR: According to the department's name pop-up keypad input, support English, spelling, and handwriting input function.
- UPDATE PATIENT: current patient information will be deleted if patient information is updated.

(3) DATE TIME SETUP(Time setup): set up local time, including year, month, day, hour, minute, second, data format and time format.

(4) Icon area: the silence icon  or alarm pause icon .


(5) Technical alarm: display technical alarm, such as ECG lead off.


(6) Physical alarm: display physical alarm, such as T2 too low.

(7) Battery: display capacity of batter. Please refer to chapter “Built-in Charging Battery” for more details.

(8) Volume setup: setup ALARM VOL (alarm volume), BEAT VOL (heart beat volume), KEY VOKL (key volume), and TOUCH SOUND.

- ALM VOL (Alarm volume): there are seven Alarm Vol levels, “0”, 1~6, where "0" level means the alarm sound is closed, that is “OFF”; and “6” is the highest level.

 Alarm volume on, Alarm level 6. Other alarm volume level can be recognized in the same manner.

 Alarm volume off.

Attention

- **Visual alarm and alarm status: Alarm light winks or shines when there is an alarm. The colour of light means the alarm level. Refer to chapter “Alarm function” for details.**

Information about alarm information and prompt messages should be found in related information of each parameter in their corresponding chapters.

- BEAT VOL (Beat volume):there are seven Alarm Vol levels, "0", 1~6, where "0" level means the alarm sound is closed, that is "OFF"; and "6" is the highest level.
- KEY VOL (Key volume):there are seven Alarm Vol levels, "0", 1~6, where "0" level means the alarm sound is closed, that is "OFF"; and "6" is the highest level.
- TOUCH SOUND: on, off. When open touch sound, click on the screen, will issue a point in the sound of the screen, when close touch sound, no voice prompts.

(9) When the waveform is frozen on the screen, the top screen will appear to "FROZEN" prompt.

(10) When you open a demo mode, the top of the screen appears "DEMO" prompt.

1.5.2 Waveform Area

There are three waveforms in the waveform area, which are from up to down respectively: two-channel ECG waveform, SpO2 volume graphic waveform and RESP waveform (possibly from ECG module or CO2 waveform). Lead of ECG monitoring can choose proper key lead to monitor when necessary. The name of selected waveform is displayed on the upper left part. For details, please refer to chapter of ECG Monitoring. ECG waveform in the first channel still shows the gain of this channel and the filtering method of ECG waveform. A 1-mv rod is on the left of ECG waveform.

When you choose/touch each waveform, submenu of waveform will be pop up, which always occupies most of space of waveform area, so that some waveforms are invisible. The original image will come back after exiting the menu.

Waveforms are refreshed at the set speed. For adjustment on waveform refresh speed, refer to the chapter of each Parameter Setting.

1.5.3 Parameter Area

Parameters can display at the fixed position (as shown in ①~⑫ of the following picture), which from top to bottom are :

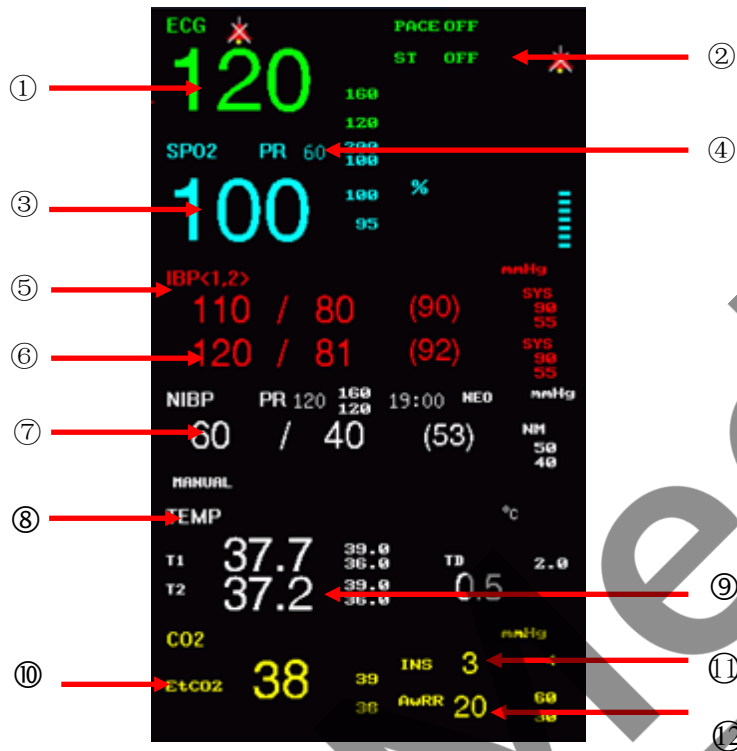


Figure 1-3 Main Screen

ECG

- Heart Rate or Pulse Rate (①, unit: bpm)
- ST-segment (②, unit: mv)
- PVCs times (Unit: times/minute)

SpO2

- SpO2 (③, unit: %)
- Pulse Rate (④, unit: bpm)

IBP (optional)

- Invisive Blood Pressure (⑤)
- (From left to right) Systolic, Diastolic, Mean (⑥, Unit: mmHg or kPa)

NIBP

- (From left to right) Systolic (NS), Diastolic (ND), Mean (NM) (⑦, Unit: mmHg or kPa)

TEMP

- TEMP (⑧)
- Temperature (⑨, unit: °C or °F)

CO2 (optional)

- end-tidal CO2 (⑩, Unit: mmHg or kPa)
- inspiratory CO2 (⑪, Unit: mmHg or kPa)

O2

— O2 density (Unit: %)

RESP



—Respiration Rate (unit: bpm)

—Air Way Respiration Rate (AWRR) (⑫,unit: bpm)

The parameters are refreshed once per second, but NIBP value, once per measurement.

Users can select the monitoring parameters and the main screen will display the relative content.

1.5.4 Menu Area

- (1) **SILENCE**: the silence button has the same function as the silence key on the panel. Press down this key for more than one second to shield or turn off all alarm sounds. The “” will appear on the icon area of the upper menu bar. After the alarm resumes, the instruct will immediately respond to the alarm and the response time will not exceed 3s.
- (2) **ALARM PAUSE**: the alarm pause button has the same function as the alarm pause/cancel button on the panel. Press this button for more than one seconds to pause all alarm sounds, including the physical alarm, and the pause time will be shown in the physical alarm area on the screen, such as “ALM PAUSE ××s”. The “” will appear on the icon area of the upper menu bar. This can be set in the “ALARM SETUP” menu of the “MONITOR SETUP” under the “MAIN MENU”. Press this button again or the pause time is out, the alarm would immediately respond to the alarm and the response time will not exceed 3s.
- (3) **PATIENT INFORMATION**: patient information configuration. Refer to chapter of Patient Information for details.
- (4) **ALARM SETUP**: set up alarm type.
 - **ALARM RECORD TIME**: in case of physiological alarm, the system can record the information before and after the alarm time. The system can give three kinds of time: 4 seconds, 8 seconds, and 16 seconds. The seconds in the options are the sum of seconds before and after the alarm time. For example, 8 seconds mean the information within 4 seconds before the alarm time and within 4 seconds after such a time; 16 seconds mean the information within 8 seconds before the alarm time and within 8 seconds after such a time.
 - **ALM PAUSE TIME** (Alarm pause time): “1 minute”, “2 minutes”, “3 minutes”, “5 minutes”, “10 minutes” and “FOREVER”.
 - **ALM LATER**: Disabled, 5s, 10s, 15s, 20s. When choosing “Disabled”, it means the equipment will make alarms as soon as there is one; when choosing “5s”, the equipment will only make alarms when the parameter keeps exceeding the upper limit or the lower limit for 5 minutes. And other options are in similar manners. This function is to reduce false alarms resulting from

instant mistakes and help doctors grasp correct information.

- (5) SURVEY SETUP: ECG, SpO₂, NIBP,RESP, TEMP, O₂ and CO₂ setup, refer to “SURVEY SETUP” in their own chapters for more details.
- (6) SCREEN CHANGE: STANDARD, LIST FACE, TREND SCREEN, oxyCRG SCREEN, BIG FONT. Users can choose different screens based on different requirements. Only one kind of screen is available in each choice. For details, please refer to chapter 4.
- (7) NIBP MEASUREMENT: press this button to inflate the cuff when not measuring blood pressure and start to manually measure blood pressure; if you want to give up measurement, press this button will stop measurement and begin to deflate.
- (8) NIBP AUTO: press this button to inflate the cuff when not measuring blood pressure and start to automatically measure blood pressure; if you want to give up measurement, press this button will stop measurement and begin to deflate.
- (9) FROZEN: press “▶▶”, turn the lower menu bar and select “FROZEN”, the screen freezes when press this button, turn the knob to review all the waveform stored for the last 4 minutes.
- (10) TREND TABLE, TRENDGRAPH, and NIBP RECALL (NIBP measurement review): refer to chapter 3 for details.
- (11) PRINT: press this button to record waveforms and patient information (This function has failed).
- (12) STANDBY: press this button and the monitor turns into a standby interface, where shows “press any key to exit the standby mode”. Now click any key in the interface or on the panel, there will pop up two options showing “New Patient” and “Continue” in the lower menu bar. Choose any one of them would exit the standby interface. Please refer to “3.16 Standby” for more details.

1.6 External Socket

1.6.1 Right Panel

The following interfaces are provided on the right panel of the monitor, shown as follows (there will be differences among different configuration):

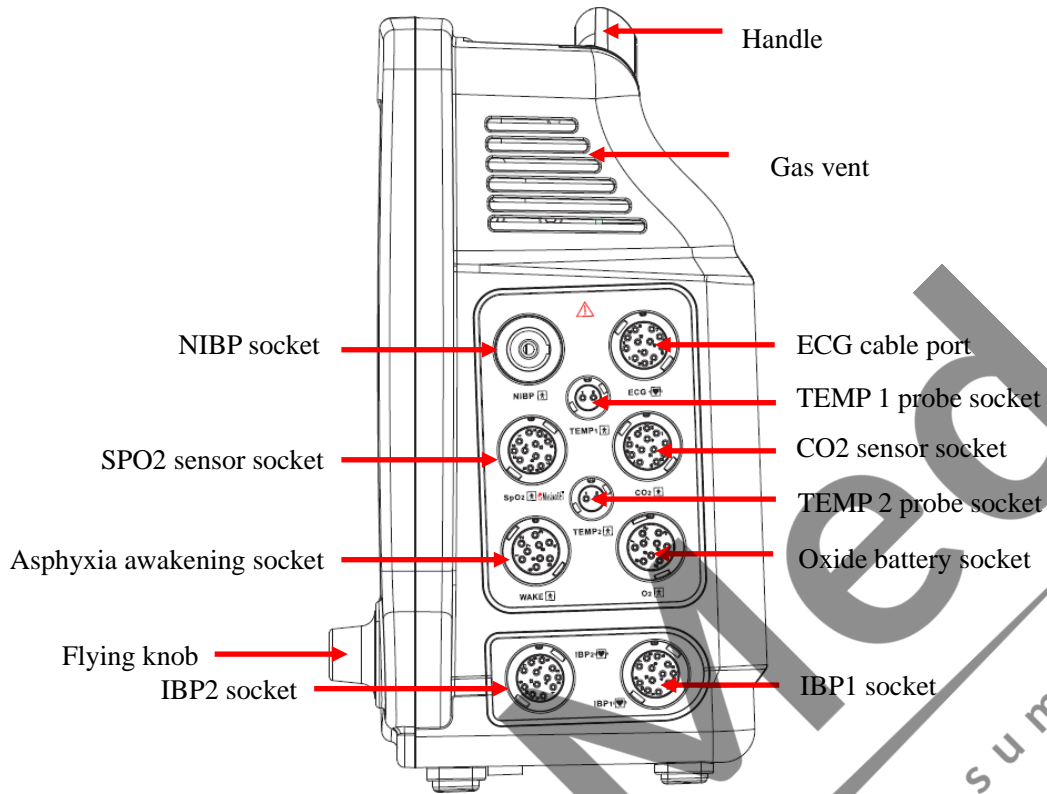


Figure 1-4 Right panel (optional IBP)

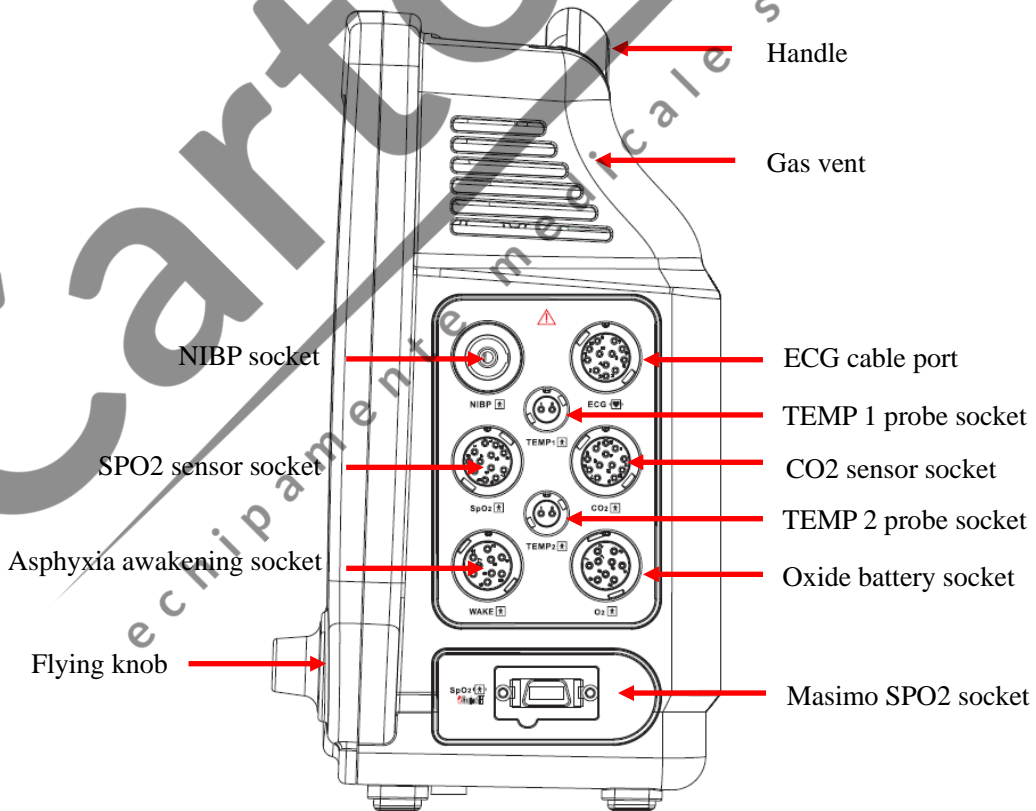


Figure 1-5 Right panel (standard)

1.6.2 Rear Panel

There are nameplate information and jacks of cables and equipotential lines in the rear panel:

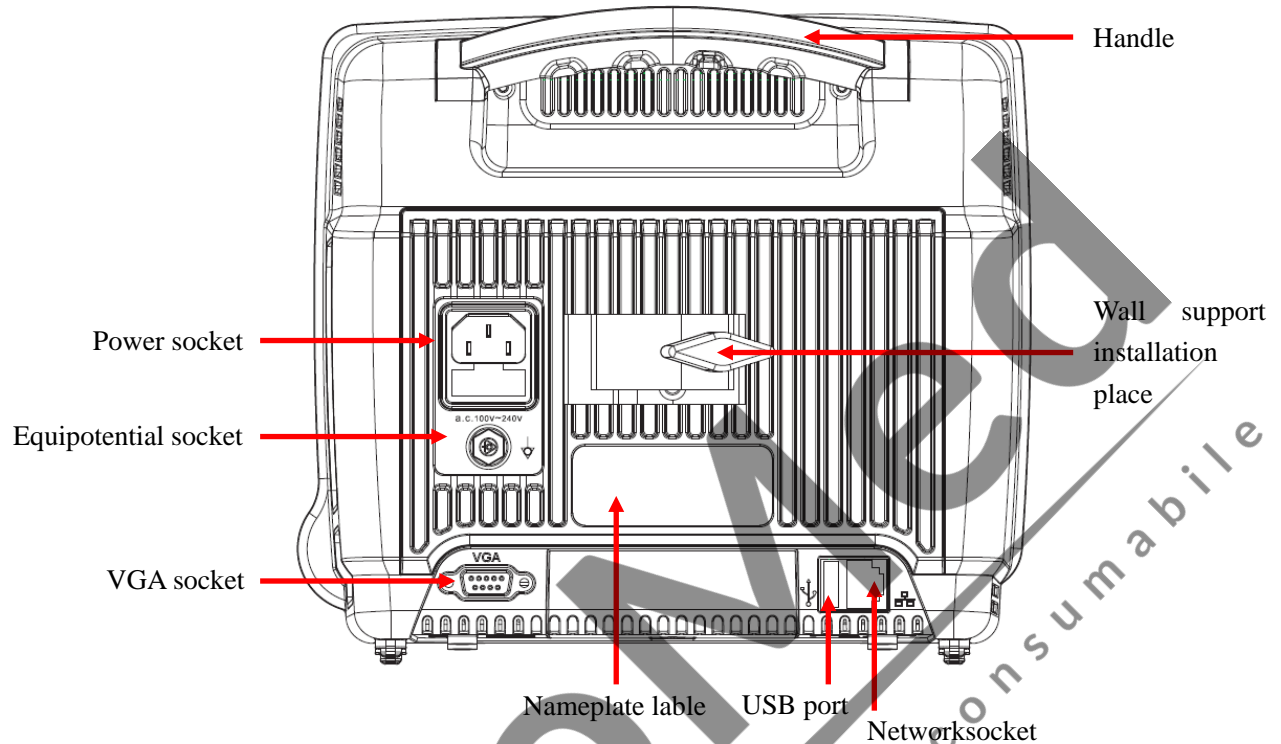
















Figure 1-6 Rear panel

⚠ Warning

- This network port only can be connected with the central monitoring system of Our company.
- All the simulation and digital equipment connected with this monitor must be the products certified by the designated IEC standards (e.g. IEC 60950 Data Processing Equipment Standard and IEC 60601-1 Medical Equipment Standard). Moreover, all configurations shall abide by the content of the valid edition of IEC 60601-1-1 System Standard. Connect the additional equipment to the staffing medical system at the input/output signal port and confirm whether the system conforms to the IEC 60601-1-1 Standard. If you have any question, please contact the supplier.
- Patient cable interface, network interface and other interfaces connected to different equipments, the leakage current should not exceed the limit.





1.7 Equipment Symbols

(a) Instrument Symbols


	Attention! Please see the accompanying documents.	 2010R260-44	Type approval mark and number of measuring instrument
	The application part of Type CF has the anti-defibrillation function.	 Y.Z.No.:00000700	Production license mark and number of measuring instrument
	The application part of Type BF		Production Date Mark
	Start/Stop Key		USB interface
	AC indicator lamp		Network connection symbol
	Battery status indicator lamp	VGA	VGA socket
	Battery charging indicator lamp		Discard of the equipment
	Equipotential symbol		

Note: Please see the content of “1.4 Key Function and Basic Operation” for the key symbols and their functions of the monitor.

(b) Packaging Symbols

	Up		Limit of stacking layers
	Fragile		Rainproof

1.8 Built-in charge battery

The multi-parameter monitor has a built-in charge battery. When connected with AC power, the battery will charge automatically until it is full. When there is an emergency power off, the equipment would supply the power with the battery automatically instead of cutting off its work. On the right side of the screen, there is a “”, it means charging state. The green, orange, red part of the battery indicates the quantity of the battery respectively: high, medium and low.

 Full capacity



Not full capacity



Low capacity



Very low capacity, need to charge soon.



Very very low capacity. The monitor now would trigger alarms of low battery capacity and begin to countdown for 1 minute, warning that “the system will be shut down in $\times\times$ ”. If the monitor fails to recharge in time, it will be shut down in 1 minute.



Indicating the battery is unavailable or malfunctioning.

If the battery is obviously defective or suffering a low capacity, it should be replaced by a new one and the old one must be recycled properly and disposed according to relative laws and regulations or rules and regulations of the hospital.



Attention

- **Please remove the battery if it will be out of service for a long time and store it properly.**
- **If a built-in battery is inside the unit, the battery must be recharged after each use to ensure enough energy in the battery.**
- **In order to extend the service life of the battery it is recommended to charge it every three months after a long dormant period so as to prevent overdischarge.**
- **Battery power supply loss depends on the configuration and operation of the monitor; for example, the unit will have a big loss of battery power if it is used to measure NIBP parameter often.**



Warning

- **Do not remove the battery or make it short-circuiting or put it into fire; otherwise, it would cause battery on fire, explosion, harmful gas leakage or other dangers.**
- **The battery liquid is harmful, In case the liquid contacts your skin or eye, wash it immediately with large amounts of clean water or seek medical advise.**
- **Keep the battery out of reach of children.**
- **Use only the supplier’s designated battery.**

Chapter 2 Monitor Assembly

Attention

- **For normal work of the monitor, before use please read this chapter and the Patient Safety chapter and assemble in accordance with the requirements.**

2.1 Open Package and Check

Carefully pick up the monitor and accessories from the package box, and properly keep the package materials for future transport or storage. Please check the accessories with the package checklist.

- Check whether there is any mechanical damage;
- Check all the exposed cables and plug in some accessories for test.

Any problems should be immediately raised to the Sales Department of our Company or our agents.

2.2 Connect with AC Cable

Procedures to connect with AC power cables:

Make sure the AC supply complies with the following specification: 100-240VAC, 50/60Hz±1Hz

Use the power cables provided with the monitor together. Plug in the power cable into power supply interface of the monitor, while insert the other end of this cable to a 3-phase earthing power socket.

Attention

- **Plug the power cord to the dedicated hospital outlet.**
- **If a battery is provided, you must charge the battery after the transport or storage of instrument. If you do not connect the AC power and directly turn on the monitor, it will probably not work because of insufficient battery power. Connect to an AC power supply and you can charge the battery ,regardless of whether the monitor is turned on or not.**

If deemed necessary, connect with an equal-potential earthing cable. Refer to the equal-potential earthing part in the chapter Patient Safety.

2.3 Power on

When the power is on, there comes the interface of “system is loading”, then the company’s logo, and later the processing screen. After the 3~5 seconds checking process, the system enters the monitoring main screen after a “ding” and the users can start operations.

Attention

- If there are significant errors in the self-test process, the system will alert.
- Check all the available monitoring functions and make sure they work properly.
- If a battery is configured, users must charge the battery after each time of use so as to ensure sufficient power storage.
- Power on again after 1 minute of power off.

Warning

- If you find signs of damage to monitor functions, or an error message, do not use this monitor for patient monitoring. Please contact the biomedical engineers of your hospital or maintenance engineer of the Company.

2.4 Connect with Sensor

Connect the required sensor between the monitor and the monitoring position of a patient.

Attention

- For the correct connection methods for sensors and related requests, see Chapters 11-17.

Chapter 3 System Menu

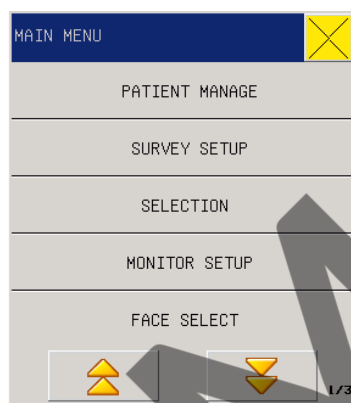

The monitor system setting is more flexible. Monitoring, waveform speed, volume and output, all can be setted by user. Press the “

Figure 3-1 Main menu

MAIN MENU including: PATIENT MANAGE, SURVEY SETUP, SELECTION, MONITOR SETUP, FACE SELECT, TREND GRAPH, TREND TABLE, NIBP RECALL, ASPHYXIA STIMULATE REVIEW, ALM RECALL ,WAVE RECALL, INFO, CALC., MAINTAIN, DEMO.

3.1 PATIENT MANAGEMENT

Warning

- For deleting the patient’s current data, please refer to the “update patient” in this chapter.

Select the “PATIENT MANAGE” item under the system menu, and then pop up the following menu:

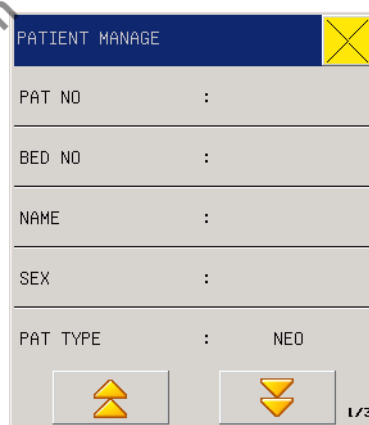


Figure 3-2 Patient Manage

Users can set the following content:

- (1) PAT NO:0-999999999 for option.
- (2) BED NO.0-999999999 for option
- (3) NAME input patient name in the popping up menu, supporting English, spelling,and handwriting input function.

Caps Lock	Shift	←	Del	Enter	←	→
Caps Lock (permanent)	Caps shift (one-off)	Backspace	delete	enter	Move forward	Move backward

 **Attention**

- **When editing the patient’s name, use the knob to change editing windows of “English, spelling and handwriting”.**
- **Select “Enter” to confirm and exit the editing window after finishing editing patient information.**

- (4) SEX Patient gender (female, male)
- (5) PAT TYPEPATIENT TYPE (Neonate)
- (6) PACE Pacemaker ON/OFF
- (7) HEIGHT (cm) 0~300, for example, 180
- (8) WEIGHT (kg) 0~200, for example, 100
- (9) BLOODO, A, B, AB, unkown
- (10)DEPT. (department) According to the department's name pop-up keypad input, support English, spelling, and handwriting input function.
- (11)DOCTORAccording to the department's name pop-up keypad input, support English, spelling, and handwriting input function.
- (12)UPDATE PATIENT current patient informationwill be deleted if the patientinformation is updated.

 **Attention**

- **The“On” PACE status is only available to the current starting up, and it would restore to its default at the next starting up. Users can also select “UPDATE PATIENT” to get into the “CONFIRMUPDATE PATIENT” dialogue box and decide whether to change to monitor another patient.**

⚠ Warning

- Patient type changed, the alarm parameters such as heart beat and NIBP may vary, usually make sure the limits are suitable for the patient.
- Pacer detection must be “Off” for non-pacing patients, or the monitor is not able to detect any arrhythmia (including PVCs counting) related to ventricular premature beat nor conduct ST analysis.

3.2 Survey setup (parameter setup)

In the main menu, select SURVEY SETUP (parameter setup), which includes: ECG SETUP, SPO2 SETUP, NIBP SETUP, RESP SETUP, TEMP SETUP, O2 SETUP and CO2 SETUP (RESP SETUP and CO2 SETUP both can appear only one of them), IBP <1, 2> SETUP. The parameters set in this menu parameters chapters details in the description of this ignored the pop-up menu, as shown below:

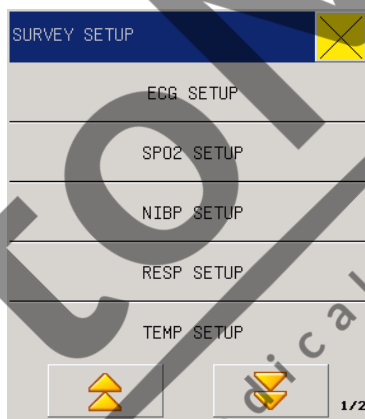


Figure 3-3 Survey setup

3.3 SELECTION

Select the “SELECTION” in the “MENU MENU” and sub-menu following with Figure below, including

SELECTION	
ALARM VOL	: OFF
BEAT VOL	: OFF
KEY VOL	: 3
LCD LIGHT	: 5
ENERY TIME	: OFF

Figure 3-4 Selection Setup

3.3.1 ALARM Volume

In the system there are seven levels of ALM VOL: OFF, 1~6. After choosing “1~6”, the system would make alarm warnings based on the chosen volume. "OFF" level means the alarm sound is closed.

Warning

- Where the alarm volume of the system is set at OFF, the monitor will not give alarm sound in case of alarm, so you should use this function carefully.

3.3.2 BEAT VOL (Alarm volume)

In the system there are seven levels of BEAT VOL: OFF, 1~6. After choosing “1~6”, the system would make beat alarm warnings based on the chosen volume. "OFF" level means the beat alarm sound is closed.

3.3.3 KNOB VOL (Keyboard volume)

In the system there are seven levels of KNOB VOL: OFF, 1~6. After choosing “1~6”, the system would make keyboard volume based on the chosen volume. "OFF" level means the alarm key sound is closed.

3.3.4 LCD LIGHT(LCD Brightness)

In the system there are five Brightness level, i.e. “1~5”, where “5” means the maximum brightness.

3.3.5 ENERGY TIME (Energy Conservation Time)

ENERGY TIME (Energy conservation time) is for conserving time the monitor consumes and adjusts the screen brightness automatically. When setting the time to “10”, the screen would darken if users have not operated the monitor for over 10 seconds. Click any places on the screen or press any key on the panel or turn the knob, the screen would return to its former brightness. The system offers six options as “OFF, 10, 15, 20, 25, and 30”.

3.4 MONITOR SETUP (Monitor Setting)

Select MONITOR SETUP in MAIN MENU, sub-menu following with figure below, including ALARM SETUP, RECORD, TIME SETUP, NURSE CALL SETUP and MODULE SETUP.

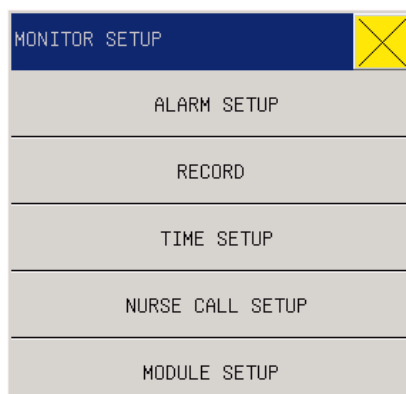


Figure 3-5 Monitor Setup

3.4.1 ALARM SETUP (Alarm Setting)

- ALM REC TIME (Alarm Record Time):

In case of physiological alarm, the system can record the information before and after the alarm time. The system can give three kinds of time, i.e., 4 seconds, 8 seconds, 16 seconds. The seconds in the options are the sum of seconds before and after the alarm time. For example, 8 seconds mean the information within 4 seconds before the alarm time and within 4 seconds after such a time, and 16 seconds mean the information within 8 seconds before the alarm time and within 8 seconds after such a time.



- ALM PAUSE TIME (Alarm pause time): “1 MIN”, “2 MIN”, “3 MIN”, “5MIN”, “10MIN” and “FOREVER”. After selecting the ALM PAUSE TIME button, the physiological alarm area would show the countdown time of alarm paused, e.g. “ALM PAUSE \times s” or “ALM PAUSE FOREVER”. After canceling alarm pause or reactivating alarm, the equipment would respond to the alarm immediately and the respond time would not exceed 3 seconds.

- ALM LATER: “Disabled”, “5s”, “10s”, “15s”, “20s”. If “Disabled” is chosen, the equipment would trigger alarms as soon as where is one; when “5s” is chosen, the equipment would trigger alarms only when the parameters keeps exceeding alarm limits for 5 seconds. This function is to reduce false alarms resulting from instant mistakes and help doctors obtain more correct information.

3.4.2 RECORD (Record output setting)

Options for record output:

- REC WAVE1/ REC WAVE2: can not change
- REC RATE: 25.0/50.0 mm/s, record speed
- REC GRID: ON/OFF, used to set record output format with “OFF” indicates no grid output and “ON” means there is.

- RT REC TIME: 3S/5S/8S/CONTINUAL (real-time record time).CONTINUAL means after pressing PRINT BUTTON , monitor will keep printing parameters and waveform, until press  to stop.

Attention

- The recorder is a component for option.
- Where two similar waveforms are selected, the system will automatically adjust the other one into a different one.

3.4.3 TIME SETUP (System Time Setting)

- "TIME SETUP" with options below:

Setup year, month, day, hours, minutes and seconds. Pitch on the content required for correction and set the local time in a new dialogue box.

3.4.4 NURSE CALL SETUP

Options in nurse call setting:

- ALM ON/OFF(Alarm on/off):on,off
- ALM LEV (Alarm level): high, middle, low.

3.4.5 MODULE SETUP

Options in module setup:

ECG and SpO2 are not optional.

- TEMP: ON/OFF.

When it is ON, machine can monitor TEMP, when it is OFF, machine can not monitor TEMP, and no parameter area of TEMP in main interface.

- RESP: ON/OFF.

When it is ON, machine can monitor RESP, when it is OFF, machine can not monitor REST, and no parameter area of RESP in main interface.

- NIBP: ON/OFF.

When it is ON, machine can monitor NIBP, when it is OFF, machine can not monitor NIBP, and no parameter area of NIBP in main interface.

- O2: ON/OFF.

- When it is ON, machine can monitor O2, when it is OFF, machine can not monitor O2, and no parameter area of O2 in main interface.

- CO2: ON/OFF.
- When it is ON, machine can monitor CO2, when it is OFF, machine can not monitor CO2, and no parameter area of CO2 in main interface

3.5 FACE SELECT

In the System Menu, select the “FACE SELECT” to enter the dialog box in the following Figure. Here there are such six options as “STANDARD”, “LIST FACE”, “TREND SCREEN”, “oxyCRG SCREEN”, “BIG FONT”. Only one choice for each set-up.

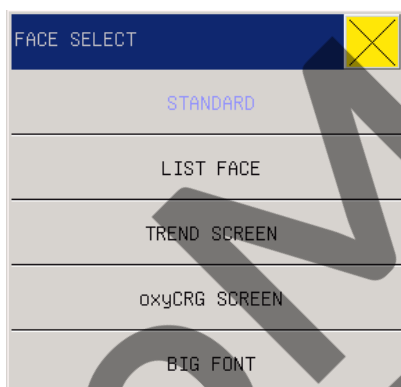


Figure 3-6 Work Interface

3.6 TREND GRAPH

Trend graph for the previous 1 hour can be displayed in the resolution of one data per one second or one data per five seconds.

Trend graph for the previous 120 hour can be displayed in the resolution of one data per minute, per five minutes or per ten minutes.

Users can select the TREND GRAPH item under the MAIN MENU so as to pop up the following window:

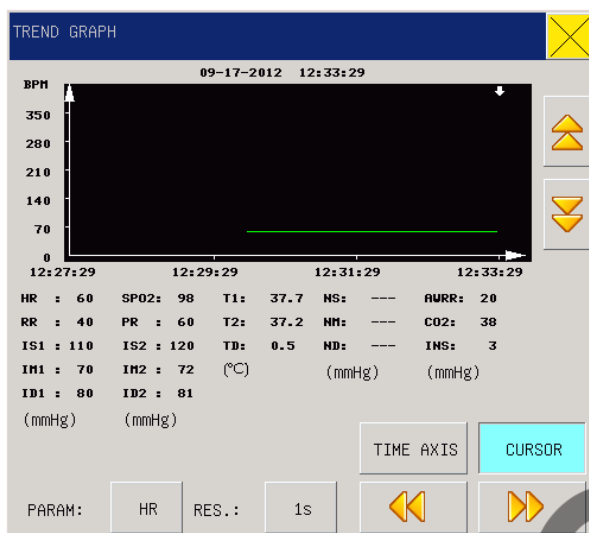


Figure 3-7Trend Graph

Parameter selection: HR、RR、SPO2、PR、TEMP、NIBP、IBP1、IBP2、CO2、INS、AWRR.Y-axis means measurement value, X-axis means measurement time. “↓” is cursor for trend graph, the measurement values it points to display at the bottom of the graph, corresponding time at the upper end of the graph.

3.7 TREND TABLE (TREND Figure)

Trend table for the previous 1 hour can be displayed in the resolution of one data per 1s, 5s, and 30s.

Trend table for the previous 120 hour can be displayed in the resolution of one data per 1MIN, 5MIN, 10MIN, 30MIN and 60MIN.

Users can select the TREND TABLE item under the MAIN MENU so as to pop up the following window:

The screenshot shows the 'TREND TABLE' window. It displays a table of vital signs data over time. The table has the following columns: TIME, HR (BPM), SPO2 (%), NIBP (mmHg), PR (BPM), and RR (RPM). The data is as follows:

TIME	HR BPM	SPO2 %	NIBP mmHg	PR BPM	RR RPM
(31) 07:26:28 PM	120	100	----	60	20
(31) 07:26:27 PM	120	100	----	60	20
(31) 07:26:26 PM	120	100	----	60	20
(31) 07:26:25 PM	120	100	----	60	20
(31) 07:26:24 PM	120	100	----	60	20
(31) 07:26:23 PM	120	100	----	60	20
(31) 07:26:22 PM	120	100	----	60	20
(31) 07:26:21 PM	120	100	----	60	20
(31) 07:26:20 PM	120	100	----	60	20
(31) 07:26:19 PM	120	100	----	60	20
(31) 07:26:18 PM	120	100	----	60	20
(31) 07:26:17 PM	120	100	----	60	20

At the bottom, there are controls for 'RES.:' (1s) and navigation buttons.

Figure 3-8 Trend Table

Time corresponding to various groups of TREND data is displayed at the left column, with dates bracketted. What are listed are the cases that have once been marked, which corresponds to the time of the marked cases. Parameters in the TREND Figures can be categorized into the following 9 groups:

HR, SPO2, NIBP, PR , RR;

T1, T2, TD

CO2, INS, AwRR, ST1, ST2

IBP1 (S/D/M)

IBP2 (S/D/M)

3.8 NIBP RECALL

The monitor can display the latest 2000 NIBP measurement data in the NIBP review function. After users select the NIBP RECALL item under the MAIN MENU, the windows will display the latest 10 NIBP measurement results and measurement time, as shown in the following:

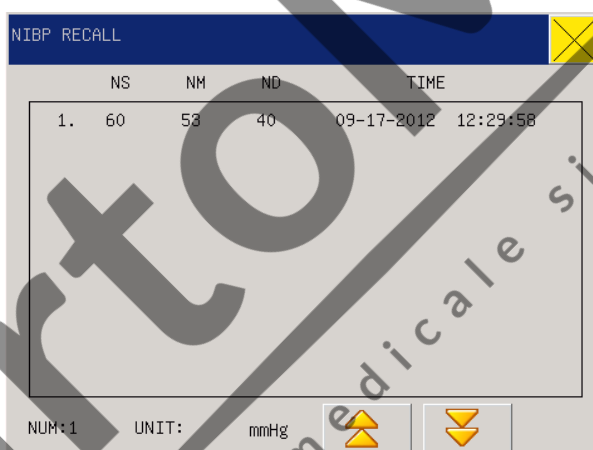


Figure 3-9 NIBP Recall

Data is sorted in time sequence, from early to late, and each screen can display 10 times of measurement data, while users can select “ ” to view later or earlier data. Maximally 2000 measurement results can be displayed, and when the measure times are over 2000, only the latest 2000 will be displayed.

3.9 ASPHYXIA STIMULATE REVIEW

The monitor can display the latest 2000 asphyxia stimulation data in the ASPHYXIA STIMULATE REVIEW function. After users select the ASPHYXIA STIMULATE REVIEW item under the MAIN MENU, the windows will display the latest 10 ASPHYXIA stimulation results and measurement time, as shown in the following:

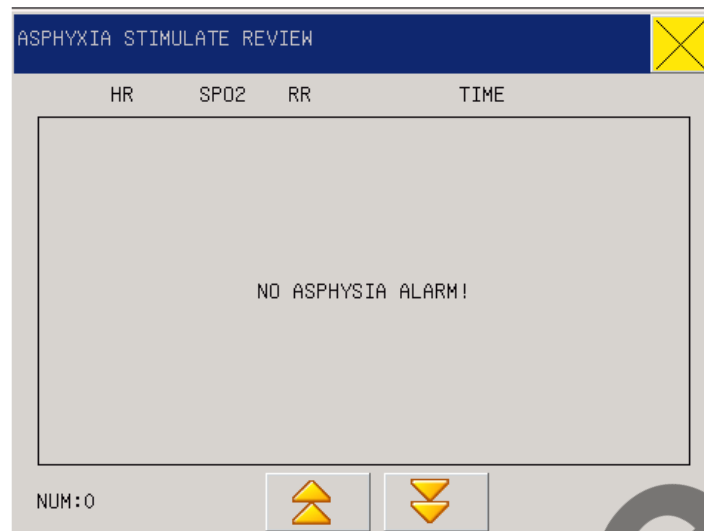


Figure3-10Asphyxia Stimulate Review

3.10 ALARM RECALL

When parameter alarm occurred, the monitor would be memory the alarm parameter data. Enter the “MAIN MENU” and select “ALM RECALL” to check one or all parameter alarms during some time as shown in the following figure:

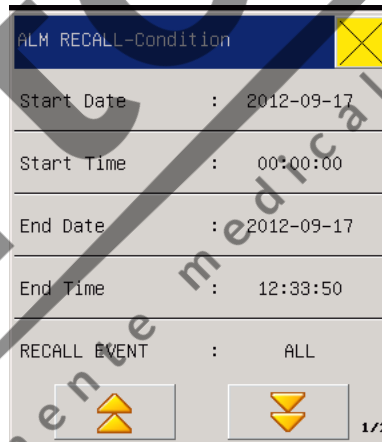


Figure 3-11 Alarm Recall-Condition

- (1) Setup up the period from start time/date to end time/date.
- (2) Would be re-check the alarm status in “RECALL EVENT” menu, the events include “ALL, ECG, SPO2, NIBP, IBP, CO2, RESP, TEMP, O2” status.
- (3) Optional “ALMRECALL_ Condition” window would be recall the alarm parameter and waveform. See figure below:

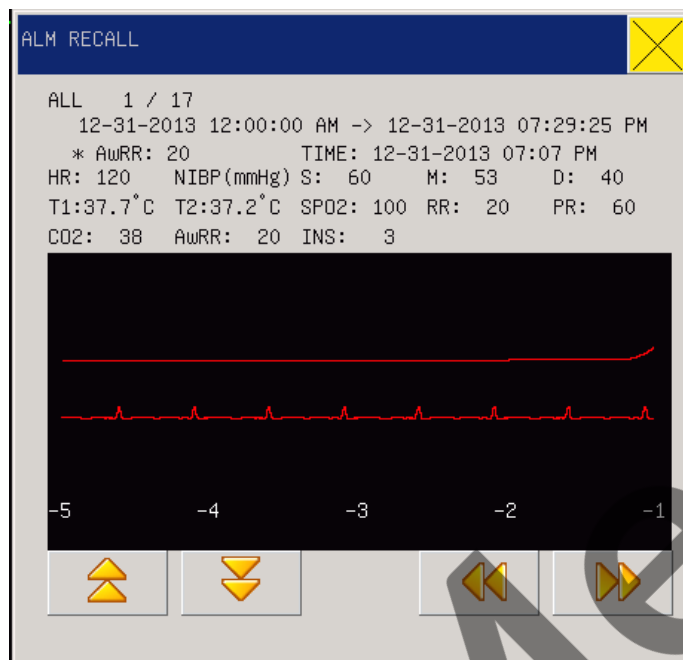


Figure 3-12 Alarm recall

3.11 WAVE RECALL

In "MAIN MENU", select the "WAVE RECALL" to recall the parts information or all information within memory data, following with figure below

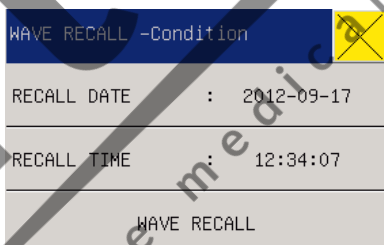


Figure 3-13 WAVE RECALL-Condition

Setup the review types of the "RECALL EVENTS" and times, enter in "WAVE RECALL-Condition" selected "WAVE RECALL" would be display the window, following with figure below:

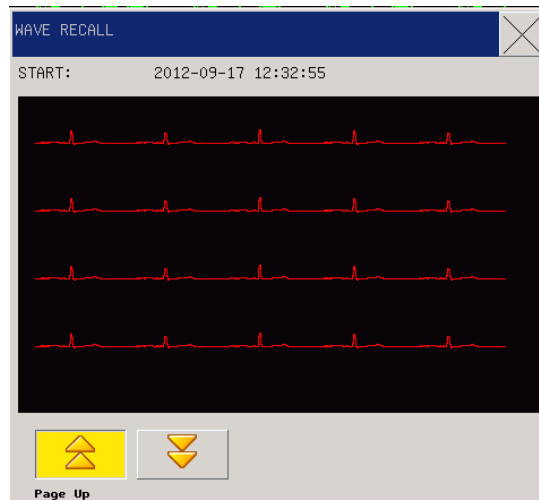


Figure 3-14 WAVE RECALL

3.12 INFO (Monitoring Information)

In the “MAIN MENU” select the “INFO” to look through the version information of the software and hardware.

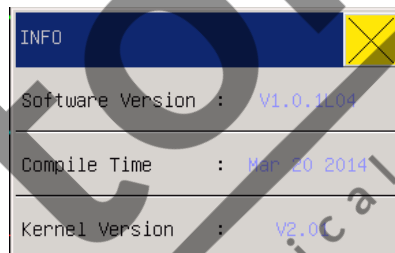


Figure 3-15 Monitoring Information


3.13 Calc.

Calculation this monitor provides calculations not data measured from patients but results calculated based on data users provided. This monitor can conduct drug calculation. Please refer to Chapter 8 Calculation for methods.

3.14 MAINTAIN (User Maintenance Settings)

In the “MAIN MENU” select the “MAINTAIN(Maintenance)”, submenu pop out: Password: 5188

- LANGUAGE: you can select CHINESE (SIMP) or ENGLISH.
- VGA SIZE:8.4”TFT

- WAVE MODE :MONO ,COLOR
- ANALOG OUT: OFF, I, II, V1, V2, V3, V4, V5, and V6 (depend on the lead type). External equipments like defibrillator can be connected to the Monitor through cables and the Monitor will output lead-I, lead-II or other analog signals for the external equipments to use.
- WIRELESS: ON/OFF. This function is only for our company’s central monitoring system. When the WIRELESS is on, the monitor can connect to the central monitoring system and the network cable is disabled at this time. When the WIRELESS is off, the monitor can connect to the central monitoring system only via network cables.
- WAVE TYPE: SpO2 waveform, RESP waveform and CO2 waveform has two types to select: LINE and FILL.
- SCREEN ADJUST: switch on touch screen as monitor indicated. Click right on the five calibration points “” to calibrate the touch screen, after which the screen would return to the main interface automatically.
- FACTORY DEFAULT: yes or no. Select “Yes” and you can save all configuration of the current patient type as the user’s default setting. Select “No” and you can abandon the current operation so that the system can continuously keep unchanged the original setting.

 **Warning**

- **If you select Default Configuration, the system would cover the current parameter setting with the default parameters the factory provides.**
- **Users cannot conduct the factory maintenance function in the MAINTAIN menu, for it is only available for maintenance workers our company appoints.**

3.15 DEMO (Password: 5188)

In the “MAIN MENU (System Menu)” select the “DEMO” to have the “KEY (Input Demo Password)” dialog box pop up. Input the correct password and the system will enter the waveform demonstration state.

 **Warning**

- **Demo waveform is a kind of simulation of waveforms, which is made by the manufacturer only to demonstrate the machine performance, and help users to set up training. In actual clinical use, the presentation is disabled, because it may make the medical staff mistake it for the monitoring waveform and parameters of patient monitored, which affects monitoring and delays diagnosis and treatment. So this menu has a password.**

3.16 STANDBY

- Press this button, the monitor would turn into the standby interface and shows “Press any key to exit the standby mode”.
- Now click anywhere on the screen or press any key on the panel, there comes two options of “New Patient” and “Continue”;
- When choosing “Continue”, the monitor would exit the standby mode and return to the previous monitoring interface; when choosing “New Patient”, the monitor would exit the standby mode, clear up the current patient information automatically and display “PATIENT” dialogue box. Users can input new patient information and start monitoring.

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Chapter 4 System Work Interface

There are five work interfaces in this monitor, that is, “STANDARD”, “LIST FACE”, “TREND SCREEN”, “oxyCRG SCREEN” and “BIG FONT”. Users can select different work screens based on different needs and get different screen information. Here are introductions for different interfaces.

4.1 Work Interface Selection

In the MAIN MENU, select the “FACE SELECT” or “SCREEN CHANGE” in the lower menu bar to enter the dialog box in the following Figure. Here there are such five interfaces to choose from:

STANDARD, LIST FACE, TREND SCREEN, oxyCRG SCREEN and BIG FONT. Users can select different work screens based on different needs and only one screen is available during each choice.

4.1.1 STANDARD

In the “FACE SELECT” menu, select the “STANDARD” to enter the standard work interface. The Standard interface provides us the parameter waveforms under monitoring and displays the parameters in the parameter area, as shown in the following picture:

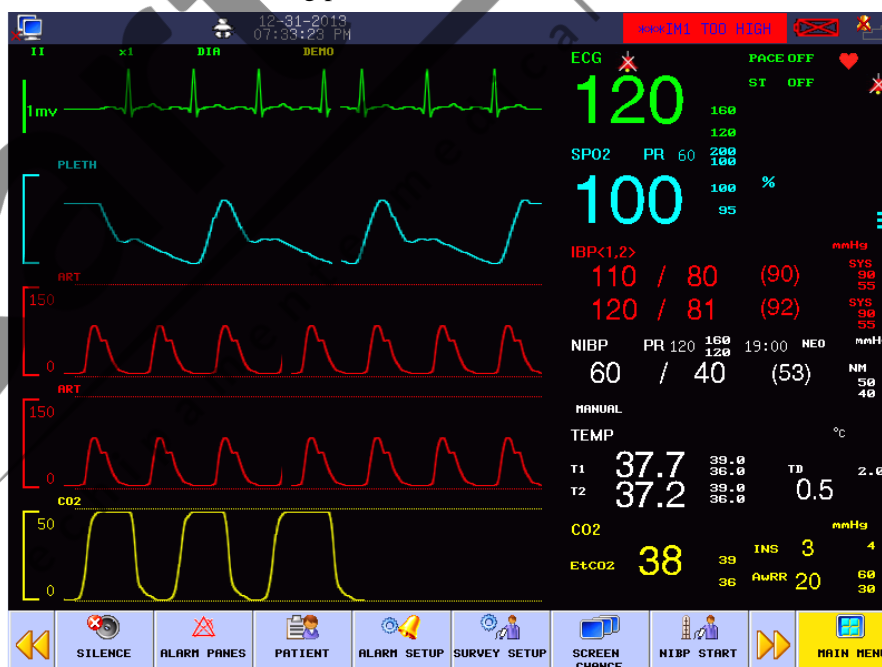


Figure 4-1 Standard Interface

4.1.2 LIST FACE

In the “FACE SELECT” menu or “SCREEN CHANGE” option in the menu bar, select the “LIST FACE” to enter the LIST FACE work interface.

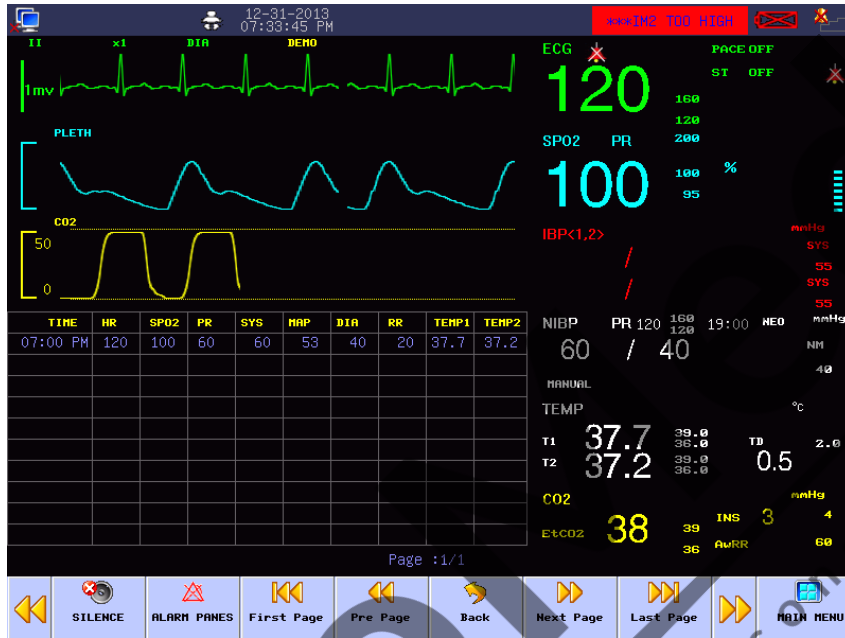


Figure 4-2List interface

4.1.3 TREND SCREEN

Enter the “FACE SELECT” or “SCREEN CHANGE” option in the menu bar, and select the “TREND SCREEN” in the Work Interface Selection menu to enter such an interface.

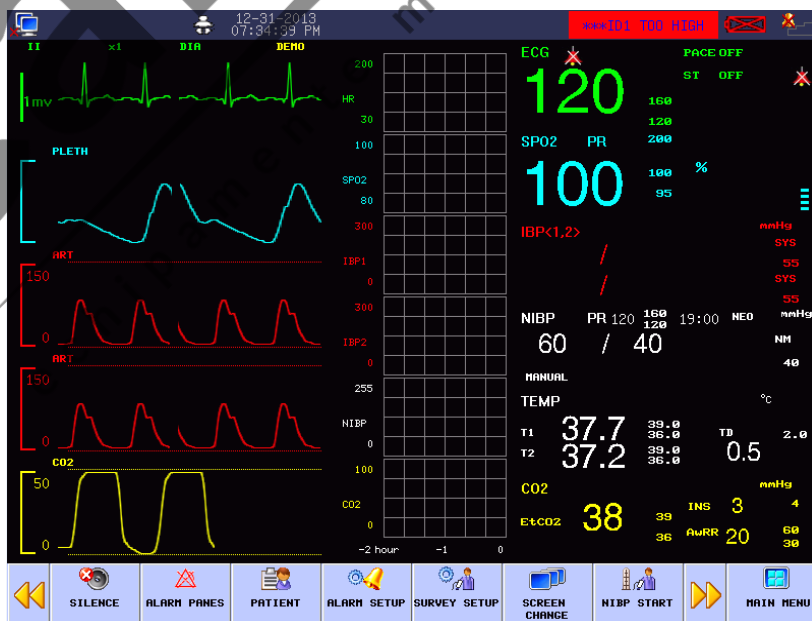


Figure 4-3 TrendSreenInterface

- Location of trend diagrams

TREND diagrams is located at right side of waveforms, with the same colors to the corresponding parameters.

- TREND length

Dynamic trend length is 2 hours; in a trend diagram, the right side of the horizontal axis is 0 hour, and the left side is 2 hours.

- End of trend concurrence interface

Out of the “Interface Selection” options, select any other work interface to end the trend concurrence interface.

4.1.4 OxyCRG SCREEN

In the Work Interface Selection menu or “SCREEN CHANGE” option in the menu bar, select the “oxyCRG SCREEN” to enter the oxyCRG work interface.

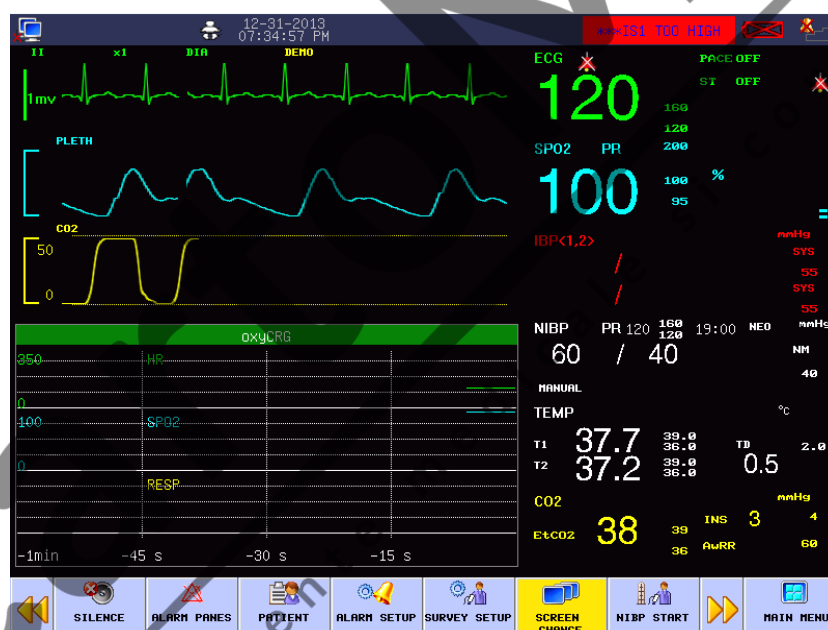


Figure 4-4OxyCRG Screen

- TREND Diagram in oxyCRG Interface

OxyCRG Dynamic Interface consists of compressed respiratory wave and RR, located in the lower part of the screen.

- OxyCRG Trend Length Selection

Two hot key at the below part of dynamic interface: TIME and TYPE. TREND Diagram for “1 minute” and “2 minute” can be selected through the trend time buttons.

- Compressed Respiratory Wave and RR

“The function of “Respiratory Rate/Compressed Respiratory Wave” means the operator can select the

“PR Trend” or “Compressed Respiratory Wave” as needed, under which the displayed content occupies the same position. Select the “PR Trend” and this position will show the TREND Diagram of the respiratory rate; select the “Compressed Respiratory Wave” and this position will show the respiratory wave after compression.

In the Work Interface Selection menu, select other work interface to end the OxyCRG work interface.

4.1.5 BIG FONT INTERFACE

In the Work Interface Selection menu or “SCREEN CHANGE” option in the menu bar, select the “BIG FONT” to enter the big font interface.

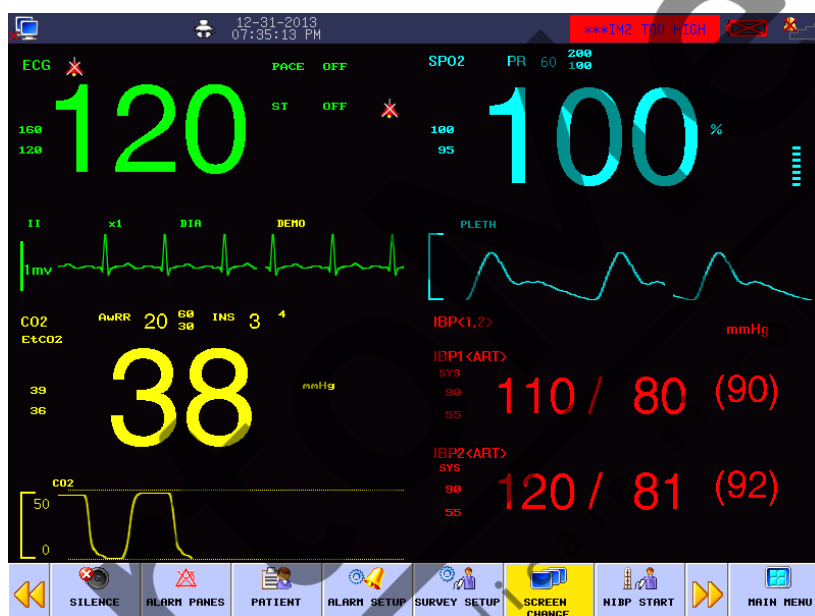


Figure 4-5 Big Font Interface

5.1 Alarm Type

The monitor can give an alarm of three types: physiological alarm, technical alarm and prompt message.

(1) Physiological alarm

Physiological alarm is usually caused by a certain physiological parameter of the patient which exceeds the set upper/lower limit scope or by the physiological abnormality of the patient. The alarm message of the physiological alarm will appear in the physiological alarm area above the screen.

(2) Technical alarm

The technical alarm is also referred to as a system error message, indicating the alarm is caused by a misoperation or system malfunction thereby causing improper operation of a system function or distortion of monitored results. The alarm message of the technical alarm will appear in the technical alarm area above the screen.

(3) Prompt message

Strictly speaking, prompt message does not belong to the domain of alarm. It is to display the information relative to the system conditions themselves, which have nothing to do with the patient's vital sign. Prompt message will appear in the prompt message area.

5.2 Alarm Level

The monitor can give an alarm in three volume levels: high, medium and low, based on the severity.

(1) High level alarm:

The patient is in a critical condition, endangering the patient's life, emergent attention required.

(2) Medium level alarm:

The patient's vital signs are abnormal, relevant measures and treatment are immediately required.

(3) Low level alarm :

The patient's vital signs are abnormal, and relevant measures and treatment may be required.

All alarm levels for technical alarms and some physiological alarms have been set before the monitors are delivered; the users are not allowed to change them. But a certain degree of physiological alarm can be modified.

5.3 Alarm Mode

When giving an alarm, the monitor will prompt the users in both sound and visual modes:

- Visual Alarm
- Sound Alarm
- Alarm
- parameter's flashing

In which visual signal, sound signal and prompting message are differentiated with different alarm levels.

5.4 Lighting Alarm

When giving an alarm, the alarm indicating lamp will show alarms in different levels with color and flashing frequency.

- High level alarm : red with flash frequency of 2 per second.
- Medium level alarm : yellow with flash frequency of one every two seconds.
- Low level alarm : yellow without flash but with a continuous light.

5.5 Sound Alarm

The sound alarm is set to prompt the alarm in different levels of severity with different sounds.

- High level alarm: Do-Do-Do--Do-Do---Do-Do-Do--Do-Do.
- Medium level alarm: Do-Do-Do.
- Low level alarm: Do.

5.6 Alarm

Prompting message means the related information will appear on the physiological alarm area or technical alarm area of the monitor when the alarm is active. The system will show different alarm levels in different background colors:

- High level alarm: Red
- Medium level alarm: Yellow
- Low level alarm: Yellow

Levels of the prompt message in the front of the alarm will be distinguished with the following symbols:

- High level alarm: ***




- Medium level alarm: **
- Low level alarm: *

5.7 Alarm Parameter Flashing

When a parameter is alarming, the parameter will flash once every second.


5.8 Icon of Alarm Status

Besides the alarm modes mentioned above, the following alarm icons will appear on the screen to indicate different alarm conditions.

- : indicating alarm muted.
- : indicating shut off of a parameter alarm.
- : indicating alarm paused.

5.9 Alarm limits

For instance :

- (1) Rotate the knob and get into ECG SETUP in the parameter area in the standard interface.
- (2) Move the knob and turn on the ALM ON/OFF to “ON”.
- (3) Move the knob and select HR ALM SETUP to set the upper limit of the HIGHT LIMIT to 120bpm and the lower limit to 50bpm. Then press the knob to confirm.
- (4) After settings, choose “”.

Warning

- **When setting alarm limits, you should make sure that the patient is neonates and set the ranges according to clinical requirements.**

5.10 Checking the alarm system

By checking sound alarm and light alarm, you can know whether the alarm system functions properly, for example:

- (1) Connect the blood oxygen cable to the monitor;
- (2) Get into SPO2 SETUP and turn the SPO2 alarm switch to “ON”.
- (3) Enter SPO2 ALM SETUP to set the alarm limits;
- (4) Enter the “MAIN MENU”, select “SELECTION” and set the ALARM VOL to one level among “1~6”.
- (5) Set the SPO2 limits of HIGHT LIMIT, MID LIMIT and LOW LIMIT to different value, rendering the alarms rest in different alarm levels, so you can observe the changes of the equipment’s sound, light and parameter flashing. Please refer to “Sound alarm, Alarm, and Alarm parameter flashing” for details.

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Chapter 6 Trend

It can store 120 hours trend data, 2000NIBP ,500 alarm events , review of 200 times of arrhythmia, 30-minutes waveform holography review for all monitoring parameters (the specific time is related to the stored waveform and its amount) and 2000 reviews of asphyxia stimulation. Observation methods are provided in this chapter.

6.1 TREND GRAPH (TREND Diagram)

TREND diagram for the latest 1 hour can be displayed one data per second or one data per five seconds; TREND diagram for latest120 hours can be displayed one data per minute, per 5 minutes, or per 10 minutes.

Select “TREND GRAPH” in the “MAIN MENU” to pop up the following TREND figure:



Figure 6-1Trend Graph

Vertical axis is for measured values and horizontal axis for measurement time. The “↓” symbol is the cursor for TREND diagrams, and the measured value at the position it arrows is displayed below the TREND diagram while its corresponding time is displayed above the TREND diagram.

6.1.1 Select trend diagrams for various parameters to be displayed:

Use the cursor to select the “PARAM” (Parameter Selection) option and revise the displayed contents.

Upon display of the expected parameter, press the knob, then the TREND diagram for this parameter will be displayed in the window.

6.1.2 Select 1-hour or 120-hour TREND diagrams:

Use the cursor to select the Resolution option, then select 1 seconds or 5 seconds if you want to observe 1-hour TREND, or select 1 minute, 5 minutes or 10 minutes if you want to observe 120-hour TREND.

6.1.3 Observe TREND diagrams of later or earlier duration:

Press the “◀ or ▶” button or rotate the knob clockwise or anticlockwise so as to observe later or earlier TREND curves.

6.1.4 Change the display zoom

Use the “▲ or ▼” button to change displayed size of the vertical axis, while displayed size of the TREND curves will follow to change. Values higher than the biggest axis value will be represented by the biggest axis value.

6.1.5 Obtain the TREND data at certain time in the current TREND diagram

Select “Cursor” and rotate the knob to control movement of the cursor; with the cursor moves, its arrowed time also changes, and the parameter value at such time will be displayed below the horizontal axis. If there is a “→” indication in the right side of the window, when the cursor moves onto this indication the TREND diagram will automatically page down to display later TREND curves; and if there is a “←” indication in the left side of the window, when the cursor moves onto this indication the TREND diagram will automatically page up to display earlier TREND curves.

6.1.6 Operation sample

Observe the NIBP TREND diagram within the latest 1 hour:

Get into the “MAIN MENU” from the lower menu bar and select “TREND GRAPH”:

- (1) Select the parameter: rotate the knob in the Parameter Selection item until “NIBP” is shown in the dropdown box;
- (2) Select 1 or 5 seconds in the Resolution item;
- (3) Press the “◀ or ▶” button or rotate the knob, while observing changes in the TREND diagram

- time and TREND curves;
- (4) Stop at the period to be carefully observed; in case the vertical axis is out of proper size, for example, some TREND values exceed the highest value of the current vertical axis, select “Adjust amplitude” to adjust or press “◀▶” or “▶▶” to do it;
 - (5) If users want to know the measured value at certain time, just select “move cursor” and move the cursor to where they wants, then time will be displayed above the curve and measured values below the curve;
 - (6) Press “☒” to exit observation on TREND diagram.

6.2 TREND TABLE (TREND Tabular)

TREND Figure data over the previous 1hour can be displayed in the following resolutions: 1 second, 5 seconds and 30 seconds.

TREND Figure data over the previous 120 hours can be displayed in the following resolutions: 1 minute, 5 minutes, 10 minutes, 30 minutes and 60 minutes.

Select “TREND TABLE” under the “MAIN MENU” to pop up the following TREND figure:

TREND TABLE					
TIME	HR BPM	SPO2 %	NIBP mmHg	PR BPM	RR RPM
<31>09:42:28 PM	120	100	----	60	20
<31>09:42:27 PM	120	100	----	60	20
<31>09:42:26 PM	120	100	----	60	20
<31>09:42:25 PM	120	100	----	60	20
<31>09:42:24 PM	120	100	----	60	20
<31>09:42:23 PM	120	100	----	60	20
<31>09:42:22 PM	120	100	----	60	20
<31>09:42:21 PM	120	100	----	60	20
<31>09:42:20 PM	120	100	----	60	20
<31>09:42:19 PM	120	100	----	60	20
<31>09:42:18 PM	120	100	----	60	20
<31>09:42:17 PM	120	100	----	60	20

RES.: 15

◀▶ ▶▶ ▲ ▼

Figure 6-2Trend Table

Time corresponding to various groups of TREND data is displayed at the left column, with dates braced. What are listed is the cases that have once been marked, which corresponds to the time of the marked cases. Parameters in the TREND Tabular can be categorized into the following several groups:

HR, SPO2, NIBP, PR, RR;

T1, T2, TD;

CO2, INS, AWRR, ST1, ST2



IBP1 (S/D/M)

IBP2 (S/D/M)



6.2.1 Select TREND Tabular in various resolutions

Resolutions: 1s, 5s, 30s, 1MIN, 5MIN, 10MIN, 30MIN and 60MIN, altogether 8 options. Use the cursor to select a resolution and use the knob to change options so as to change the time interval for TREND data.

6.2.2 Observe earlier or later TREND curves

Press “ or ” button or rotate the knob clockwise or anticlockwise so as to observe later or earlier TREND curves.






6.2.3 Observe TREND data of various parameters

Press “ or ” button and select one group parameters out of 6 available groups.

6.2.4 Operation sample

Get into the “MAIN MENU” from the lower menu bar and select “TREND TABLE”:

To observe a NIBP TREND Tabulation:

- (1) Press “ or ” button or rotate the knob to select the NIBP;
- (2) Select the resolution: click the left item and select the expected data interval;
- (3) Press “ or ” button or rotate the knob, while observing NIBP TREND data over various time;
- (4) Press “” to exit observation on TREND table.

6.3 NIBP RECALL

The monitor can record the latest 2000 NIBP datas. After select the NIBP RECALL in MAIN MENU, the window will display 10 groups of NIBP records as follows:

	NS	NM	ND	TIME
1.	60	53	40	09-17-2012 12:29:58

NUM: 1 UNIT: mmHg [Up Arrow] [Down Arrow]

Figure 6-3NIBP RECALL

Data is sorted in time sequence, from early to late, and each screen can display 10 times of measurement data, while users can Press “ or ” button to view later or earlier data. Maximally 2000 measurement results can be displayed, and when the measure times are over 2000, only the latest 2000 will be displayed.

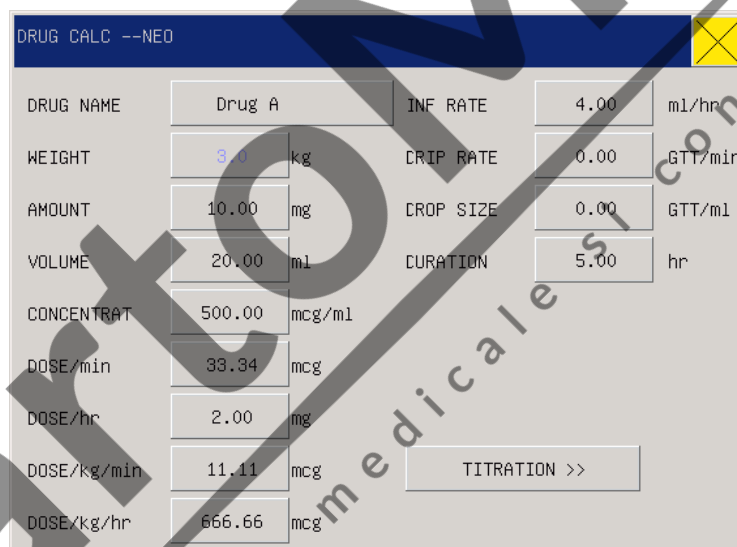
Chapter 7 Calculation

The portable-type multi-parameter monitor can provide the computation for 15 kinds of Drugs as well as the Titration List Display Function.

7.1 DRUG CALC

Drugs able to be calculated under this system are: aminophylline, dobutamine, dopamine, epinephrine, heparin, isuprel, lidocaine, nipride, nitroglycerin and pitocin. Besides, there are Drug A, Drug B, Drug C, Drug D and Drug E provided to flexibly replace any Drug.

Users can select “Calc. (Drug Calculation)” under the MAIN MENU to pop up the following window:



The screenshot shows a window titled "DRUG CALC --NEO" with a yellow close button in the top right corner. The window contains a table of input and calculated values for a drug calculation. The inputs include Drug Name (Drug A), Weight (3.0 kg), Amount (10.00 mg), Volume (20.00 ml), Concentration (500.00 mcg/ml), Infusion Rate (4.00 ml/hr), Drop Rate (0.00 GTT/min), Drop Size (0.00 GTT/ml), and Duration (5.00 hr). The calculated results are: Dose/min (33.34 mcg), Dose/hr (2.00 mg), Dose/kg/min (11.11 mcg), and Dose/kg/hr (666.66 mcg). A "TITRATION >>" button is located at the bottom right of the window.

DRUG NAME	Drug A	INF RATE	4.00	ml/hr
WEIGHT	3.0 kg	DRIP RATE	0.00	GTT/min
AMOUNT	10.00 mg	DROP SIZE	0.00	GTT/ml
VOLUME	20.00 ml	CURATION	5.00	hr
CONCENTRAT	500.00 mcg/ml			
DOSE/min	33.34 mcg			
DOSE/hr	2.00 mg			
DOSE/kg/min	11.11 mcg			
DOSE/kg/hr	666.66 mcg			

Figure 7-1 Drug Calculation

The following formulae are used for drug dosage calculation:

Drug contents = Total drug volume / Liquid volume

Infusion speed = Drug dosage / Drug contents

Continued time = Total drug volume / Drug dosage

7.1.1 Operation method

In the drug calculation window, operators should firstly select names of the drugs to be calculated, and then confirm patient weight, and input other known values. Subsequently, operators move the cursor to the various calculation items in the calculation formulae, press the knob and rotate it, so as to select the

calculation value. After the calculation value is selected, value of the items to be calculated will be displayed at the corresponding position. Values for each calculation item have their limits, if the calculated results invalid, the system will display “0”.

 **Attention**

- **Under this Drug calculation function, other menu items are available for input only after operators input patient weight and medicine names. The values firstly given in the system are only a random group of initial values, and operators should not take such values as calculation standard, instead, should re-input a group of values suitable for the current patient, based on the comments by doctors.**
- **Each kind of drug is subject with fixed units or unit series, and operators must select proper unit based on comments by doctors. Under the same unit series, numbering system of the units will be automatically adjusted with the current input values, and when the input value exceed out of expression of the relevant unit, the system will display “0”.**

Select drugtype: move the cursor onto “Drugname”, rotate the knob and select one from-aminophylline, dobutamine, dopamine, epinephrine, heparin, isuprel, lidocaine, nipride, nitroglycerin, pitocin, Drug A, Drug B, Drug C, Drug D and Drug E, altogether 15 types. At one time, only one type of drug can be selected for calculation.

 **Attention**

- **The above introduced A, B, C, D, and E are not actual drug names but only codes for medicines. Units for these five types of drugs are fixed, and operators can select proper units based on general practice of drugs. The expression rules of their units are as follows:**
 - ◇ **Drug A, B, and C are fixed under the “mg” unit series, including g, mg, and mcg.**
 - ◇ **Drug D is fixed under the “unit” unit series, including unit, k unit, and m unit.**
 - ◇ **Drug E is fixed under the “mEq” unit.**

Patient weight: this option is unavailable. The value in it has already been set in the “WEIGHT” in “PATIENT”.

 **Attention**

- **This function of drug calculation is only to provide a drug calculator, while values in the list should not be related with the patient under monitoring. Thus the patient weight under this menu is different from the patient weight in the system; when the system refresh with a new patient, values in this menu will not be affected.**

7.2 TITRATION

In the “DRUG CALC” menu, pitch on the “TITRATION” to enter the Titration list interface.

The Titration list interface for drugs is shown in the following Figure:

DRUG TITR--Drug A

AMOUNT	160.00	mg	VOLUME	100.00	ml
DOSE/hr	48.00	mg	INF RATE	30.00	ml/hr
WEIGHT	20.0	kg	DRIP RATE	20.00	GTT/min

DOSE	INF RATE	DOSE	INF RATE	DOSE	INF RATE
0.00	0.00	10.00	6.25	20.00	12.50
1.00	0.62	11.00	6.88	21.00	13.12
2.00	1.25	12.00	7.50	22.00	13.75
3.00	1.88	13.00	8.12	23.00	14.38
4.00	2.50	14.00	8.75	24.00	15.00
5.00	3.12	15.00	9.38	25.00	15.62
6.00	3.75	16.00	10.00	26.00	16.25
7.00	4.38	17.00	10.62	27.00	16.88
8.00	5.00	18.00	11.25	28.00	17.50
9.00	5.62	19.00	11.88	29.00	18.12

BASIC DOSE STEP 1 DOSE TYPE DOSE/hr

▲ ▼

Figure 7-2 Titration List

The specific operations are as follows:

1. In the Titration list, move the cursor to the “Reference Item” with the knob first, and then press the knob to select the required item. “Dosage” and “Injection Speed” are two options.
2. Move the cursor to the “Step Length” and press the knob to select the step length in the range of 1~10.
3. Move the cursor to the “Dosage Type” and press the knob to select the dosage unit.
4. Move the cursor to the “▲ or ▼” button and press and turn the knob to check the previous and next pages of the list.
5. Move the cursor to the “☒” and press the knob to return to the “Drug Calculation” menu.

8.1 Safety explanation

The portable monitor is designed to meet the international safety requirements IEC60601-1, EN60601-2-27 and EN60601-2-30 formulated for medical electric equipments. It's furnished with floating inputted defibrillation resistance and surgery electric knife protection. If correct electrodes (referring to the ECG and RESP chapters) are installed following supervision of the manufacturer, screen display will be recovered within 10 seconds after defibrillation.

8.2 Environment

Users should follow the following guides to ensure absolute safety of electricity installation.

For an environment where the portable monitor is located, users should reasonably avoid vibration, dusts, corrosive or explosive gases, extreme temperature and moisture.

In case installed inside a chamber, the front side must be given sufficient space for convenient operations, and while the chamber door is open, the rear side must be given sufficient space for easy repair. Moreover, there should be at least 2 inch (5 cm) of space reserved surrounding the monitor to ensure air flow.

The monitor, when working in an ambient temperature between 5°C ~ 40°C, can meet the technical indexes, otherwise may have equipment accuracy affected or parts or circuits damaged.

8.3 Power Source

Please refer to the chapter **Product Specification** or **General Information**.

8.4 Monitor earthing

To protect patients and medical staff, the portable monitor must have its cover connected with the earth; for such reason the monitor is equipped with a dismountable 3-line cable, which should be plugged into a matching 3-line socket and further connected with the earth through the ground line of the power supply cable. In case of no 3-line socket, please consult with the electricity staff of your hospital.

 **Warning**

- **Don't connect the 3-line cable of this monitor with a 2-line socket.**

Connect the ground line with the equal-potential earthing terminal of the monitor. If unaware whether a certain equipment combination is risky in terms of equipment specification, for example, whether gathered leakage current is dangerous, users should consult with relevant manufacturers or specialists, so as to make sure the necessary safety of the relevant equipment will not be damaged by the proposed combination.

8.5 Equal-potential earthing

First level protection on the equipment has been contained in the housing protective earthing system through earthing of the power socket. For heart or head internal check, this portable monitor must be individually connected with an equal-potential earthing system. One side of the equal-potential cable (potential balanced cable) should be connected with the equal-potential earthing terminal on the rear panel of the monitor, while the other side connected with one interface of the equal-potential system. In case of any damage to the protective earthing system, the equal-potential earthing system will take the safety function of protecting the earthing cable. Heart or head checks should be conducted within areas for medical use installed with protective earthing systems. Before each time of use, users should check whether the equipment is under good working status and pay attention the cable connecting patients and the equipment must be free from electrolytes pollution.

 **Warning**

- **If the protective earthing system is instable, the monitor should be applied with internal power supply.**

8.6 Condensation

During work period the equipment must be made sure of no condensation. When the equipment is shifted from one room to another room, condensation may be formed as the equipment is exposed in moistured atmosphere and different temperature. The equipment should wait to be dry to use in case of condensation to avoid further problems.

Note: condensation refers to gas' condensation or liquid's congealment because of coldness, for example, vapour condenses to water and water congeals to ice. The lower the temperature is, the faster condensation is.

 **Warning**

- If the monitor is used where there are flammable anesthetic agents, there may be explosion.

8.7 Explanations on Symbols Used in the Monitor

See contents in “1.7 symbol instruction”.

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Chapter 9 Maintenance & cleaning

9.1 Maintenance check

Before monitoring patients, you shall:

- (1) Check whether there is any physical damage;
- (2) Check all the disclosed leads, plugs, and accessories;
- (3) Check all the functions to be used to monitor the patients and ensure the equipment works well.

If any phenomenon is observed with the possibility of damaged functions, the Monitor shall not be used onto the patients and please contact the biomedical engineers of your hospital or the maintenance engineers of our company.

Comprehensive checks, including safety checks, must be conducted by qualified personnel once per 6-12 months and after each time of repair.

According to the hospital's maintenance plan, check the monitor's synchronous defibrillation function and check that by qualified maintenance workers at least once three months.

All safety checks and maintenance work about detachable equipments should be done by professional maintenance workers. Non-professional workers' operation may cause equipment malfunction or leave potential safety hazard and jeopardize the patient's health.

Comen Company will provide circuit diagrams when customers ask to help them maintain equipment elements subject to self-maintenance classified by Comen via qualified technical members.

Warning

- **If any hospital or agency responsible for using the Monitor fails to implement a set of satisfying maintenance plan, unusual functional failure may be resulted to the Monitor and may threaten the people's health.**

9.2 Cleaning and Sterilization

9.2.1 Note on Cleaning and Sterilization

 **Warning**

- **Power must be turned off and the AC power must be cut off before cleaning monitor or sensors.**

 **Caution**

- **Do not damage the monitor:**
 - (1) **No strong solvent such as acetone shall be used;**
 - (2) **Most of cleaning liquids shall be used only after diluted, and you shall dilute them following the instructions given by manufacturers;**
 - (3) **No abrasive material (such as fiber wire or silver polisher) shall be used;**
 - (4) **No liquid shall enter the cover, and you shall not immerse any part of the Monitor into any liquid;**
 - (5) **No cleaning liquid shall be remained on the surface of the Monitor.**

 **Attention**

- **Please refer to user manuals attached with the accessories when cleaning or sterilizing repeatedly-used accessories.**
- **Surface of the monitor and its sensors can be cleaned with medicinal alcohol, natural air drying or dry clean lint-free cloth.**
- **Comen is not responsible for the effectiveness of these chemicals as anti-infectious diseases control. Please consult principal of infectious diseases control in the hospital or experts.**
- **Disposable accessories must be recycled or properly handled to protect the environment.**
- **In order not to pollute people, environment and other equipments, sterilization and depollution must be done before discarding monitors. Then discard the monitor according to the country's regulations on discarding equipments containing electronic and electric parts. If there are no regulations about thermometers, you can follow the local regulations on discarding hospital waste.**

9.2.2 Cleaning

The Monitor must be kept dust-free. Regular cleaning of the monitor shell and screen is strongly recommended. More cleaning is needed in the environmental polluted or sandstorm areas. Before cleaning

the monitor or the sensor, please consult with customer service or understand the hospital equipment cleaning regulation.

1) Cleaning agents are listed below:

- Diluted Ammonia Water
- Diluted Sodium Hypochlorite(Bleaching agent)
- Diluted Soapy Water
- Hydrogen Peroxide 3%
- Alcohol 70%
- Isopropanol70%

2) Before cleaning the monitor:

- Make sure that the equipment is switched off and disconnected from the power line.
- Use soft cotton ball to adsorb a small amount of cleaning agents and clean the screen.
- Use soft cloth to adsorb a small amount of cleaning agents and clean the monitor shell.
- If necessary, use a soft dry cloth to wipe away the excess cleaning agents.
- Dry the monitor in air.

9.2.3 Sterilization

To avoid damage to the monitor, sterilization is recommended only when stipulated as necessary in the Hospital Maintenance Schedule. Monitor facilities should be washed first.

Recommended sterilization material:Ethyl alcohol 70%, Isopropanol 70%,Glutaraldehyde 2%.

Caution

- **Do not use ETO gas to disinfect the monitor.**
- **Use a moistened cloth to wipe up any agent remaining on the monitor**
- **Try to use low-content liquids or dilute liquids following the instructions of manufacturers.**
- **Don't let any liquid enter the cover and don't immerse any part of the equipment into any liquids.**
- **Don't remain any cleaning liquid on the equipment surface.**
- **Don't pour liquids onto the equipment during the disinfection process.**

10.1 Definition of ECG Monitoring

ECG monitoring describes continuous waveforms of cardiac activities of patients so as to accurately assess the current psychological status of the patients. Thus proper connection of ECG cables must be ensured in order to obtain correct measurement values. This portable monitor concurrently can display 2 waveforms under normal work status.

A patient cable consists of two parts:

- Wire connecting the monitor;
- Leads connecting patients.

With a 5-lead facility for monitoring, ECG can obtain two waveforms from two different leads. Users can use the knob, in the left side of the ECG waveforms on the screen, to directly select the lead to be monitored.

Displayed monitoring parameters include HR, ST segment measurement value and arrhythmia.

All the above parameters can be taken as alarm parameters.

Attention

- Under factory settings in the instrument, the ECG waveforms are displayed in the top-two waveform positions.

10.2 Attentions during ECG Monitoring

Warning

- Don't touch patients, tables or the equipment during defibrillation.
- ECG lead wire provided by your company should be used when monitoring the ECG signal by this instrument.
- When connecting the electrode or patient cable, you should insure that the patient is absolutely not in contact with any other conductive instrument or with the ground. In particular, you should make sure that all ECG electrodes, including the neutral electrodes, are connected to the patient, to prevent them contacting the ground or each other.

 **Attention**

- **Disturbance from non-earthing equipments around a patient or ESU disturbance may affect waveforms to function improperly. Where this monitor is operated according to the conditions specified in the EN60601-1-2 (anti-radiation ability: 3V/M) and the electric-field strength above 1V/M may give rise to the measurement mistakes under various frequencies, it is suggested that the electroradiant equipment should not be used in the place next to the ECG/Respirometer.**

10.3 Monitoring Procedures

10.3.1 Preparation

Take patient skin preparation before installation of electrodes:

- (1) Skin is bad conductor, thus to ensure good touch between electrodes and skin it's very important to well prepare patient skin.
- (2) When necessary, remove body hair surrounding the electrode positions.
- (3) Clean thoroughly the skin with soap and water (don't use ethyl ether or pure alcohol, as they will increase skin resistance).
- (4) Drily sweep the skin so as to increase capillary blood flow as remove skin scraps and oil.
- (5) Install spring clamp or snap before installation of electrodes.
- (6) Put the electrodes on patient body; in case the electrodes contain no conductive paste, coat the conductive paste before installation.
- (7) Confirm power supply.

 **Warning**

- **ECG contact area should be checked daily for irritation. If there are signs of allergy, you should replace the electrode or change the position every 24 hours.**
- **Before monitoring check whether the leads work properly. After users plug out the ECG cables, screen will display the error information of "Sensor disconnected" and activate voice alarming.**
- **Electrode plates are forbidden to use for people whose skin suffers from inflammation or fester. People who are alleged to electrode conductive medium are prohibitten to use it.**

 **Attention**

- **To protect the environment, used electrode must be recycled or properly treated.**

10.3.2 Install ECG leads

10.3.2.1 Identification and color code of electrodes

⚠ Attention

- The following table lists the lead names under the European and US standards (leads are represented in RA, LA, RL, LL, and V under the US standard and in R, L, N, F and C under the European standard).

US standard		European standard	
Lead name	Color	Lead name	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White

10.3.2.2 Installation position of three-lead ECG monitoring electrodes

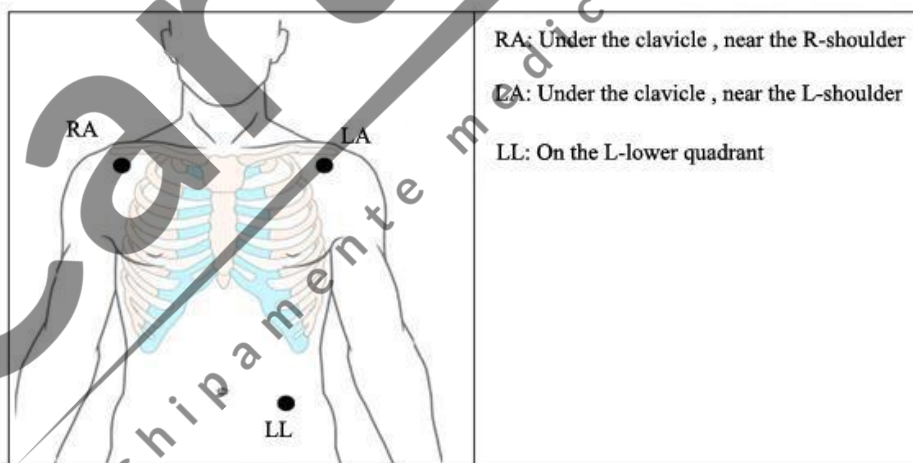


Figure 10-1 Three-lead ECG electrodes position

10.3.2.3 Installation position of five-lead ECG monitoring electrodes

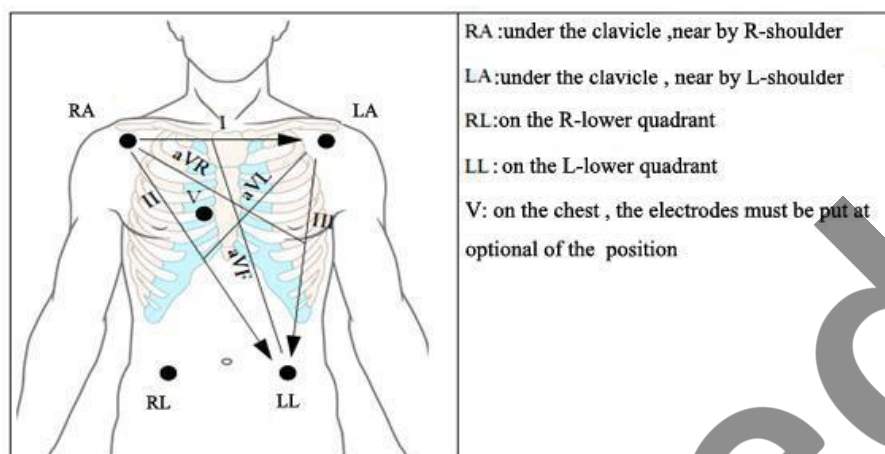


Figure 10-2 Five-lead ECG electrodes position

⚠ Attention

- **In order to ensure the safety of patients, all leads must be connected to the patient.**

As with 5-lead devices, the chest lead electrodes should be put in one of the positions as follows (Figure10-3):

V1: in the fourth intercostal space on the right edge of the sternum.

V2: in the fourth intercostal space on the left edge of the sternum.

V3: in the middle position of V2 and V4.

V4: in the fifth intercostal space of the left mid-clavicular line.

V5: at the left anterior axillary line, with horizontal position the same as the V4.

V6: at the left median axillary line, with horizontal position the same as the V4.

V3R-V7R: in the right chest wall, with its position corresponding to the left position.

VE: at the eminence of xiphoid.

V7: in the fifth intercostal space of left posterior axillary line on the back.

V7R: in the fifth intercostal space of right posterior axillary line on the back.

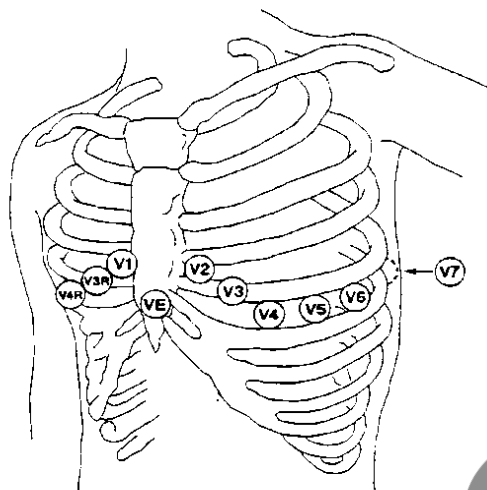


Figure 10-3 Position of Chest lead electrode of five-lead device

10.3.2.4 ECG lead connection recommended for surgery patients

Warning

- When using electricity surgical equipment (ESU), put the ECG electrode at the middle position between ESU earth plate and electricity surgical knife to avoid burn. the cable of electricity surgical equipment and the cable of ECG can't be entwined.
- In the use of surgical electric equipment (ESU), never let the electrodes are close to the electrosurgery equipment on the earth plate, or ECG signal would be interfered a lot.

Positioning of ECG leads is up to operation types, for example, for chest operation, electrodes can be put on breast sides or back. Inside operation rooms using surgery electric knives, sometimes artificial discrepancy may affect ECG waveforms; to reduce such artificial discrepancy, users may put the electrodes at the left and right shoulders, near left and right abdomen, with breast lead at left to the middle breast. No electrodes should be put on left arm; otherwise the ECG waveforms will be very small.

10.3.2.5 Usage of five-lead device

The users can arrange the lead on channel one and channel two according to their needs. The name of lead on the channel is displayed on the left side of the corresponding waveform; you can directly select them and make changes. Two waveform channels, only channel 1 can display the ECG waveform, click the screen ECG waveform, enter the ECG waveform settings, select the appropriate name of the lead from the “I, II, III, the AVR, AVL, AVF, V” and select the way of gain and filtering according to your need. See

figure 10-4.

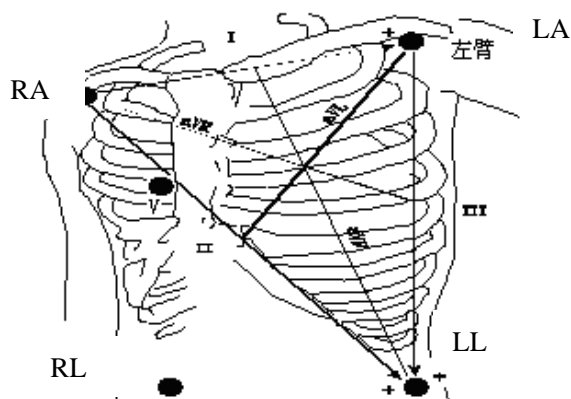


Figure 10-4 Five-lead ECG

⚠ Attention

- If the electrode paste is correct, while the ECG waveform is not accurate, then replace the lead.
- Interference of the instrument which is ungrounded and electrical surgical equipment (ESU) near the patient's may cause the waveform problems.

Feature of a good signal:

- Tall, narrow and without notch.
- R wave tall, completely above or below the baseline.
- Signal of pace lower than height of R wave.
- T waves less than 1/3 height of the R wave.
- P wave should be much smaller than the T wave.

In order to obtain 1 mV calibration ECG wave .ECG should be calibrated, at the same time,the screen displays the prompt: can not monitor the patient during calibration.

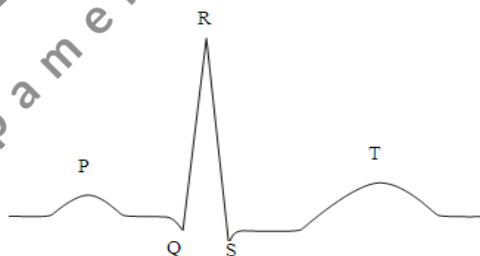


Figure 10-5 Standard ECG wave form

10.4 ECG Hot Key

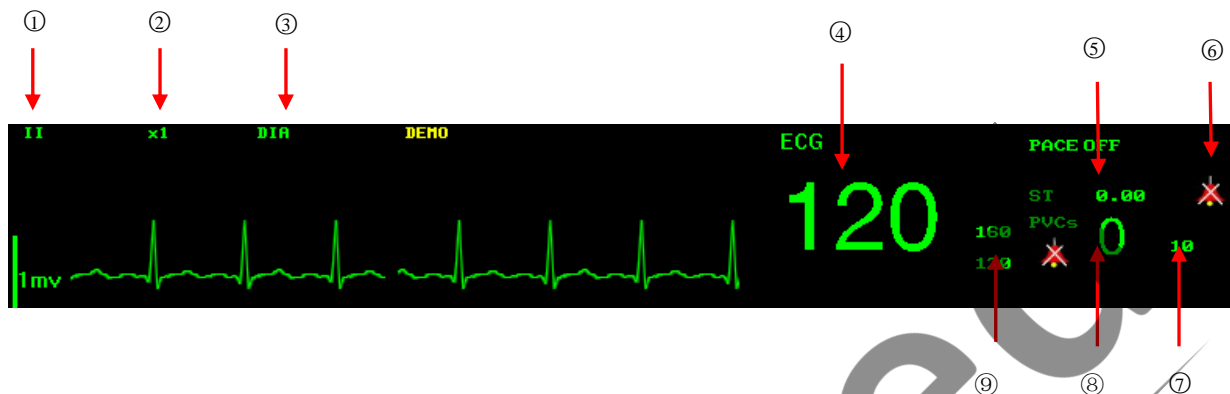


Figure 10-6 ECG Hot Key

⚠ Attention

- The pacing signal detected will show as “!” at the top of the waveform of the ECG waveform

① Name of the First ECG Lead:

ECG using 5-lead, the selectable leads include I, II, III, aVR, aVL, aVF and V₆;

ECG using 3-lead, the selectable leads include I, II and III. (For neonate);

The leads on the ECG waveform should not have the same name; otherwise the system will automatically change the similar name into another.

② The 1st-ECG Waveform Gain: used to adjust the amplitude of ECG waveform.

The gain of each calculation channel can be selected, which has such columns as, $\times 0.25$, $\times 0.5$, $\times 1$, $\times 2$ and $\times 4$ as well as auto mode. Auto mode means that the monitor can automatically adjust the gain. On the right side of each ECG waveform there is a 1-mv rod of which height and amplitude are proportional.

⚠ Attention

- When the input signal is too large, the peak may be truncated. The user can refer to the actual waveform to manually change the gain of the ECG waveform in order to avoid the waveform display incomplete.

③ Filtering Mode: The cleaner or precise waveform can be obtained through filtering.

There are three filtering modes for option. The unfiltered ECG waveform is shown in the diagnostic mode; the monitoring mode will possibly lead to the artifact filtering; the operation mode used in the surgery can reduce the artifact and interference from the electrosurgery unit. The filtering mode can be used in two channels and displayed on the upper part of the first ECG waveform.

⚠ Warning

- ECG waveforms have varying degrees of distortion in the filter mode of “monitoring” and “operation” . At this time the system can only provide the basic status of the ECG, and it may have greater impact for the result of the ST segment analysis. so we recommended that when the interference is small, try to use the diagnostic mode for the monitoring of the patient.

④ ECG value:

Display the value of ECG measured

⑤ST analysis value:

Display the value of ECG measured

⑥ST alarm off icon:

When this icon appears beside the measured parameter, it means the alarm switch has not been opened.

⑦PVCs alarm upper limit

When ARR analysis is “ON” in ECG SETUP, the upper alarm limit is displaying beside.

⑧PVCs value

Display the value of PVCs

⑨Limits of the LOW LIMIT of HR

Displaying the upper and lower limits of LOW LIMIT of HR ALM SETUP in ECG SETUP.

10.5 ECG Menu

10.5.1 ECG setting menu

Use turn knob and move cursor on the main screen to the ECG hot keys in the parameter area, then press the knob to pop up the ECG Setting menu:

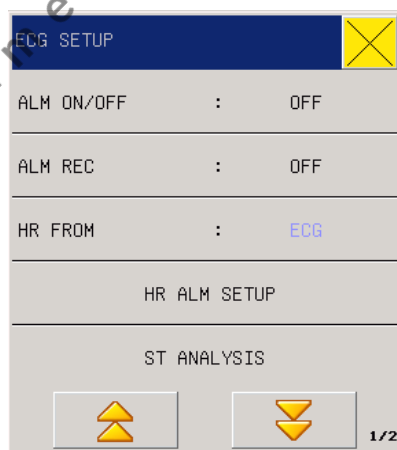



Figure 10-7ECG Setup

■ ALM ON/OFF: Select “ON” to give alarm prompt and storage when the heart rate alarm happens.  will be prompted beside ECG.

■ ALM REC(Alarm record): Users can select “On” to print HR alarms when they happen

■ HR FROM: ECG or SPO2 is available for monitoring HR; choose “AUTO” means the monitor would decide the HR source based on the signal quality; choose “BOTH”, the monitor would display PR as well as HR. If there is SPO2, it will indicate PULSE with sound of PR. When HR FROM selects ECG, the monitor would not alarm against HR but PR. When selecting “BOTH”, there will be PR value displaying at the right side of SPO2 in the main interface; and HR and PR are all subject to warning. The heart pace is based on HR; there will a sound prompt as long as HR has got data. If HR has not, then PR will.

■ HR ALM SETUP: setup heart rate hightlimit, middlelimit, low limit of the upper and lower limits. The HIGHT LIMIT alarm is red, MID LIMIT alarm yellow and LOW LIMIT alarm green. When the measured value is higher than the upper limit of the HIGHT LIMIT or lower than its lower limit, the monitor would trigger high level alarm.

When the measured value is higher than the upper limit of MID LIMIT and lower than the upper limit of HIGHT LIMIT; or the value is lower than the lower limit of MID LIMIT and higher than the lower limit of HIGHT LIMIT, the monitor would trigger mid level alarm.

When the measured value is higher than the upper limit of LOW LIMIT and lower than the upper limit of MID LIMIT; or the value is lower than the lower limit of LOW LIMIT and higher than the lower limit of MID LIMIT, the monitor would trigger low level alarm.

The minimum gap between the upper limit of MID LIMIT and that of HIGHT LIMIT is 2bpm, the lower limit of MID LIMIT and that of HIGHT LIMIT is 2bpm; upper limit of LOW LIMIT and that of MID LIMIT is 2bpm, the lower limit of them 2bpm.

Adjustable ranges for HR alarm upper & lower limits are as follows:

	Highest upper limit	Lowest lower limit	Adjustment step length
HR newborn	350	15	1

Attention

- Users should set the alarm upper & lower limits based on the clinical conditions of every patient.
- Setting of the HR alarm upper limit is very important, and users should not set it too high but consider fluctuation factors. The set HR alarm upper limit should not be over 20 beats/ minutes than patient HR.

10.5.2 ECG setting in waveform area

Turn the knob to waveform area; press the knob to enter ECG waveform setting:

ECG SETUP		
LEAD NAME	:	II
GAIN	:	x1
SWEEP	:	25
WAVE COLOR	:	GREEN
FILTER	:	DIA

Figure 10-8 ECG Setup

■ LEAD NAME

ECG using 5-lead, the selectable leads include I, II, III, aVR, aVL, aVF and V₁.

ECG using 3-lead, the selectable leads include I, II and III.

- **GAIN:** used to adjust the amplitude of ECG waveform. The gain of each calculation channel can be selected, which has such columns as, $\times 0.25$, $\times 0.5$, $\times 1$, $\times 2$ and $\times 4$ as well as auto mode. Auto mode means that the monitor can automatically adjust the gain. There is a scaleplate of 1mV at the right side of each ECG waveform. The height of the 1mV scaleplate is in direct proportion to range of the waveforms.
- **SWEEP:** ECG Waveform scanning wave has four levels for option, such as 6.25, 12.5, 25.0 and 50.0mm/s.
- **WAVE COLOR:** green, cyan, red, white, blue, violet, yellow.
- **FILTER (Filtering Mode):** The cleaner or precise waveform can be obtained through filtering. There are three filtering modes for option. The unfiltered ECG waveform is shown in the diagnostic mode; the monitoring mode will possibly lead to the artifact filtering; the operation mode used in the surgery can reduce the artifact and interference from the electrosurgery unit. The filtering mode can be used in two channels and displayed on the upper part of the first ECG waveform.

10.5.3 ECG setting in measurements

Select “SURVEY SETUP” (parameter setup) in the lower menu bar and choose “ECG SETUP” as follows:

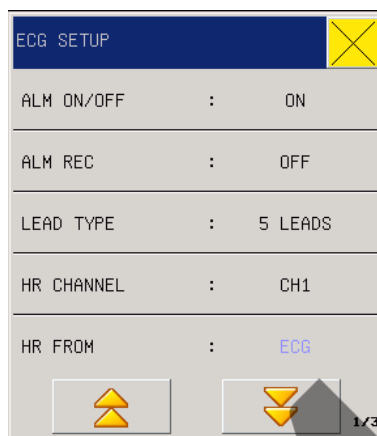



Figure 10-9 ECG Setting menu

- ALM ON/OFF: When the heart rate alarm happens. Select “OFF”  will be prompted beside ECG.
- ALM REC(Alarm record): Users can select “On” to print HR alarms when they happen
- LEAD TYPE: 5-leads, or 3-leads.
- HR CHANNEL (Selection of HR calculation channel):CH1,CH2,AUTO.
 - ◆ “Channel 1” means the HR is calculated according to the first ECG waveform data.
 - ◆ “Channel 2” means the HR is calculated according to the second ECG waveform data.
 - ◆ “Auto” means the monitor will automatically select the channel of calculating HR.
- HR FROM: ECG ,SPO2 ,AUTO ,BOTH
 - ◆ Users can select to check HR through ECG or PLETH (blood-oxygen volume recording waveform); if users select “Automatic”, the monitor will decide HR source based on signal quality; if users select “All”, the monitor will concurrently display HR and PR.In case PLETH is taken as the HR source, the PULSE reminder will be displayed together with pulse voice.In case PLETH is taken as HR source, no alarm judgment on HR but alarm judgment on PR will be conducted. In case “All” is selected, PR measurement values will be displayed in the right to SpO2 on the main screen, and HR & PR make alarms at the same time. Pulse voice will give priority to HR, as long as there is HR data, voice reminder will be there; only when there is no HR data, voice reminder will be subject with PR.
- SWEEP, WAVE COLOR, FILTER: See this chapter “ECG SETUP”parameter area corresponding.
- NOTCH: OFF, 50Hz and 60Hz. When set to OFF, there is no power frequency restrained. This option is related to “FILTER”. When “FILTER” is set to “DIA”, all choices can be chosen. When it is

“MONITOR” or “SURGERY”, only 50Hz and 60Hz can be chosen, which means under the monitor or surgery status, it must restrain power frequency. It is a method of inhibiting the method and apparatus of the power frequency common mode interference, for bioelectric signals measurement system including a common mode interference signal extraction circuit and a drive circuit connected to the circuit; particular, the apparatus further includes a phase compensation processing means for receiving from the subject organisms of biological signals and the driver circuit to provide the amplified signal, the output is sent to a feedback signal by measuring biometric.

- HR ALM SETUP: setup heart rate high limit, middle limit, low limit of the upper and lower limits.
- ST ANALYSIS: ST Segment Analysis Select this item and enter the “ST Segment Analysis” menu.


- ◆ About ST analysis

The normal heart beat and atrioventricular pacing are used for ST segment analysis. The monitor analyzes these heart beats and calculates the elevation and depression of the ST segment. The monitor can display that information for ST numerical form. It can continuously monitor all available leads. For ST-segment analysis, the ECG waveform is not required to be displayed on the monitor. When the ST analysis is in the implementation, it usually uses a special filter which ensures diagnostic quality. If you use the "diagnosis" filter out of the ECG filtering mode to monitoring ECG, the ST segment of the ECG wave will be slightly different from ST segment in the ST fragment with the same waveform. In order to diagnostically assess the ST-segment, please always switch to filter mode of "diagnosis". You can also select the "monitoring" or "operation" mode, but ST-segment data will have a serious distortion.

 **Warning**

- **Some clinical conditions makes it difficult to get reliable ST monitoring, such as:**
 - ✧ **Unable to obtain the low noise of the lead;**
 - ✧ **the irregular baseline arrhythmia such as atrial fibrillation / atrial flutter;**
 - ✧ **The patient is continuous ventricular pacing**
 - ✧ **Patients with left bundle block**
 - ✧ **When these things happen, you should consider to close ST monitoring**
 - ✧ **ST level change information provided by this monitor, its clinical significance should be decided by the physician**

- ◆ ST analysis

- ST ANALYSIS: this switch is mainly used to set the state of ST Segment Analysis. Only when the switch is ON, ST Segment Analysis can proceed.
- ALM ON/OFF: Where “ON” is selected, the alarm prompt and saving will proceed when ST analysis result is alarmed; where “OFF” is selected, alarming will not happen, but  will be prompted beside ST in the screen parameter area. ST Alarm will be triggered only when its

measured value exceeds ST Alarm Upper Limit or ST Alarm Lower Limit.

- ALM LEV (Alarm Level): “Low”, “Middle”, “High”.
- ALM REC (Alarm Record): when it is set at “ON”, the system will start the recorder for alarm record.
- ST ALM SETUP (ST alarm setup): set the upper and lower alarm limit for the ST segment of each lead.

The adjustable range for upper limit and lower limit of alarm as follows:

	Max. Upper Limit	Min. Lower Limit	Single Adjustable Quantity
ST	2.0mv	-2.0mv	0.1mv

- DEF POINT (Determine the ST Segment AP (Analysis Point)): Select this option to enter the “Determine the ST Segment AP” window and set the values at ISO and ST.
- ISO (BP: base point): set the baseline point. Power on time is set at 96ms.
- ST (SP: starting point): set the measuring point. Power on time is set at 128ms.

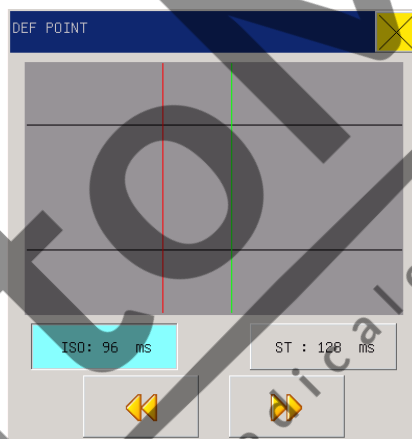


Figure 10-10 Determine the ST Segment

ISO and ST are two measuring points of ST Segment, which are adjustable. R wave crest point is the reference point in setting of ST measuring point (as shown in the following figure):

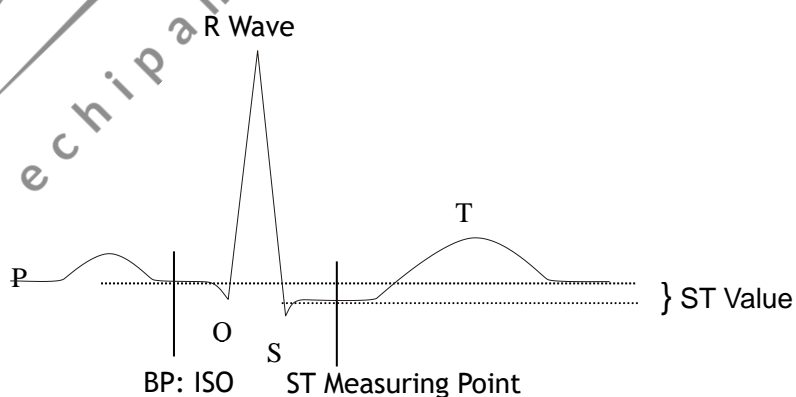


Figure 10-11 ST Analysis Point

ST measured value of each HB composite waveform is the vertical distance between this waveform and the crossing of two measuring points.

⚠Attention

- **If the patient's heart rate or ECG waveform changes obviously, you need to adjust the location of the point of ISO and ST. The abnormal QRS wave groups are not considered when the ST section analysis is made.**

- **Method of Adjusting ISO and ST**

Adjust the values by turning the knob.

Setting the measuring point of ST Segment, please open the “Determine Analysis Point” window and the window will show QRS wave-group module (if the channel is not opened, “ST Analysis Switch OFF” will be prompted). The location for high-brightness line in the window can be adjusted. Select the ISO or ST first, and then turn the knob both leftward and rightward to move such a line in parallel so as to determine the reference point or measuring point.

⚠Attention

- **The abnormal QRS wave group will not be taken into consideration when ST segment is analyzed.**

- ◆ Alarms & Reminders used in ST Segment Analysis

Attention

- **The alarm limits for two measured values of ST SEGMENT are coincident. The alarm limit of each channel can't be set alone.**

The alarm record switch in the related menu being opened, the physiological alarm caused by the parameter alarm super-limit will make the recorder automatically output the alarm parameter values and related measured waveforms.

For the physical alarm, technical alarm and noticed information possible to happen in the ST Segment measurement please see the following table.

Physical alarms:

Prompt Messages	Causes	Alarm Levels
ST1 too high	The measured value for ST Segment of Channel 1 is higher than the set alarm upper limit.	Selectable by users

ST1 too low	The measured value for ST Segment of Channel 1 is lower than the set alarm lower limit.	Selectable by users
ST2 too high	The measured value for ST Segment of Channel 2 is higher than the set alarm upper limit.	Selectable by users
ST2 too low	The measured value for ST Segment of Channel 2 is lower than the set alarm lower limit.	Selectable by users

Technical alarms

Prompt Message	Causes	Alarm Level	Solutions
ST Alarm Limit is wrong.	Function safety failure	High	Stop use of ST SEGMENT alarm and advise the biomedicine engineer or our company's servicemen.

Prompt Message (including general alarm message):

Prompt Messages	Causes	Alarm Level
ST1 measurement out of scope	The measured value for ST Segment of Channel 1 exceeds the measured range.	High
ST2 measurement out of scope	The measured value for ST Segment of Channel 2 exceeds the measured range.	High

■ Arrhythmia analysis

◆ About arrhythmia analysis

Arrhythmia analysis is used in clinical monitoring the ECG of baby and adult patients, detecting the HR change and PVB, saving the arrhythmia events and producing alarm messages. Besides, it can be used to monitor the patients with or without the pacemaker. The qualified personnel can evaluate the patient's status (such as HR, PVCs (PVB), frequency, rhythm and abnormal HB) according to arrhythmia analysis and make a diagnosis and give treatment. In addition to detect the ECG change, arrhythmia analysis can monitor patients and give a suitable alarm.

The functional default of arrhythmia monitoring in the system is the off state. Users can start this function as needed.


Arrhythmia monitoring can arouse the doctor's attention to the patient's cardiac rhythm and give an alarm through test and classification of arrhythmia and HB abnormality.

This monitor can perform 17 kinds of arrhythmia analysis.

In arrhythmia analysis, the system will save the latest 200 alarm events (the single-channel ECG waveform four seconds before and after alarm). The operator can edit the arrhythmia events through this menu.

◆ Arrhythmia analysis setup

In the “ECG SETUP” menu, select the “ARR ANALYSIS” to enter the submenu.

- ARR ANAL(Arrhythmia Analysis): during monitoring it can be set at “ON” and during default, “OFF”;
- ALM ON/OFF: select the “ON” and the alarm prompt and saving will proceed; select the “OFF” and PVCs alarm won’t start, but prompting  do beside PVCs in the screen parameter area.
- ALM LEV (Alarm Level): there are such three options as “high”, “middle” and “low”. “High” means the most serious PVCs alarm.
- ALM REC (Alarm Record): select the “ON” and the recorder will output during PVCs alarm.
- ALM HI (Alarm Upper Limit): PVCs alarm is based upon the set alarm upper limit. The alarm will happen when PVCs exceeds the upper limit.

Upper and lower limit of alarm:

Name	Maximum	Minimum	Singleregulatingvariable
PVCs	10	1	1

Arrhythmia alarm Message and Prompt Message:

When the alarm record switch in the related menu is turned on, the physical alarm arising out of that the parameters exceeds the alarm limit will make the recorder automatically output the alarm parameter values and related waveforms.

The physical alarm and technical alarm that may happen in PVCs parameter measurement are listed in the following table.

Physical alarms:

Prompt Message	Causes	Alarm Level
PVCs too high	PVCs measured value is above the set alarm upper limit.	Selectable by users

Technical alarms

prompt message	Causes	Alarm Level	Solutions
PVCs alarm limit is wrong.	Function safety failure	High	Stop use of PVCs alarm and advise the biomedicine engineer or our company’s servicemen.

- TACHYCARDIA (TACHY threshold): set the tachycardia threshold to 100-350bpm. An alarm will be triggered when the HR value exceeds such threshold.
- ARR RELEARN (ARR self-learning): in the ECG monitoring process, when the patient’s ECG template changes a lot, ARR self-learning may need to be enabled to learn a new ECG template for the purpose of correcting the arrhythmia alarm and HR value and restore ST measurement.

- ARR ALARM(ARR alarm setup):
 - ① ARR TYPE:ASYSRTOLE, VFIB/VTAC, R ON T, VT>2, COUPLET, PVC, BIGEMINY, TRIGEMINY, TACHY, BRADY, PNC, PNP, MISSED BEATS, ARRHYTHMIA, LEARNING, NOIS SIGNAL, SIGNAL WEAK.
 - ② ALM ON/OFF:ON ,OFF
 - ③ ALM LEV: HIGH, MED, AND LOW.
 - ④ ALM REC: ON/OFF.
 - ⑤ ARR ALM QUICK SETUP: The alarm fully open, the alarm fully closed, the record fully open, to record fully closed, and the alarm level. The user can select the alarm fully open various arrhythmia alarm is set to "On", select "Alarm full off various arrhythmia alarm set to" Off ". Similarly, the record fully open "alarm record switch can be all set to" On ", the record fully closed alarm record switch can be all set to" Off ".
- ARR RECALL (Arrhythmia Recall): Select this option and you can view and edit the patient's arrhythmia information.

The latest saved arrhythmia events are listed in the window (one page can show 10 events and at most 6 pages can display):

- ① Press “▲” & “▼” : To observe the list of arrhythmia events in other pages.
- ② Move the cursor to select the arrhythmia events in the list. Press this button and the window will show the waveforms, occurrence time and parameters of the selected arrhythmia events.



Figure 10-12 Arrhythmia Review

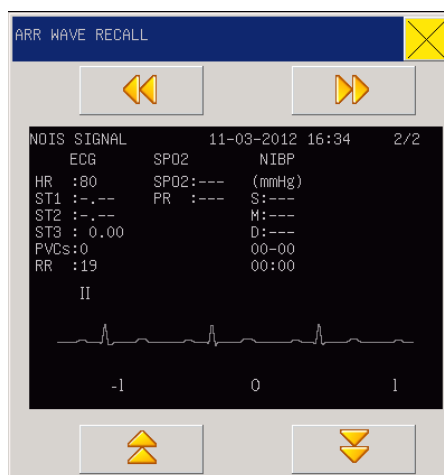


Figure 10-13 Arrhythmia Waveform Review Window

- ③ Press “◀” & “▶” to observe waveforms of other arrhythmia events.
- ④ Press “▲” & “▼” to observe all waveforms, times and parameters of arrhythmia events in the window within 8 seconds.

⚠ Attention

- In the event that the number of arrhythmia event is more than 200, the monitor will retain the latest instead of the earliest. As for the monitor with the power-fail saving function, it can save 200 arrhythmia events with power-fail.

◆ Arrhythmia alarm

In case of arrhythmia, the system will give an alarm sound. If “Alarm Switch” is ON, the system will give an alarm sound and the indicator light; if “Alarm Record Switch” is ON, the alarm record will be outputted (ECG waveform of channels analyzed 4 seconds before and after alarming).

The alarm or prompt message related to arrhythmia analysis is as shown in the following table.

Physical alarms:

Prompt Message	Applied Patient Type	Conditions	Alarm Level
Asystole	Full	No QRS waveforms successively for 4 seconds	Selectable by users
VFIB/VTAC	No pacing	F Wave successively for 4 seconds or the continuous ventricular beats are greater than the number upper limit of serial ventricular beats (≥ 5 pcs), of which R-R time is smaller than 600ms.	Selectable by users
Multiple PVS	No pacing	The number of serial PVS greater than or equal to 3 and smaller than 5.	Selectable by users

Two PVS	No pacing	Two continuous PVS	Selectable by users
PVS bigeminy	No pacing	PVS bigeminy	Selectable by users
PVS trigeminy	No pacing	PVS trigeminy	Selectable by users
R ON T	No pacing	HR<100, RR interval < 1/3of average interval, after which there is a compensation interval of which length is 1.25 x R-R mean (next R waveform is moved up to the previous T wave.)	Selectable by users
Single PVS	No pacing	Single PVS not belonging to the above types	Selectable by users
Tachycardia	Full	Successively 5 QRS waveforms and RR mean smaller than 0.5s	Selectable by users
Bradycardia	Full	Successively 5 QRS waveforms and RR mean greater than 1.5s	Selectable by users
MB(Missed Beat)	No pacing	Where HR is smaller than 100times/minute, HB is not detected in the 1.75 times of time for RR mean; or where HR is greater than 100times/minute, pulsation is not detected within 1 second.	Selectable by users
Pacemaker doesn't work.	Pacing	In the 1.75 times of time for RR mean there are no QRS waveform and pacing pulse (only for the patient with the pacemaker).	Selectable by users
Pacemaker doesn't capture pacing.	Pacing	In case of pacing pulse there is no QRS wave in the 1.75 times of time for RR mean (only for the patient with the pacemaker).	Selectable by users

Prompt Message:

Prompt Message	Cause	Alarm Level
ARR Learning	QRS wave template necessary in ARR analysis is forming.	No Alarm

Attention

- Arrhythmia name displays in the alarm message area.

- ECG calibration: when ECG is calibrating, the patient is not monitored. And there is a prompt message in the middle of the screen: Do not monitor patients during calibration. You should get back to "ECG SETUP" and select "STOP ECG CALIBRATION" to stop calibration.

 **Attention**

- When the patient is under pacemaker monitoring, the switch of “PACE” should be “ON”; when the patient is not, it should be “OFF”; when the switch is on, the monitor will not conduct some kinds of ARR analysis. Please refer to section of arrhythmia analysis for more details.
- When the pace analysis is on, the monitor will not detect any PVCs-related arrhythmia (including PVCs counting) and ST analysis.

 **Warning**

- For patients who need pacemakers, the pacemaker pulse analysis function must be turned on, or the monitor would count the pace pulse as normal QRS by mistake, leaving an alarm failure for “too weak electrocardiosignal”.
- DEFAULT: open the “ECG DEFAUL CONFIG” dialogue box, and users can choose from “Yes” or “No” to decide “will adopt the default config” or “the previous configure will be lost”.

10.6 ECG Alarms information & Prompt messages

10.6.1 Alarm information

Alarms during ECG measurement are classified into physical alarms and technical alarms, while during measurement there may be various reminders. The visual and audio appearance of the monitor upon happening of such alarms or reminders, are as described in the Alarm chapter. On the display screen, physical alarms and general reminders are displayed in the alarm area, while technical alarms and those reminders unable to activate alarms are displayed in the information area. In this chapter all the descriptions on alarms applies out of the arrhythmia and ST segment analysis parts.

When the alarm record function under relevant menu is turned on, those physical alarms activated because parameters exceed alarm limits may activate the recorder to automatically output alarming parameter values and the relevant measurement waveforms. The following classified table lists various possible alarms during such measurement process.

Physical alarms:

Reminders	Causes	Alarm levels
ECG signal over-weak	Fail to detect patient ECG signals	High

HR over-high	HR measurement values higher the set alarming limit	User customized
HR over-low	HR measurement values lower the set alarming limit	User customized

Technical alarms:

Reminders	Causes	Alarm levels	Solution
ECG lead disconnected	ECG electrodes drop off from patient body or ECG cables drop off from the monitor	Low	Make sure electrodes, leads and cables are all connected properly
ECG V-lead disconnected or ECG C-lead disconnected			
ECG LL-lead disconnected or ECG L-lead disconnected			
ECG RA-lead disconnected or ECG R-lead disconnected			
ECG module initialization error	Failure in ECG measurement module	High	Stop using the measurement function provided from the ECG module and inform biochemical engineers or our maintenance personnel
ECG module initialization error 1			
ECG module initialization error 2			
ECG module initialization error 3			
ECG module initialization error 4			
ECG module initialization error 5			
ECG module initialization error 6			
ECG module initialization error 7			
ECG module initialization error 8			
ECG module communication stopped	ECG measurement module failure or communication failure	High	Ditto
ECG module communication error	Casual communication error	High	Ditto if the failure continues
HR alarm limit error	Function / safety error	High	Stop using HR alarm and inform biomedical engineers or our maintenance personnel

ECG over-disturbance	ECG measurement signals are heavily disturbed	Low	Keep patients quiet, electrode connection reliable, and AC supply earthing well
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Prompt message (including general alarm information):

Reminders	Causes	Alarm levels
HR measurement out of scope	HR measurement values out of measurement scope	High

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Chapter 11 RESP Measurement

11.1 Measure RESP (Respiration)

11.1.1 How to measure RESP

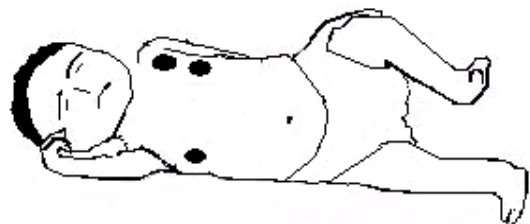
This monitor measures RESP values from the breast impedance values at two electrodes; impedance change between such electrodes (due to breast activities) will generate a RESP waveform on the screen. The monitor will calculate RESP by calculating the variation of the waveforms.

11.1.2 Setting of RESP monitoring

For RESP monitoring, no additional electrodes are required, but how to install electrode is critical. For example:

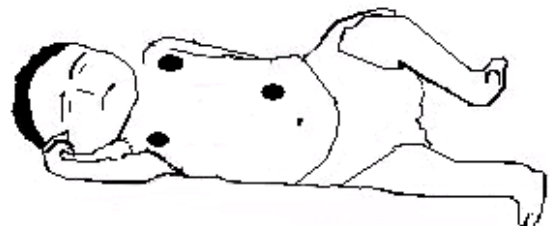
■ Lateral thoracic expansion

Some patients' thorax may expand laterally, especially for the neonates. At the right time, two breathing electrodes shall be placed on the right mid-axillary line and the left lateral thorax where the patient has the maximum breathing movement to make sure that the breathing waveform is distinct as the figure below shows:



■ Abdominal respiration

For some patients the chest movement is limited so they primarily conduct a abdominal respiration. And right now, you shall remove the electrode which was placed on the left leg to the left abdomen where there is maximum expansion to make sure the breathing waveform is clear as the figure below shows:



⚠ Attention

- **Breath monitoring can not be applied to the patient who moves frequently, because it may provide a wrong alarm.**

RESP monitoring checks:

Provide patient skin preparation before installation of electrodes;

Install spring clamp or snap for electrodes, and follow the later-introduced method to install electrodes on patient body;

Turn on power supply for the monitor system.

11.1.3 Place Electrodes for the Breathing Measurement

For example, if the three leads are applied, the connecting methods are shown on the charts below (for the connecting methods of other leads, please refer to the related sections of Chapter 10):

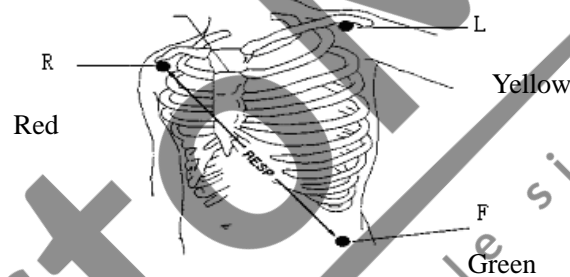


Figure 11-1 Position of electrode of three lead device

⚠ Attention

- **Put the green and the red electrodes at opposing angles so as to get the best breathing wave. You should avoid putting the electrodes over the liver area and the left ventricle on the line of the respiratory electrodes, which can help to avoid slight errors made from cardiac overlap or the pulsing blood flow. This is particularly important for newborn babies.**
- **Check the attaching area every two to three hours to make sure the skin is normal and optical alignment is correct. If the skin has something wrong, then move the sensor to another place. Change the placement of electrodes at least every four hours.**

11.2 RESP setting in parameter area (RESP SETUP)

Users can rotate the knob and move the cursor to the RESP hotkey on the parameter area of the main screen, then press the knob to enter the RESP SETUP menu.

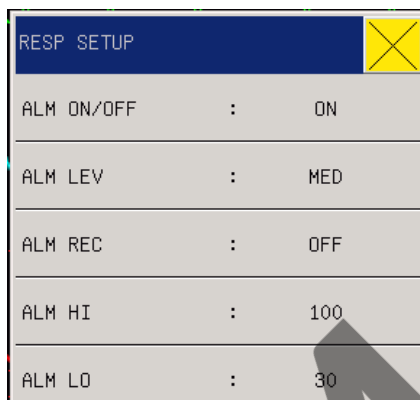



Figure 11-2RESP Setup

1. ALM ON/OFF: select the “ON” and the alarm prompt and saving will proceed during RR alarm; select the “OFF” and “” will be prompted beside RESP in the screen parameter area.
2. ALM REC (Alarm record): If users select “On”, upon RESP alarming, the recorder will output the alarm.
3. ALM LEV (Alarm levels): HIGH, MID and LOW.
4. Alarm HI: used to be set with the upper limit for RR alarm.
5. Alarm LO: used to be set with the alarm lower limit.

RESP alarm takes the set upper & lower limits as standard, and once the RESP values exceed such limits there will be alarms.

Adjustable range of RESP alarm upper & lower limits:

	Max upper limit	Min lower limit	Adjusted amount per time
RR newborn	150	6	1

11.3 RESP setting in waveform area

Users can rotate the knob and move the cursor to the RESP hotkey on the parameter area of the main screen, then press the knob to enter the RESP SETUP menu.

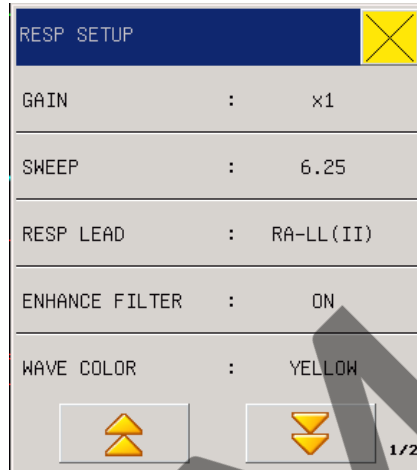


Figure 11-3RESP Setup

- SWEEP (Waveform speed): Three optional speeds, 6.25mm/s, 12.5mm/s and 25.0mm/s.
- GAIN (Waveform amplitude): Users can set enlarged display of RESP waveforms under five optional enlargement rates: $\times 0.25$, $\times 0.5$, $\times 1$, $\times 2$ and $\times 4$.
- WAVE COLOR: green, cyan, red, yellow, white, blue, violet.
- WAVE TYPE : FILL or LINE.

11.4 RESP setting in measurements

Users can rotate the knob and move the cursor to the RESP hotkey on the parameter area of the main screen, then press the knob to enter the RESP SETUP menu.



Figure 11-4RESP Alarm Setup

- ALM ON/OFF: see reference in RESP SETUP menu.
- ALM LEV: see reference in RESP SETUP menu.
- ALM REC: see reference in RESP SETUP menu.
- SWEEP: Waveform speed, Three optional speeds, 6.25mm/s, 12.5mm/s and 25.0mm/s.
- WAVE COLOR:green, cyan, red, yellow, white, blue, violet.
- RR GAIN: Users can set enlarged display of RESP waveforms under seven optional enlargement rates: $\times 0.25$, $\times 0.5$, $\times 1$, $\times 2$, $\times 3$, $\times 4$ and Auto. The auto method is gain automatically adjusted by the monitor.
- APNEA ALM: Set the time diagnosing a patient suffocation:NO,1s, 2s, 5s, 10s, 15s, 20s, 25s ,30s ,35s ,40s.
- ALM HI: see refence in “ALM HI” of RESP SETUP in parameter area.
- ALM LO: see refence in “ALM LO” of RESP SETUP in parameter area.
- DEFAULT:Select this option to enter "default configuration" dialog box, select the "Yes" that is, using the default default configuration, the original configuration will be overwritten, select "No" to abandon the current operation, the system remains the original configuration unchanged.

11.5 RESP Alarms information & Prompt messages

When the alarm record function under relevant menu is turned on, those physical alarms activated because parameters exceed alarm limits may activate the recorder to automatically output alarming parameter values and the relevant measurement waveforms. The following classified table lists various possible alarms during such measurement process.

Physical alarms:

Reminders	Causes	Alarming levels
RR over-high	RESP measurement values higher the set alarm limit	User customized
RR over-high	RESP measurement values lower the set alarm limit	User customized
RESP APNEA	No respiration measured during designated period	high

Technical alarms:

Reminders	Causes	Alarm levels	Solution

RESP alarm is wrong	Safety failure for the function	high	Stop using the RESP alarm function and inform the biomedical engineers or maintenance workers of Comen
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Prompt message (including general alarm information):

Reminders	Causes	Alarming levels
RR measurement out of scope	RR measurement values out of measurement scope	High

11.6 Maintenance & Cleaning

Warning

- Before cleaning the monitor or the sensors, you must turn off the power and switch off the AC power.
- If any ECG cable is damaged or aging, the cable should be replaced with a new one.

Cleaning:

Surface of the monitor and sensor can be swept by medical alcohol, naturally dried or cleaned by clean and dry clothes.

Disinfection:

To avoid long-term damage to the equipment, we recommend you to disinfect the products only when deemed as necessary under the maintenance plan of your hospital. We also recommend you to clean the products before disinfection.

Recommended disinfection materials for the monitor:

Ethanol: 70% alcohol, 70% isopropyl

Glyoxyl

Sterilization

To avoid long-term damage to the equipment, we recommend you to sterilize the products only when deemed as necessary under the maintenance plan of your hospital. We also recommend you to clean the products before sterilization.

Chapter 12 SpO2 Monitoring

12.1 Definition of SpO2 Monitoring

The SpO2 volume recording parameter is used to measure arterial SpO2, i.e., percentage of oxyhemoglobin. For example, if there are 97% of hemoglobin molecules combining with oxygen out of the arterial red blood cells, the blood will be described as SpO2 97%, and the SpO2 reading on the monitor will be 97%. SpO2 values thus can show the percentage of oxygen-attached hemoglobin molecules (will form oxyhemoglobin), meanwhile, SpO2 volume recording parameters can also provide the PR signals and volume recording waves.

12.1.1 Principle for Measurement of SpO2 Volume Recording Parameter

BOS (blood oxygen saturation) is measured and determined in the method of pulse oximetry, which is a method of measuring and determining the oxyhemoglobin saturation continuously and without any hurt, mainly used to measure and determine how many rays from the light source of the sensor penetrate the patient's tissue (such as fingers or ears) and reach another receiver.

As for the wave length measurable by the sensor, generally the red LED is 660nm and the infrared LED, 940nm. The maximum selectable output power of LED is 4mW.

The number of penetrated rays rests with many factors where most are constant, but one of these factors means the arterial flow changes through time because it is pulsant. The arterialized blood's BOS can be obtained through measurement of absorbed rays during pulsation. A "volume recording" waveform and PR signal can be given through detection of pulsation.

"SpO2" value and "Volume Recording" waveform can display on the main screen.

Warning

- **If there is carbonyl hemoglobin, methemoglobin, or dye dilution chemical present, the SpO2 value will deviate.**

12.1.2 Blood Oxygen Saturation (BOS)/Pulse Monitoring

Warning

- The cable for the equipment of electrosurgery can't be twisted together with the sensor cable.
- Please don't place the sensor on the limb with arterial duct or vein injection syringe.

Attention

- Please don't place SpO₂ detector and cover on the same limb for measurement of blood pressure, because in the course of measuring blood pressure the vascular obstruction will affect the BOS reading.

12.2 Precautions in SpO₂/Pulse Monitoring

Attention

- The detector sensor should be fixed on the back of hand or foot.
- SpO₂ value is always displayed in a fixed place.
- Only in the following cases PR will appear:
 - ✧ In ECG menu, set "HR Source" as SPO2 or all.
 - ✧ In ECG menu, set "HR Source" as "AUTO" and there is no ECG signal at this time.
- SpO₂ waveform and pulse volume are out of proportion.

Warning

- First check whether the sensor cable is normal before the monitor is started. When you unplug the cable of the SpO₂ sensor from the jack, the screen will display error message as "sensor off" and simultaneously trigger an audible alarm.
- If the sensor or its packaging has signs of damage, do not use it and return to the factory.
- Continuous and prolonged period of monitoring may increase the risk of undesirable changes in the skin characteristics, such as extremely sensitive, reddening, blistering, or even pressure necrosis etc, especially of the newborns, or patients with perfusion disorders and varying or immature forms of skin. Particular attention to checking placement of the sensor according to the changes in the quality of skin, correct optical alignment and

attachment methods. Also check, periodically, the location where the sensor is attached and make a change of the position if there is a decline of skin quality. More frequent examination may be required due to different status of individual patents.

12.3 Monitoring Procedures

⚠ Warning

- The standard SPO2 sensor this monitor equips is digital SPO2 sensor and NELLCOR SPO2 sensor. When using the sensor, first be careful of what kind of sensor you have chosen because it is very important to choose to a suitable sensor to work with the monitor; otherwise, it may cause damage to the monitor or sensor. Therefore, do not use digital sensor in the monitor which is equipped with NELLCOR sensor and vice versa.
- The red double-tank socket in the left side of the monitor indicates a socket for NELLCOR sensor, the blue single-tank one for digital sensor.
- Select the appropriate placement according to the instrument and its supporting oxygen probe, which is fundamentally vital to a neonatal. The storage methods of these two have been stated below and please refer to the appendix for methods of other sensors.

(1) SpO2 volume recording measurement:

- Turn on the monitor;
- Paste the sensor on a proper position of the patient finger based on different types of the sensor;
- Insert the connector at the other side of the sensor cable into the SpO2 hole of the SpO2 module.

(2) Digital SPO2 sensor measurements

(a) neonate SPO2 sensor

Neonate SPO2 sensor includes Y type SPO2 sensor and SPO2 sensor jacket, put the LED end of Y type SPO2 sensor into the SPO2 sensor jacket, refer to the Figure below.

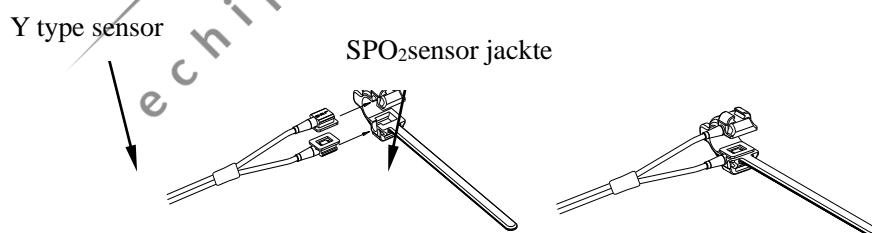


Figure 12-1neonate SPO2 sensor

(b) The placement for the digitalneonatal SPO2 sensor

Put the neonatal SPO2 sensor on hand or foot of neonate patients (Figure12-2). Fix the SPO2 sensor in the

right position. Hold the sensor and place the belt into the hing slot. If the belt is too long, you can guide it to go through the second hing slot. Meanwhile, remember not to pull the belt too tightly, for it will lead to false measurement and hinder the blood circulation.

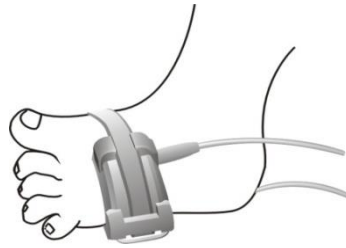


Figure 12-2 The placement for the neonatal SpO2 sensor

(3) Nellcor SpO2

(a) Constitution of Nellcor SpO2 sensor

NELLCOR SpO2 transducer consists of Nellcor SpO2 connection cable, Nellcor infant SpO2 sensor, and wraps. From left to right as figure 12-3 shows, they are NELLCOR SpO2 connection cable, NELLCOR infant SpO2 sensor and wraps.



Figure 12-3 Consist of Nellcor SpO2

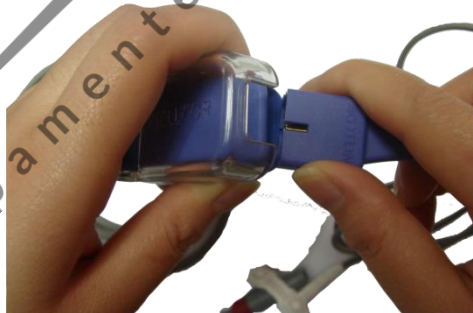


Figure 12-4 Connection between extension cable and sensor

(b) Fix Nellcor SpO2 sensor

Firstly tear off the adhesive plaster in the bandage and stick the bandage to the NELLCOR SpO2 sensor and wraps. Then stick the LED end of the sensor to the measured position. See the figure

below:

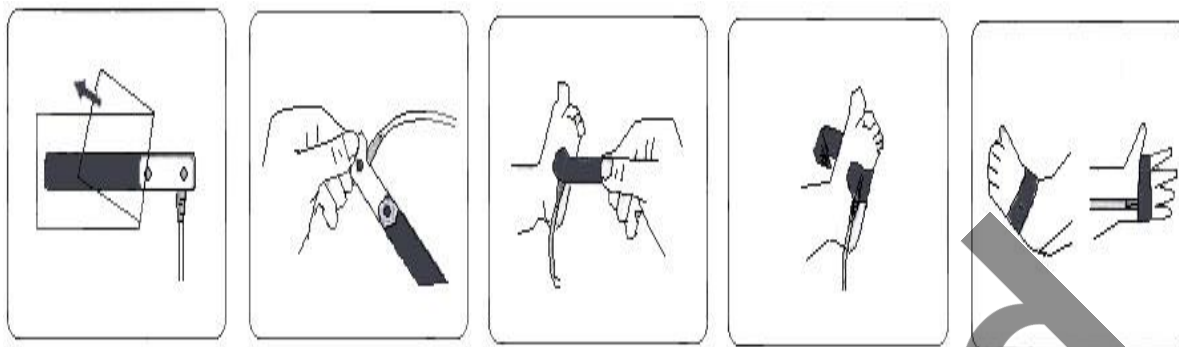


Figure 12-5

⚠ Attention

- When the accurate positioning between the test site and the probe fails, it may result in wrong readings of blood-oxygen saturation, and even stop monitoring because of the failure of the search for the pulse wave. In this case you should re-position the two.
- Excessive movement of measured sites may affect the accuracy of the measurement, therefore, you should calm the patient or replace site in order to reduce the impact of excessive movement.

⚠ Warning

- In a long and continuous monitoring process, check the condition of the peripheral circulation and skin under measuring every 2 hours or so, and if negative conditions happen, timely change the site under measurement.
- In a long and continuous monitoring process, it is advisable to check periodically the positioning of the probe to avoid inaccurate measurement due to changing in the positioning from moving or other factors.

12.4 Measurement restriction

(1) Measurement restriction

During operation, the following factors may affect accuracy of SpO2 measurement:

- High-frequency electric disturbance, such as disturbance generated from the system itself or electrosurgery equipments connected with the system;
- A photo-oximeter and SPO2 sensor are used during MRI process, as the inductive current may cause burns;

- Intravenous Dye;
- Frequent movement by patient;
- Light radiation from outside;
- Improper installation of the sensor or improper touching position with objects;
- Improper sensor temperature (ideal temperature should be 28°C-42°C);
- The sensor is put onto body with blood pressure cuff, arterial duct or vein tube;
- Contents of non-functional Hb such as COHb and MetHb;
- SPO2 over low;
- Bad microvascular perfusion at the test position;
- Shock, anemia, low temperature and application of vessel shrinking medicines, which all can reduce the arterial blood flow to a non-measurable level;
- Measurement is also up to absorption of lights with special wavelengths by oxyhemoglobin and deoxygenated hemoglobin. Existence of other materials that absorbs the same wavelengths, such as carbonated hemoglobin, hemoglobin, methylene blue and indi carmine, will make artificial or low SPO2 values.
- SPO2 sensor introduced in the accessory is recommended.

12.5 SpO2 Setting in parameters menu

Users can rotate the knob and move the cursor onto the SPO2 hotkey in the parameter area, then press the knob to enter the SpO2 SETUP menu.

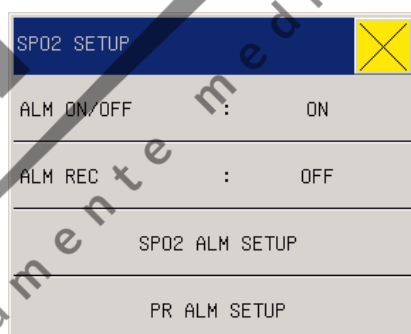



Figure 12-6 SPO2 SETUP (Masimo SPO2)

Warning

- **Setting the SpO2 alarm upper limit to be 100% means to release the upper limit. However, high SpO2 level will make early-born infants infected with retrolental fibroplasias, thus the SpO2 alarm upper limit must be carefully selected based on common acknowledged clinical practice.**

- ALM ON/OFF: Where “ON” is selected, the alarm prompt and saving will proceed when SpO2 (BOS) is alarmed; where “OFF” is selected, alarming will not happen, but  will be prompted beside SpO2 in the screen parameter area.
- ALM LEV (Alarm level): used to set alarm levels and, during SpO2 alarming, for alarm reminder and saving. Options include “High”, “Middle”, and “Low”; “High” for the most serious alarm.(This feature is only effective NELLCOR blood-oxygen).
- Sar-second: 10s, 25s, 50s, 100s and Disabled. Please refer to “12.7 SPO2 in measurements” for more details. (This feature is only effective NELLCOR blood-oxygen).
- ALM REC (Alarm record): If “On” is selected, the recorder will output during SpO2 alarming.
- SPO2 ALM SETUP:setup SPO2high limit, middlelimit, low limit of the upper and lower limits. When the SPO2 exceeds the upper or lower limits, there will be alarms. (If the monitor SPO2 is NELLCOR, setup alarm limit, have not high limit, middlelimit, low limit.)
- PR ALM SETUP: setup pulse rate highlimit, middle limit ,low limit of the upper and lower limits.When the SPO2 exceeds the upper or lower limits, there will be alarms. (If the monitor SPO2 is NELLCOR, setup alarm limit, have not high limit ,middle limit ,low limit.)

Masimo SPO2 can automatically identify the hardware inside the machine, the following feature is only effective Masimoblood-oxygen, is unchangeable items.

- DSP VERSION: 2.0.1.7
- HARD VERSION: 0.1.0.1
- PRODUCT ID: 0.0.0.1
- MCU VERSION: 0.0.0.0
- SENSOR TYPE: no sensor

SpO2 & PR adjustable limits:

Parameter	Max upper limit	Min lower limit	Adjustable amount each time
SpO ₂	100%	0	1
PR	300bpm	0	1

12.6 SPO2 setting in waveform area

Users can rotate the knob and move the cursor onto the SPO2 hotkey in the parameter area, then press the knob to enter the SpO2 SETUP menu.

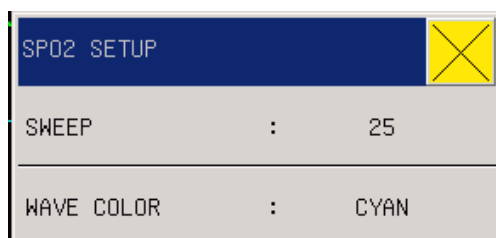


Figure 12-7SPO2 Setting

- SWEEP: Waveform Speed, the scanning speed of SpO2 volume recording waveform is provided with 12.5 and 25.0mm/s for option.
- WAVE COLOR (Waveform Colour): green, cyan, red, yellow, white, blue, violet.

12.7 SpO2 Setting in measurement menu

Users can rotate the knob and move the cursor onto the SPO2 hotkey in the parameter area, then press the knob to enter the SpO2 SETUP menu.



Figure 12-8SPO2 setup

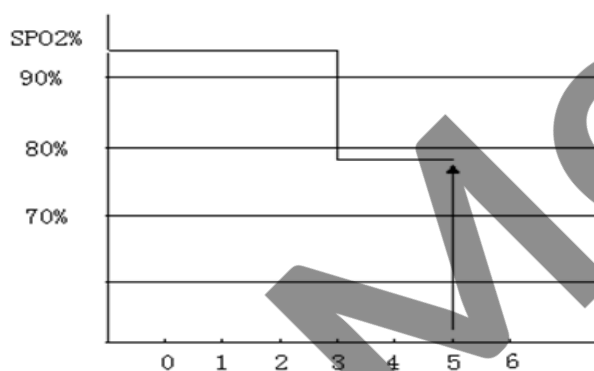
- ALM ON/OFF: see the content of this chapter parameter area the SPO2 set the “ALM ON/OFF”
- ALM REC: see this chapter parameter area the SPO2 set “ALM REC”.
- ALM LEV: see the content of this chapter parameter area the SPO2 set “ALM LEV”(This feature is only effective NELLCOR oxygen).
- SatSecond: 10, 25, 50, 100 seconds, disable.For example, set the intelligent alarm range as 50, the upper limit of NELLCOR blood oxygen alarm as 97%, and lower limit as 90%, the measured blood oxygen value turns out to be 80% and remains for 3 seconds, then, it decreases to 78% and remains for 2 seconds, so calculating from the time the alarm limit is exceeded, the sound-light alarm will initialize instantly only when the blood oxygen value is out of the alarm range for 5 seconds. Meanwhile , the circle beside the blood oxygen value returns to origin.(This function is only effective for NELLCOR blood-oxygen).

Its calculation is as follow:

Minus percentage points x seconds = SatSeconds integer

values of the calculated SatSeconds are shown:

%SpO2	second	SatSeconds
(90%-80%) x	3 =	30
(90%-78%) x	2 =	24
Total SatSeconds	=	54



SatSeconds Example:

After about 4.9 seconds, the instrument will report SatSeconds alarm, because 54 is beyond the intelligent alarm range 50 SatSeconds.

Within a few seconds, saturation will fluctuate a bit, and not be stable. Generally, the patient's SpO2 value may fluctuate between the upper and lower limits of the alarm, and may re-enter to non-alarm range several times. In this volatile period, the system will store the positive and negative points of the SpO2, till it reaches the SatSeconds limit or patient's SpO2 values returned to and remains in the non-alarm range.

- SWEEP: see the content of this chapter parameter area the SPO2 set the "SWEEP".
- WAVE COLOR: see the content of this chapter parameter area the SPO2 set the "WAVE COLOR".
- ASPHYXIA ALARM: 1s, 2s, 5s, 10s, 20s, 25s, 30s, 35s, 40s and NO ALM. These options are time from the patient's asphyxia detected by the monitor to the alarm.
- SMARTTONE:ON, OFF. SMARTTONE effects pulse beep and allows a pulse beep to continue even when the Pleth waveform is corrupt due to motion. When SMARTTONE is off, the pulse beep suppressed during signs of motion.

SMARTTONE is useful in situations where clinicians cannot observe the monitor display (e.g. OR, during patient intubation, transport etc.). When enabled SMARTTONE supports seamless monitoring of changes in patient saturation and pulse rate in the presence of motion and low perfusion. When this menu is started, "SIGNAL IQ" and "BEEP" are simultaneously turned on, they can be smartly managed. However, turning off the menu can't manage these two. (This feature is only available on

the Masimo blood-oxygen)

- **SIGNAL IQ: ON and OFF.** This Signal IQ waveform shows the acquired measurement confidence and timing of each detected pulse relative to the Pleth. It is ideally implemented in a manner that the height of vertical lines/bars indicate the relative confidence of the measurement (higher bar graph = higher confidence). In addition to the Signal IQ waveform visually correlating to the peak of the Pleth waveform, it also coincides with an audible pulse beep that occurs with each vertical line/bar graph. During motion (and SMART TONE OFF), the audible beep is suppressed while the vertical line/bar graph confidence bar continues to display.
- **BEEP: ON, OFF.** Turning on the pulse sound, you can get a prompt of PULSE (pulse) sound. No PULSE (pulse) sound prompt as it is turning off. (This feature is only available on the Masimo blood-oxygen)
- **FAST SAT: ON, OFF.** FAST SAT enables rapid response to, and display of, fast changes in SPO2 by giving priority to the most recent data. This aids the clinician in clinical settings requiring fast response time such as those seen with induction, intubation, sleep studies and resuscitation. When you start the rapid blood-oxygen measurements, you can choose "on", also "off" not using this feature. (This feature is only available on the Masimo blood-oxygen)
- **AVE TIME(S): 2-4, 4-6, 8s, 10s, 12s, 14s, 16s.** The user-selectable averaging feature allows the clinician to select the desired level of visibility to subtle variations in the measured value. Depending on the patient acuity and area of care, shorter averaging times are sometimes preferred (sleep testing) over longer averaging times (telemetry & neonates) and vice-versa. 8-second averaging is generally considered the most common averaging interval and recommended for most patients since it is short enough to provide visibility to subtle desaturations while also being long enough to minimize major changes in SPO2 due to quick, transitory desaturations. Although averaging times greater than 10 seconds are more likely to reduce visibility to rapid, brief desaturations, this may be desirable in care areas where brief desaturations that do not require clinician intervention occur more often (i.e., NICU). (This feature is only available on the Masimo blood-oxygen)
- **SENSITIVITY: NORMAL, MAX, APOD.** The three sensitivity settings allow the clinician to adapt the SPO2 measurement sensitivity to the patient's level of SPO2 signal strength and quality at the measurement site.
 - The **NORMAL** setting is recommended for the majority of patients. This setting provides the best overall combination of measurement sensitivity plus responsiveness to inadvertent sensor detachment.
 - The **MAXIMUM (MAX)** setting is recommended for use on patients with weak signals (e.g. high ambient noise and/or patients with very low perfusion) and for use during procedures or when clinician and patient contact is continuous such as in higher acuity settings.
 - The **APOD (Adaptive Probe Off Detection)** setting is used to protect against erroneous pulse rate and SPO2 readings that can occur when a sensor becomes detached from the patient. However,

this setting is the least effective setting for patients with low perfusion, but may be optimum for patients in settings where patients are often left unattended.

- According to the level, “APOD” has the highest sensitivity. (This feature is only available on the Masimoblood-oxygen)
- SPO2 ALM SETUP: see the content of this chapter parameter area the SPO2 set alarm settings.
- PR ALM SETUP: see the content of this chapter parameter area the SPO2 set alarm settings.
If the oxygen probe in the machine NELLCOR probe "SPO2 alarm settings, PR (pulse rate) alarm settings set upper and lower limits of the alarm limit.
- DEFAULT: Select this option to enter the the SPO2 default configuration dialog box, the user can choose "yes" or "no" to "will be the default configuration" or "original configuration will be set.

12.8 Alarms & Reminders

When the alarm record function under certain menus is on, those physical alarms caused because relevant parameters exceed the specified alarm limits will automatically output alarm parameter values and relevant measurement waveforms.

Possible physical alarms, technical alarms and reminders during SpO2 module measurement are as listed here:

Physical alarms:

Reminders	Causes	Alarming levels
SPO2 over-high	SpO2 measurement value higher than the set upper limit	User defined
SpO2 over-low	SpO2 measurement value lower than the set lower limit	User defined
PR over-high	PR measurement value higher than the set upper limit	User defined
PR over-low	PR measurement value lower than the set lower limit	User defined

Technical alarms

Reminders	Causes	Alarm Levels	Remedial Measures
SPO2 disconnected	Sensor SpO2 sensor drops down from the patient or monitor.	Low	Ensure the sensor is fixed on the patient's finger or other location and that the monitor is normally connected with the cable.
SPO2 module initialization wrong	SpO2 module wrong	High	Stop use of SpO2 module measurement function and advise the biomedical engineer or User Service Dept.
SPO2 module initialization wrong 1			

SPO2 module initialization wrong 2			
SPO2 module initialization wrong 3			
SPO2 module initialization wrong 4			
SPO2 module initialization wrong 5			
SPO2 module initialization wrong 6			
SPO2 module initialization wrong 7			
SPO2 module initialization wrong 8			
SPO2 module communication stop	SpO2 module wrong or communication mistaken	High	Stop use of SpO2 module measurement function and advise the biomedical engineer or User Service Dept.
SPO2 module communication wrong			
SPO2 alarm limit wrong	Function/safety faulty	High	Stop use of SpO2 module measurement function and advise the biomedical engineer or User Service Dept.
PR alarm limit wrong	Function/safety faulty	High	Stop use of SpO2 module measurement function and advise the biomedical engineer or User Service Dept.
SPO2 NO SENSOR	The SPO2 sensor on the monitor is not connected, or poor contact with the monitor socket	middle	Re-connecting SPO2 sensors or check the monitor socket performance is intact
DEFECTIVE SENSOR	SPO2 probe has problem	middle	Stop using SPO2 probe notify biomedical engineer or Koeman service department.

PI LOW	Perfusion index is too low, because the signal is too weak	middle	SPO2 probe over the better part of the perfusion
SEARCH PULSE	SPO2 probes are searching for the patient pulse	low	SPO2 probe is connected to the body on after about 5-10 seconds to search for patients pulse, then let the patient quiet, waiting patiently to. Than 15 seconds still unable to find the pulse of the patient, please check the patient's vital signs, if the patient is normal, there may be damage to SPO2 sensors, please notify biomedical engineer or comen service department
INTERFERENCE	The movement interference or next electrosurgical equipment	middle	To avoid the patient frequent strenuous exercise, and next to the patient avoid electrosurgical equipment interference.
EXCESSIVE LIGHT	SPO2 probe is too loose	middle	Re-check and connecting SPO2 probe SPO2 probe appropriately tight bundle on the patient's body
UNKNOWN SENSOR	SPO2 module failed to identify SPO2 probe	middle	Recheck SPO2 probe connection is normal, if normal is still not disarm the alarm, please notify biomedical engineer or Koeman service department
SIGNAL IQ LOW	Signal indicating low	middle	First check the patient's vital signs, enter the SPO2 menu settings, the sensitivity is set to the highest level, and re-oxygen probe guardianship site looking for a better perfusion measurements.
MASIMO PROCESSING	The SPO2 sensor connected to the monitor interface is not	middle	Check the monitor interface is a foreign body, and notify biomedical engineer or the Komen company

	available		service department
NO ADHESIVE	SPO2 probe is not stuck in the patient's body	middle	Reconnect SPO2 probe to ensure an appropriate degree SPO2 probe stuck in the patient's body

Prompt Message (including general warnings):

Reminders	Causes	Alarm Levels
SPO2 Measurement out of scope	SpO2 measured value is out of range	High
PR Measurement out of scope	PR measured value is out of range	High
Seek pulses	SpO2 module seeks pulse.	No alarm
Pulse not found	SpO2 module can't find SpO2 signal.	High

12.9 Maintenance & Cleaning

Warning

- Before cleaning monitors or sensors, you must switch off and disconnect the AC power.

Caution

- Do not autoclave the sensor.
- Do not soak the sensor in liquids.
- If the sensor or cable is damaged or has signs of deterioration, do not use it again.

Cleaning:

Having cleansed the surface of the sensor with the cotton ball or cotton cloth soaked with medical alcohol, dry it with the dry cloth. The luminotron and receiver of the sensor can be cleaned in the same method.

The cable can be cleaned and sterilized with 3% of hydrogen peroxide or 70% of isopropyl alcohol. Active reagent can also be used for this purpose. However, the joint can't be soaked in the above solution.

12.10 Masimo Information



- Masimo Patent

It contains one or more of the following U.S. patents: RE38,492, RE38,476, 6,850, 787, 6,826,419, 6,816,741, 6,699,194, 6,684,090, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,584,336, 6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,206,830, 6,157,830, 6,067, 462, 6,011,986, 6,002,952, 5,919,134, 5,823,950, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036, international patents or a item or a number of patents referred to in the www.masimo.com/patents. Including functions from products of Satshare ® and the U.S. Patent 6,770,028. Other patents are under application.

- Other Information

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RadNet, Radicalsreen, signal IQ, FastSat, fastStart are trademarks of APOD and Masimo Corporation.

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Chapter 13 NIBP Monitoring

13.1 General Information

NIBP measurement can be performed in the oscillation method;

It can be used in adults, children and newborns;

Measurement mode: manual, automatic and continuous measurement. Each mode can show NS, NM and ND.

- “Manual” mode: measurement can only be done once.
- “Auto” mode: measurement can be repeated. The interval time can be set as 1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes.
- “Continuous” mode: measurement can continuously be done within 5 minutes.

Warning

- Don't apply NIBP measurement onto a patient with sickle cell disease or any skin damage or expected to have skin damage.
- For patients with serious DIC, users should decide whether to apply NIBP measurement based on clinical assessment, as there may have blood tumor at the measurement area between body and cuff.

13.2 NIBP Monitoring

13.2.1 NIBP Measurement

Warning

- Before starting the measurements, make sure the selected criteria applies to your patients (newborn).
- Do not install the cuff on a limb with an intravenous infusion tube or a catheter. During cuff inflation, if infusion is lowed down or clogged, the area around the tube may be damaged.
- Ensure that inflatable tubes that attached blood pressure cuff and monitor are smooth and with no tangles.

- (1) Insert the pumping pipe into the interface of a blood pressure cuff and turn on the power supply.
- (2) In accordance with the following method (Pic 13-1), tie the blood pressure cuff on upper arm of upper leg of a patient.
 - Confirm the cuff is fully vented.
 - Select a cuff in proper size for the patient, and make sure the mark is just along the proper vein and cuff tie the body non-toughly; otherwise remote body part may have color change or even ischaemia.



Figure 13-1 Use of a Cuff

⚠ Attention


- **The width of the cuff should be 40% (or 50% for neonates) of the circumference of the limb, or 2/3 of the length of the upper arm. The length of the inflated part of the cuff should be long enough to wrap 50~80% of the limb; a size unsuitable cuff will produce a wrong reading. If the size of the cuff has a problem, use a larger cuff in order to reduce errors.**

Neonatal/infant can use the cuffs repeatedly:

patient type	Limb Circumference	Cuff width	Inflatable pipe length
neonate	6~11 cm	5cm	2 m
infant	10~19 cm	8 cm	


Neonatal/infant disposable cuffs:

Size	Limb Circumference	Cuff width	Inflatable pipe length
Neonate 1	3.0 ~ 5.5 cm	2.6cm	2 m
Neonate2	4.0 ~ 7.6 cm	3.7 cm	
Neonate3	5.6 ~ 10.6 cm	4.5 cm	
Neonate4	7.0 ~ 12.8 cm	5.3 cm	
Neonate 5	8.9 ~ 15.0 cm	6.0 cm	

- Check the cuff edges are between the “<->” marks; otherwise users should change with a more proper cuff.
- (3) Connect the cuff with appropriate tubing. Make sure the body part used for pressure measurement is at the same horizontal level with patient heart, and if failing to realize this, users should apply the following correction method to correct the measurement results:
- In case horizontal level of cuff is higher than that of heart, add 0.75mmHg (0.10kPa) onto the displayed value for each cm difference.
 - In case horizontal level of cuff is lower than that of heart, deduct 0.75mmHg (0.10kPa) onto the displayed value for each cm difference.
- (4) Confirm correctness of the monitoring mode (as displayed on the information area); if requiring changing the monitoring mode, users need go to the “Patient Information Setting” item under the Main menu and change “PATIENT TYPE”.
- (5) Select the measurement mode under the NIBP menu. Refer to the following Operational Guide for details.
- (6) Press the  button on the front panel to start pressure measurement.

13.2.2 Operational guide


- Conduct one-time automatic measurement

Enter the “NIBP SETUP” menu, select a proper time interval at the “Time Interval” item, and press the “” button on the front panel. Then the system will start automatic pumping measurement in the specified time interval.


 **Warning**


- **If NIBP measurement under the Automatic mode lasts too long, body touching with the cuff may have allergic reaction, ischemia and neural injury. During monitoring on patients, users should often check color, warmth and sensitiveness of remote body parts. Once any abnormal phenomenon is found, users should put the cuff at another location or immediately stop measuring blood pressure.**


- Stop automatic measurement

At any moment during the automatic measurement process, press the  button will stop the automatic measurement.

- Conduct one time manual measurement

Enter the “NIBP SETUP” menu, select the “Time Interval” item and set its value as ”Manual”, then press the  button on the front panel so as to start manual measurement.

During spare time of an automatic measurement, press the  button will start a manual

measurement; then if users press the  button again, the manual measurement will stop and the automatic measurement will continue.

- **Conduct a manual measurement during automatic measurement process**

Just press the  button on the control panel.


- **Stop a manual measurement**

Re-press the  button on the control panel.

- **Conduct a continuous measurement**

Enter the “NIBP SETUP” menu and select the “Continuous” item to start a continuous measurement, which will always last 10 minutes.

- **Stop continuous measurement**

At any moment during the continuous measurement process, press the  button will stop the continuous measurement.

Attention

- **If you doubt reading accuracy, use the same method to check patient vital signs before checking the monitor function.**

Warning

- **If liquid splashes on the devices or accessories, especially when the liquid is likely to enter into channels or monitor, please contact the hospital's maintenance department.**

13.2.3 Measurement restriction

Vibration measurement has its restriction subject with patient conditions. This measurement method looks for regular pulse waves generated from arterial pressure, so when patient conditions make this wave detection method difficult, measured values are no longer reliable and measurement time last longer. Users must understand the following cases will upset the measurement method, making measurements press unreliable or measurement time extended. In such cases of patient conditions, discontinue patient measurement.

- **Patient movement**

In case a patient is moving, shaking or convulsing, measurement will be unreliable or even impossible; as such scenarios will disturb detection of arterial pulse and extend measurement time.

- **Arrhythmia**

In case a patient shows irregular heartbeats resulted from arrhythmia, measurement will be unreliable or even impossible, while measurement time will also be extended.

- **Heart-lung machine**

If a patient is connected with an artificial heart-lung machine, measurement can't be realized.

■ **Pressure change**

Within certain time if the patient blood pressure immediately changes while users are analyzing arterial pulse so as to obtain measurement values, measurement will be unreliable or even impossible.

■ **Serious shock**

In case a patient is under serious shock or extreme low temperature, measurement will be unreliable as reduction in blood flowing peripherally will result reduction in arterial pulse.

■ **HR limits**

In case of HR lower than 40bpm or higher than 240bpm, no blood pressure measurement can be done.

■ **Obese Patients**

A thick layer of fat around a limb damps oscillations from the artery, thus preventing them from reaching the cuff. The accuracy is lower than the normal one.

13.2.4 NIBP Parameter Setting & Adjustment

NIBP measurement results and relevant information are laid on screen as follows:



Figure 13-2

13.3 NIBP setting in parameter area

Rotate the knob, move the cursor onto the NIBP hotkey in the parameter area, and then press the knob to enter the NIBP SETUP menu.

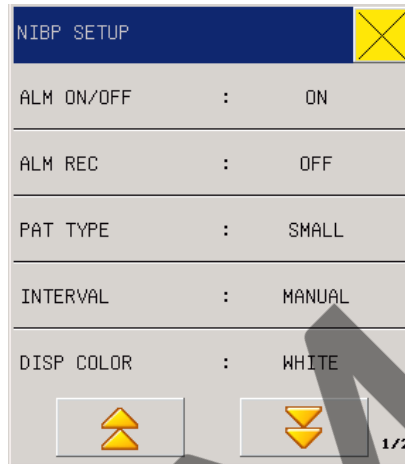



Figure 13-3 NIBP SETUP

- ALM ON/OFF(Alarm switch): Where “ON” is selected, the alarm prompt and saving will proceed when the pressure is alarmed; where “OFF” is selected, alarming will not happen, but  will be prompted beside NIBP in the screen parameter area.
- ALM REC(Alarm record): Users can select “On” to output through recorder when blood pressure alarms happen
- PAT TYPE(Patient type): neonate
- INTERVAL: MANUAL and auto(1min, 2min, 3min, 4min, 5min, 10min, 15min, 30min, 60min, 90min, 120min, 180min, 240min, 480min)
- DISP COLOR (DisplayColour): green, cyan, red, yellow, white, blue, violet.
- NIBP SYS / NIBP MAP / NIBP DIA ALM STEUP: set the valve of NS, NM, ND high limit, middle limit, low limit.

Neonate:

NS: upper limit: 42-135 mmHg lower limit: 42-133 mmHg

ND: upper limit: 12-95mmHg lower limit: 10-93 mmHg

NM: upper limit: 22-110 mmHg lower limit: 22-108 mmHg

- PR ALM SETUP: set up the PR limits for HIGHT LIMIT, MID LIMIT and LOW LIMIT.

13.4 NIBP setting in measurements

Users can choose “SURVEY SETUP (parameter setup)” in the menu bar, then press the knob to enter the NIBP SETUP menu.

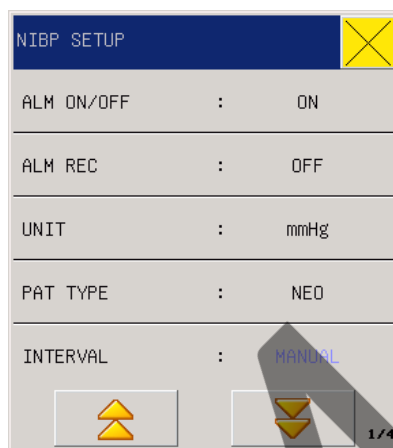



Figure 13-4 NIBP Setup

- ALM ON/OFF: Where “ON” is selected, the alarm prompt and saving will proceed when the pressure is alarmed; where “OFF” is selected, alarming will not happen, but  will be prompted beside NIBP in the screen parameter area.
- UNIT: mmHg/kPa.
- PAT TYPE (Patient type): neonate.
- INTERVAL (Time interval): Time interval (Unit: minute) for automatic measurement: 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240, 480 minutes, Manual, and Continuous. After users select an interval, there will be a display of “Please press the ‘START/STOP’ button” in the NIBP reminder area, then users just press the button to start pumping for the first time of automatic measurement. To end the automatic measurement and return to the manual mode, users need only select “Manual” during the measurement interval.
- DISP COLOR: green, cyan, red, yellow, white, blue, violet.
- INFLATION: neonate 60-120mmHg; default is 100mmHg.
- NIBP SYS/NIBP MAP/NIBP DIA ALM STEUP: set the content of “NIBP SYS/NIBP MAP/NIBP DIA ALM STEUP” in NIBP setting in parameter area in this chapter.
- RESET: Reset of measuring status of blood pressure pump. Press the reset button, the inflated value of blood pressure pump will recover the initial settings. When blood pressure pump is not working properly but the monitor does not question why, this is the recommended key. Because it allows self checking of blood pressure pumps, allowing automatic recovery of pump exception due to some accident.

- CONTINUAL: After select continuous measurement, the menu will disappear automatically and continuous measurement starts immediately; if you want to stop it, press the key of blood pressure measurement on the shell.
- CALIBRATE: The manufacturer recommends using pressure meter or mercurial sphygmomanometer with calibrated precision higher than 1mmHg for calibration. Users can select the Calibration item to start calibration, while this item turns to be “Stop calibration”; if at such moment press the button, the system will stop calibration. Pressure alarm is based on upper and lower limits. When the pressure exceeds the limits, the monitor will alarm. NS, NM and ND can be delt with separately.

Warning

- **Calibration of NIBP measurements should be carried out once every two years (or by your hospital's maintenance Program). Machine performance should be checked as following details .**

- PENUMATIC (Leak detection): This button is used to detect gas leakage from the NIBP measurement pump. Users, after connecting with a NIBP cuff, can use this button to start NIBP pumping process so as to observe whether the NIBP gas route is sealed well. If such a gas leakage test gives a good result, the system will make no reminder; otherwise there will be the corresponding error reminder in the NIBP information area.
- DEFAULT: Users can select this item to enter the “NIBP DEFAULT SETUP” dialogue box. If choosing “No”, the system would keep the precious configurarion. If choosing “Yes”, the system would adopt the default configuration.

Warning

- **This leak detection is different from those described in the standard EN 1060-1, which is for users to simply test air leakage in NIBP inflation. If the system displays the NIBP leaks at the end of testing, please contact the Our comany maintenance engineers.**

13.5 Gas leakage detection process

- (1) Properly connect the cuff with the NIBP hole of the monitor.
- (2) Wrap the cuff onto a column body in proper size.
- (3) Enter the “NIBP SETUP” menu
- (4) Rotate the knob, move the cursor onto the “Gas Leakage Detection” item, then press the knob. There will be a reminder of “Gas leakage detection in progress” at bottom of the NIBP parameter area of the screen, meaning the system has started executing gas leakage detection. The system automatically pumps to the pressure of 180mmHg. In about 20 seconds, the system will automatically open the air

bleeder, indicating completion of gas leakage measurement.No reminder information displaying on the NIBP parameter area doesn't mean no gas leakage within the system. Display of "Pump leaking..." means there is possible gas leakage with the gas route, in such case operators should check whether there is any loose connection, and after making sure of no more loose connection re-do the gas leakage detection; if the error reminder is still displayed, please contact with the manufacturer for repair.

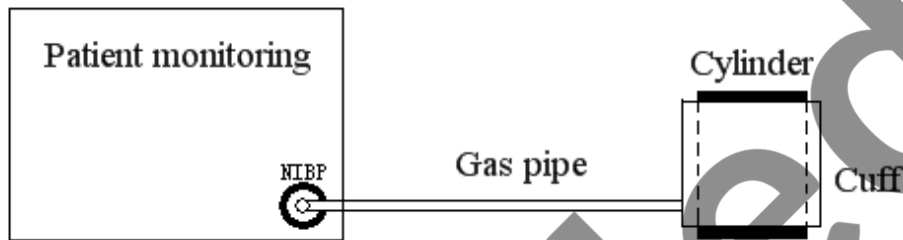


Figure 13-5 Connection for NIBP Gas Leakage Detection

13.6 Calibration procedures of a pressure sensor

Use a metal container of 500ml±5% to replace cuff. Connect a calibrated standard pressure meter with inaccuracy less than 0.8mmHg, T-interface ball pump and the pumping tube into the NIBP holes on the module. Set the monitor to be under "Standard" mode, then take the ball pumps to pump the metal container to be 0, 50 ad 200mmHg; in such cases values of standard pressure meter and press values indicated on the monitor will differ within 3mmHg, otherwise please contact with our Maintenance engineers.

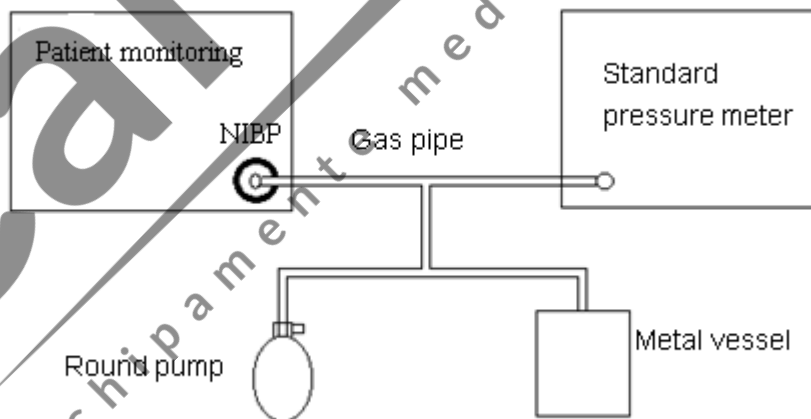


Figure 13-6 Connection for NIBP calibration

13.7 NIBP Alarms & Reminders

Provided that the alarming record function under relevant menu is turned on, those physical alarms activated because parameters exceed alarming limits may activate the recorder to automatically output alarming parameter values and the relevant measurement waveforms. The following table lists various possible alarms during NIBP measurement process.

Physical alarms:

Reminders	Causes	Alarming levels
NS over-high	Measured NIBP systolic pressure higher than specified alarming upper limit	User defined
NS over-low	Measured NIBP systolic pressure lower than specified alarming lower limit	User defined
ND over-high	Measured diastolic pressure higher than specified alarming upper limit	User defined
ND over-low	Measured diastolic pressure lower than specified alarming lower limit	User defined
NM over-high	Measured average pressure higher than specified alarming upper limit	User defined
NM over-low	Measured average pressure lower than specified alarming lower limit	User defined

Technical alarms 1 (displayed in the monitor information area):

Reminders	Causes	Alarming levels	Solution
NS alarming limit error	Function/safety failure	High	Stop using the NIBP module alarming function and inform biomedical engineers or our maintenance team
NM alarming limit error	Function/safety failure	High	Stop using the NIBP module alarming function and inform biomedical engineers or our maintenance team
ND alarming limit error	Function/safety failure	High	Stop using the NIBP module alarming function and inform biomedical engineers or our maintenance team

Technical alarms 2 (displayed in the reminder area below NIBP values):

Reminders	Causes	Alarming levels	Solution
-----------	--------	-----------------	----------

NIBP self-detection error	Sensor or other hardware failure	High	Stop using the NIBP measurement function and inform biomedical engineers or our maintenance team
NIBP communication error	Communication failure with NIBP measurement module	High	If the failure continues, stop using the NIBP measurement function and inform biomedical engineers or our maintenance team
Cuff loose or out of connection	Cuff isn't properly wrapped or no cuff	Low	Wrap the cuff properly
Gas leakage with cuff pumping pipe	Damage with cuff, pipe or connector	Low	Check and change the part with leakage, and if necessary also inform biomedical engineers or our maintenance team
Air pressure error	Fail to obtain stable pressure value, e.g., because of pipe wrapping	Low	Check whether there is pipe wrapping; if the problem continuous, inform biomedical engineers or our maintenance team
Signal too weak	Cuff too loose or patient pulse too weak	Low	Apply other methods to measure blood pressure
Pressure out of scope	Measurement scope exceeding specified upper limit	High	Reset the NIBP measurement module; and if the problem continuous, stop using the NIBP measurement module and inform biomedical engineers or our maintenance team
Arm movement	Big signal noise or irregular PR due to arm movement	Low	Make sure the patient is silent, without movement
Overpressure protection	Pressure exceeding specified upper limit	High	Re-measure. If the problem continuous, stop using the NIBP measurement module and inform biomedical engineers or our maintenance team
Signal saturation	Significant movement	Low	Stop the patient from movement
Pump leakage	Leakage during	Low	Check and change the part(s) with leakage,

	the leakage test		and if necessary, inform biomedical engineers or our maintenance team
NIBP system failure	Blood pressure pump system running failure	High	Stop using the NIBP measurement function and inform biomedical engineers or our maintenance team
Wrong cuff type	Current cuff type not suitable for patient	Low	Select proper cuff
Measurement time out	Measurement time over 120 seconds (for adults) or 90 seconds (for newborns)	High	Re-measure or apply other measurement methods
NIBP reset error	Module reset improperly	High	Re-use the reset function
Measurement error	During measurement the system can not execute measurement analysis or calculation	High	Check the cuff and re-measure while making sure the patient is silent during monitoring

Reminders (displayed in the reminder area below NIBP values):

Reminders	Causes	Alarming levels
Manual measurement	Manual measurement in process	No alarm
Continuous measurement	Continuous measurement in process	
Automatic measurement	Automatic measurement in process	
Please press START	After you select the measurement time interval	
Measurement stopped	During measurement users press the START button to stop measurement	
Calibration	Calibration in process	
Calibration stopped	Calibration completed	
Gas leakage detection	Gas leakage detection in process	

Gas leakage detection stopped	Gas leakage detection is stopped	
Module reset	Reset after NIBP module is loaded	
Manual reset	NIBP reset (activated by users) in process	
Fail to reset	Fail to reset	

13.8 Maintenance & Cleaning

Warning

- **Don't compress the rubber pipe on a cuff.**
- **Keep water or cleaning liquids out of the connector socket in the front of the monitor, otherwise the equipment may be damaged.**
- **During monitor cleaning, users need only sweep the outer surface of the connector socket instead of its inner surface.**
- **In case a recyclable cuff is disconnected with the monitor or being cleaned, users should locate the cover cap above the rubber pipe so as to prevent any liquids from entering the rubber pipe and being absorbed into the module.**

13.8.1 Recyclable blood pressure cuff

Normally cuff may be disinfected within a hot air cabinet under the high pressure, gas or radiation disinfection methods or sterilized by immersion into decontamination solutions. But users must take away the rubber bag when applying such methods. Cuff can not be dry washed but machine washed or hand washed only, and hand wash can extend service life of cuff. Before cleaning, users should take away the rubber bag and put back after cleaning and cuff drying. To put the rubber bag back into the cuff, users should put the rubber bag near the cuff opening side, making the rubber pipe aligned with the long opening of the cuff, then vertically roll the rubber bag and insert it into the long opening, hold on the rubber pipe and cuff, and then shake the whole cuff until the rubber bag is positioned exactly. Insert the rubber pipe into the cuff, letting it go through the hole liner and extend out.

13.8.2 Disposable blood pressure cuff

Disposable cuffs can only be used for one patient. Don't use the same cuff with different patients. Don't take disposable cuffs for disinfection or high-pressure vapor sterilization.

 **Attention**

- The width of the cuff should be 40% (or 50% for neonates) of the circumference of the limb, or 2/3 of the length of the upper arm. The length of the inflated part of the cuff should be long enough to wrap 50~80% of the limb; a size unsuitable cuff will produce a wrong reading. If the size of the cuff has a problem, use a larger cuff in order to reduce errors.

 **Attention**

- To protect the environment, one-time blood cuffs after use must be recycled or properly treated.

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Chapter 14 TEMP Monitoring

14.1 TEMP Monitoring

The monitor has two TEMP measuring channels. The temperature data can be measured with the TEMP detector.

For one-time TEMP detectors, users must insert the TEMP cables into slots and then connect the detectors with such cables; for reusable TEMP detectors, users can directly insert them into slots.

Closely paste TEMP detectors with patient body.

Turn on the system power supply.

Warning

- **At the beginning of monitoring, you should check that the probe cable is normal. Then unplug the temperature probe cable from the jack, the screen will display the message "temperature sensor is off" and sound the alarm.**
- **Be careful in handling the temperature probe and cable, when not in use, the probe and cable should be pulled into the loose ring. If the wire is pulled too tight, it will lead to mechanical damage.**
- **Calibrate the temperature measuring instrument at least once every two years (or according to the required time in the hospital directive rules). Please contact the manufacturer when calibration is needed.**

Attention

- **Disposable temperature probe can only be used once.**
- **During the monitoring process, the temperature measuring instrument will automatically check itself once per hour. Self-checking will last 2 seconds, and will not affect the normal working of the temperature monitor.**

14.2 TEMP setting in parameter area

Users can use the knob to move the cursor onto the TEMP hotkey in the parameter area and press the knob to enter the TEMP SETUP menu.

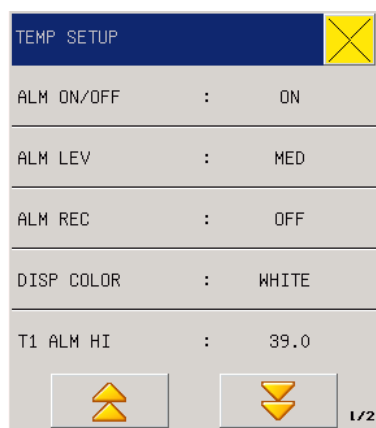



Figure 14-1TEMP setting

- ALM ON/OFF: Select “ON” and the alarm prompt and saving will proceed when TEMP is alarmed; select “OFF” and no alarm will happen, but  will be prompted beside TEMP in the screen parameter area.
- ALM LEV (Alarm levels): High, Middle or Low to be selected by users to set alarming levels.
- ALM REC (Alarm Record): it is mainly used in starting/closing the output function of TEMP alarm record. If “On” is selected, the present TEMP alarm will be outputted through the recorder.
- DISP COLOR: green, cyan, red, yellow, white, blue, violet.
- T1\T2 ALM HI/LO: Temperature alarm is set high limit and low limit alarm when the temperature exceeds the high limit or below the lower limit.
- TD ALM HI: Temperature alarm is set high limit when the temperature exceeds the high limit.

Adjustable range of TEMP alarm upper & lower limits:

Parameters	Max upper limit	Min lower limit	Adjusted amount per time
(T1/T2)	50°C 122°F	0	0.1°C
TD	50°C 122°F	0	0.1°C

TEMP UNIT: °C or °F.

14.3 TEMP setting in measurements

Select “TEMP SETUP” from the menu bar as follows:

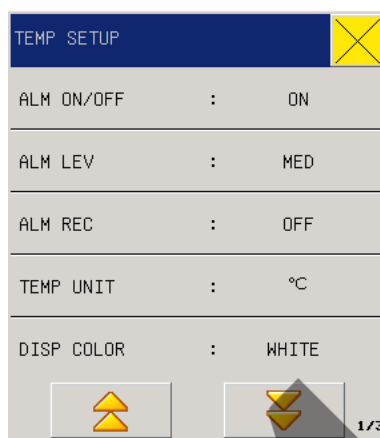


Figure 14-2TEMP setting

- ALM ON/OFF: see reference in “ALM ON/OFF” of TEMP setting in parameter area in this chapter.
- ALM LEV: see reference in “ALM LEV” of TEMP setting in parameter area in this chapter.
- ALM REC: see reference in “ALM REC” of TEMP setting in parameter area in this chapter.
- UNIT: °C or °F.
- DISP COLOR: see reference in “DISP COLOR” of TEMP setting in parameter area in this chapter.
- T1\T2 ALM HI/LO: see reference in “T1\T2 ALM HI/LO” of TEMP setting in parameter area in this chapter.
- TD ALM HI: Temperature alarm is set high limit when the temperature exceeds the high limit
- DEFAULT:Users can select this item to enter the “TEMP DEFAULT SETUP” dialogue box. If choosing “No”, the system would keep the precious configurarion. If choosing “Yes”, the system would adopt the default configuration.

14.4 Alarms & Reminders

In case the alarm record function under relevant menus is enabled, those physical alarms caused because relevant parameters exceed relevant alarming limits will activate the recorder to automatically output alarming parameter values and relevant measurement waveforms. The physical alarms, technical alarms and reminders possible happening during TEMP measurement are listed as follows:

Physical alarms:

Reminders	Causes	Alarming levels
TEMP over-high	TEMP measurement value higher than the set upper limit	User defined

TEMP over-low	TEMP measurement value lower than the set lower limit	User defined
---------------	---	--------------

Technical alarms

Reminders	Causes	Alarming levels	Solutions
TEMP Sensor disconnected	TEMP cable disconnected from the monitor	Low	Make sure the cable is reliably connected
Alarming limit error	Function/ safety failure	High	Stop using the TEMP alarm function and inform biochemical engineers or our maintenance personnel

Reminders:

Reminders	Causes	Alarm levels
TEMP Measurement out of scope	TEMP measurement value out of measurement scope	High

14.5 Maintenance & Cleaning

Warning

- Turn off the power and disconnect the AC power supply before cleaning monitor or the connected sensor.

Maintenance and cleaning for reusable TEMP detectors:

Heating onto a TEMP detector can not be over 100°C (212°F), as such detector can only undertake 80°C (176°F)–100°C (212°F) within short period.

During use of straight detectors, users should cover them with protective adhesive.

When cleaning detectors, users should use one hand to hold on one end and the other hand to downward hold wet lint-free cloth to wash detectors towards the connector direction.

Attention

- If you are using a one-time TEMP probe, this probe is NOT allowed to be re-disinfected or reused.
- To protect the environment, one-time TEMP detectors should be recycled or properly disposed.

Chapter 15 CO₂ Monitoring

15.1 General information

The module measures CO₂ pressure (PCO₂) to get end-tidal CO₂ (EtCO₂), inspiratory CO₂ (InsCO₂) and air way respiration rate (AWRR) and displays pressure waveform of CO₂.

The monitor adopts Sidestream and Mainstream CO₂ measurement modes.

- Sidestream measurement mode conducts constant samples from patients' respiratory gas sensor and analyzes it with the built-in remote CO₂ sensor in the measurement system.
- Mainstream measurement mode will install the CO₂ sensor on the air passage joint inserted into the patients' respiration system.

CO₂ measurement provides (CO₂ is optional):

- CO₂ waveform
- End-tidal CO₂ (EtCO₂): CO₂ value measured at the end of the respiration.
- Inspiratory CO₂ (Ins CO₂): the minimum value measured during inhalation.
- Air way respiration rate (AWRR): respiration rate calculated from CO₂ waveforms.

Warning

- **The bumping and shaking of the CO₂ module should be avoided whenever possible.**

Attention

- **Do not use this instrument where combustible anesthetic gases are present in the environment.**
- **This instrument can be operated only by professionals who are occupationally trained and familiar with this manual.**

Select the "MODULE SETUP" option in the "MONITOR SETUP" menu and set the CO₂ on-off to be on.

The following figure (the present figure is in demonstrating mode) will come out:

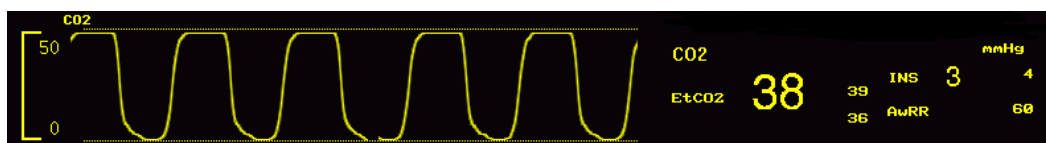


Figure 15-1 Main interface of CO₂ module

15.2 Measuring principle and working procedure

The measurement is done based on the characteristic that CO₂ can absorb infrared rays with a wavelength of 4.3µm. The measurement procedure includes first delivering CO₂ into the measurement chamber and then irradiating it with infrared rays at one side and, at the other side, using a sensor to determine the attenuation degree of received infrared rays. The attenuation degree is in positively proportional to CO₂ concentration.

The conversion relation between CO₂ partial pressure and CO₂ concentration is:

$$\text{CO}_2 \text{ partial pressure (mmHg)} = \text{CO}_2 \text{ concentration (\%)} * \text{Pamp (atmosphere pressure)}$$

CO₂ module adopts automatic (Autorun) command measuring modes with a waveform sampling rate of once per 31msec.

15.3 Operating Instruction for CO₂ Connection

- (1) The schematic of connection of the mainstream module produced by the RESPIRONICS company is shown in the figure below:

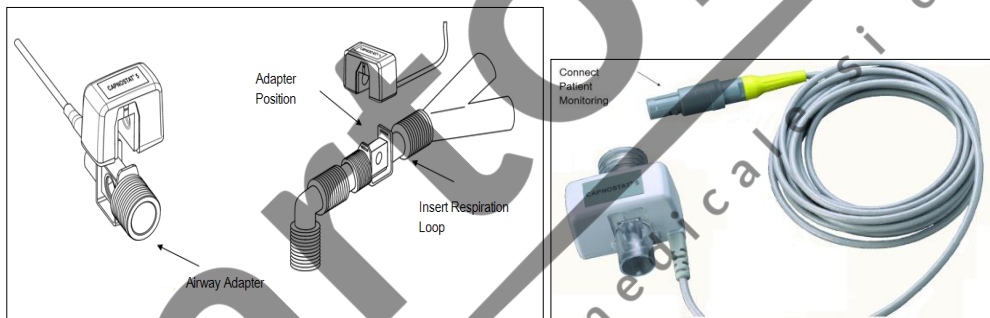


Figure 15-2 (A, B) Mainstream Mode CO₂ Connection

- (2) The schematic of connection of the sidestream module produced by the RESPIRONICS company is shown in the figure below:



Figure 15-3 (A, B, C) Sidestream Mode CO₂ Connection Schematic

- (2) The schematic of connection of the ISA™ sidestream analyzer produced by the PHASEIN company is shown in the figure below:

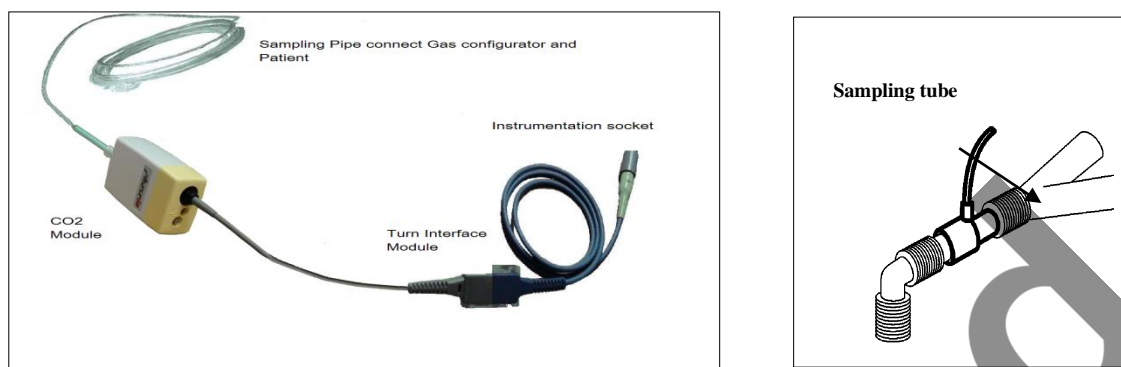


Figure 15-4 ISA™ Sidestream Analyzer (ISA CO₂) CO₂ Connection Schematic

- (4) The schematic of connection of the IRMA™ mainstream analyzer produced by the PHASEIN company is shown in the figure below:

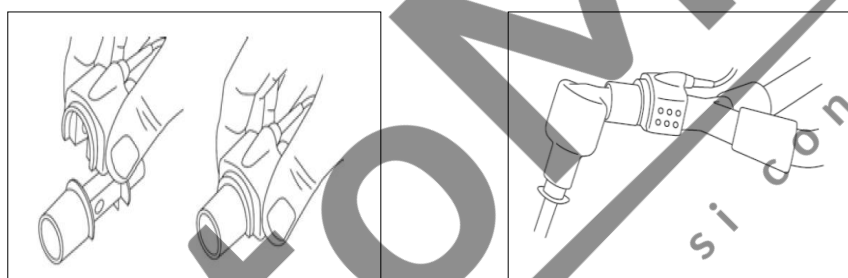


Figure 15-5 IRMA™ Mainstream Analyzer (IRMA CO₂) CO₂ Connection Schematic

The monitoring equipment produced by this company supports CO₂ measurement by using a sidestream or mainstream module produced by the IRONICES company, or an ISA™ sidestream analyzer (ISA CO₂ (CO₂) CAT. NO. 800101) produced by the PHASEIN company.

⚠ Attention

- When an ISA™ sidestream analyzer (ISA CO₂ (CO₂) CAT. NO. 800101) produced by the PHASEIN company is used for monitoring CO₂, please refer to the contents of the section titled “17.6 Measuring Procedure and Before-Using Checking” for the measuring procedure, and change the procedure for setting the AG module menu to CO₂ menu setting.

⚠ Warning

- Before use, please check airway joints. Do not use when visible damage or breaks are found on the airway adapter.

- When CO2 is not used, it must be turned off, otherwise the CO2 module will be in a working condition all the time.

15.4 CO₂ Measurement Procedures

Based on different CO₂ modules used, determine if it is necessary to set such menu items as “Oxygen Compensation”, “Balancing Gas”, “Altitude” and “Atmospheric Pressure” etc for the instrument. When an ISA™ sidestream analyzer (ISA CO₂ (CO₂) CAT. NO. 800101) produced by the PHASEIN company is used, if there are no such settings as altitude and atmospheric pressure etc, it means that such functions have been carried by the module itself, need not to be set manually. Please refer to the instruction manual coming with the module.

If you need the CO₂ alarm message function, you can set this function in “CO2 SETUP”.

15.5 Measuring Procedure of RESPIRONICS Branded Mainstream and Sidestream Modules

The RESPIRONICS branded sidestream analyzer operating procedure is roughly the same as the mainstream analyzer operating procedure; please refer to the sidestream analyzer operating procedure for the mainstream analyzer operating procedure.

- (1) Start the host monitoring equipment. Press the Main button and get into the “MAIN MENU”, select “MONITOR SETUP” and then “MODULE SETUP” and turn the CO2 SETUP to “ON”.
- (2) Or insert the CO₂ plug-in module into the host monitoring equipment (make connections according to the CO₂ module type or Figure 16-2 or Figure 16-3);
- (3) Rotate the knob to the CO₂ parameter area, press the knob to enter “CO2 SETUP”, turn “CO2 ON/OFF” to “ON” (generally, this switch is “on” as soon as the CO₂ module is connected to the equipment, but users need to reset it to be sure about that).
- (4) In the [CO2 SETUP] menu, set [Oxygen Compensation] to 21 (usually, although it is 21 in this menu, in order to make sure that its datum is in an activated state, the customer still needs to reselect it);
- (5) In the [CO2 SETUP] menu, select an appropriate [Balancing Gas]: Room air, N₂O or helium (usually if there is no unused N₂O or helium indoors, you can just select indoor air);
- (6) In the [CO2 SETUP] menu, select a correct [Altitude]: 0~5029. 2m, instrument default: 0m; mainly refer to the following table for its standard:

Air Pressure Conversion Table – End-of-Respiration CO₂ Data Read By Basing the Standard on Altitude

Sea-Level Elevation		Atmospheric Pressure	5%CO ₂
Inch	m	mmHg	ETCO ₂ mmHg

Sea Level (0)	Sea Level (0)	760	38
500	152. 4	745	37
750	228. 6	738	37
1, 000	304. 8	731	37
1, 500	457. 2	717	36
2, 000	609. 6	704	35
2, 500	762	690	35
3, 000	914. 9	677	34
3, 500	1066. 8	665	33
4, 000	1219. 2	652	33
4, 500	1371. 6	640	32
5, 000	1524	628	31
5, 500	1676. 4	616	31
6, 000	1828. 8	604	30
6, 500	1981. 2	593	30
7, 000	2133. 6	581	29
7, 500	2286	570	29
8, 000	2438. 4	560	28
8, 500	2590. 8	549	27
9, 000	2743. 2	539	27
10, 000	3048	518	26
10, 500	3200. 4	509	25
11, 000	3352. 8	499	25
11, 500	3505. 2	490	24
12, 000	3657. 6	480	24
12, 500	3810	471	24
13, 000	3962. 4	462	23
13, 500	4114. 8	454	23
14, 000	4267. 2	445	22
14, 500	4419. 6	437	22
15, 000	4572	428	21
15, 500	4724. 4	420	21
16, 000	4876. 8	412	21
16, 500	5029. 2	405	20
16, 800	5120. 6	400	20

Table 15-1

Note: It is assumed that the atmospheric pressure is 760mmHg and the ambient temperature is 0°C at the sea level. Calculation of Atmospheric Pressure: the sea-level based ambient temperature is assumed as 0°C. Refer to the above Table.

Warning

- **By setting sea-level elevation, the monitor is not automatically changed with air pressure compensations. Correct sea-level elevation must be set before the first use of CO₂ Measurement Program. Improper setting of sea-level elevation will result in incorrect CO₂ readings. A 5% CO₂ deviation is generally generated corresponding to difference of each 1000m height.**

- (7) In the [CO2 SETUP] menu, select a correct [Atmospheric Pressure]: 405~760mmHg, the instrument default is 760 mmHg; when CO₂ value is on the high side or on the low side, select an appropriate atmospheric pressure based on the local condition by referring to the table above (since the atmospheric pressure and the altitude are corresponding, the atmospheric pressure can be adjusted only by setting the altitude.)
- (8) In the [CO2 SETUP] menu, select [Zeroing]; after zeroing, the following prompt is displayed at the lower right corner of the screen: Zeroing...Please Wait for 30s; you can start measuring CO₂ only after the prompt disappears.
- Mark: if the CO₂ asphyxia alarm function is required, users can set it up in "CO2 SETUP".

15.6 Measuring Procedure of PHASEIN Branded Sidestream and Mainstream Analyzers

The PHASEIN branded sidestream analyzer operating procedure is roughly the same as the mainstream analyzer operating procedure; please refer to the sidestream analyzer operating procedure for the mainstream analyzer operating procedure.

15.6.1 Measurement Steps

If you want to set the host monitoring equipment in order to start gas analysis, please execute the following procedure:

- Start the host monitoring equipment. Press the Main button and get into the "MAIN MENU", select "MONITOR SETUP" and then "MODULE SETUP" and turn the CO₂ SETUP to "ON" (if there is already CO₂ waveforms and parameters in the interface, users can skip this step).

- b) Or insert the CO₂ plug-in module into the host monitoring equipment; the indicator of the CO₂ plug-in module will illuminate, which means that the module has been successfully connected to the host monitoring equipment; otherwise, please reinsert the CO₂ plug-in module.
- c) Connect the Nomoline sampling tube to the input interface of the ISA analyzer (CO₂ module)
- d) Connect the interface cable of the ISA analyzer to <Host monitor equipment>
- e) Rotate the knob to the CO₂ parameter area, press the knob to enter “CO₂ SETUP”, turn “CO₂ ON/OFF” to “ON” (generally, this switch is “on” as soon as the CO₂ module is connected to the equipment, but users need to reset it to be sure about that).
- f) Set appropriate [Oxygen Compensation], [Laughing Gas Compensation].
- g) To connect the outlet of the sample gas to the discharge system, or to make the gas to flow back to the patient’s circuit.
- h) If it is green LED indication, ISA Analyzer is available.
- i) To carry out inspection before use according to the statement in the “Check before use”.
- j) If the inspection is normal, start to monitor the CO₂ Gas.

15.6.2 Check before use

Before connecting the Nomoline sampling pipe to the breathing circuit, carry out the following steps:

- a) Connect the sampling tube to the gas entrance interface (LEGI) of the ISA CO₂ module.
- b) Check whether the green light of LEGI is steadily on or not (The indication system is normal) .
- c) Exhale to the sampling tube, check if a valid CO₂ waveform and value are displayed on the host monitoring equipment.
- d) Use the finger tip to block up the sampling pipe, and hold on for 10 seconds.
- e) Examine whether there is obstruction warning and if the LEGI shows a red flashing light.
- f) Under proper circumstances: Carry out enclosure check on the patient’s circuit that is linked with the sampling pipe.

Attention

- If the interface shows the prompt of ‘no connection to the oxygen sensor’, please reinstall the oxygen sensor.
- The end of the gas circuit adapter which connects the gas sampling pipe should point upward so as to prevent the condensing water drops entering the gas sampling pipe and blocking it up.

Warning

- Hang the external CO₂ analyzer onto the CO₂ bracket on the rear casing of the instrument; prevent the dropping damage of the CO₂ module.

- Unless HME is used to protect the IRMA probe, the state indicating LED should face upward all the time during IRMA probe placement.
- Do not pull the cable of ISA By-flow Gas Analyzer.
- Do not operate the ISA By-flow Gas Analyzer in the environment beyond the designated working temperature.
- Make sure all connections are firm and reliable. Any leakage will result in the inclusion of ambient air in the patients respiratory gas, which leads to a wrong reading.

15.7 CO2 Settings in Parameter Area

Rotate the rotary shuttle button to move the cursor on the display interface to the CO2 hotkey in the parameter area, and then press the rotary shuttle button to enter the menu "CO2 SETUP".



Figure 15-6CO2 SETUP

- ALM ON/OFF(Alarm Switch): select "On" to enable CO2 alarms, or select "Off" to disable CO2 alarms with the icon "✘" appearing beside "CO2" in the parameter area on the screen.
- ALM REC (Alarm Record): select "On" to enable the recorder output when there is any CO2 alarm.
- SWEEP (Alarm Speed): 12.5mm/s, 25.0mm/s.
- WAVE COLOR(Waveform Color): Green, Cyan, Red, Yellow, White, Blue, or Purple
- UNIT: mmHg/kpa.
- CO2 ON (CO2 Switch): ON or OFF; select "On" to monitor the CO2.
- O2 COMPEN (Oxygen Compensation): 0~100(RESPIRONICS); HIGH, MID and LOW (PHASEIN)
- LAUGHING GAS COMPEN (Laughing gas Compensation): ON, OFF. (This option is only for PHASEIN.)
- BALAN GAS (Balance Gas): Indoor Air, Laughing Gas, or Helium. (No such option for PHASEIN).
- ALTITUDE: 0~5029.2 m (adjustable based on the geographical location). (No such option for

PHASEIN).

- BARO PRE (Atmospheric Pressure): 405~760 mmHg (adjustable based on the geographical location: either Altitude or Atmospheric Pressure, not both). (No such option for PHASEIN).
- INS ALM HI (Upper Limit of INS Alarm): adjust the upper limit of INS alarm; if the measured INS value exceeds the upper limit, there will be an alarm and prompting.
- APNEA ALM (apnea alarm): NO, 10s, 15s, 20s, 25s, 30s, 35s, 40s.
- CO2 ALM SETUP: Used for to adjust CO2 the upper and lower limits of the range of the high limit, middle limit and lower limit alarm. When the alarm limit CO2 measurement value is greater than or less than the alarm limit, the instrument alarm and prompt.
- AWRR ALM SETUP: Used for to adjust AWRR the upper and lower limits of the range of the high limit, middle limit and lower limit alarm. When the alarm limit CO2 measurement value is greater than or less than the alarm limit, the instrument alarm and prompt.
- ZERO CAL: zero before monitoring the CO2, in order to obtain a more accurate measured value.
- DEFAULT: override the original settings.

15.8 CO2 Settings in Waveform Area

Rotate the shuttle button to move the cursor on the display interface to the CO2 hotkey in the waveform area, and then press the shuttle button to enter the menu "CO2 SETUP" as below:

CO2 SETUP	
CO2 Ruler Setup	
SWEEP	: 6.25
WAVE COLOR	: YELLOW
WAVE TYPE	: LINE

Figure 15-7CO2 SETUP

- CO2 Ruler Setup: the ruler is displaying in the CO2 waveform area with setting of HI, MID, and LOW, making it easier to observe changes of the CO2 waveforms, in which, the mid ruler is set based on the value of high ruler and low ruler.
- SWEEP: 6.25 mm/s, 12.5mm/s, 25.0mm/s.
- WAVE COLOR: Green, Cyan, Red, Yellow, White, Blue, or Purple.
- WAVE TYPE: LINE or FILL.

15.9 CO₂ Settings in Measurement Setup

Select “CO2 SETUP” in the menu “SURVEY SETUP ” or rotate the shuttle button to move the cursor to CO2 hotkey in the parameter area on the main screen, and then press the shuttle button to enter the menu “CO2 SETUP” as below:



Figure 15-8CO2 SETUP

Note: Refer to the section “CO2 Settings in Parameter Area” for the specific options of the menu “CO2 SETUP” in “SURVEY SETUP”.

15.10 Discharging Waste Gases

When nitrous oxide and/or an anesthetic gas is used, you should prevent these gases from polluting the operating room. Usually the gasscavenging outlet should be connected to (via the gas scavengingoutlet connected to the sample gas outlet of the host equipment):

A scavenging system (used for removing collected gases) or the patient circuit (used for the back flowing of collected gases).

Warning

- **Anesthetics:**When an anesthetic which is being used or a patient who recently used an anesthetic is measured, the gas scavenging outlet on the module must be connected to a waste gas processing system or the patient circuit (on the anesthesia machine or the respirator), so as to prevent medical personnel from inhaling the anesthetic.

15.11 Maintenance and Cleaning of RESPIRONICS Branded Mainstream and Sdestream Modules

15.11.1 Common Cleaning

Clean with cloth, optionally dipped with 70% isopropanol, aqueous solution containing 10% sodium hypochlorite (bleacher), sterilizing spray cleaner (such as Steris Coverage Spray HB), ammonia water or mild soap water. Before cleaning, wash the cloth with rinse water and then wring out and air-dry the washed cloth. Make sure that sensor windows are clean and are air-dried before being used repeatedly.

15.11.2 Airway Adapter for Cleaning Reusable Mainstream Sensor

Rinse it with warm soapy water first and soak it in liquid sterilizing fluid, such as 70% isopropanol, aqueous solution containing 10% sodium hypochlorite (bleacher), 2.4% glutaraldehyde solvent, e. g. Cidex Plus or Steris System 1 or ammonia water. Wash it with clean water completely.

15.11.3 Method for Sterilizing Reusable Adapter

Autoclave Sterilizer-operable only to adult-used adapters.

Ethylene oxide (ETO)- Sterilizing for 1.5h.

Soaking in Cidex Plus for 10h.

Soaking in Perasafe for 10h.

U. S. Steris System 1 pasteurizer.

Before adapters are reused, please make sure that the windows are dried without any residuals and that adapters stand intact during operation or cleaning/sterilization:

15.11.4 Sterilization Times for Reusable Airway Adapter

The reusable airway adapters can be reused 100 times if the above sterilization method is used.

15.11.5 Zeroing

Please zero before monitoring CO₂; zeroing is to eliminate the effect of baseline drifting on the results during measurement, thus ensuring the correctness of measured results.

Usually, the module will zero itself automatically when necessary. The user can zero the module manually when the user considers it necessary: Select [CO₂] in the parameter area, in the [CO₂ SETUP] menu popping

up, select [Zeroing] to zero the CO₂ module. During zeroing, make sure that the patient circuit is exposed to the ambient air (21% oxygen and 0% CO₂) for approximately 30 seconds; when the 30s zeroing prompt on the screen ends, it means zeroing is completed.

15.12 PHASEIN Branded Mainstream and Sidestream Analyzer Related Information

15.12.1 Safety alarm information

15.12.1.1 ISA Sidestream Gas Analyzer Safety Warning Information

Warning

- The ISA sidestream gas analyzer is designed to be used by authorized or trained medical personnel.
- Only Nomoline sampling tubes produced by PHASEIN can be used.
- The ISA sidestream gas analyzer shall not be used in an inflammable anesthetic gas.
- You should earnestly neaten the sampling tube in order to reduce the risk of it wrapping or reining the patient.
- Do not repeatedly use a disposable sampling tube.
- Do not lift the ISA/host equipment by grasping the sampling tube; otherwise it may break away from the ISA/host equipment, which may result in that the ISA/host equipment falls onto the patient.
- Used disposable sampling tubes should be disposed according to local medical waste stipulations.
- Do not use a sampling tube configured for an adult or a child on an infant; otherwise the invalid cavity in the patient circuit will increase.
- Do not use a sampling tube configured for an infant on an adult; otherwise it will result in a too big flowing resistance.
- Do not use the ISA sidestream gas analyzer together with a quantitative spraying agent or spray; otherwise it may result in the clogging of the germ filter.

- Check if the flowing speed of the gas sample is too high for the given patient type.
- Since successful zeroing requires that the gas analyzer exists in the ambient air (21% oxygen and 0% CO₂), you should make sure that the ISA is placed at a well ventilated position. Before and after executing the zeroing procedure, avoid breathing in the vicinity of the ISA sidestream gas analyzer.
- The Nomoline sampling tube and its interface are not germ free devices. In order to prevent the sampling tube from causing damages, please never carry out high pressure sterilization on any part of the sampling tube.
- Never disinfect the ISA sidestream gas analyzer or soak it into a liquid.
- Mobile and radio frequency communication equipment will affect measurement. Make sure that the ISA gas analyzer is used in the electromagnetic environment designated in this operating instruction manual.
- The ISA gas analyzer can only be used as a piece of auxiliary equipment for patient evaluation. It must be used together with other vital sign and symptom evaluation equipment.
- If the input interface of the sampling tube starts showing red blinking, or a Nomoline clogging message is displayed on the host, the sampling tube should be replaced.
- It is not allowed to alter this equipment without the manufacturer's authorization. If this equipment is altered, appropriate checking and testing must be conducted in order to make sure that it can be safely operated over a long period of time.
- The ISA gas analyzer is not designed for being used in a MRI environment.
- During MRI scanning, the host equipment must be placed outside the MRI room.
- Using high frequency electrosurgical equipment in the vicinity of the ISA/host equipment may produce interference, which will result into incorrect measurements.
- Do not use the external natural heat dissipation function of the ISA equipment.
- Do not apply a negative pressure (such as using a syringe) onto the Nomoline to remove condensed water.
- If the positive or negative pressure in the patient circuit is too high, it may affect the sample's flowing speed.
- If the discharging or sucking pressure is too high, it may affect the sample's flowing speed.
- The discharged gas should be discharged into the patient circuit, or into a discharging system.
- If the collected gas sample needs to supply air for respiration, a germ filter should be used at the discharging side all the time.

- When placing the ISA gas analyzer, try not to place it at a position where the analyzer might fall onto the patient's body.

15.12.1.2 IRMA Mainstream Gas Analyzer Safety Warning Information

Warning

- Do not use an IRMA airway adapter configured for an adult or a child on an infant, since the adapter will add 6ml of invalid cavity to the patient circuit.
- If the airway adapter has water drops/condensation, it should be replaced.
- Use an IRMA airway adapter made by PHASEIN.
- Do not use an IRMA infant airway adapter on an adult; otherwise it will result in a too big flowing resistance.
- When an energized part is contacted, sufficient protection should be provided to the host equipment.
- Only an adapter cable approved by PHASEIN AB can be used.
- A warning must be implemented in the host equipment, displayed during demonstrative data displaying.
- The host equipment should be equipped with an appropriate alarm system to remind the user of circumstances which may cause death or serious damages to the patient's health.
- Every corresponding alarm message in IRMA state abstract fields must be implemented in the host equipment.
- The IRMA probe is not designed to be contactable to the patient.
- Incorrect probe zeroing will result in false gas readings.
- The IRMA probe is designed for being used by authorized or trained medical personnel.
- The IRMA probe is not designed shall not be used in an inflammable anesthetic gas.
- A disposable IRMA airway adapter shall not be used repeatedly. Repeatedly using a disposable adapter will cause cross infection.
- Used disposable airway adapters should be disposed according to local medical waste stipulations.
- Only oxygen sensors made by PHASEIN can be used. Oxygen exhausted oxygen sensors should be disposed according to local battery disposal stipulations.

- Never try to open the oxygen sensor device. The oxygen sensor in the IRMA probe is a disposable product, containing corrosive electrolytes and lead.
- The IRMA probe is designed only as an auxiliary means for patient evaluation. It must be used together with other vital sign and symptom evaluation equipment.
- Never place the IRMA airway adapter somewhere between the trachea catheter and the elbow; otherwise it may result in the adapter window being clogged by the patient's secretions and operating errors.
- In order to prevent secretions and moisture from aggregating at the window and the oxygen sensor port, always place the IRMA probe at a vertical position and let the LED face upwards.
- Never use the IRMA airway adapter together with a quantitative spraying agent or spray; otherwise it may affect the light traveling of the airway adapter window.
- If an IRMA OR (without the automatic anesthetic gas identification function) user select a wrong anesthetic gas, it will result in false anesthetic gas readings.
- If the IRMA OR (without the automatic anesthetic gas identification function) is applied to a mixed gas containing several anesthetic gases, it will result in false anesthetic gas readings.
- Mobile and radio frequency communication equipment will affect measurement. You should make sure that the IRMA probe is used in the electromagnetic environment designated in this operating instruction manual.
- Never disinfect the IRMA probe or soak it into a liquid.
- The IRMA oxygen cell and the IRMA airway adapter are not germ free devices. Never carry out high pressure sterilization on the equipment; otherwise it will result in equipment damage.
- Even if an IRMA probe has not been used, do not install an oxygen exhausted oxygen cell on the probe.
- Do not stretch the sensor cable.
- Do not run this equipment beyond the temperature environment designated by this operating instruction manual.
- (USA): According to the federal law, this product can only be sold by doctors or based on prescriptions.

15.12.2 Zeroing

An infrared gas analyzer needs to determine the zero reference level for CO₂ measurement. This zeroing standard is called as “zeroing” here.

Automatic Zeroing

The ISA sidestream gas analyzer executes zeroing automatically by switching the gas sample from the respiration circuit to the ambient air. To execute automatic zeroing once every 24 hours, the ISA sidestream gas analyzer takes less than 3 seconds. If the ISA sidestream gas analyzer is equipped with an oxygen sensor, automatic zeroing also includes the indoor air calibration of the oxygen sensor.

Manual Zeroing

Select [CO₂] in the parameter area, in the [CO₂ SETUP] menu popping up, select [Zeroing] to zero the CO₂ module. During zeroing, make sure that the patient circuit is exposed to the ambient air (21% oxygen and 0% CO₂) for approximately 30 seconds; when this menu is in a non default (settable) condition, zeroing can be executed.

Warning

- Since successful zeroing requires that the gas analyzer exists in the ambient air (21% oxygen and 0% CO₂), you should make sure that the ISA is placed at a well ventilated position. Before and after executing the zeroing procedure, avoid breathing in the vicinity of the ISA sidestream gas analyzer.





15.12.3 Fault handling












When the sampling system of CO₂ module goes something wrong, first check when the sampling tubes are intertwined together. **If there is a red flashing at the joint of the sampling tube or Nomoline blockage information shown on the host computer, then replace the sampling tubes.**

15.12.4 Calibration

Sidestream CO₂ module needs no daily checking, but calibration is needed twice a year or existence of huge deviation.

15.12.5 Safety information

Symbol	Title	Explanation
	Instructions for use	Consult instructions for use
	Catalog number	
	Serial number	
	Batch code	

Symbol	Title	Explanation
	Use by date [YYYY-MM-DD]	The device should not be taken into operation after the date accompanying the symbol.
	Do not re-use	Nomoline and Nomoline Airway Adapter Set are intended for single patient use
	For EU only: Waste Electrical and Electronic Equipment (WEEE)	For EU only: Electrical and electric equipment shall be collected and recycled in accordance with (Directive 2002/96/EC)
 0413	Conformité Européenne	Complies with 93/42/EEC Medical Device Directive when connected to medical devices approved by PHASEIN AB.
	CO ₂	ISA equipped to measure CO ₂ only
	Gas Inlet	
	Gas Outlet	
	Defibrillation-proof type BF applied part	The applied part of ISA is the Nomoline Family sampling line
	Patient circuit connection	Diagram of Nomoline and patient circuit
	Connect to ISA	Diagram of Nomoline and ISA
	non-aseptic, latex free	The product is non-aseptic equipment and latex free.

15.12.6 Cleaning the Analyzer

The “Plug in and measure” ISA/IRMA gas analyzer should be cleaned regularly. Use ethanol or isopropyl alcohol with a maximum concentration of 70% and a wet rag to clean the analyzer.

In order to prevent the cleaning liquid and dust from entering into the ISA gas analyzer from the LEGI interface, the Nomoline sampling tube should be connected all the time during analyzer cleaning.

Warning

- **The Nomoline sampling tube is not a germ free device. In order to prevent the sampling tube from causing damages, please never carry out high pressure sterilization on any part of the sampling tube.**
- **Never sterilize the ISA sidestream gas analyzer or soak it into a liquid.**

15.12.7 Patents and Trademarks

(1) Patent Statement

PHASEIN AB owns the following patents for relevant products described in this operating instruction manual: SE519766; SE519779; SE523461; SE524086. Other patents are being applied.

(2) Trademark

PHASEIN IRMA™, PHASEIN ISA™, PHASEIN XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMA EZ Integrator™, PHASEIN GasMaster™ and ISA MaintenanceMaster™ are trademarks of PHASEIN AB.

Tygothane® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

15.12.8 CO₂ Module Lighting Information

Overview of States Indicated by LEGI:

Indicating Signal	State
Not blinking green light	The system is normal
Blinking green light	Zeroing
Not blinking red light	Sensor Error
Blinking red light	Checking the sampling tube/airway adapter

15.12.9 Adverse effects on performance

(1) The following circumstances can cause known adverse effects on indicated performance:

- Quantitative effects of humidity or condensation.
- Quantitative effects of atmospheric pressure.
- Disturbing gases or water vapor.
- Other disturbing sources.

(2) Gas measurement unit

Volume percentage is used as the unit of concentration of a reported gas. Concentration is defined below:

$$\%_{\text{gas}} = \frac{\text{Partial pressure of gas component}}{\text{Total pressure of gas mixture}} * 100$$

The total pressure of a mixed gas is measured by the cup pressure sensor in the ISA gas analyzer.

If you want to convert it into another unit, you can use the actual atmospheric pressure sent by the ISA sidestream analyzer; for example:

$\text{CO}_2 \text{ (mmHg)} = (\text{CO}_2) \times (\text{atmospheric pressure (kPa) from the ISA}) \times (750 / 100)$.

For example: 5.0 vol% CO_2 @ 101.3 kPa $0.05 \times 101.3 \times 750 / 100 = 38 \text{ mmHg}$

(3) Effects of Moisture

The partial pressure and volume percentage of CO_2 , N_2O , oxygen or an anesthetic gas depend on the content of water vapor in the measured gas. Oxygen measurement will be calibrated; at the actual ambient temperature and humidity level, 20.8 vol%, in stead of the actual partial pressure, will be displayed. 20.8 vol% of oxygen corresponds to the actual oxygen concentration of indoor air (the water concentration is 0.7 vol%) (for example: at 1013 hPa, corresponding to 25°C and 23% RH). The actual partial pressure at the current humidity level will be displayed all the time when CO_2 , N_2O , oxygen and anesthetic gases (all the gases measured the infrared cell) are measured.

In the pulmonary alveoli of a patient, the water vapor in breathing gases become saturated at the body temperature.

After breathing gases is collected and sent into the sampling tube, their temperature gets near to the ambient temperature before they enter into the ISA sidestream gas analyzer. After Nomoline has removed all the condensed water, water molecules will not enter into the ISA sidestream gas analyzer. The relative humidity of all the gases collected is approximately 95%.

If you need the CO_2 value under BTPS, you can use the following equation:

$$Et\text{CO}_2(\text{BTPS}) = Et\text{CO}_2 * (1 - \frac{3.8}{P_{\text{amb}}})$$

Where:

Et CO_2 = Et CO_2 value [vol %] sent by the ISA

P_{amb} = Atmospheric pressure [kPa] sent by the ISA

3.8 = Typical partial pressure [kPa] of water vapor condensed between the patient's circuit and the ISA

Et CO_2 (BTPS) = Et CO_2 gas concentration [vol%] under BTPS

It is assumed that standard oxygen of indoor air has been used at a humidity level of 0.7 vol% H_2O

15.12.10 Consumables

The Nomoline sampling tube cannot be used repeatedly.

Replace the Nomoline sampling tube every two weeks or when "The sampling tube is clogged" is displayed (based on whichever comes first).

15.12.11 Maintenance

The user should verify gas readings regularly; If finding any problem, please contact an engineer of the manufacturer for maintenance.

Chapter 16 IBP Monitoring

16.1 General information

This chapter mainly introduces invasive blood pressure (IBP) monitoring methods and contents relevant to maintenance and cleaning of accessories.

The C60 infant portable-type multi-parameter monitor can be directly used for measuring vascular pressures (diastolic pressure, systolic pressure and mean blood pressure). The following waveforms can be displayed:

Waveform Name	Definition
ART	arterial pressure
PA	pulmonary arterial pressure
CVP	central venous pressure
RAP	right atrial pressure
LAP	left atrial pressure
ICP	intracranial pressure

Remark: IBP monitoring part is an optional component.

16.2 Considerations of IBP monitoring

Warning

- When you apply an accessory, make sure that the selected accessory meets medical instrument safety requirements.
- When connecting or using an accessory, you should avoid touching any metal part connected to an electric appliance.
- When the monitor is connected to high frequency electrosurgical equipment, in order to prevent electric leakage from burning the patient, you should prevent the sensor of the monitor from contacting a cable or high frequency electrosurgical equipment.
- Do not repeatedly use a disposable pressure sensor.

- **Before starting monitoring, you should check if the sensor cable is normal. When you pull the sensor out from the receptacle, the screen will display such a prompt message as “The IBP sensor comes off”, and issue an alarm sound.**
- **If a liquid (not the solution used for filling the pressure tube and sensor) is spattered onto the equipment or accessory, especially when the liquid may enter into the sensor or monitor, please contact the maintenance department of the hospital.**

 **Attention**

- **Only pressure sensors designated in this operating instruction manual can be used.**

The specified sensor has shock-proof function (with resistance to leakage current) and can prevent influence of cardiac defibrillators. It can be used in surgeries. When the patient is in the defibrillation period, the pressure wave may exhibit temporary disorders; but after defibrillation, the monitor will work normally and the operation mode and user configuration of it won't be affected.

 **Attention**

- **No matter a new sensor or a used sensor, it should be calibrated regularly in accordance with hospital regulations.**
- **When invasive blood pressure monitoring starts, the user should carry out zeroing on the transducer; during monitoring, the user should maintain the pressure sensor and the heart at the same level all the time; in order to prevent tube clogging, the user should keep injecting heparin saline to wash the tube and maintain the unobstructed condition of the pressure measurement path, and securely fixed the tube in order to prevent it from moving or coming off, which will affect invasive blood pressure measurement.**

16.3 Monitoring procedure

Measurement preparation:

- 1) Insert cables into corresponding sockets and check to ensure the monitor has been plugged in.
- 2) Have the pressure pipe and the sensor prepared. Fill the system full with physiological saline solution to make sure no bubble exists therein.
- 3) Connect the patient catheter to the pressure pipe and make sure that there is no air in the catheter and the pressure pipe or the sensor.

Warning

- If there are bubbles in the pressure tube or the sensor, wash the system again with the filled liquid.

- 4) Position the sensor on the same level as the heart, approximately on the midaxillary line.
- 5) Confirm correct ruler names have been chosen. See the following section for details.
- 6) Do zero-adjustment of the sensor. See the following section for details.

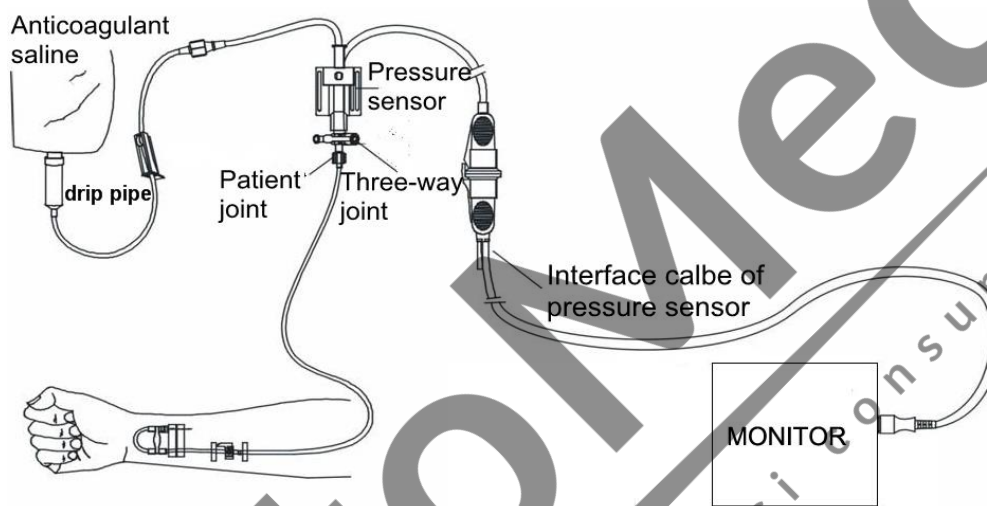


Figure 16-1IBP Monitoring

16.4 IBP Menu

Select the “MODULE SETUP” option in the “MONITOR SETUP” menu and set the IBPON-OFF to be on. The following figure (the present figure is in demonstrating mode) will come out:

16.4.1 IBP<1,2>setup in the parameter area

Rotate the knob and move the cursor to the IBP hotkey in the parameter area of the screen.

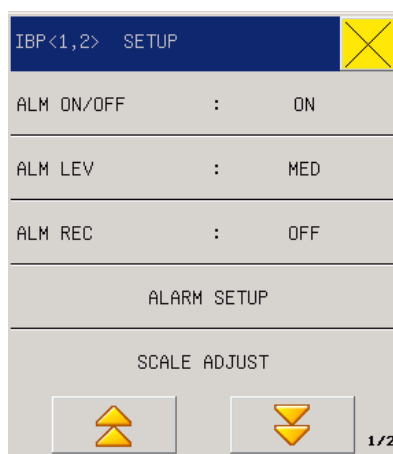


Figure 16-2IBP Parameter Setting Menu

Settings can be done on the following items:

- ALM ON/OFF(Alarm switch): Where “ON” is selected, the alarm prompt and saving will proceed when the IBP (invasive blood pressure) is alarmed; where “OFF” is selected, alarming will not happen, but ~~IBP~~ will be prompted beside IBP in the screen parameter area.
- ALM LEV(Alarmlevels): Optional levels are “High”, “Middle” and “Low”.
- ALM REC(Alarm record): select “On” to enable the recorder output when there is any IBP alarm.
- ALARM SETUP: When the alarm measurement value is greater than or less than the alarm limit, the instrument alarm and prompt.
 - CH1: ART, PA, CVP, RAP, LAP ,LAP ,ICP ,P1,P2 limit Hi setup:
 - SYS: UpperSYS alarm limit: used for setting the upper alarm limit
 - MAP: Upper MAP alarm limit:used for setting the upper alarm limit
 - DIA: Upper DIA alarm limit: used for setting the upper alarm limit
 - CH1: ART, PA, CVP, RAP, LAP ,LAP ,ICP ,P1,P2 limit Lo setup:
 - SYS: LowerSYS alarm limit: used for setting the lower alarm limit
 - MAP: Lower MAP alarm limit:used for setting the lower alarm limit
 - DIA: Lower DIA alarm limit: used for setting the lower alarm limit
 - CH2: ART, PA, CVP, RAP, LAP ,LAP ,ICP ,P1,P2 limit Hi setup:
 - SYS: UpperSYS alarm limit: used for setting the upper alarm limit
 - MAP: Upper MAP alarm limit:used for setting the upper alarm limit
 - DIA: Upper DIA alarm limit: used for setting the upper alarm limit
 - CH2: ART, PA, CVP, RAP, LAP ,LAP ,ICP ,P1,P2 limit Lo setup:
 - SYS: LowerSYS alarm limit: used for setting the lower alarm limit
 - MAP: Lower MAP alarm limit:used for setting the lower alarm limit
 - DIA: Lower DIA alarm limit: used for setting the lower alarm limit

 **Attention**

- **Users should guarantee that zero calibration has been done on the sensor before the measurement; otherwise the instrument has no effective zero value, which may lead to inaccuracy of measured data.**

Once the measured data exceed the alarm limits, the alarm will be triggered.

IBP alarm limits:

Pressure Scale Name	Max Upper Limit (mmHg)	Min Lower Limit (mmHg)	Adjustable Single-Step Length (mmHg)
ART	300	0	1
PA	120	-6	1
CVP	40	-10	1
RAP	40	-10	1
LAP	40	-10	1
ICP	40	-10	1

- **SCALE ADJUST** : The IBP waveform area provides scales for waveforms. Two dash line of each IBP waveform, from the upper to the lower, respectively represents the upper-limit scale and the lower-limit scale of the waveform. Values of the two scales may be set. The detailed setting method is introduced in the current menu.

- ◆ **CH1:ART/PA /CVP /RAP/LAP/ICP/P1/P2 Ruler Setup:**

- Upper scale: The pressure value represented by the upper scale limit. The choice range is the measurement range of the current pressure.
- Lower scale: The pressure value represented by the lower scale limit. The choice range is the measurement range of the current pressure.
- Mean scale: he pressure value represented by the middle scale limit. The choice range is the measurement range of the current pressure.

- ◆ **CH2:ART /PA /CVP/RAP/LAP/ICP /P1 /P2 Ruler Setup:**

- Upper scale: The pressure value represented by the upper scale limit. The choice range is the measurement range of the current pressure.
- Lower scale: The pressure value represented by the lower scale limit. The choice range is the measurement range of the current pressure.
- Mean scale: he pressure value represented by the middle scale limit. The choice range is the measurement range of the current pressure.

- **CH1/CH2 ZERO:** the IBP1 and IBP2 module into the socket, the need for invasive pressure zeroing.

 **Attention**

- The scale upper limit shall not lower than the lower limit.
- The scale lower limit shall not higher than the upper limit.
- The lower pressure limit, the upper pressure limit, the reference scale and the waveform are displayed simultaneously on the screen so that users can observe waveform changes after the scales are adjusted.

16.4.2 IBP<1,2>setup in the waveform area

Rotate the knob and move the cursor to the IBP hotkey in the waveform area of the screen.



Figure 16-3IBP Parameter Setting Menu

Settings can be done on the following items:

- CH Press Setup: eight options including ART, PA, CVP, RAP, LAP, ICP, P1 and P2 are provided.
- SWEEP: 6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s.
- FILTER: SMOOTH, NORMAL, NO FIL.
- WAVE COLOR: green, cyan, red, yellow, white, blue, purple.
- WAVE TYPE: line, fill.

16.4.3 IBP<1,2>setup in the measurement setup

The following figure (the present figure is in demonstrating mode) will come out:

Press the knob to enter the “IBP selection” menu.

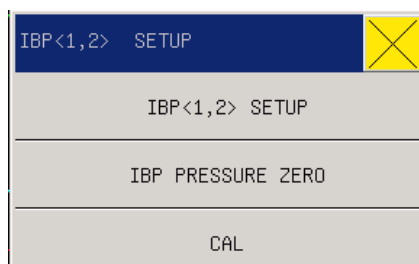


Figure 16-4IBP Parameter Setting Menu

Settings can be done on the following items:

■ IBP<1,2>SETUP:

- ALM ON/OFF: see this chapter parameter area IBP <1,2>setup the ALM ON/OFF.
- ALM LEV: see this chapter parameter area IBP <1,2>setup the ALM LEV
- ALM REC: see this chapter parameter area IBP <1,2>setup the ALM REC
- SWEEP: see this chapter waveform area IBP <1,2>setup the SWEEP
- UNIT : mmHg,kPa,cmH2O.
- FILTER: see this chapter waveform area IBP <1,2>setup the FILTER.
- CH PRESS SETUP: see this chapter waceform area IBP <1,2>setup the CH Press Setup
- ALARM SETUP: see this chapter parameter area IBP <1,2>setup the ALARM SETUP
- SCALE AGJUST see this chapter parameter area IBP <1,2>setup the SCALE AGJUST
- DEFAULT: checked into the IBP <1,2> Default Settings dialog box, select "No" to abandon the current operation, the system remains the original configuration unchanged, select "Yes", and will be using the default settings,the original configuration will be overwritten.

■ IBP PRESSURE ZERO

- CH1 ZERO: the IBP1 and IBP2 module into the socket, the need for invasive pressure zeroing.
- CH2 ZERO: the IBP1 and IBP2 module into the socket, the need for invasive pressure zeroing.

■ CAL(calibration)

- CH1 CAL VALUE:Adjustable from 80 to 300 values.
- CH2 CAL VALUE: Adjustable from 80 to 300 values.
- CH1 ADJUST
- CH2 ADJUST

⚠ Attention

- The user should ensure that the sensor has been calibrated by zeroing before measurement; otherwise the instrument will not have an effective zero, which will result in inaccurate measurement data.
- When setting alarm limits, users should confirm the item to be set.

16.5 Zero calibration of sensor

Press the “IBP zero calibration” key with the rotary knob and the system will begin zero calibration.

Zero calibration consideration:

- Before zero calibration, close the three-way stop cock at the patient side.
- Before zero calibration, the sensor should communicate with the atmosphere.

The sensor must be positioned at the same level with the heart, approximately on the midaxillary line.

- Zero calibration should be done before monitoring start and at least once per day (zero calibration must be done each time after the cable is plugged or pulled).

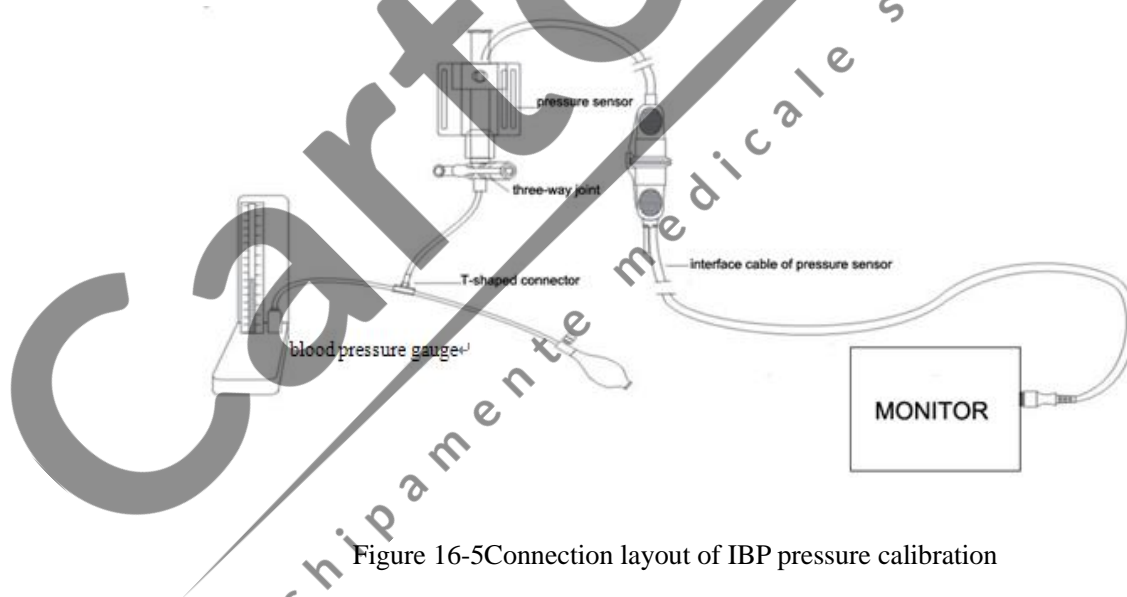


Figure 16-5 Connection layout of IBP pressure calibration

Calibration of the mercury manometer should be done when a new sensor is being started to use or at the specified cycle in the hospital practice.

The purpose of calibration is to ensure the system to provide accurate measured results.

Before calibration of the mercury manometer, pressure zero calibration should be done.

If the procedure is to be carried out by yourself, you should have the following devices.

- standard blood pressure gauge

- three-way stop cock
- pipeline with a length of about 25cm

Mercury manometer calibration procedures:

Warning

- **The following operation should never be done when a patient is being monitored.**
 - 1) **Close the three-way stop cock which is opened to the atmosphere for zero calibration.**
 - 2) **Connect the pipeline with the blood pressure gauge.**
 - 3) **Confirm that connection to the patient has been off.**
 - 4) **Connect a three-way stop cock with the three-way joint that hasn't been connected to the patient catheter (when the patient is being monitored). Connect a syringe to one end of the three-way stop cock and connect the blood pressure gauge and the pipeline with the other end.**
 - 5) **Open the end open to the blood pressure gauge.**
 - 6) **Select the channel to be calibrated in the pressure calibration menu and adjust the pressure values of the channel to be calibrated.**
 - 7) **Charge gas to raise the scale of the mercury column to the set pressure value in the menu.**
 - 8) **Repeatedly adjust until values in the menu equal to pressure values in the blood pressure gauge.**
 - 9) **Press once the calibration button in the calibration menu to command the instrument to begin calibration.**
 - 10) **Wait until the calibration ends. Make corresponding countermeasures to be taken according to prompt information.**
 - 11) **Detach the pipeline of the blood pressure gauge and the added three-way stop cock after completion of the calibration.**

16.6 Alarm information and prompt information

Alarm information

When alarm record switches in related menus are turned on, physiological alarms given when parameters exceeds alarm limits will trigger the recorder to automatically output alarmed parameters and related measured waveforms.

Possible physiological alarms, technical alarms and prompt messages in IBP module measurement are listed in the following tables:

Physiological alarms:

PROMPT MESSAGE	CAUSE	ALARM LEVEL
IS too high	Measured SP value is higher than the set upper alarm limit.	User Optional
IS too low	Measured SP value is lower than the set lower alarm limit.	User Optional
ID too high	Measured DP value is higher than the set upper alarm limit.	User Optional
ID too low	Measured DP value is lower than the set lower alarm limit.	User Optional
IM too high	Measured MP value is higher than the set upper alarm limit.	User Optional
IM too low	Measured MP value is lower than the set lower alarm limit.	User Optional

Technical alarms:

PROMPT MESSAGE	CAUSE	ALARM LEVEL	SOLUTION
IBP lead detached	IBP cable is detached from the monitor	Low	Make sure the cable is connected reliably.
IBP module initialization wrong	IBP measurement module has faults	High	Suspend the IBP measurement function and inform biomedical engineers or maintenance workers.

16.7 Maintenance and Cleaning

Warning

- Please turn off the monitor and disconnect the AC power supply before cleaning the monitor or sensor.

16.7.1 Washing of Repeatedly Usable Pressure Sensors

When the operations of pressure monitor is finished, please remove the airway and cap from the sensor and clean the film of the sensor with water. You can use the soapy solution or any of the following detergents to clean the sensor and cable.

Diluted ammonia water

Sodium hypochlorite (Bleaching powder used for cleansing)

Hydrogen Peroxide 3%

Alcohol 70%

Do not immerse the connector in any liquid. After cleaning, do not put it away until the sensor is completely dry. It is normal that the cable fades slightly or has a stronger adhesiveness on the surface. If it is necessary to remove the residue of adhesive tape from the sensor, please use the double-sided adhesive scavenger. Be careful to use the cable, in order to minimize the damage. Please do not use such strong solvents as acetone, alcohol, ammonia water or chloroform, as they could damage the vinyl cable as time goes on.

Attention

- **No one-off sensor or cap is allowed to be re-disinfected or reused.**
- **For the purpose of environmental protection, please recycle or dispose of the one-off sensor or cap in a proper way.**

16.7.1.1 Disinfection

1) Disinfection by Chemical Liquid

Follow the above steps to remove the visible dirt. Select an effective chemical disinfectant applicable to the equipments in the operation room, like buffered glutaraldehyde (glutaraldehyde or preservative). Do not use any quadrivalent cationic detergent, like benzalkonium chloride. To disinfect the whole instrument, please remove the cap, immerse the sensor (except the electrical connector) in the disinfectant for the recommended time, and then use the sterile water or physiological saline to rinse out all components (except the electrical connector) of the sensor. Do not put the sensor away until it is completely dry.

2) Disinfection by Gas

For a complete sterility, a gas disinfectant is necessary:

Follow the above steps to remove the visible dirt. In order to restrict the ethylene glycol, please make sure the sensor is completely dry when you use the ethylene oxide gas disinfectant.

Please follow the operating instructions provided by the manufacturer of the gas disinfectant.

Warning

- **The disinfectant temperature should not be higher than 70°C (150°F), or the plastics inside the pressure sensor could deform or melt.**

Chapter 17 Neonates Awakening Function

17.1 Neonates Awakening Function

It awakens neonates with bradypnea caused by deep sleep or other reasons. The enabling of the awakening function of the monitor depends on breathing frequency. The awakening device will wake up neonates with vibration mode when the breathing frequency of neonates is lower than 7 bpm and lasting time exceeds the limit set for asphyxia alarm; and it will stop working when breathing frequency is above 7 bpm.

17.2 Connect Awakening Device

Place the awakening device at the sole centre of one foot of the neonate, and wind the bands around the foot. DO NOT bond the band too loose as it may slip off which may disable its awakening function; nor bond it too tight to avoid obstructed blood circulation and cause change in foot color, as shown in the following figure:



Figura 17-1 Connect Awakening Device

Warning

- Do not disinfect the awakening device or submerge it into liquid.
- Do not pull the cables of awakening device.
- Do not use the awakening device in a circumstance out of working temperature limit.
- Do not apply the awakening device on an injured foot.

17.3 Asphyxia Awakening Settings

Select “SURVEY SETUP (parameter setup)” in the “MAIN MENU” or click “SURVEY SETUP” in the lower menu bar, then choose “ASPHYXIA STIMULATE SETUP” as the following picture:

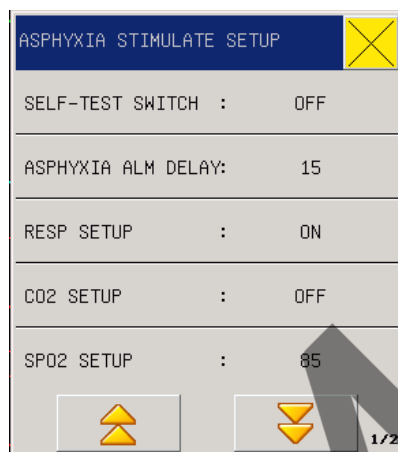


Figura 17-2 Asphyxia stimulate setup

- **SELF-TEST SWITCH:** self-test is a test for checking whether the asphyxia awakening probe functions normally. When it is “ON” and the probe keeps vibrating, it means the probe works normally. When it is “OFF”, the self test function is closed.
- **ASPHYXIA ALM DELAY (s):** if the neonate’s respiration or blood oxygen or heart rate has triggered asphyxia, the monitor will wait for some time to start the awakening function. Users can set the time from 0s to 20s with a default at 15s.
- **RESP SETUP/CO2 SETUP:** ON/OFF.
- **SPO2 SETUP:** 80-90, unit: %. The default is 85.
- **HR SETUP:** 90-110, unit: bpm. The default is 100.

The RESP SETUP and CO2 SETUP both conduct respiration monitoring. When one of them is “ON”, the awakening vibration would be triggered when there is no respiration; it would not be triggered when there is respiration. When both of them are “OFF”, the awakening vibration would be triggered once either of the SPO2 and HR meets the activation condition. The activation condition is the value set at SPO2 and HR.

- **DEFAULT:** choose to enter the “DEFAULT ASPHYXIA STIMULATION” dialog box. Select “No” to give up the current operation and the system would keep the current configuration. Select “Yes”, then the system would cover the current configuration with the default settings.

17.4 Application Precautions and Procedures

- (1) Insert the cable plug into WAKE socket on left side of the monitor.
- (2) Wind the band of awakening device at the sole centre of neonate's foot, referring to 18.2 Awakening Device Connection in this Chapter
- (3) Install ECG leads, referring to 11.3.2 Installing ECG Leads in C60 multi-parameter monitor manual.
- (4) Set asphyxias alarming time. Enter "MEASURING SETTINGS" and select "RESP SETTINGS". Set "ASPHYXIA ALARMING" as 10 to 40 seconds. It is advised not to set an excessively long time.
- (5) Awakening device begin vibrating to wake up the neonates when the breathing frequency is lower than 7 bpm, and lasting longer than the set asphyxia alarming time limit. The device stops after neonates' breathing frequency is over 7 bpm.

Warning

- **Following conditions must be met for normal working of awakening device under system settings: ALARMING SWITCH of RESP must be set as ON; ASPHYXIA ALARM cannot be set as NON-ALARM.**

17.5 Cleaning

Clean the awakening device under regular intervals with cloth dipped with ethanol or isopropanol with maximum concentration at 70%.

Warning

- **Never disinfect the oxygen sensor or submerge it into liquid.**

Chapter 18 Oxygen Concentration Monitoring

18.1 About Oxygen Concentration

Oxygen is diffused into battery through the osmotic membrane of the oxygen sensor. There is a sensing electrode (cathode) made of precious metals (gold or platinum etc.), and a working electrode (anode) made of basic metals (lead or zinc etc.). Both of the two electrodes are submerged into electrolyte. Oxygen sensor is current generator, which needs no external power supply. Voltage which is in direct ratio with oxygen concentration will be generated when a resistor is connected between the anode and the cathode.

Chemical reaction occurs during measuring process, thus the batteries need to be replaced regularly when the battery powers runs low (even before the equipment is used).

Oxygen concentration monitoring is mainly intended to prevent oxygen poisoning. Oxygen therapy is a common treatment since some organs of premature and low weighted infants are immature. But high oxygen concentration may cause side effects such as retinopathy of prematurity (ROP), lung hurt, denitrified absorption atelectasis or other syndromes.

Currently in developed countries, as central oxygen supplying and compressed air are adopted, proper oxygen therapy for neonates is realized through oxygen mixture of different concentrations using an air mixer. Most of the developing countries are still directly applying pure oxygen therapy. Oxygen concentration probe of the device will monitor the oxygen concentration and protect neonates from oxygen poisoning for intaking oxygen of over high concentration.

Infants with premature lungs will survive well when put into 100% oxygen masks, while they often suffer problems when they breathe 21% oxygen (concentration in the nature air) after leaving 100% pure oxygen environment. For example, increased blood supplying and increased brain blood flow may cause bleeding inside brain and on retinas, and lead to cerebral injury and blindness; and oxygen poisoning is tend to happen for neonates, especially premature infants, after breathing 100% pure oxygen in a long time.

18.2 Connecting Oxygen Sensors

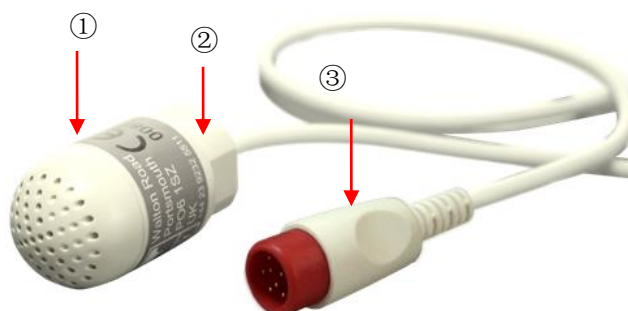


Figura 18-1 Connecting Oxygen Sensor

- (1) Screw tight the top cover of the oxygen sensor probe clockwise.
- (2) Insert the connector into the oxygen sensor, with a click sound indicating that it is inserted firmly.
- (3) Insert the cable plug of oxygen sensor into the O₂ socket on left side of the monitor.

18.3 21% Calibration

- (1) Start the monitor;
- (2) Enter “MAIN MENU “of the monitor, and select “MODULE SETUP” in “MONITOR SETUP”, select O₂ as ON.
- (3) Insert the cable plug of oxygen sensor into the O₂ socket on left side of the monitor, referring to 19.2 Connecting Oxygen Sensor of in this Chapter.
- (4) Place the oxygen sensor in the air.
- (5) Enter “O₂ SETUP” menu, and select “21% CALIBRATION”. Choose “YES” in the pop-up dialogue box.
- (6) “CALIBRATION SUCEED” appears in the prompt area of the instrument, if calibration succeeds after 3 minutes; and recalibration is needed when “CALIBRATION FAILED” prompt appears for a failed calibration.

⚠Attention

- **Make O2 calibration when oxygen concentration measuring error is oversized or when replacing oxygen sensor.**
- **O2 calibration must be made when there is no patient under monitoring.**
- **Observe for relative technical fault alarm if calibration fails, and recalibrate after eliminating the fault.**
- **Replace the oxygen sensor and recalibrate it after repeated failure calibration, or contact the equipment maintenance staff or our company if problems still exist.**
- **Do not burn the oxygen sensor during disposal. Please follow relative regulations on biological hazard.**

18.4 100% Calibration

- (1) Ensure “21% CALIBRATION” is made with success;
- (2) Place oxygen sensor into pure oxygen;
- (3) Select “100 % CALIBRATION” in O2 SETUP menu, and choose “YES” in the pop-up dialogue box;
- (4) “CALIBRATION SUCEED” appears in the prompt area of the instrument, if calibration succeeds after 3 minutes; and recalibration is needed when “CALIBRATION FAILED” prompt appears for a failed calibration.

⚠Attention

- **Observe for relative technical fault alarm if 100% O2 calibration fails, and recalibrate it after eliminating the fault.**
- **Replace the oxygen sensor and repeat 21% O2 calibration after repeated failure calibration, and then make 100% O2 calibration. Contact the equipment maintenance staff or our company if problems still exist.**

18.5 Alarm Settings

- (1) Enter “O2 SETUP” menu.
- (2) Set“ALM ON/OFF” to ON.
- (3) Select “O2 ALM SETUP”, and enter upper and lower limit short-cut keys of the High, Middle, and Low alarms, and set proper upper/lower limit.

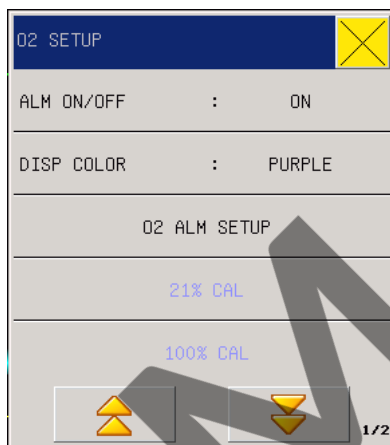


Figura 18-2Set O₂ Alarm

Upper/lower limits of the alarm:

	High	Medium	Low	Steplength
O2 Upper limit	(10~100)%	(8 ~ High upper limit-2) %	(6 ~ Medium upper limit-2) %	1%
O2 Lower limit	(0 ~ medium lower limit-2) %	(2 ~ Low lower down limit-2) %	(4~94) %	1%

18.6 Oxygen Concentration Measure Procedures

- (1) Make pre-monitoring preparation referring to Connecting Oxygen Sensor, 21% Calibration, and 100 % Calibration above in this Chapter.
- (2) Set properly alarm switch, upper/lower alarm limit etc.
- (3) Put the oxygen sensor into the oxygen environment to be tested.
- (4) Read O2 concentration value indicated in the parameter area.

⚠ Warning

- **Place the oxygen sensor securely and firmly to avoid injury or damage from dropping.**
- **Do not stretch the oxygen sensor cable.**
- **Do not operate the oxygen sensor out of designated working temperature environment.**

18.7 Cleaning

Clean the oxygen sensor regularly with cloth dipped with ethanol or isopropanol with maximum concentration at 70%.

Keep the crystal plug connected when the cleaning oxygen sensor to prevent the cleaning liquid or dust from entering the device via the port, and avoid liquid around the plug.

⚠ Warning

- **Do not disinfect or submerge the oxygen sensor.**

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Appendix I Accessories

According to the manufacturer's recommendation, the following accessories should be used for the monitor.



Warning

- Please use the accessory model designated by the manufacturer. Using accessories of other models might cause damage to the monitor.

Standard accessories:

No	Code	Name	Quantity
1	040-000073-00	Electrodes	1 bag
2	040-000492-00	Patient lead branch cable	1pcs
3	040-000413-00	Patient lead main cable	1pcs
4	040-000361-00	Reusable blood oxygen probe	1 pcs
5	040-000313-00	Blood oxygen extension cable	1 pcs
6	049-000256-00	Blood oxygen Y-shaped sleeve	2 pcs
7	040-000006-00	Handwritten pen	1pcs
8	040-000008-00	Ground cord	1pcs
9	040-000323-00	one-time sleeve 1#	1pcs.
10	040-000324-00	one-time sleeve 2#	1pcs.
11	040-000325-00	one-time sleeve 3#	1pcs.
12	040-000326-00	one-time sleeve 4#	1pcs.
13	040-000328-00	Blood pressure catheter	1pcs.
14	040-000074-00	power cord	1pcs.
15	040-000387-00	Surface temperature sensor	1pcs

Optional accessories:

No	Code	Name	Quantity
1	040-000386-00	Body cavity temperature probe	1pcs
2	040-000443-00	Asphyxia awakening stimulator	1pcs
3	040-000199-01	Baby awakening belt	10 pcs
4	040-000196-00	O2 battery	1pcs
5	040-000401-00	O2 concentration cable	1pcs

Accessories

6	043-000373-00	O2 concentration round cover	1pcs
7	040-000023-00	Cable fixed card slot	1pcs
8	040-000242-01	CO2 interface connection	1pcs
9	040-000024-00	Side current way adapter (with desiccant tube)	1pcs
10	040-000025-00	Side stream module clamp	1 pcs
11	040-000360-00	IBP cable	1pcs
12	040-000013-00	IBP pressure sensor	1 pcs

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Appendix II Specification

1. Monitor type

Name	Type
Anti-electric-shock type	Class I equipment with the external power supply, anti-defibrillation equipment with internal power supply, continuously operating equipment;
Anti-electric-shock degree	quipment belonging to application part of BF, CF Type(among which,ECG testingpart belongs to CF-based application, remaining all other testing parts belong to BFtype application parts);
EMC catogory	A type
Anti-leakage extent	Common seal apparatus, without anti-leakage character
Disinfection / sterilization methods	Refer to Chapter 10 -19for details
work mode	Continuous
Safety standards	IEC 60601-1 and GB9706.1, IEC 60601-2-27 and GB 9706.25, IEC 60601-1-2 and YY0505, IEC 60601-2-30 and YY 0667, IEC 60601-2-49 and YY0668, IEC 60601-1-8 and YY 0709, JJG 760, YY 0670, YY1079.

2. Monitor Specifications

(1) Size and weight

Name	Specifications
Sizeand weight	Size: 245.5mm×220mm×110mm
	Weight: 3kg

(2) Environment requirement

Name	Specifications	
Working environment	Environment temperature range	5℃~40℃
	Relative humidity range	<80%
	Atmospheric pressure range	700hPa~1060hPa
	Power frequency	50Hz/60Hz±1Hz
Transport:	Must avoid severe shock ,vibration, rain and snow during transport	
Storage	Packed monitors must be stored in well ventilated rooms with -10℃~+40℃ temperature, relative humidity no more than 80%, and without corrosive gases	

(3) Battery

Name	Specifications
AC input voltage	a.c.100V~240V
AC power frequency	50Hz/60Hz \pm 1Hz
Power supply	Built-in battery or external AC power supply
Input power	70VA
Battery Specifications	14.8V Lithium Battery. In fully-charged normal-using conditions, battery can continuously work for at least 4 hours.

(4) Displayer specification

Name	Specifications
display	8.4 inches high light color touch LCD displayer
Resolution	800×600
display information	maximum 6 waveforms display

(5) ECG Specification

Name	Specifications
ECG should be subject to YY1079.	
Range and accuracy of heart rate detection	Neonate: 30~250bpm \pm 10% or \pm 5bpm (both maximum)
Upper and lower limits and error of alarm	Neonate: Upper limit of alarm 100bpm~250bpm Lower limit of alarm 30bpm~100bpm Error of alarm should be setting value \pm 10% or \pm 5bpm (both maximum)
Heart rate alarm occurring time	\leq 10s
cardiac electrophysiology channel bandwidth	Monitoring mode: 0.5~40Hz; Diagnostic mode: 0.05~130Hz; Surgical mode: 1~20Hz.
Lead selection	Standard 3,5
Three Lead mode	RA, LA, LL, displaying I, II, III
Five Lead mode	RA, LA, LL, RL, V, displaying I, II, III, aVR, aVL, aVF, V
Electrode disconnection Indication	Automatic detection display
Scanning speed	12.5, 25, 50mm/s
Gain selection	\times 1/4, \times 1/2, \times 1, \times 2, auto

Cardiac Electrophysiology Noise level	$\leq 30\mu\text{VP-P}$.
Cardiac Electrophysiology Input loop current	$\leq 0.1\mu\text{A}$
Input impedance	signal attenuation, (0.67Hz~40Hz) less than 5%
Cardiac Electrophysiology common mode rejection ratio(CMRR) (10V RMS industrial frequency noise is allowed)	$\leq 1\text{mV}$
Time constant	Monitoring, surgical mode: $\geq 0.3\text{s}$; Diagnosis mode: $\geq 3.2\text{s}$.
Anti-interference	Anti power frequency interference; anti endotherm knife interference; protection for defibrillator discharge

Heart rate algorithm	
Tall T wave Inhibition	When testing according to YY 1079 Part 4.1.2.1c, heart rate device will inhibit all QRS wave groups whose amplitudes are below 1.0mV, 100ms, and T wave whose intervals are 180ms and Q-T intervals 350ms
Average heart rate	According to the requirement of YY 1079 Part 4.1.2.1 d, average heart rate is calculated with following methods: if the last successive RR intervals are over 1200ms, get the average of the 4 closest RR intervals to calculate heart rate; otherwise, get the 12 closest RR intervals, remove the max and min, then calculate the average of them
Heart rate calculation accuracy and response to arrhythmia	According to the requirement of YY 1079 Part 4.1.2.1 e, after 20 sec of a stabilizing period, the heart rate value is displayed as: figure 3 a) (coupled rhythm) $80\pm 1\text{bpm}$; figure 3 b) (slowly varying coupled rhythm) $60\pm 1\text{bpm}$; figure 3 c) (quickly varying coupled rhythm) $120\pm 1\text{bpm}$; figure 3 d) (Two-way contraction) $90\pm 2\text{bpm}$.
Time of response to heart rate variation	According to the requirement of YY 1079 Part 4.1.2.1 f, heart rate rise from 80 to 120bpm: in less than 10s; from 80 to 40bpm: in less than 10s.
Time of initiation of alarm of tachycardia	According to the requirement of YY 1079 Part 4.1.2.1 g, waveform: figure 4 a) 1-range: 10s; figure 4 a) 0.5-range: 10s; figure 4 a) 2-range: 10s; figure 4 b) 1- range: 10s;

	figure 4 b) 0.5- range: 10s; figure 4 b) 2- range: 10s.
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(6)SpO₂ specification

Name	Specifications
Displaying	Pulse waveform, SPO2
Detection range and accuracy	0~100%
Display Resolution	1%
Detection accuracy	Within range of 90%~100%, measurement error should be±1% (No state of motion); Within range of 70%~90%, measurement error should be±2% (No state of motion).
Upper and lower limit of alarm preset and accuracy	Upper limit of alarm: 1%~100% Lower limit of alarm: 0%~99% Error of alarm should be setting value±1%
PR range and accuracy	Range: 20 - 250bpm accuracy : ±1 bpm
Satuation range accuracy and resolution	(Masimo) Saturation Adult/Pediatrics: 70%~100%, ±2 digits (No state of motion); 0%~69%, unspecified Neonates: 70%~100%, ±3 digits (No state of motion); 0%~69%, unspecified Adult/Pediatrics: 70%~100%, ±3 digits (State of motion); 0%~69%, unspecified Neonates: 70%~100%, ±3 digits (State of motion); 0%~69%, accuracy unspecified
Pulse Rate range accuracy and resolution	(Masimo) Pulse rate Adults/Pediatrics/Neonates:25~240, ±3 digits (No state of motion) Adults/Pediatrics/Neonates: 25~240, ±5 digits (State of motion)
Resolution of Masimo SPO2	Satuation 1% Pulse rate 1

(7) NIBP specification

Name	Specifications		
NIBP should be subject to YY0670			
Measuring mode	Automatic oscillation		
Messuring parameter	systolic pressure, diastolic pressure, mean arterial pressure		
Working mode	Manual, auto		
Cycle time of auto measuring	1~480 mins		
Measurement range	Measurement range for neonate	Systolic blood pressure	5.3-20kPa (40-150mmHg)
		Diastolic blood pressure	1.3-13.3kPa (10-100mmHg)
		Mean blood pressure	2.7-14.7kPa (20-110mmHg)
	Accuracy	±5mmHg, when non-invasive BP exceeds the above range, the monitor can still display normally, but without accuracy	
Range and accuracy of static pressure	Scope:	should be 0mmHg~150mmHg。	
	accuracy	should be ±3mmHg	
Overpressure Protection	Neonate mode	150mmHg	
	tolerance	±3mmHg	
Alarm range	Newborn	systolic pressure	upper limit:5.6kPa~18kPa (42mmHg~135mmHg) , lower limit:5.3kPa~17.7kPa (40mmHg~133mmHg)
		diastolic pressure	upper limit:1.6kPa~12.6kPa (12 mmHg~95mmHg) , lower limit:1.3kPa~12.3kPa (10 mmHg~93mmHg)
		mean pressure	upper limit: 2.9kPa~14.6kPa(22mmHg~110mmHg), lower limit: 2.6kPa~14.3kPa(20 mmHg~108mmHg)
	Error	±0.1kPa or±1mmHg (Both maximum)	
NIBP measurement recall	2000 NIBP measurement data		

(8) TEMP specification

Name	Specifications	
Measurement range and accuracy	Detection range	0℃~50℃
	Measurement error	±0.1℃
Alarm setting and accuracy	Alarm setting range	Upper limit of alarm should be 0.1℃~50.0℃

Specification

		Lower limit of alarm should be 0°C ~49.9°C
	Alarm error	±0.1°C
Display Resolution	0.1°C	
Channel	Two-channel	

(9) Respiration specification

Name	Specifications		
Way	Thoracic impedance method (RA-LL impedance method)		
Range and accuracy of measurement	Range of detection	neonate	0bpm-120bpm
	Accuracy	±1bpm	
Accuracy and error of preset alarm of respiration rate	neonate	upper limit	1~120bpm
		lower limit	0~119bpm
	Error	±1bpm	
Range and error of suffocation alarm	range	Neonate10s~40s	
	error	±5s.	

(10) CO₂ specification

Name	Specifications
CO ₂ should be subject to YY0601	
Respiration gain	×0.25, ×0.5, ×1, ×2, ×4
CO ₂ 's range of measurement	0mmHg~150mmHg, And air pressure (0~19.7%, 0kPa~20kPa (at760mmHg)) is supplied by the mainframe.
CO ₂ 's accuracy	±2mmHg between 0mmHg ~40mmHg ; ±5% between 41mmHg ~70mmHg; ±8% between 71mmHg ~100mmHg; ±10% between 101mmHg~150mmHg
Atmospheric pressure/altitude	405~760mmHg/0~ 5029.2 M
Unit	mmHg、KPa、%
O ₂ compensation	0~100 mmHg
Range of alarm set and error of alarm set	0~ 150mmHg/0~20 KPa (at 760mmHg); ±1mmHg/±0.1 KPa。
Wave speed	6.5mm/s, 12.5 mm/s
Equilibrium gas	N ₂ O, indoor air ,Helium

(11) O2 sensor specifications

Name	Specifications
Measurement range	0~100%, error $\pm 3\%$
Output	9-13 mV O2 at 210hPa
Range	0~1500hPa O2
100% O2 signal bias	100 $\pm 1\%$
100% O2 measurement bias	0-100 $\pm 3\%$
Resolution	1hPa O2
Expectation of working life	20°C, 1.5 $\times 10^6$ % measurement hour 40°C, 0.8 $\times 10^6$ % measurement hour
Response time (21% air to 100% O2)	<15s
linearity	0-100% O2
Range of working temperature	-20°C~+50°C
Temperature compensation	0-40°C, $\pm 2\%$
Pressure range	50~200KPa
relative humidity	0 ~ 99%
100% O2 effect on Output	More than 1 year, the typical value <5%
Materials	White ABS
Package	Sealed package
Period of validity	Less than 13 months after the package is opened (according to the manufacturer, or the time may vary)

(12) IBP Specifications

Name	Specifications
Number of IBP channel	2 channels
Names of channel pressure	Artery pressure(ART), pulmonary artery pressure(PA), central vein pressure(CVP), right atrial pressure(RAP), left atrial pressure(LAP), intracranial pressure(ICP), plus pressure(P1,P2).
Range and accuracy of	ART 0~40kPa (0~300mmHg)

Specification

measurement	PA	-0.8~16kPa(-6~120 mmHg)
	CVP	-1.3~5.3kPa(-10~40mmHg)
	RAP	-1.3~5.3kPa(-10~40mmHg)
	LAP	-1.3~5.3kPa(-10~40mmHg)
	ICP	-1.3~5.3kPa (-10~40mmHg)
	P1, P2	-1.3~40kPa(-10~300mmHg)
error of IPB's alarm set	±0.1 or ±1mmHg of the set value	
pressure sensor	sensitivity: 5μV/V/mmHg	
	range of impedance: 300~3000Ω	

(13) Alarm system

Name	Specifications
Alarm system should be subject to YY0709	

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Appendix III Description of System Alarm Prompt

PROMPT MESSAGE	CAUSES	SOLUTIONS
"XX is too high "	XX is higher than the upper limit value of alarm limit.	Check whether the alarm limit values are suitable, and the current status of the patient.
"XX is too low"	XX is lower than the lower limit value of alarm limit.	
XX means all parameter values in such systems as HR, ST1, ST2, RR, SPO2, IBP, NIBP and CO2.		
"ECG signal is too weak "	The patient's ECG signal is too small, so the system can't do ECG signal analysis.	Check whether the electrode and lead cable are connected correctly, and the current status of the patient.
"Pulse is not found "	The patient's pulse signal is too small, so the system can't do pulse signal analysis.	Check the connection of the sensor, and the current status of the patient.
"RESP apnea"	The patient's RESP signal is too small, so the system can't do RESP signal analysis.	Check the connection of the lead cable, and the current status of the patient.
"ASYSTOLE "	The patient suffers from arrhythmia of a systole.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"VFIB/VTAC "	The patient suffers from arrhythmia of VFIB/VTAC.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"COUPLET (two PVS)"	The patient suffers from arrhythmia of two PVS.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"BIGEMINY (PVS bigeminy)"	The patient suffers from arrhythmia of PVS bigeminy.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"TRIGEMINY (PVS trigeminy)"	The patient suffers from arrhythmia of PVS trigeminy.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"R ON T"	The patient suffers from arrhythmia of R ON T.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"PVC (single PVS)"	The patient suffers from arrhythmia of single PVS bigeminy.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"TACHY (tachycardia)"	The patient suffers from tachycardia.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"BRADY (bradycardia)"	The patient suffers from bradycardia.	Check the current status of the patient,

Description of System Alarm Prompt

		and whether the electrode and lead cable are connected correctly.
"VT>2 (multiple PVS)"	The patient suffers from arrhythmia of multiple PVS.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"MISSED BEATS"	The patient suffers from arrhythmia of missed beat.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"PNP (Pacemaker not paced)"	The pacemaker doesn't pace.	Check the connection of the pacemaker, the current status of the patient, and whether the electrode and lead cable are connected correctly.
"PNC (Packer not captured)"	No pacemaker signal is captured.	Check the current status of the patient, and whether the electrode and lead cable are connected correctly.
"ECG lead disconnected"	ECG lead cable is not joined well.	Check the connection of ECG lead cable.
"ECG V lead disconnected"	ECG V-lead cable is not joined well.	Check the connection of ECG V-lead cable.
"ECG LL lead disconnected"	ECG LL-lead cable is not joined well.	Check the connection of ECG LL-lead cable.
"ECG LA lead disconnected"	ECG LA-lead cable is not joined well.	Check the connection of ECG LA-lead cable.
"ECG RA lead disconnected"	ECG RA-lead cable is not joined well.	Check the connection of ECG RA-lead cable.
"ECG C lead disconnected"	ECG C-lead cable is not joined well.	Check the connection of ECG C-lead cable.
"ECG F lead disconnected"	ECG F-lead cable is not joined well.	Check the connection of ECG F-lead cable.
"ECG L lead disconnected"	ECG L-lead cable is not joined well.	Check the connection of ECG L-lead cable.
"ECG R lead disconnected"	ECG R-lead cable is not joined well.	Check the connection of ECG R-lead cable.
"SPO2 sensors fall off "	SPO2 sensor is not joined well.	Check the connection of SPO2 sensor.
"Searching pulse"	SPO2 sensor is not joined well, or the patient moves his arms.	Check the connection of SPO2 sensor and the current status of the patient.
"TEMP sensors fall off "	TEMP sensor is not joined well.	Check the connection of TEMP sensor.
"IBP lead disconnected"	IBP sensor is not joined well.	Check the connection of IBP sensor.
"IBP needs zeroing"	IBP needs zeroing before measurement.	Zero pressure for IBP.
"ECG interference too strong "	Stronger interference signal appear in ECG signal.	Check the connection of ECG R-lead cable, the current status of the patient and whether more actions happen.
"XX module initialization wrong X"	Error X appears when XX module is initialized.	Restart the monitor for trial. If errors still exist, please contact the manufacturer for

Description of System Alarm Prompt

"XX module communication stop"	XX module can't communicate with the main system normally.	maintenance.
"XX module communication wrong "	XX module can't communicate with the main system normally.	
XX means all parameter modules in the system such as ECG module, NIBP module, SPO2 module, IBP module and etc.		
"XX alarm limit wrong "	The alarm limit of XX parameter is changed accidentally.	Contact the manufacturer for maintenance.
"XX measurement out of scope "	The measured value of XX parameter goes out of the range of measurement by the system.	Contact the manufacturer for maintenance.
XX means the names of all parameters in the system, such as HR, ST1, ST2, RR, SPO2, IBP, NIBP and etc.		
"The real-time clock needs resetting."	If the system time is 2000-1-1, the system will remind users that this time is wrong.	Reset the system time. After resetting, please restart the monitor for fear of unnecessary time error being saved.
"The real-time clock doesn't exist "	No button batteries exist in the system or the batteries have no charge.	Increase or change the button battery.
"System failure: software"		
" System failure: cmos full"		
" System failure: cmos err"		
" System failure: fpga"		
" System failure 2"		
" System failure 3"		
" System failure 4"		
" System failure 5"		
" System failure 6"		
" System failure 7"		
" System failure 8"		
" System failure 9"		
" System failure 10"		
" System failure 11"		
" System failure 12"		
"Keyboard unusable ";	The keys on the keyboard are unusable.	Please check whether the keys are held on to artificially or other articles. If no abnormal pressing is found, please contact the manufacturer for maintenance.
"Communication with keyboard wrong ";	The keyboard fails, so it is unusable.	Please contact the manufacturer for maintenance.
"Key wrong ";		
" Keyboard wrong 1";		
" Keyboard wrong 2";		
"Network initialization wrong (G.)"	Something wrong happens to the network of the system so the system	Please contact the manufacturer for maintenance.

Description of System Alarm Prompt

" Network initialization wrong (Ram)"	can't start network function.	
" Network initialization wrong (Reg)"		
" Network initialization wrong (Mii)"		
" Network initialization wrong (Loop)"		
" Network wrong (Run1)"		
" Network wrong (Run2)"		
" Network wrong (Run3)"		
"5V voltage too high"	Something wrong happens to the power supply of the system.	Please contact the manufacturer for maintenance if such a prompt appears frequently.
"5V voltage too low"		
"Power system wrong 3"		
" Power system wrong 4"		
"12V voltage too high "		
"12V voltage too low "		
" Power system wrong 7"		
" Power system wrong 8"		
"3.3V12V voltage too high "		
"3.3V voltage too low "		
" Button battery voltage too high"	Something wrong happens to the button battery.	Please replace the battery. If the fault still exists, please contact the manufacturer for maintenance.
"Button battery voltage too low. Please change it."	The button battery is short of charge or it is not fixed or the connection of button battery is loose.	
"Recorder self-check wrong "	The system fails in connection with the recorder module in self-check.	In the recorder-setting menu, start the record-deletion function that can make the upper machine and the lower machine reconnected. If the fault still exists, please contact the manufacturer for maintenance.
"Recorder voltage too high"	The recorder module voltage fails.	Please contact the manufacturer for maintenance.
" Recorder voltage too low"		
"Recorder head too hot "	Maybe the continuous recording time is too long.	After the recorder is fully cooled, do the record output. If the fault still exists, please contact the manufacturer for maintenance.
"The position of the recorder head wrong "	The paper-pressing handle of the recorder doesn't work.	Depress the paper-pressing handle of the recorder.
"Recorder short of paper "	There is no record paper in the recorder.	Install the record paper.
"Recorder having paper jam "	The recorder has a paper jam.	Place the recorder correct first and then start recording.

Description of System Alarm Prompt

"Recorder communication wrong "		In the record setting menu, start the record-deletion function that can make the upper machine and the lower machine reconnected. If the fault still exists, please contact the manufacturer for maintenance.
"The serial port of recorder wrong in communication"	The recorder communication is not normal.	
"The paper position of recorder wrong "	The paper is not placed correctly in the recorder.	Re-place the corder paper rolls at the correct location.
"Recorder unusable "	The recorder can't be communicated.	In the record setting menu, start the record-deletion function that can make the upper machine and the lower machine reconnected. If the fault still exists, please contact the manufacturer for maintenance.
"NIBP initialization wrong "		
"NIBP self-check wrong "	NIBP initialization is wrong.	Select the resetting function in NIBP menu. If the error persists, please contact the manufacturer for maintenance.
"NIBP resetting wrong "	Abnormal resetting happens when NIBP is measured.	Please do measurement again after checking the air path of NIBP and whether there is air jam. If the error persists, please contact the manufacturer for maintenance.
"NIBP communication wrong "	Something wrong happens to the NIBP communication.	Select the resetting function in NIBP menu. If the error persists, please contact the manufacturer for maintenance.
"Cuff too loose or not joined "	NIBP cuff is not joined well.	Please reconnect the NIBP cuff.
"Cuff gas tube leaked "	NIBP cuff is not joined well, or the air path is leaked. .	Please check the connection of all parts or replace a cuff. If the error persists, please contact the manufacturer for maintenance.
"Air pressure wrong"	Something wrong happens to the measuring curve so that the system can do measurement, analysis and calculation.	Please check the connection of all parts or replace a cuff. If the error persists, please contact the manufacturer for maintenance.
"Signal too weak "	Something wrong happens to the measuring curve so that the system can do measurement, analysis and calculation.	After inspecting whether patient type is set correctly, please check the connection of all parts or replace a cuff. If the error persists, please contact the manufacturer for maintenance.
"Pressure out of scope "	Something wrong happens to the measuring curve so that the system can do measurement, analysis and calculation.	Please check the connection of all parts or replace a cuff. If the error persists, please contact the manufacturer for maintenance.
"Arms movement "	The patient's arm moves.	Please do measurement again after

Description of System Alarm Prompt

		checking the connection of all parts and the patient's condition. If the error persists, please contact the manufacturer for maintenance.
"Overpressure protection "	Maybe the air path has once been folded.	Please do measurement again after checking whether the air path is smooth and the patient's condition. If the error persists, please contact the manufacturer for maintenance.
"Signal saturated "	Something wrong happens to the measuring curve so that the system can do measurement, analysis and calculation.	Please do measurement again after checking the connection of all parts and the patient's condition. If the error persists, please contact the manufacturer for maintenance.
"Measurement time-out "	Something wrong happens to the measuring curve so that the system can do measurement, analysis and calculation.	Please do measurement again after checking the connection of all parts and the patient's condition. If the error persists, please contact the manufacturer for maintenance.
"Cuff type wrong "	Maybe the cuff doesn't accord with the set patient type.	After inspecting whether patient type is set correctly, Please check the connection of all parts or replace a cuff. If the error persists, please contact the manufacturer for maintenance.
"Pump with air leakage "	NIBP air path is leaked.	Please check the connection of all parts or replace a cuff. If the error persists, please contact the manufacturer for maintenance.
"NIBP measurement failure "	Something wrong happens to the measuring curve so that the system can do measurement, analysis and calculation.	Please do measurement again after checking the connection of all parts and the patient's condition. If the error persists, please contact the manufacturer for maintenance.
"NIBP system failure "	Something wrong happens to the measuring curve so that the system can do measurement, analysis and calculation.	Please do measurement again after checking the connection of all parts and the patient's condition. If the error persists, please contact the manufacturer for maintenance.

C.O. Description of System Alarm Prompt

Prompt message	Cause	Level	Countermeasure
Physiological alarm:			
O2 concentration too high	Higher than the alarm upper limit	Optional by users	Check whether the alarm limits are suitable for the patient's current condition

Description of System Alarm Prompt

Prompt message	Cause	Level	Countermeasure
O2 concentration too low	lower than the alarm upper limit	Optional by users	
Technical alarm:			
O2 module disconnected	O2 sensor cables disconnected to the monitor	low	Re-insert the O2 module and make sure the cables are surely connected
21% O2 concentration calibration	calibrating	low	Wait for the calibration to end
100% O2 concentration calibration	calibrating	low	Wait for the calibration to end
Prompt message:			
21% O2 concentration calibration succeed	Successful calibration	low	None
100% O2 concentration calibration succeed	Successful calibration	low	None

Appendix IV Guidance and Manufacturer's Declaration

Guidance and manufacturer's declaration

Guidance and manufacturer's declaration – electromagnetic emissions The C60 is intended for use in the electromagnetic environment specified below. The customer or the user of the C60 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The C60 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity The C60 is intended for use in the electromagnetic environment specified below. The customer or the user of the C60 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	±4kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for Power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5% UT for 0.5 cycle 40% UT for 5 cycles 70% UT for 25 cycles <5% UT for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the C60 requires continued operation during power mains interruptions, it is recommended that the C60 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.

Guidance And Manufacturer's Declaration – Electromagnetic Immunity – for equipment and systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity The C60 is intended for use in the electromagnetic environment specified below. The customer or the user of the C60 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the C60, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between Portable and mobile RF communications equipment and the C60			
The C60 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the C60 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the C60 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 p$	80 MHz to 800 MHz $d = 1.2 p$	800 MHz to 2.5 GHz $d = 2.3 p$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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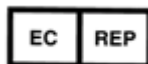
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