Portable Patient Monitor

(8 inch)

Model:JR2000B

User Manual

CE 0482

Contents

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

′ NOTE ′

- **This equipment is not intended for family usage.**
- **Important! Before use, carefully read this manual, all safety information and specifications.**
- **The warranty for main unit is 12 months, and 6 months for accessory, except man-made damage.**
- **Transport: According to agreement, additionally, it should avoid rain and snow splash and mechanical collision.**
- **Storage: The device should be stored in a dry and well-ventilated room, away from strong sunlight and other corrosive gases.**
- **Date of production and S/N NO. : See the back label of the device.**
- **The life for main unit is 5 years.**
- **The built-in lithium battery has a life of 500 charges and discharges.**

⚠ Warning ⚠

This monitor is not a device for treatment purpose.

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

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

Warranty

Workmanship & Materials topplor

Our company guarantees new equipment other than accessories to be free from defects in workmanship and materials for a period of one year (six months for multi-site probes and SpO2 sensor) from date of shipment under normal use and service. 's obligation under this warranty is limited to repairing, at ’s option, any part which upon 's examination proves defective.

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

Exemptions

1、It's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the substitution upon it of parts or accessories not approved by Our company or repaired by anyone other than a authorized representative.

2、This warranty shall not extend to any instrument which has been subjected to misuse, negligence or accident; any instrument from which 's original serial number tag or product identification markings have been altered or removed, or any product of any other manufacturer.

Safety, Reliability and Performance

Our company is not responsible for the effects on safety, reliability and performance of the JR2000B Portable Patient Monitor if:

- JR2000B assembly operations, extensions, re-adjusts, modifications or repairs are carried out by persons other than those authorized by .
- the Portable Patient Monitor is not used in accordance with the instructions for use, or the electrical installation of the relevant room does not comply with NFPA 70: National Electric Code or NFPA 99: Standard for Health Care Facilities (Outside the United States, the relevant room must comply with all electrical installation regulations mandated by the local and regional bodies of government).

Return Policy

Return Procedure

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

Obtain return authorization. Contact the Our company Service Department and obtain a Customer Service Authorization number. The number must appear on the outside of the shipping container. Return shipments will not be accepted if the number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return.

Freight policy. The customer is responsible for freight charges when equipment is shipped to our company for service (this includes customs charges).

Preface

1、This manual gives detailed description to Portable Patient Monitor concerning its performance, operation, and other safety information. Reading through this manual is the first step for the user to get familiar with the equipment and make the best out of it.

2、Following symbols indicates some important facts that you have to pay special attention to:

⚠ **Warning** ⚠ Points to be noted to avoid injury to the patient and the operator.

⚠ **Caution** ⚠ Points to be noted to avoid damage to the equipment.

Chapter 1 Introduction

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

⚠ **Warning** ⚠

1、Portable Patient Monitor is intended for clinical monitoring application with operation only granted to appropriate MEDICAL INSTRUMENT staff.

2、There could be hazard of electrical shock by opening the monitor casing. All servicing and future upgrading to this equipment must be carried out by personnel trained and authorized by .

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

4、The user must check that equipment and accessories function safely and see that it is in proper working condition before being used.

5、Alarm must be set up according to different situation of individual patient. Make sure that audio sounds can be activated when alarm occurs.

6、Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such devices may result in strong interference with the monitor performance.

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

8、The equipment and devices connected to it should form an equipotential body to ensure effective grounding.

9、When the monitor is used with Electrosurgery equipment, the operator (surgeon and nurse) must give top priority to the patient safety.

1.1 General Information

Environment:

Temperature	Working	0 ~ 40 (°C)	Transport and Storage	-20 ~ 60	(°C)
Humidity	Working	<= 85 %	Transport and Storage	<= 93 %	
Altitude	Working	-500 to 4,600m(-1,600 to 15,000ft)			
	Transport and Storage	-500 to 13,100m(-1,600 to 43,000ft)			

Power Supply 100~250 (V)AC, 50/60 (Hz) Pmax=40VA FUSE T 1.6A

General instruction:

Patient Monitor (Figure 1-1) is adaptable to adult, pediatric and neonatal usage. It can monitor vital signals as ECG, Respiratory Rate, SpO2, NIBP, TEMP, and $ETCO_2$(optional). It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Replaceable built-in battery facilitates transportation of patient. Large high-resolution display provides clear view of 5 waveforms and full monitoring parameters.

The POWER switch is on the left quarter of the front panel (in Figure 1- 1). The POWER indicator(in Figure 1- 1) and the BATT indicator (in Figure 1- 1) lights when the device is

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

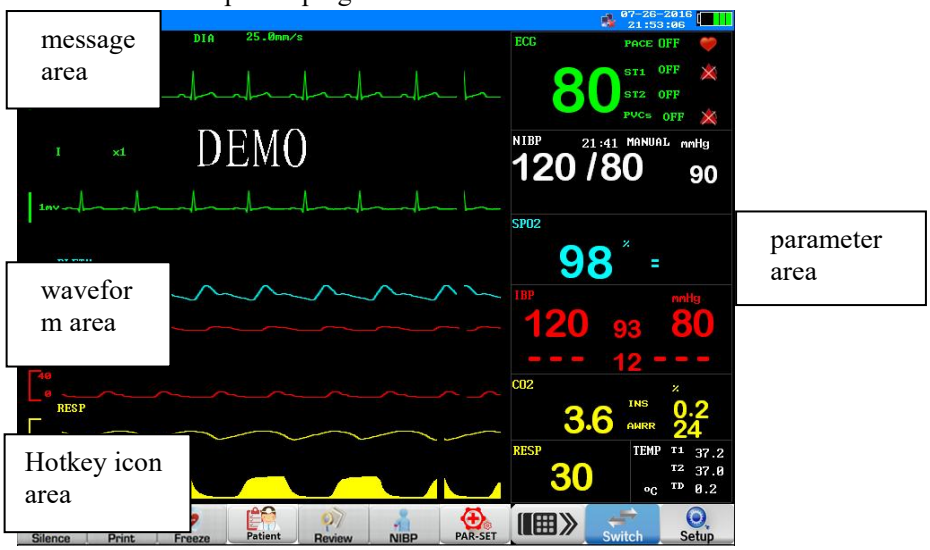


Figure 1- 1 Portable Patient Monitor

Hotkey icon explain:

icon explain(from left to right)：silence，print；feeze；patient information；Trend review；nibp； parameter set;hotkey sw;screen change;menu

Portable Patient Monitor performs monitoring of:

ECG Heart Rate (HR), 3 or 5-channel ECG waveforms, S-T segment analysis, Arrhythmia

RESP Respiratory Rate (RR) Respiration Waveform

SpO2 Oxygen Saturation (SpO2), Pulse Rate (PR) SpO2 Plethysmogram

NIBP Systolic Pressure (NS), Diastolic Pressure (ND), Mean Pressure (NM)

TEMP Temperature DATA

CO2 CO2 waveforms CO2 DATA

JR2000B provides extensive functions as visual & audible alarm, storage and report printout for trend data, NIBP measurements, and alarm events, and drug dose calculation function is provided either.

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

1.2 Screen Display

The display of JR2000B may be color or monochrome liquid crystal display. The patient parameters, waveforms, alarm messages, bed number, date, system status and error messages can be reflected from the screen.

1、Message Area

The Message Area is at top of the screen displaying operating state of the monitor and status of the patient.

The messages and their meanings are:

2、BED NO Bed number of the monitored patient

3、ADU Type of patient

4、"2006-5-13" Current date

5、"13:51:32" Current time

The above messages appear on the screen throughout the monitoring process.

Other information of the Message Area comes up only with respective monitoring status. They are:

- Signs indicating the operating status of the monitor and the sensors are displayed at the right side of time numeric. When appears, this message will cover the sex and name information of the patient.
- "  " Indicates that all sounds are disabled manually. It appears z SILENCE button is pressed for more than 1 seconds.
- "  " flag for alarm SILENCE. Press "SILENCE" button once (more than 1 second) to manually mute the alarm sound and this flag appears at the same time. The SILENCE status terminates when you discharge the status or new alarm occurs.
- "  " Is the mark indicating that the alarm volume is closed. When select the "OFF" item in the ALARM SETUP menu, this mark appears indicating that the operator has permanently closed the audio alarm function. This audio alarm function can resume only after the operator discharges the closing alarm volume setup.

′NOTE′

When "  " mark appears, the system can not give the audio alarm prompt. Therefore, the operator should be considerate in using this function. One method of discharging this status is in the ALARM SETUP menu, select the item that the alarm volume is in Non-close. Another method is to press the SILENCE button so as to make the mark change into a"  ". Then press SILENCE button again, the system will immediately restores the normal alarm status.

- Alarm message is displayed at the right most area.
- "FREEZE" appears when the waveforms are frozen.

Waveform/Menu Area

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

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

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

Parameter Area

Parameters are displayed at a fixed position.

1、ECG: Heart Rate (Unit: bpm) ST-segment analysis of Channel 1 & 2 (Unit: mv)
2、NIBP: (From left to right) Systolic, Mean, Diastolic (Unit: mmHg or kPa)
3、SpO2: SpO2 (Unit: %)
4、RESP: Respiration Rate (Unit: breath/min)
5、TEMP: Temperature (Unit:℃ or ℉)
6、The above monitoring results are displayed in the Parameter Area.
The parameters refresh every second, except that NIBP values refresh each time the measurement is over.
User can select the monitor parameters, and the screen display will change accordingly.
Alarm indicator:
In normal mode, no indicator lights.
In alarm mode, the alarm indicator lights or flashes.

1.3 Button Function

All the operations to the monitor are through the buttons and a knob at the bottom of the screen. The names of the buttons are above them. They are (from left to right, Figure 1-3):

Figure 1-3 Buttons and Knob

- NIBP (Figure 1-3)

Press to inflate the cuff to start a blood pressure measurement. When measuring, press to cancel the measurement and deflate the cuff.

- SILENCE(ALARM)(Figure 1-3)

symbol appears in the Message Area. Push this button for more than 1 second to mute all kinds of sounds (including alarm sound, heart beat, pulse tone, key sound). At the same time, a “ ” symbol appears in the Message Area. Push this button again to restore all kinds of sounds and the “ ” symbol appears from the screen.

⚠ **Note** ⚠

1、If new alarm occurs in Alarm Pause/Silence status, the system will discharge Pause/Silence status automatically. For specific rules, see Chapter Alarm.
2、The system will begin to give alarm information again once there exist alarm-triggering event. Nevertheless, remember pushing SILENCE button can permanently shut off audible alarm sound of ECG LEAD OFF and SPO2 SENSOR OFF alarms.

- FREEZE(Figure 1-3)

Press this button and the system will access the FREEZE status. In this status the user may review the waveform of 40 seconds. Also, the frozen waveform can be printed out. In the FREEZE status, press this button again to discharge the FREEZE status. For detailed information, refer to related chapter: Freeze.

- MENU(Figure 1-3)

Press this button to call up the SYSTEM MENU, in which the user may set up system information and perform review operation. For detailed information, refer to related chapter: System Menu and related chapter: Trend and Event.

- POWER(Figure 1-3)

POWER ON/OFF switch

- Rotary knob(Figure 1-3)

The user may use the rotary knob to select the menu item and modify the setup. It can be rotated clockwise or counter-clockwise and pressed like other buttons. The user may use the knob to realize the operations on the screen and in the system menu and parameter menu.

Method to use the knob to operate on the screen:

The rectangular mark on the screen that moves with the rotation of the knob is called “cursor”. Operation can be performed at any position at which the cursor can stay.

When the cursor is in the waveform area, the user may immediately modify the current setup. When the cursor is in the parameter area, the user may open the setup menu of the corresponding parameter module so as to set up the menu items of the module.

Operating method:

- Move the cursor to the item where the operation is wanted
- Press the knob
- One of the following four situations may appear:

1. The cursor with background color may become into the frame without background color, which implies that the content in the frame can change with the rotation of the knob.
2. Menu or measuring window may appear on the screen, or the original menu is replaced by the new menu.
3. A check mark “ √ ” appears at the position, indicating that the item is confirmed.
4. The system immediately executes a certain function.

Rotary Knob

1、e square frame that moves with the knob turning is referred to as "cursor".

2、en the cursor is placed at any of the first six items, the user can change the current settings.

3、When at any of the last six items, related parameter menu can be called up for setting changes. Operation is as follows:

When you move the cursor to a certain item, and press the knob, then:

1. A menu pops up, or the current menu is replaced by a new one; or,
2. The cursor frame turns to dotted line, indicating contents in the frame can be changed by turning the knob; or,
3. A “ √ ” mark appears indicating "selected"; or,
4. A certain function executes.

1.4 Interfaces

For the convenience of operation, the different kinds of interfaces are in different parts of the monitor.

At the left side are the connectors to patient cables and the sensors, as shown in Figure 1-4.

Figure 1- 4 left Side

This symbol means “BE CAREFUL". Refer to the manual.

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

Other symbols in the monitor are explained in **chapter Patient Safety.**

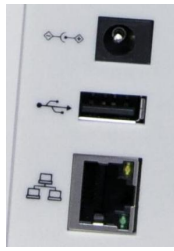


Figure 1-5

On the rear panel are the following sockets, shown in Figure 1-5

Power Supply: 90~250 (VAC), 50/60 (Hz)

Equipotential Grounding： Equipotential grounding terminal for connection with the hospital’s grounding system.

FUSE: T1.6A/250V


5MM GND connect


internet connect

Warning

1、Through network interface only Clinical Information Center can be connected in.

2、 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for MEDICAL INSTRUMENT equipment). Furthermore all configurations shall comply with the valid version of the system

standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a MEDICAL INSTRUMENT system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

1.5 Built-in Battery

Patient Monitor is equipped with a rechargeable battery. The battery in the Monitor can automatically recharge when connected to AC INPUT until it is full. A symbol "▬" is displayed on the bottom of the screen to indicate the status of recharging, in which the yellow part represents the relative electric energy of the battery.

⚠ **Warning** ⚠

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

When operating on battery, the monitor will prompt alarm and shut off automatically when the energy is low. When the electric energy is going out, the monitor will sound continuous level 1 alarm beeping and display "BATTERY TOO LOW" in the Message Area. Connect the monitor to AC power at this moment can recharge the battery while operating. If keep operating on the battery, the monitor will shut off automatically (about 5 minutes since alarming) upon exhaustion of the battery.

Chapter 2 Getting Started

- Open the package and check
- Connect the power cables
- Power on the monitor
- Connect patient sensors
- Check the recorder

′NOTE′

To ensure that the monitor works properly, please read Chapter Patient Safety, and follow the steps before using the monitor.

2.1 Open the Package and Check

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

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

If there is any problem, contact the distributor immediately.

2.2 Connect the Power Cables

Connection procedure of the AC power line:

- Make sure the AC power supply complies with following specification: 100~250 VAC, 50/60 Hz.
- Apply the power line provided with the monitor. Plug the power line to INPUT interface of the monitor. Connect the other end of the power line to a grounded 3-phase power output.

′NOTE′

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

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

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

2.3 Power on the Monitor

Press POWER to power on the monitor. Then a beep will be heard and at the same time the indicator will flash twice in yellow and red. After 10 seconds or so, the system will enter monitoring screen after self-test, and you can perform normal monitoring now.

During self-test, the software version will display.

′ NOTE ′

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

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

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

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

⚠ **Warning** ⚠

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

2.4 Connect Patient Sensors

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

Chapter 3 System Menu

PATIENT MANAGE , MONITOR SETUP, ALARM MENU, MAINTAIN, RECALL, DRUG CALG, DEMO or EXIT DEMO, HELP

Patient Monitor features flexible configurations. You can configure various aspects of the monitor, including the parameters to be monitored, sweeping speed of the waveforms, audio signal volume, and printout text.

Press the “MENU” hot key on the lower right part of the screen to call up “SYSTEM MENU”. The configuration is realized through operations on the SYSTEM MENU, as shown below.

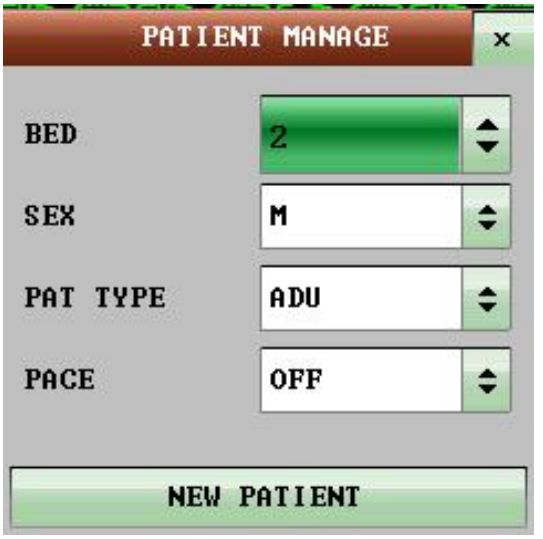


Figure 3- 1 SYSTEM MENU Figure 3- 2 PATIENT SETUP

3.1 Patient Information Setup

′ NOTE ′

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

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

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

DEPARTMENT	Department in which the patient receives treatment.
D NO	Patient bed number (Range: 1-200)
PACE	Pace ON or OFF
SEX	Patient gender (Available options: "F" for Female, "M" for Male)
PAT TYPE	Patient type (Available options: ADU, PED, and NEO)
NEW PATIENT	Admission of new patient

Also in this menu, the user may select “NEW PATIENT” item to access “CONFIRM TO UPDATE PATIENT” dialog box as shown below, in which the user decide whether to

monitor a new patient. Figure 3-3

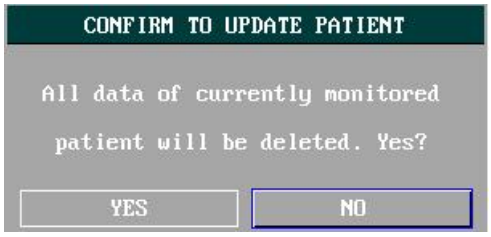


Figure 3-3 NEW PATIENT Menu Figure 3-4 CONFIRM SAVE DEFAULT CONFIG

Pick YES to erase stored record of the previous patient and exit the menu.

Pick NO to refuse the new patient and keep the previous information and exit the menu.

′ Note ′

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

3.2 Default Setup

′ Note ′

Select any item in this sub-menu to cancel the current setup and use the selected default setup.

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

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

CONFIRM SAVE DEFAULT CONFIG

Pick YES to erase stored record of the previous patient and exit the menu.

Pick NO to refuse the new patient and keep the previous information and exit the menu.

′ NOTE ′

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

3.3 Trend Function

Pick RECALL in the SYSTEM MENU, as shown in the figure below. Figure 3-5 RECALL

Figure 3- 5 RECALL

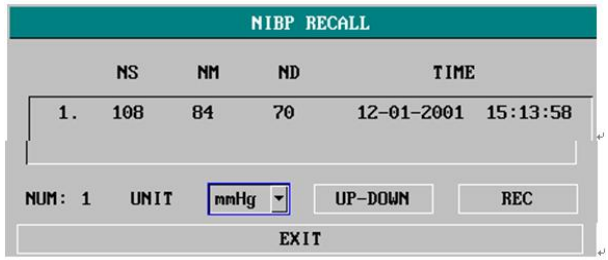


Figure 3- 6 NIBP RECALL

3.3.1 NIBP Recall

The monitor can review the latest 1000 NIBP measurement data.

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

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

3.3.2 Alarms recall

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

3.3.3 Trend graph review

■ Can display the latest 1-hour trend graph in increment of one data every second or every 5 seconds；

■ Can display the latest 96-hour trend graph in increment of one data every minute or every 5 minutes or 10 minutes.

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

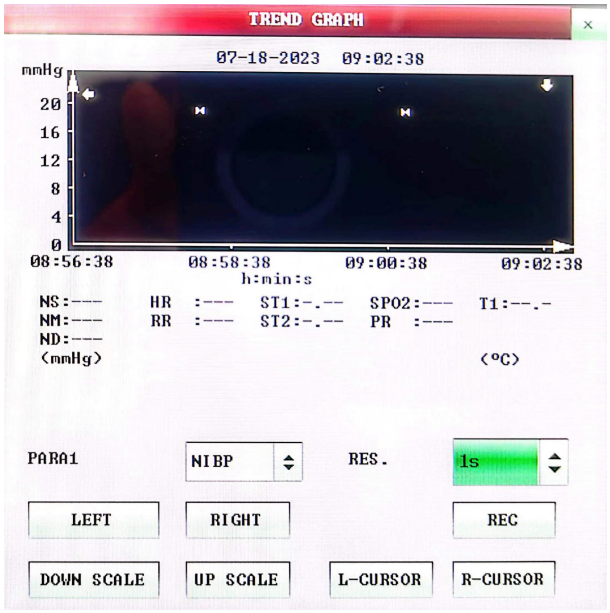


Figure 3-7 trend graph

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

Select different parameters for trend graph display:

Select option for "parameter selection", press the knob when it appears the exact parameter you want, you will see the relevant trend graph then.

Select 1-hour or 96-hour trend:

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

To review trend graph even more earlier or latter:

If there's an"🡺", press the "right"button, turn the knob clockwise, to review the latter graph, and if there's "🡸", press the "left"button, turn the knob anti-clockwise, to review earlier graph.

To revise display scale:

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

How to get exact data for a specific moment on current trend graph:

Select the cursor, and turn the knob left or right, the cursor will move accordingly, time changes too, the data will be shown below the horizontal axis. If there's "🡺"on right side of the screen, when cursor move to this position,the trend graph will automatically come to next page; while if there's "🡸" on the left side of screen, when cursor move to this position,the trend graph will automatically come to a former page, so you can see the earlier trend graph then.

Operation examples:

To review NIBP trend graph for past 1-hour:

- press "menu" button, then press "system menu";
- select "recall" option, then select "trend graph";
- select parameter: select "parameter selection" option, turn the knob, until there is "NIBP":

■ select “resolution” option, can select “1 second” or “5 seconds”;

■ select “left & right”, turn the knob, check the change on time and trend curve;

■ stop when it comes to the time period you want to recheck, can revise the display scale to see more clearly. (by press the “adjust amplitude” button)

■ if want to know exact data for a specific moment on current trend graph, select the cursor,move the cursor to the exact position to check, time will be shown above, and measure data will be shown at bottom.

■ press “quit” to exit trend graph.

3.3.4 trend table review

■ recent 336-hour trend table can be shown with resolution 1 minute, 5 minutes, 10 minutes, 30 minutes, 60 minutes.

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

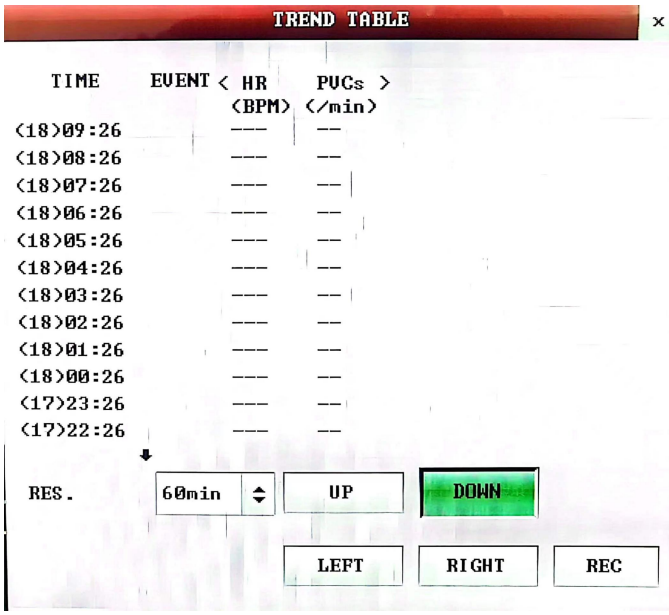


Figure 3-8 trend table

The time relevant to each group of trend data is displayed in the left side of column, with the date in parentheses.The event column will show the events have been marked, which corresponds to the time marked the event. The parameters in the trend table can be divided into 10 groups as below: HR、SPO2、PR、SYS、MAP、DIA、RR、T1、T2、TD

The display of NIBP trend data has its particularity.Beside the measured value, time for NIBP measurement is also displayed under "Measuring Point". If there are multiple measured values during this time period, only one value can be displayed on screen,others will be displayed at "MORE" with a "*" means there are two or more measurement results.

How to review trend table with different resolution:

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

To review trend table even more earlier or latter:：

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

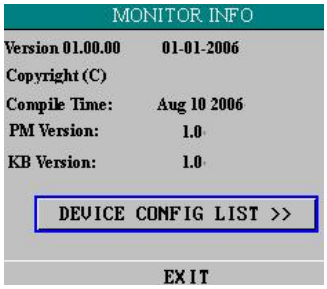
Select different parameters for trend table：

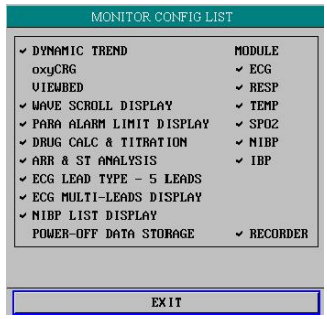
Select “left & right”, can review one of the parameters among the 14 of them.there’s “>” on the right side of the parameter, which means can come to the right page; there’s “<” on the left side of the parameter, which means can come to the left page.

Monitor Information

3.4 Monitor Information

Select the [VERSION] item in the “SYSTEM MENU” to know the software version of the monitor.





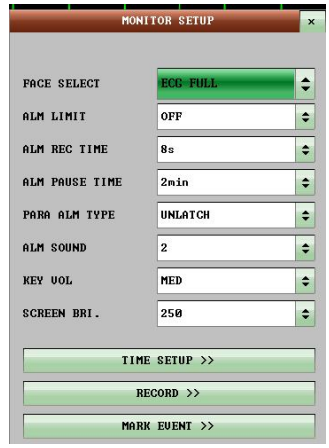


Figure 3- 9 Version Figure 3- 10 Monitor Info Figure 3- 11 Monitor Setup

Select the [DEVICE CONFIG LIST] to know the configuration of the monitor. Figure 3- 10 Monitor Info

3.5 Monitor Set

Select the [MONITOR SETUP] item in the “SYSTEM MENU” to know Below Figure 3- 11 Monitor Setup

3.5.1 Alarm Limit

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

ALM LEV: selectable from HIGH, MED, LOW. Level HIGH represents the most serious case.

ALM REC: pick "ON" to enable report printing upon ECG alarm.

ALM HI: used to set up the upper limit of ECG alarm.

ALM LO: used to set up the lower limit of ECG alarm.

Select “SELECTION” item in “SYSTEM MENU” to access “SELECTION” sub-menu, in which the user may set up the alarm limit. Set “ALM LIMIT” to ON to display the alarm limits of the parameters displayed on the screen or OFF to hide the alarm limits.

3.5.2 Length of Alarm Records

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

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

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

3.5.3 Time Setup

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

Figure 3- 12 TIME SETUP Figure 3- 13 MARK EVENT Menu Figure 3- 14 RECORD Menu

3.5.4 Mark Event

There are four types of events that you can define.

Select “MARK EVENT” item in “MONITOR SETUP” to call up the following menu: Figure 3- 13 MARK EVENT Menu

To mark the event: Use the rotary knob to select one from event A, B, C and D. There is a “@” signal for the one selected. To cancel your selection, repress the knob at selected item. Press EXIT to return to the previous menu.

You can use event function:

To differentiate the patient events that have impact on parameter monitoring, such as dose taking, injection, therapy status, etc.

3.5.5 Recorder Setup

Select "RECORD" in “MONITOR SETUP” menu to call up the following menu: Figure 3- 14 RECORD Menu

In the sub-menu, the user may select the waveforms to be output in “REC WAVE1” and “REC WAVE2” items.

ECG1-ECG 7	The first to the seventh ECG waveform on the screen (there are seven ECG waveforms in full leads display) (If no ECG waveform is currently displayed on the screen, this item cannot be picked)
SPO2	SpO2 Plethysmogram.
RESP	RESP waveform (If no RESP waveform is currently displayed on the screen, this item cannot be picked,).
OFF	No display for this waveform

- RT REC TIME represents “real-time recording time”, for which two selections are available: CONTINUAL and 8S. “CONTINUAL” means once pressing the ‘REC/STOP’ button on the recorder or on the panel, the recorder will continuously print out the waveform or parameter until this button on the recorder is pressed again.
- TIMING REC TIME represents “time interval between two times of timing recording”. 10 selections are available: “OFF, 10MIN, 20MIN, 30MIN, 40MIN,

50MIN, 1HOUR, 2HOURS, 3HOURS and 4HOURS". It means that the system will trigger the recording operation according to the selected time interval. The recording time is fixed at 8 seconds.

' NOTE '

1、RT REC TIME has the priority compared with TIMING REC TIME.

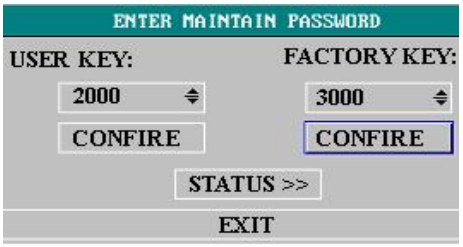
- REC RATE has two selections: 25.0 and 50.0 mm/s.
- REC GRID is used to decide output format: OFF is without grid, and ON is with grid.
- CLEAR REC TASK can be used by the user to stop recorder from printing out too many tasks that are triggered by alarm events.

2、The recorder is an optional part.

3、If two same waveforms are selected, one of them is switched to a different waveform automatically.

3.6 Maintenance

Select "MAINTAIN" item in "SYSTEM MENU" access "ENTER MAINTAIN PASSWORD" dialog box as shown below, in which the user may enter password and set up the user-defined maintenance settings. The user may not execute the factory maintenance function, which is only available for appointed personnel of the Company. The user may select "STATUS" to access "STATUS" sub-menu, in which the user may view the information of the monitor start up and errors detected.



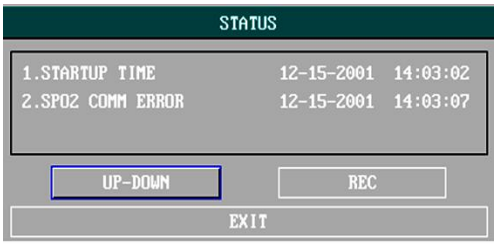


Figure 3- 15 ENTER MAINTAIN PASSWORD Figure 3- 16 STATUS

In "STATUS" sub-menu, the user may use rotary knob to select "UP-DOWN" item and then turn the knob clockwise or counter-clockwise to view the monitor information such as start up time, alarm and the like. The user may select the "REC" item by using knob to print out the currently displayed information via the recorder. Figure 3- 16 STATUS

For user default, enter the user key and press the "CONFIRM" key to access "USER MAINTAIN" menu. Following is the detailed description on the settings able to be realized in this menu.

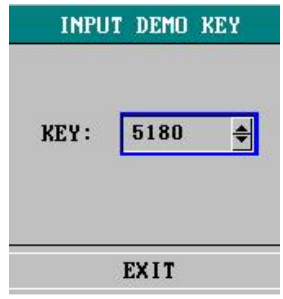


Figure 3- 17 User Maintain Figure 3- 18 COLOR SELF-DEFINE Figure 3-19 Input Demo Key

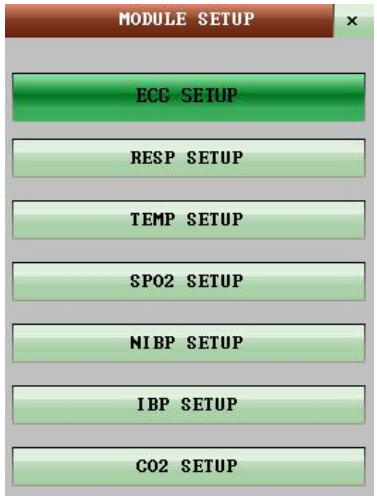
- LANUGAGE: two selections are available:CHINESE and ENGLISH.
- LEAD: refers to the net No.
- COLOR SELF-DEFINE: is used by the user to define the color of the waveform displayed on the screen. Five colors can be chosen from green, cyan, red, yellow and white. Figure 3- 15 COLOR SELF-DEFINE

3.7 DEMO function

Select the [DEMO] item in the “SYSTEM MENU” to call up the “ENTER DEMO PASSWORD”. After entering the password, the system enters DEMO status. Figure 3-19 Input Demo Key

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

3.8 Parameters setup



Set ECG、RESP、TEMP、SPO2、NIBP、CO2parameters.

Chapter 4 Patient Safety

The Portable Patient Monitor is designed to comply with the International National Safety requirements for MEDICAL INSTRUMENT electrical equipment. This device has floating inputs and is protected against the effects of defibrillation and electrosurgery. If the correct electrodes are used and applied in accordance with the manufacturer instructions, the screen display will recover within 10 seconds after defibrillation.

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

⚠ **Warning** ⚠

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

Environment

Follow the instructions below to ensure a completely safe electrical installation. The environment where the JR2000B Portable Patient Monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

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

Grounding the Portable Patient Monitor

To protect the patient and hospital personnel, the cabinet of the JR2000B Portable Patient Monitor must be grounded. Accordingly, the JR2000B Portable Patient Monitor is equipped with a detachable 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electrician. If completeness of the protective grounding wire is in doubt, the equipment must be operated with internal power supply.

⚠ **Warning** ⚠

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

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

Equipotential Grounding

Protection class 1 instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug. For internal examinations on the heart or the brain, the JR2000B Portable Patient Monitor must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the instrument rear panel and the other end to one point of the equipotential grounding system. The equipotential grounding system assumes the safety function of the protective grounding conductor if ever there is a break in the protective grounding system. Examinations in or on the heart (or brain) should only be carried out in MEDICAL INSTRUMENTly used rooms incorporating an equipotential grounding system. Check each time before use that the instrument is in perfect working order. The cable connecting the patient to the instrument must be free of electrolyte.

⚠ **Warning** ⚠

1、If the protective grounding (protective earth) system is doubtful, the monitor must be supplied by inner power only.

Condensation

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

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

Explanation of Symbols in the Monitor

 1、s symbol means 'BE CAREFUL '. Refer to the manual.

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

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

 3、Equipotential grounding system

 4、 Protective earth ground

 5、Partial On/Off

Chapter 5 Care / Cleaning

5.1 System Check

Before using the monitor, do the following:

- check if there is any mechanical damage;
- check all the outer cables, inserted modules and accessories;
- check all the functions of the monitor to make sure that the monitor is in good condition.

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

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

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

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

The circuits diagrams, parts lists and calibration instructions of the monitor can be provided by the manufacturer.

⚠ **Warning** ⚠

1. **If the hospital or agency that is responding to using the monitor does not follow a satisfactory maintenance schedule, the monitor may become invalid, and the human health may be endangered.**
2. **Refer the battery replacement only to our service technician.**

⚠ **Note** ⚠

To ensure maximum battery life, it is recommended that, at least once a month, the monitor be run on battery until it turns itself off and then recharged.

5.2 General Cleaning

⚠ **Warning** ⚠

Before cleaning the monitor or the sensor, make sure that the equipment is switched off and disconnected from the power line.

The Monitor must be kept dust-free.

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

⚠ **Note** ⚠

Please pay special attention to the following items:

1. **Avoid using ammonia-based or acetone-based cleaners such as acetone.**
2. **Most cleaning agents must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.**
3. **Don't use the grinding material, such as steel wool etc.**
4. **Don't let the cleaning agent enter into the chassis of the system.**
5. **Don't leave the cleaning agents at any part of the equipment.**
6. **If there is any sign that the ECG cable may be damaged or deteriorated, replace it with a new one instead of continuing its application on the patient.**

Reusable TEMP Probes

1. The TEMP probe should not be heated above 100℃(212℉). It should only be subjected briefly to temperatures between 80℃ (176℉) and 100℃ (212℉).
2. Only detergents containing no alcohol can be used for disaffection.
3. The rectal probes should be used, if possible, in conjunction with a protective rubber cover.
4. To clean the probe, hold the tip with one hand and with the other hand rubbing the probe down in the direction of the connector using a moist lint-free cloth.

Disposable TEMP probe must not be re-sterilized or reused.

For protecting environment, the disposable TEMP probe must be recycled or disposed of properly.

5.3 Cleaning Agents

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

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

⚠ **Note** ⚠

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

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

⚠ **Note** ⚠

1、the monitor and sensor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.

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

5.4 Sterilization

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

Recommended sterilization material: Ethylate, and Acetaldehyde.

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

⚠ **Caution** ⚠

- **Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.**
- **Do not let liquid enter the monitor.**
- **No part of this monitor can be subjected to immersion in liquid.**
- **Do not pour liquid onto the monitor during sterilization.**
- **Use a moistened cloth to wipe up any agent remained on the monitor.**

5.5 Disinfection

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

Appropriate disinfection materials for ECG lead, SpO2 sensor, blood pressure cuff, TEMP probe, and CO_2 cable are introduced in Chapters 12-18 respectively.

⚠ **Caution** ⚠

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

Chapter 6 Alarm

- This chapter gives general information about the alarm and corresponding remedies.
- Alarm setup and prompt messages are provided in respective parameter setup sections.

6.1 Alarm Modes

6.1.1 Alarm Level

Each alarm, either technical or physiological, has its own level. For alarm of higher level, when it occurs, the system will give prompt in a more alert way. Some alarm's level can be set by the user via software. Others can not by changed once defined by the system. Alarms in JR2000B are divided into three levels, that is, high, medium and low.

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

Medium-level alarm means serious warning.

Low-level alarm is a general warning.

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

JR2000B has preset the alarm level for the parameters. You can also modify the alarm level using the method described in this chapter.

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

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

6.1.2 Alarm Modes

When alarm occurs, JR2000B may raise the user's attention in at least three ways, which are audio prompt, visual prompt and description. Audio and visual prompt is given by TFT/touch screen display device, the speaker on the display device and the alarm indicator. Description is displayed on the screen. Physiological alarm is displayed in the Physiological Alarm area. Most of technical alarms are displayed in the Technical Alarm area. Technical alarms related to NIBP measurement are displayed in the NIBP Technical Alarm area at the bottom of NIBP parameter area.

′ NOTE ′

1、 The Physiological Alarm area is on the upper right part of the screen. The

Technical Alarm area is to the left side of the Physiological Alarm area.

2、If JR2000B is connected to the external alarm prompt system (e.g. the alarm speaker and indicator connected onto the rear panel of JR2000B), when alarm occurs, the external alarm prompt system responds in the same way as the JR2000B .

3、The concrete presentation of each alarm prompt is related to the alarm level.

Alarm prompt of the parameter exceeding the alarm limit.

When physiological alarm of the monitored parameter exceeds the alarm limit, besides using the above-mentioned three ways to give the alarm prompt, the monitor also gives alarm by making the monitored parameter flash in the frequency of 1Hz. If at this time the upper and lower limits of the parameter are displayed, they will flash in the same frequency (1Hz).

Screen Display

When an alarm occurs, the parameter triggering the alarm flashes. "*" signal appears on the screen indicating the occurrence of alarm. Red "***" indicates high-level alarm, yellow "**" indicates medium-level alarm, and yellow "*" indicates low-level alarm. Technical alarm will not prompts "*" signal.

Lamp light

The high/medium/low-level alarms are indicated by the system in following different visual ways:

Alarm level	Visual prompt
High	Alarm indicator flashes in red with high frequency.
Medium	Alarm indicator flashes in yellow with low frequency.
Low	Alarm indicator lights on in yellow.

Alarm Sound

The high/medium/low-level alarms are indicated by the system in following different audio ways:

Alarm level	Audio prompt
High	Mode is "DO-DO-DO------DO-DO, DO-DO-DO------DO-DO", which is triggered once every 8 seconds.
Medium	Mode is "DO-DO-DO", which is triggered once every 24 seconds.
Low	Mode is "DO-", which is triggered once every 24 seconds.

′NOTE′ When alarms of different levels occur at the same time, the monitor prompts the one of the highest level.

6.1.3 Alarm Setup

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

Press the "ALARM SETUP" button on the MONITOR SETUP menu to call up "ALARM SETUP" menu (default menu) as shown below. In the "ALM SEL" item, the user may set up the information about common alarm setup (represented by "COMMON ALM SETUP") and the alarm setup of each parameter.

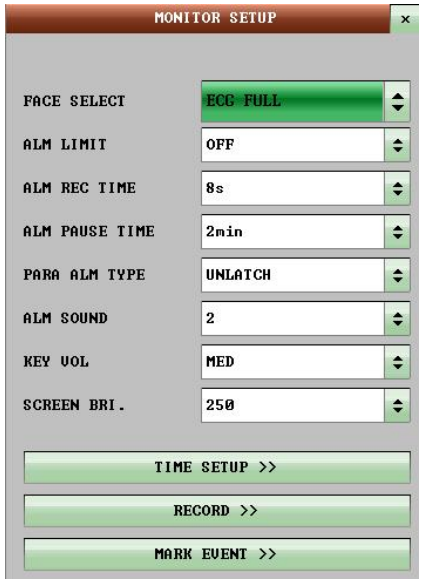


Figure 6- 1 ALARM SETUP

■ **COMMON ALM SETUP**

Select “COMMON ALM SETUP” selection in “ALM SEL” item. This operation may call up the dialog box as the default one.

- ALARM VOL: which has three selections: OFF, LOW, MED and HIGH.
- ALM REC TIME: which has three selections: 8S, 16S, 32S.
- ALM PAUSE TIME: refers to the alarm suspension time span, which has three selections: 1MIN, 2MIN, 3MIN.
- PARA ALM TYPE: which has two selections: LATCH, UNLATCH. LATCH refers to the situation once alarm occurs, the system will alarm always until the intervention of the operator (press PAUSE or SILENCE on the panel). UNLATCH refers to the situation that once the alarm condition is discharged, the alarm will disappear automatically.

■ **Alarm setup of each parameter**

In “ALARM SETUP” menu select “ALM SEL” item to set up the alarm information of following parameters. They are HR, ST, PVC, SPO2, NIBP, RESP, TEMP. For example:

Method to set up alarm information of HR:

Step 1: Select “HR ALM SETUP” in “ALM SEL” item to call up the dialog box “ALARM SETUP” for HR only.

Step 2: Five items are available for the user to set up, which are HR ALM (on/off of the alarm switch), ALM LEV(alarm level), ALM REC(alarm recording switch), ALM HI (higher limit of HR alarm), ALM LO (lower limit of HR alarm). When use the knob to select each item and press the knob, a pull-down list appears for the user to choose his desired selection.

The method for setting the alarm information of other parameters is the same as HR.

6.2 Alarm Cause

Alarm occurs when:

1.Physiological alarm is evoked;

2. Alarm for error of the system (technical alarm) is evoked;

3. General alert occurs.

A. Conditions that activate the parameter alarms:

When the measurement value exceeds the alarm limit and the alarm is set “ON”. Alarm will not activate if the alarm is set “OFF”.

B. Conditions that activate the system alarms (technical alarm):

Upon the system error, the monitor prompts alarm immediately and proceeds corresponding remedy, stops all monitoring and eliminates the final results in order to avoid faulted treatment. If more than one error occur, they will be displayed by turns.

C. General alert

In some circumstances, alerts will behave as physiological alarm but in normal sense, we don’t regard them as real patient health related items.

6.3 SILENCE and PAUSE

- SILENCE

Press the SILENCE button on the panel for more than 1 seconds can shut off all sounds until the SILENCE button is pressed again. When the system is in SILENCE status, any newly generated alarm will discharge the SILENCE status and make the system give normal status giving audio and visual alarm.

- PAUSE

Press the SILENCE button on the panel once to close all audio and visual prompt and description about all the physiological alarms and to make the system enter ALARM PAUSE status. The rest seconds for alarm pause is displayed in the Physiological Alarm area. And the symbol  is displayed in the System Prompt area.

The user may set up the time for Alarm Pause in the ALARM SETUP menu. Three selections are available: 1min, 2min and 3min.

When in the PAUSE status, press the SILENCE button to restore the normal alarm status. Besides, during PAUSE status, newly occurring technical alarm will discharge the PAUSE status and the system will access the normal alarm status. The  symbol disappears, too.

′ NOTE ′

Whether an alarm will be reset depends on the status of the alarm cause. But by pressing SILENCE button can permanently shut off audio sound of Lead Off/Sensor Off alarms.

6.4 Parameter Alarm

The setup for parameter alarms is in their menus. In the menu for a specific parameter, you

can check and set the alarm limit, alarm status. The setup is isolated from each other.

When a parameter alarm is off, a symbol  displays near the parameter. If the alarms are turned off individually, they must be turned on individually.

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

1. Alarm message displays on the screen as described in alarm mode;
2. The monitor beeps in its corresponding alarm class and volume;
3. Alarm lamp flashes;
4. Store all parameter values during the alarm and 4,8 or 16 second waveform prior to and after alarm.
5. If alarm recording is on, the recorder starts alarm recording. For further information on alarm recording, please refer to Chapter Recording.

6.5 When an Alarm Occurs

′ NOTE ′

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

The alarm message appears at the top of the screen on the right side. It is needed to identify the alarm and act appropriately, according to the cause of the alarm.

1. Check the patient's condition.
2. Identify the cause of the alarm.
3. Silence the alarm, if necessary.
4. When cause of alarm has been over, check that the alarm is working properly.

You will find the alarm messages for the individual parameter in their appropriate parameter chapters of this manual.

6.6 ST Segment Alarm

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

6.7 Arrhythmia Alarm

The monitor records 2-channel ECG waveforms 4 seconds prior to and after the alarm (totally 8 seconds). All measurement results during the alarm will also be recorded.

Chapter 7 ECG/RESP Monitoring

7.1 What Is ECG Monitoring

Monitoring the ECG produces a continuous waveform of the patient's cardiac electric activity to enable an accurate assessment of his current physiological state. Only proper connection of the ECG cables can ensure satisfactory measurement. On the Normal Display, JR2000B provides display of 2-channel ECG waveforms.

- The patient cable consists of 2 parts(See Chapter **Accessories and Ordering Information for detail** information of the ECG accessories);
  The cable that connects to the monitor;
  The lead set that connects to the patient.
- Using a 5-lead set, the ECG can derive up to two waveforms from two different leads. For requested lead, you may choose from the left side of ECG waveform.
- The monitor displays the Heart Rate (HR), ST segment and Arrhythmia analysis.
- All of the parameters above can be set as alarm parameters.

′ NOTE ′

In the default settings of , the ECG waveforms are the first two waveforms from top in the Waveform Area.

7.2 Precautions during ECG Monitoring

⚠ Warning ⚠

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

2、Use only the original JR2000B ECG cable for monitoring.

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

′ NOTE ′

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

7.3 Monitoring Procedure

7.3.1 Preparation

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

- The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.
- Shave hair from sites, if necessary.
- Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).

- Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

2. Attach clip or snap to electrodes prior to placement.
3. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.
4. Connect the electrode lead to the patient's cable.
5. Make sure the monitor is ready with power supply.

⚠ Warning ⚠

1. **Check everyday whether there is skin irritation resulted from the ECG electrodes. If so, replace electrodes every 24 hours or change their sites.**
2. **Verify lead fault detection prior to the start of monitoring phase. Unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm is activated.**

′ Note ′

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

7.3.2 Installing ECG lead

Placing the Electrodes for ECG Monitoring

Electrode placement for 5-lead set (Figure 8- 2)

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

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

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

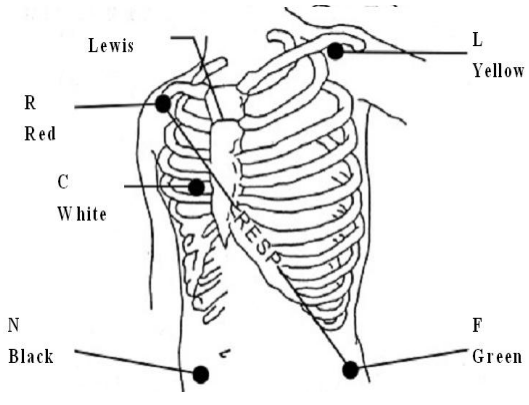


Figure 7-1 Electrode placement for 5-lead set

′ NOTE ′

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

For 5-lead set, attach the C-electrode to one of the indicated positions as below

⚠ **Warning** ⚠

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

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

⚠ **Warning** ⚠

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

■ Using 5-lead ECG set

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

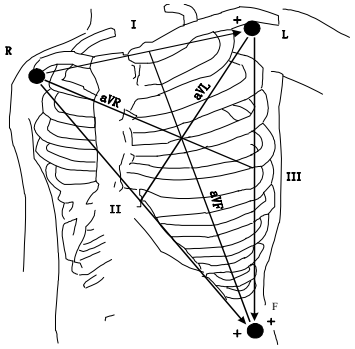


Figure 7- 2 ECG lead

′ NOTE ′

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

′ NOTE ′

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

Normal QRS complex should be:

- Tall and narrow with no notches.
- With tall R-wave completely above or below the baseline.
- With pacer spike no higher than R-wave height.

- With T-wave less than one-third of the R-wave height.
- With P-wave much smaller than the T-wave.

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

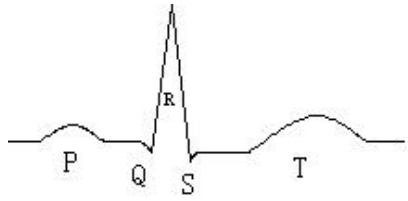


Figure 7-3 Standard ECG Waveform

⚠ **Warning** ⚠

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

7.4 ECG Menu

ECG SETUP Menu

Pick the ECG hot key on the screen, and the following menu will popup.

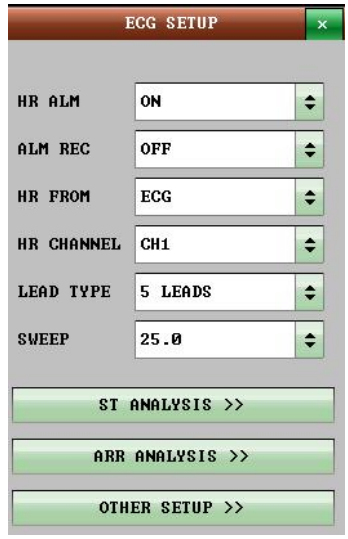


Figure7-4 ECG SETUP menu

- ECG alarm setting

- HR ALM: pick "ON" to enable prompt message and data record during the ECG alarm; pick "OFF" to disable the alarm function, and there will be a beside “ECG”.
- ALM LEV: selectable from HIGH, MED, LOW. Level HIGH represents the most serious case.
- ALM REC: pick "ON" to enable report printing upon ECG alarm.

ECG alarm is activated when the heart beat exceeds set ALM HI value or falls below ALM LO value.

′ NOTE ′

Please set the alarm limits according to clinical condition of individual patient. The

upper limit shall not exceed 20 beat/min higher than the patient's heart rate.

■ HR FROM

ECG, SpO2, AUTO and BOTH may detect heart rate. AUTO distinguishes heart rate source according to the quality of signal. By picking ECG, the monitor prompts HR and activates HR beep. By picking SpO2, the monitor prompts PULSE and activates pulse beep. BOTH mode displays HR and PR simultaneously, when this item is picked, PR parameter is displayed to the right side of SpO2. As for the sound of HR or PR in BOTH mode, HR is given the priority, i.e., if HR is available, whose sound will be sent out, but if HR is not available, then the sound will be for PR.

■ HR CHANNEL

"CH1" to count the heart rate by CH 1 waveform

"CH2" to count the heart rate by CH 2 waveform

"AUTO" the monitor selects a channel automatically

■ LEAD TYPE Used to select either 5 LEADS or 3 LEADS.

■ SWEEP Available options for SWEEP are 12.5, 25.0, and 50.0 mm/s.

■ ST ANALYSIS

Pick this item to access ST ANALYSIS menu, the detailed information about the menu is to be discussed in the following section.

■ ARR ANALYSIS

Pick this item to access ARR ANALYSIS menu, the detailed information about the menu is to be discussed in the following section.

■ OTHER SETUP Pick this item to access ECG SETUP menu as shown below:

Figure 7-5 ECG SETUP menu

In the sub-menu, following functions are available:

● BEAT VOL

Four selections are available: OFF, LOW, MED, HIGH. HIGH indicates maximum volume. OFF indicates no sound.

● PACE

"ON" detected signal will be marked by a " ' " above the ECG waveform.

"OFF" for non-pacemaking patient

' NOTE '

If monitoring a patient with the pacemaker, set "PACE" to ON. If monitoring a

patient without pacemaker, set "PACE" to OFF.

If "PACE" is on, the system will not perform some types of ARR analysis. For detailed information, please refer to the section: ARR ALARM. In the table, the ARR type marked by All types applies to the analysis in all situations, marked by Non-paced applies only to the analysis in the situation when the patient does not use pacemaker.

- ECG CAL

Pick this item to start calibrating ECG. The method to end CAL: re-select the ECG CAL key in the menu or re-select the lead name on the screen.

- DEFAULT

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

⚠ **Warning** ⚠

For pacemaker patient, the pacing impulse analysis function must be switched on, otherwise, the pacing impulse may be counted as normal QRS complex, which results in failure of "ECG LOST" error detection.

Note: For monitor with ST segment & Arrhythmia analysis software, refer to ST Segment Monitoring and Arrhythmia Analysis for details.

′ NOTE ′

When Pacer Switch is On, the Arrhythmia events related to PVCs will not be monitored. At the same time, the ST analysis will not be performed either.

7.5 ECG Alarm Information and Prompt

Alarm Message

Alarms occurring in the process of ECG measurement contain two types: physiological alarm and technical alarm. Prompt message may also appear in the mean time. For the audio and visual features during the appearance of these alarms and prompt messages in the process of ECG measurement, please refer to the related description in Chapter Alarm. In the screen, physiological alarm messages and the prompt messages able to trigger alarms (general alerts) all displayed in the alarm area of the monitor while technical alarms and prompt messages unable to trigger alarms are then displayed in the information area of the monitor. This section does not describe the content about Arr. and ST analysis.

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

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

Physiological alarms:

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

Technical alarms:

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

Prompt messages (include general alerts):

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

7.6 ST Segment Monitoring

- ST segment monitoring function is shutoff by default. You can switch it to ON when necessary.

′ NOTE ′

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

- It is available to measure the variance of ST segment with ST analysis at the waveform tracks for selected lead. The corresponding ST measurement result displays numerically at ST1 and ST2 in the Parameter Area. The trend can be viewed with table or graphic form.
- Measurement unit of ST segment: mv.
- Measurement symbol of ST segment: "+" = elevating, "-" = depressing.
- Measurement range of ST segment: -2.0 mv, ~ + 2.0 mv.

Pick the ST ANALYSIS item in the ECG SETUP menu to access the ST ANALYSIS sub-menu as shown below.

7.6.1 ST ANALYSIS menu

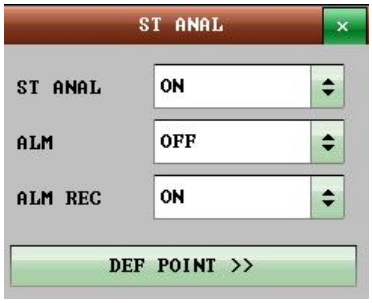


Figure 7-6 ST ANALYSIS menu

ST analysis alarm setting

- ST ANAL: the switch for ST analysis. Set it to ON to activate the ST analysis or OFF to disable the ST analysis.
- ST ALM: pick "ON" to enable prompt message and data record during the ST analysis alarm; pick "OFF" to disable the alarm function, and there will be a beside ST. ST alarm is activated when the result exceeds set ST HI value or falls below ST LO value.
- ALM LEV: used to set up the ST alarm level. There are three selections: HIGH, MED and LOW.
- ALM REC: pick "ON" to enable report printing upon ST analysis alarm.
- ALM HI: used to set up the upper limit of ST alarm. The max. higher limit is 2.0. The minimum higher limit is 0.2 larger than the set lower limit.
- ALM LOW: used to set up the lower limit of ST alarm. The minimum lower limit is –2.0. The max. lower limit is 0.2 lower than the set higher limit.

ST analysis alarm limits

	Max. ST HI	Min. ST LO	Step
ST	2.0 mv	-2.0 mv	0.1

- DEF POINT pick this item to access the DEF POINT window, in which the position of ISO and ST point can be set up.
- ISO Base point. Default is 78 ms.
- ST Measurement point.

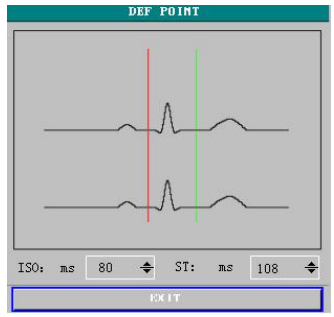


Figure 7-7 DEF POINT window

The operator can adjust the position of both ISO and ST measurement points.

The reference point is the position where the peak of R-wave locates (see Figure 8- 10).

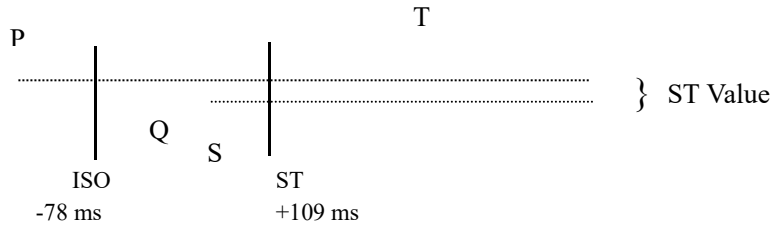


Figure 7-8 DEF Point

The ST measurement for each beat complex is the vertical difference between the two measurement points.

′ NOTE ′

The ST measurement point should be adjusted if the patient's HR or ECG morphology changes significantly.

- Adjusting ISO, ST

These two points can be adjusted turning the knob.

When adjusting ST measurement point, the system will show the ST Measurement Point Window. The QRS complex template displays in the window (If the template is not established, a horizontal line will display. If the channel is not at ON position, a horizontal line will also display). It is adjustable of the highlight bar in the window. You may select ISO or ST, then switch the knob left or right to move the cursor line. When the cursor is at the required position, you may select the base point or the measurement point.

′ NOTE ′

Abnormal QRS complex is not considered in ST segment analysis.

ST Alarm Message

Note: The alarm limits for two ST measurements are identical. No setting of alarm limits can be made only for one channel.

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

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

Physiological alarms:

Message	Cause	Alarm Level
STI TOO LOW	ST measuring value of channel 1 is below the lower alarm limit.	User-selectable

ST2 TOO HIGH	ST measuring value of channel 2 is above the upper alarm limit.	User-selectable
ST2 TOO LOW	ST measuring value of channel 2 is below the lower alarm limit.	User-selectable

Technical alarms:

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

Prompt messages (include general alerts):

Message	Cause	Alarm Level
ST1 EXCEED	ST measuring value of channel 1 exceeds the measurement range.	HIGH
ST2 EXCEED	ST measuring value of channel 2 exceeds the measurement range.	HIGH

7.7 Arr. Monitoring

Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of neonate and adult patient in clinical, detect the changing of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarming information. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting changing of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.

- The arrhythmia monitoring is shutoff by default. You can enable it when necessary.
- This function can call up the doctor's attention to the patient's heart rate by measuring and classifying the arrhythmia and abnormal heart beat and triggering the alarm.
- The monitor can conduct up to 13 different arrhythmia analyses.
- The monitor can store the latest 60 alarm events when taking arrhythmia analysis to a peculiar buffer. The operator can edit these arrhythmia events through the menu below.

Pick the item ARR ANALYSIS in ECG SETUP menu to access the ARR ANALYSIS sub-menu.

ARR ANALYSIS Menu

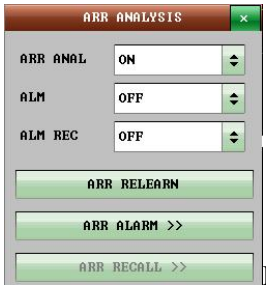


Figure 7-9 ARR ANALYSIS Menu

- ARR ANAL: Pick "ON" during monitoring. Default set is "OFF".
- ALM: Pick "ON" to enable prompt message and data record when alarm occurs; pick "OFF" to disable the alarm function, and there will be a  beside “PVCs”.
- ALM LEV: selectable from HIGH, MED, LOW. Level HIGH represents the most serious case.
- ALM REC: pick "ON" to enable report printing upon PVCs alarm.
- ALM HI: PVCs alarm is activated when the PVCs exceeds set PVCs ALM HI value.

PVCs alarm upper limits:

	Max	Min	Step
PVCs	10	1	1

PVCs alarm and prompt message:

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

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

Physiological alarms:

Message	Cause	Alarm Level
PVCs TOO HIGH	PVCs measuring value is above upper alarm limit.	User-selectable

Technical alarms:

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

- ARR RELEARN Pick this item to start a learning procedure.
- ARR ALARM Pick this item to access the ARR ALARM dialog box to set arrhythmia alarm parameters.

Set ALM to ON/OFF to enable/disable the alarm function; Set REC to ON/OFF to enable/disable alarm record function, turn the knob under LEV column to set alarm level to HIGH, MED or LOW.

Figure7-10 ARR ALARM Menu

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

' NOTE '

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

ARR ALARM

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

Physiological alarms:

Arr. Type	Applicable Patient Type	Occurring Condition	Prompt	Alarm Level
ASYSTOLE	All patients	No QRS is detected for 4 consecutive seconds	ASYSTOLE	User-selectable
VFIB /VTAC	Without pacemaker	Fibrillatory wave for consecutive 4 seconds; or The number of continuous Vent beats is larger than the upper limit of cluster Vent beats (>5). The RR interval is less than 600ms.	VFIB/VTAC	User-selectable
VT>2	Without pacemaker	3 < the number of cluster PVCs < 5	VT>2	User-selectable
COUPLET	Without pacemaker	2 consecutive PVCs	COUPLET	User-selectable
BIGEMINY	Without pacemaker	Vent Bigeminy	BRGEMINY	User-selectable
TRIGEMINY	Without pacemaker	Vent Trigeminy	TRIGEMINY	User-selectable
R ON T	Without pacemaker	A type of single PVC under the condition that HR<100，R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval(the next R wave advances onto the previous T wave).	R ON T	User-selectable
PVC	Without pacemaker	Single PVCs not belonging to the type of above mentioned PVCs.	PVC	User-selectable
TACHY	All patients	5 consecutive QRS complex , RR interval is less than 500ms.	TACHY	User-selectable
BRADY	All patients	5 consecutive QRS complex, RR interval is longer than 1.5s.	BRADY	User-selectable
BEAT MISS	Without pacemaker	When HR is less than 100 beats/min., no heart beat is tested during the period 1.75 times of the average RR interval; or When HR is larger than 100 beats/min., no beat is tested with 1 second.	BEAT MISS	User-selectable

PNP	With pacemaker	No QRS complex and pacing pulse are availabe during the period 1.75 times of the average R-R interval (only considering patients with pacemaker.)	PNP	User-selecta ble
PNC	With pacemaker	When pacing pulse is available, no QRS exists during the period 1.75 times of the average RR interval (only considering patients with pacemaker.)	PNC	User-selecta ble

Patient type:

All patients: refers to perform Arr.analysis on patients either with pacemakers or without pacemakers.

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

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

Prompt message:

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

′ NOTE ′

Arrhythmia name displays in the Alarm Message Area.

7.8 Measuring RESP

7.8.1 How to measure RESP?

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

7.8.2 Setting Up RESP measurement

1、For RESP monitoring, it is not necessary for additional electrodes, however, the placing of electrodes is important.

2、Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of breathing movement to optimize the respiratory waveform.

′ NOTE ′

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

Checklist for RESP Monitoring

1. Prepare the patient's skin prior to placing the electrodes.
2. Attach snap or clip to the electrodes and attach the electrodes to the patient as described below.
3. Switch on the monitor.

7.8.3 Installing electrode for RESP measurement

Placing the Electrodes for Respiratory Monitoring

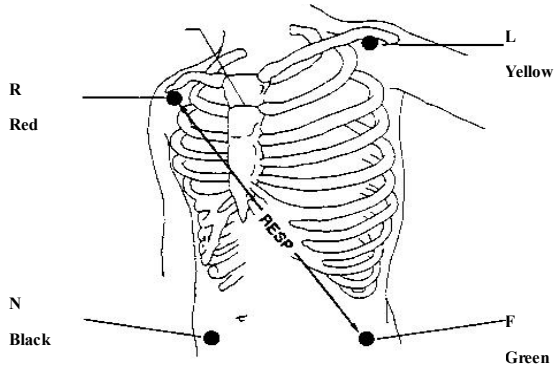


Figure 7-13 Electrodes placement (5-lead)

′ NOTE ′

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

7.8.4 RESP menu

RESP SETUP Menu

Pick RESP hot key on the screen to call up the following menu:

Figure 7-14 RESP SETUP Menu

➢ RESP alarm setting

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

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

RESP alarm limits:

- APNEA ALM: to set the standard of judging an apnea case. It ranges from 10 to 40 seconds, increases / decreases by 5.
- SWEEP: Available options are 6.25, 12.5 and 25.0 mm/s.
- WAVE AMP: The user may set up the displaying amplitude of the RESP waveform.

The selections are 0.25, 0.5, 1, 2, 3, 4, 5.

- HOLD TYPE: AUTO/MANUAL adjustable. When it is AUTO mode, HOLD HI and HOLD LO menus cannot be used and the monitor automatically calculates the RESP RATE.
- HOLD HI and HOLD LO: When the HOLD TYPE is MANUAL, the user can use the knob to pick either HOLD HI or HOLD LO and turn the knob to adjust the two dashed lines in the RESP WAVEFORM area respectively. The positions of the dashed lines will be used to calculate the upper and lower limits of RESP RATE by the monitor.
- DEFAULT: pick this item to access the RESP DEFAULT CONFIG dialog box, in which the user may select whether the FACTORY DEFAULT CONFIG or the USER DEFAULT CONFIG is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation

RESP Alarm Msessage

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

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

Physiological alarms:

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

Technical alarms:

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

Prompt message (general alerts):

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

Chapter 8 SpO2 Monitoring

8.1 What is SpO2 Monitoring

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

8.1.1 How the SpO2 / PLETH Parameter Works

- Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side.
- The sensor measurement wavelengths are nominally 660nm for the Red LED and 940nm for Infrared LED. Maximum optical power output for LED is 4 mW.
- The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.
- The SpO2 value and the PLETH waveform can be displayed on the main screen.

⚠ Warning ⚠

Pulse oximetry can overestimate the SpO2 value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.

8.1.2 SpO2 / Pulse Monitoring

⚠ Warning ⚠

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

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

′ Note ′

Do not perform SpO2 measuring and NIBP measuring in same arm at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO2 value.

8.2 Precautions during SpO2/Pulse Monitoring

′ Note ′

- **Make sure the nail covers the light window;**
- **The wire should be on the backside of the hand.**

′ Note ′

SpO2 value always displays at the same position. Pulse Rate will display when HR FROM

is set at "SPO2", “BOTH” in the ECG SETUP menu.

′ Note ′

SpO2 waveform is not proportional to the pulse volume.

⚠ **Warning** ⚠

1、Verify sensor cable fault detection before beginning of monitoring phase. Unplug the SpO2 sensor cable from the socket, the screen will display the error message “SPO2 SENSOR OFF” and the audible alarm is activated.

2、Do not use the sterile supplied SpO2 sensors if the packaging or the sensor is damaged and return them to the vendor.

3、Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. Check per 2~3 hours the sensor placement and move it when the skin deteriorates. More frequent examinations may be required for different patients.

8.3 Monitoring Procedure

SpO2 plethysmogram measurement

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient finger.
3. Plug the connector of the sensor extension cable into the SpO2 socket on the JR2000B.

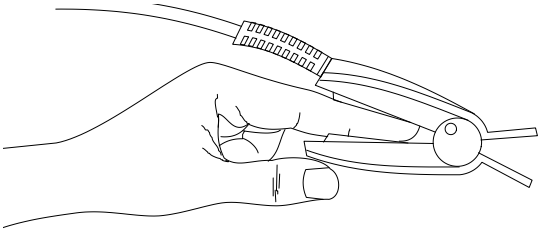


Figure8-1mounting of the sensor

8.4 Limitations for Measurement

Measurement Limitations

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

- High-frequency electrical noise, including noise created by the host system, or noise from external sources, such as electrosurgical apparatus, which is admitted by the host system.
- Do not use oximeters and oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.
- Intravascular dye injections
- Excessive patient movement
- Improper sensor application
- Sensor temperature (maintain between 28° C and 42° C for best operation)

- Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line.
- Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin.
- External illumination more than 5,000 lumens/square meter (typical office lighting)
- Venous pulsations
- It is recommended to use SpO2 sensors described in chapter Accessories and Ordering Information.

8.5 SpO2 Menu

SPO2 SETUP Menu

Pick the SPO2 hot key on the screen to call up the SPO2 SETUP menu as shown below.

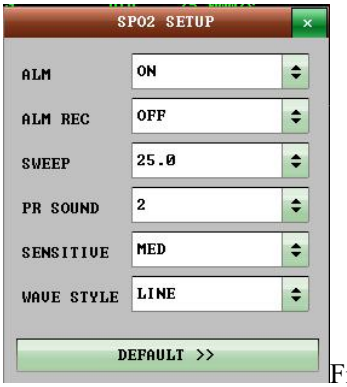


Figure 8-2 SPO2 SETUP menu

⚠ **Warning** ⚠

Setting the SpO2 upper alarm limit to 100% is equivalent to switching off the alarm on upper limit. High oxygen levels may predispose a premature infant to retrolental fibroplasia. Therefore, the upper alarm limit for oxygen saturation must be carefully selected in accordance with commonly accepted clinical practices.

➢ SpO2 alarm setting

- ALM: pick "ON" to enable prompt message and data record during the SpO2 alarm; pick "OFF" to disable the alarm function, and there will be a  beside “SpO2”.
- ALM REC: pick "ON" to enable report printing upon SpO2 alarm.

■ SWEEP

Available options are 12.5, 25.0 mm/s.

■ PR SOUND

Pulse beep volume. Options are OFF, HIGH, MED, LOW.

■ AVG TIME

4S, 8S, 16S represent times that SpO2 average value is counted.

■ DEFAULT:

Pick this item to access the SPO2 DEFAULT CONFIG dialog box, in which the user may select whether the FACTORY DEFAULT CONFIG or the USER DEFAULT CONFIG is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user’s confirmation.

8.6 Alarm Description and Prompt

SpO2 Alarm Message

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

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during SpO2 measurement.

Physiological alarm:

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

Technical alarms:

Message	Cause	Alarm Level	Remedy
SPO2 SENSOR OFF	SpO2 sensor may be disconnected from the patient or the monitor.	LOW	Make sure that the monitor and the patient are in correct connection with the cables.

Prompt message (include general alerts):

Message	Cause	Alarm Level
SEARCH PULSE	SpO2 module is searching for pulse.	No alarm
NO PULSE	SpO2 module cannot detect SpO2 signal for a long time.	HIGH

8.7 Maintenance and Cleaning

Care and Cleaning

⚠ **Warning** ⚠

Before cleaning the monitor or the sensor, make sure that the equipment is switched off and disconnected from the power line.

Do not subject the sensor to autoclaving.

Do not immerse the sensor into any liquid.

Do not use any sensor or cable that may be damaged or deteriorated.

For cleaning:

- Use a cotton ball or a soft mull moistened with hospital-grade ethanol to wipe the surface of the sensor, and then dry it with a cloth. This cleaning method can also be applied to the luminotron and receiving unit.
- The cable can be cleaned with 3% hydrogen dioxide, 7% isopropanol, or other active reagent. However, connector of the sensor shall not be subjected to such solution.

Chapter 9 TEMP Monitoring

9.1 TEMP Monitoring

TEMP monitoring setup

- If you are using disposable TEMP probes you need to plug the TEMP cable into the monitor and then connect the probe to the cable. With a reusable TEMP probe you can plug the probe directly into the monitor
- Apply the TEMP probe(s) securely to the patient.
- Switch on the system.

⚠ **Warning** ⚠

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

2、The calibration of the temperature measurement is necessary for every two years (or as frequently as dictated by your Hospital Procedures Policy). When you need calibrate the temperature measurement, contact the manufacture please.

′ Note ′

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

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

9.2 TEMP SETUP Menu

Pick the TEMP hot key on the screen to call up the TEMP SETUP menu shown as below:

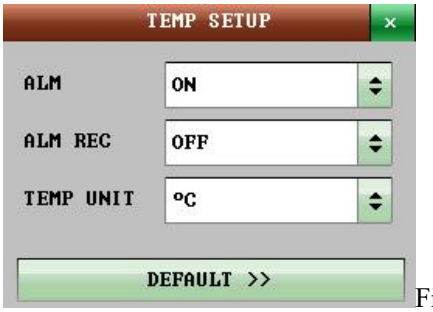


Figure 9-1 TEMP SETUP Menu

- TEMP alarm setting
- ALM: pick "ON" to enable prompt message and data record during the TEMP alarm; pick "OFF" to disable the alarm function, and prompt the symbol beside TEMP numeric.
- ALM LEV: used to set up the alarm level, selectable from HIGH, MED or LOW.
- ALM REC: used to start/stop recording TEMP alarms. Pick "ON" to enable report printing upon TEMP alarm.

Alarm for TEMP occurs when the measured temperature exceeds set alarm high limit or falls below alarm low limit.

TEMP alarm limits:

	Max. TEMP HI	Min. TEMP LO	Step
TEMP	50	0	0.1

■ UNIT

To set temperature unit (ºC or ºF).

■ DEFAULT

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

9.3 TEMP Alarm message

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

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

Physiological alarms:

Message	Cause	Alarm Level
TEMP TOO HIGH	Measuring value of sensor is above upper alarm limit.	User-selectable
TEMP TOO LOW	Measuring value of sensor is below lower alarm limit.	User-selectable

Technical alarms:

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

Prompt message:

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

Chapter 10 NIBP Monitoring

10.1 Introduction

- Reference to the European standard EN 1060-1: Specification for Non-invasive sphygmomanometers Part 1, General requirements.
- The Non-invasive Blood Pressure (NIBP) module measures the blood pressure using the oscillometric method.
- It is applicable for adult, pediatric, and neonatal usage.
- There are three modes of measurement available: manual, automatic and continuous. Each mode displays the diastolic, systolic and mean blood pressure.
- In the MANUAL mode, only one measurement is conducted for each time.
- In the AUTO mode, the measurement is cycled; you can set the interval time to 1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes.
- In the continuous mode, the monitor measures the blood pressure as many times as possible in five minutes.

⚠ **Warning** ⚠

1. **You must not perform NIBP measurements on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.**
2. **For a thrombasthemia patient, it is important to determine whether measurement of the blood pressure shall be done automatically. The determination should be based on the clinical evaluation.**
3. **Ensure that the correct setting is selected when performing measurements on children. It may be dangerous for the children to use an over pressure level.**

10.2 NIBP Measuring

10.2.1 NIBP Measuring

⚠ **Warning** ⚠

- **Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, pediatric or neonate.)**
- **Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.**
- **Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.**

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

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

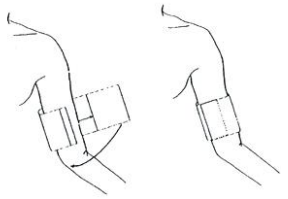


Figure 10- 1 Applying Cuff

′ Note ′

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

Size of reusable cuff for neonate/children/adult

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

Size of disposable cuff for neonate/children/adult

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

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

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

- If the cuff is placed higher than the heart level, add 0.75 mmHg (0.10 kPa) for each inch of difference.
- If it is placed lower than the heart level, deduct 0.75 mmHg (0.10 kPa) for each inch of difference.

4. Check whether the patient mode is appropriately selected. Access PATIENT SETUP menu from SYSTEM MENU and pick PAT TYPE item and turn the knob to select the required patient type.
5. Select a measurement mode in the NIBP SETUP menu. Refer to the following paragraphs Operation Hints for details
6. Press the NIBP button on the front panel to start a measurement.

Operation Hints

1. To start auto measuring:

Access NIBP SETUP menu and pick the INTERVAL item, in which the user may choose the selections other than MANUAL to set up the time interval for auto measurement. After that, press NIBP button on the front panel to start the auto measuring according to the selected time interval.

⚠ **Warning** ⚠

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purport, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

2. To stop auto measuring:

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

3. To start a manual measuring:

- Access NIBP SETUP menu and pick the INTERVAL item. Select the MANUAL selection. Then press the NIBP button on the front panel to start a manual measurement.
- During the idle period of auto measuring process, press the NIBP button on the front panel at any time to start a manual measurement. Then press the NIBP button to stop manual measurement and the system continues executes auto-measuring program according to selected time interval.

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

Press NIBP button on the front panel.

5. To stop a manual measuring

Repress the NIBP button again.

6. To perform continuous measuring:

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

⚠ **Warning** ⚠

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purport, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

7. To stop continuous measuring:

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

′ Note ′

If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by an alternative method before checking the functioning of the monitor.

⚠ **Warning** ⚠

If liquid is inadvertently splashed on the equipment or its accessories, or may enter the conduit or inside the monitor, contact local Customer Service Center.

Measurement Limitations

To different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could

interfere with the measurement, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible.

- Patient Movement

Measurements will be unreliable or may not be possible if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

- Cardiac Arrhythmia's

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

- Heart-lung Machine

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

- Pressure Changes

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

- Severe Shock

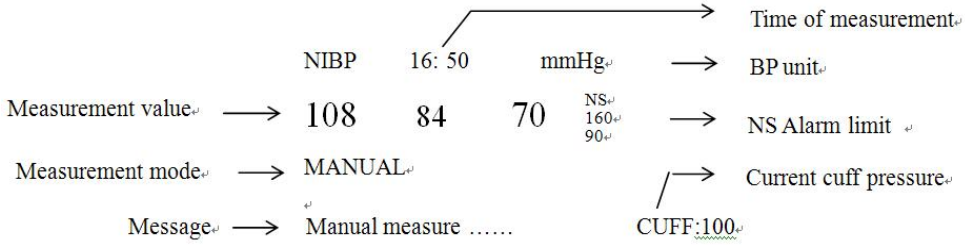
If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

- Heart Rate Extremes

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

10.2.2 NIBP monitoring screen

NIBP measurement result and corresponding message are displayed as follows:



10.3 NIBP SETUP menu

Pick the NIBP hot key on the screen to call up the NIBP menu shown as below:

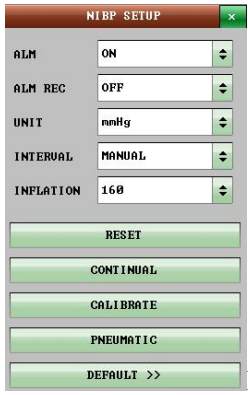


Figure 10-2 NIBP SETUP Menu

- NIBP alarm setting
- ALM: pick "ON" to enable prompt message and data record during the NIBP alarm; pick "OFF" to disable the alarm function, and there will be a  beside “NIBP”.
- ALM LEV: selectable from HIGH, MED to LOW. HIGH represents the most serious case.
- ALM REC: pick "ON" to enable report printing upon NIBP alarm.
- Sys alm hi, sys alm lo, mean alm hi, mean alm lo, dia alm hi, dia alm lo are for the user to set up the alarm limit for each type of pressure. NIBP alarm is activated when the pressure exceeds set upper alarm limits or falls below lower alarm limits.

➢ NIBP alarm limits:

Adult Mode : SYS 40-270 mmHg，DIA 10-215 mmHg Mean 20-235 mmHg
Pediatric Mode: SYS 40-200 mmHg，DIA 10-150 mmHg Mean 20-165 mmHg
Neonatal Mode: SYS 40-135 mmHg，DIA 10-100 mmHg Mean 20-110 mmHg

➢ RESET

Restore measurement status.
Pick this item to restore initial settings of the pressure pump.
When the pressure does not work properly and the system fails to give message for the problem, pick this item to activate self-test procedure, thus restore the system from abnormal performance.

➢ CONTINUAL

Start continuous measuring.
When this item is picked, the menu will disappear automatically.

➢ INTERVAL

Interval time for automatic measuring. Available selections: 1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes. Press NIBP button on the front panel to start the first auto measuring.
Pick MANUAL selection in INTERVAL item to set up the measuring mode to MANUAL.

➢ UNIT

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

➢ CALIBRATE

Calibrate the cuff pressure reading with a calibrated reference manometer. Pick the CALIBRATE item to start the calibration and the item will change into STOP CAL, which if picked, the system will stop calibration.

➢ DEFAULT

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

⚠WARNING⚠

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

Procedure of the Pressure Transducer Calibration:

Replace the cuff of the device with a rigid metal vessel with a capacity of 500 ml ± 5%. Connect a calibrated reference manometer with an error less than 0.8 mmHg and a ball

pump by means of a T-piece connector and hoses to the pneumatic system. Set the monitor in CALIBRATE mode. Inflate the pneumatic system to 0, 50 and 200 mmHg by ball pump separately. The difference between the indicated pressure of the reference manometer and the indicated pressure of the monitor will not exceed 3 mmHg. Otherwise, please contact our customer service.

- PNEUMATIC

This item is used for air leakage test. Turn the knob to pick the item to start the air leakage test. Then the item will change into STOP PNEUM, which if picked, the system will stop air leakage test.

⚠WARNING⚠

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

Procedure of the air leakage test:

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

10.4 Maintenance and Cleaning

⚠ Warning ⚠

- **Do not squeeze the rubber tube on the cuff.**
- **Do not allow liquid to enter the connector socket at the front of the monitor.**
- **Do not wipe the inner part of the connector socket when cleaning the monitor.**
- **When the reusable cuff is not connected with the monitor, or being cleaned, always place the cover on the rubber tube to avoid liquid permeation.**

Reusable Blood Pressure Cuff

The cuff can be sterilized by means of conventional autoclaving, gas, or radiation sterilization in hot air ovens or disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use this method. The cuff should not be dry-cleaned.

The cuff can also be machine-washed or hand-washed, the latter method may prolong the

service life of the cuff. Before washing, remove the latex rubber bag, and for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing, then reinsert the rubber bag.

To replace the rubber bag in the cuff, first place the bag on top of the cuff so that the rubber tubes line up with the large opening on the long side of the cuff. Now roll the bag lengthwise and insert it into the opening on the long side of the cuff. Hold the tubes and the cuff and shake the complete cuff until the bag is in position. Thread the rubber tubes from inside the cuff, and out through the small hole under the internal flap.

Disposable Blood Pressure Cuffs

Disposable cuffs are intended for one-patient use only. Do not use the same cuff on any other patient. Do not sterilize or use autoclave on disposable cuffs. Disposable cuffs can be cleaned using soap solution to prevent infection.

′ Note ′

For protecting environment, the disposable blood pressure cuffs must be recycled or disposed of properly.

Chapter 11 CO2 Measuring(Optional)

11.1 General

This chapter offers some relevant data concerning CO2 monitoring.
The monitor provides two kinds of CO2 measuring methods as per the requirements of users, which are MainStream(optional) and SideStream(optional) .
This module can be applied in operation room, monitor units etc, it can measure the CO2 partial pressure or concentration of patient Air Way, obtain EtCO2, Inspired Maximum CO2 (InsCO2), Air Way Respiration Rate (AwRR), and display CO2 concentration waveforms. The parameter symbols displayed on the screen are defined as following:
CO2：EtCO2　　INS:　InsCO2。
AWRR: Air Way Respiration (AwRR)(Resp. times/MIN)。
⚠ Note ⚠
1、Don't use the device in the environment with flammable anesthetic gas.
2、The device can only be operated by personnel having taken professional training and familiar with this manual.
⚠ Warning ⚠　CO2 module shall be avoided from crash and vibration.

11.1.1 Monitoring Procedure

Principle of CO2 measurement is primarily based on the fact that CO2 molecule can absorb 4.3um infrared ray. Absorption intensity is proportional to CO2 concentration of patient sample, the CO2 concentration will compute from the detecting CO2 absorption intensity of patient sample. The relation between partial pressure and percentage of CO2 concentration is given below : P(mmHg) = Percentage(%) * Pamp(ambient pressure)
Of CO2 MainStream and CO2 SideStream modules, whichever is selected by the user, Autorun measuring mode is adopted. Rate for waveform sampling is 31 msec/time. The operating series for the two modules are respectively:
MainStream work sequence: After the system is powered on, CO2 module automatically begins warming-up for about 45S to 90S. Then the sensor motor is activated. After 5S to 10S, the light source of infrared ray is opened. After 10S, the system enters the normal measuring status.
SideStream work sequence: Except the procedures that after being powered on, the system needs not warming-up and the air pump should be activated, other procedures are the same as those in MainStream sequence.
CO2 measurement setups:
Verify the type of the configured CO2 module (MainStream or SideStream);
For MainStream, connect the sensor to the receptacle of CO2 module. For SideStream, plug the water trap onto its fixing chassis. Add a permanently used nafion tube between the sampling line and the watertrap to further remove the influence of water vapor.
Power on the system. For MainStream, technical prompt information of "CO2 WARM UP" is always displayed on the screen until the sensor reaches to the operating temperature.
After CO2 module is activated and enters the normal status, for MainStream, "MAIN" is displayed following CO2 waveform identifier, and for SideStream, the "SIDE" is displayed

following CO2 waveform identifier.

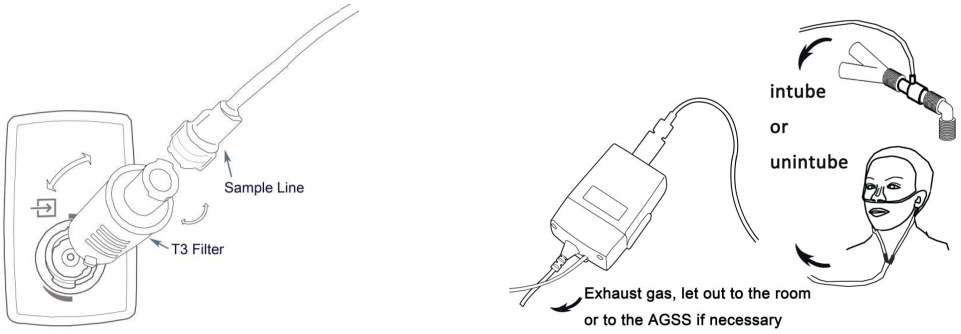


Figure 11- 1 Sidestream Connection

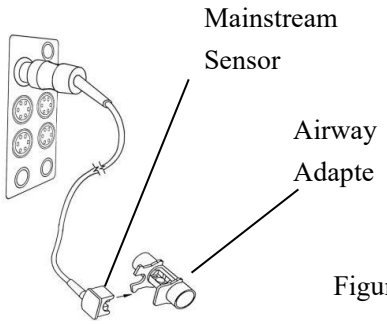


Figure 11- 2 Mainstram Connection

- Do not use the sterile supplied CO2 Water trap set (for side stream including water trap and sample line and cannula) and Air adapter (for main stream) if the packaging or the sensor is damaged and return them to the vendor.
- "CO2 WARM UP" or "CO2 SENSOR START UP" displayed on the screen indicates that the sensor is in warm-up or starting-up. After the information disappears from the screen, the standard measurement can then be generated.
- Monitor has water trap beside it, which is used to prevent the moisture or water drops produced by patient's respiration from entering the module. The sample line and the water trap are one-off consumables that can not be repeatedly used by different patients.

11.2 CO2 Menu

Parameter setup and adjustment
Turn the knob to select and press CO2 hot key on the screen to activate "CO2 Setup" menu as shown below:

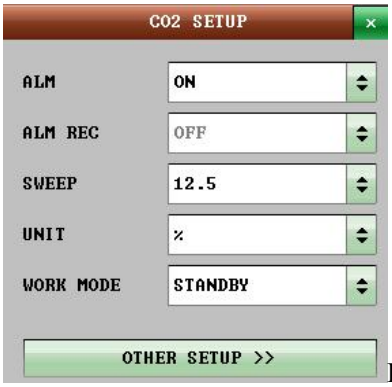


Figure 11-3 CO2 Setup Menu

Following functions can be realized via CO2 SETUP menu.

■ ALM: select “ON” to enable and store alarm prompt when CO2 parameters have alarms. Select “OFF” to disable alarm and display beside CO2. The default is “ON”.

■ ALM REC: select “ON” to generate output from the recorder ever since CO2 parameter alarm occurs. The default is “OFF”.

■ ALM LEV: select from HIGH, MED and LOW. Level HIGH represents the most serious alarm, followed by Level MED and Level LOW with a decrease of seriousness. Change in “ALM LEV” can only affect the physiological alarm levels of CO2 parameters including EtCO2 upper limit, EtCO2 lower limit, InsCO2 upper limit, AwRR upper limit and AwRR lower limit. The default alarm level is “MED”.

■ CO2 ALM HI: to adjust the upper alarm limit of EtCO2. If the measuring value is larger than CO2 upper alarm limit, “CO2 TOO HIGH” appears on the screen. After the measuring value returns to the normal one, the information disappears.

■ CO2 ALM LO: to adjust the lower alarm limit of EtCO2. If the measuring value is smaller than CO2 lower alarm limit, “CO2 TOO LOW” appears on the screen. After the measuring value returns to the normal one, the information disappears.

■ INS ALM HI: to adjust the upper alarm limit of InsCO2. If the measuring value is larger than InsCO2 upper alarm limit, “INS TOO HIGH” appears on the screen. After the measuring value returns to the normal one, the information disappears.

■ AWRR ALM HI: to adjust the upper alarm limit of AwRR. If the measuring value is larger than the upper alarm limit of AwRR, “AWRR TOO HIGH” appears on the screen. After the measuring value returns to the normal one, the information disappears.

■ AWRR ALM LO: to adjust the lower alarm limit of AwRR. If the measuring value is smaller than the lower alarm limit of AwRR, “AWRR TOO LOW” appears on the screen. After the measuring value returns to the normal one, the information disappears.

■ UNIT: to change the display units of CO2 and InsCO2 parameters. “mmHg” and “kPa” are available for selection.

■ SWEEP: to adjust the display rate of CO2 waveforms with “6.25 mm/s”, “12.5 mm/s”, or “25.0 mm/s” selectable.

Exit: to close CO2 SETUP menu.

⚠ **Note** ⚠ **“APNEA ALM” cannot be closed.**

When various alarms occur simultaneously, the alarm information of highest level will be displayed on the screen.

OTHER SETUP: pick this item in the menu to call up CO2 more setup sub-menu.

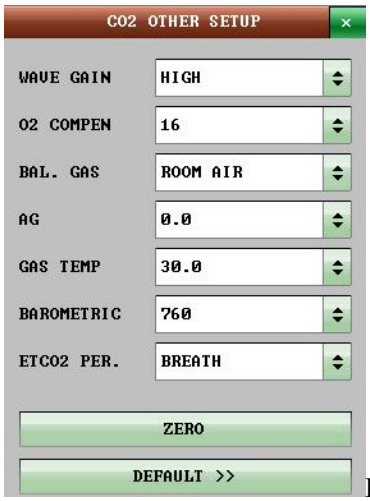


Figure 11-4 CO2 More Setups Menu

Now we introduce you to the functions of each item in CO2 SETUP submenu.

- WAVE SCALE: to adjust full scale size of CO2 waveform display area with “LOW” or “HIGH” selectable. The default value is “LOW”.
- WORK MODE: to change the work mode of CO2 with “MEASURE” mode or “STANDBY” mode selectable. The default is “STANDBY” mode. When it is required to monitor CO2, select “WORK” mode. “STANDBY” mode disables the air pump in SideStream module, the sensor and the IR (infrared ray) source in MainStream module, thus decreases the power consumption and extends the life cycles of IR source and the whole CO2 module.

⚠ **Note** ⚠

When not using CO2 monitoring function, it is suggested not to connect MainStream sensor or SideStream water trap and to adjust to “STANDBY” mode.

- O2 COMPEN: to perform compensate operations as per the selection of the user.
- BALANCE GAS: ROOM AIR, N2O, HELIUM.
- Anaesthesia Agent: The intensity of the Anaesthesia Agent
- GAS TEMP: Current Temperature of the gas
- Barometric: Current Atmospheric Pressure
- ETCO2 Period: The period to calculate the ETCO2, Per breath, 10s, 20s

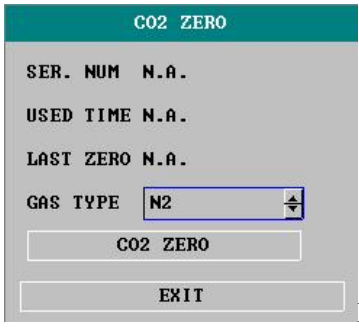


Figure 11-5 CO2 More Setups Menu

- To perform the ZERO. The usage of the module will be display in the MENU.

⚠ Note ⚠

1. If Compensate item is not correctly set as per the operation conditions, the result will be far from the actual value, thus leading to severe misdiagnosis.
2. The default of Water Vapor Compensate is on. Turn it off when measuring dry gas,

such as when performing regular maintenance or measurement validation by using dry calibrated gas.

3. The default of BTPS is on. Turn it on when measuring the VA saturated “damp” gas under the body temperature and ambient pressure and turn it off when measuring the “dry” gas under the ambient temperature and pressure.
4. Operate by strictly observing the Compensate operation method.

- DEFAULT: pick this item to access the CO2 DEFAULT CONFIG dialog box, in which the user may select whether the FACTORY DEFAULT CONFIG or the USER DEFAULT CONFIG is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user’s confirmation.

EtCO2 upper alarm limit: when parameter value exceeds this limit, there will be alarm for exceeding the upper limit.
Default: Adult: 50 mmHg， Pediatric: 50 mmHg ，Neonatal: 45 mmHg
EtCO2 lower alarm limit: when parameter value is smaller than the lower limit, there will be alarm for exceeding lower limit.
Default: Adult: 15 mmHg， Pediatric: 20 mmHg ，Neonatal: 30 mmHg
InsCO2 upper alarm limit: when parameter value exceeds this limit, there will be alarm for exceeding upper limit.
Default: Adult: 4 mmHg， Pediatric: 4 mmHg ，Neonatal: 4mmHg
AwRR upper alarm limit: when parameter value exceeds this limit, there will be alarm for exceeding upper limit.
Default: Adult: 30 rpm， Pediatric: 30 rpm ，Neonatal: 100 rpm
AwRR lower alarm limit: when parameter value is smaller than the limit, there will be alarm for exceeding lower limit.
Default: Adult: 8 rpm， Pediatric: 8 rpm ，Neonatal: 30 rpm
APNEA Time: Selections are 10S to 40S, Default: 20S.
Work Mode: MainStream: Standby, Measurement;
SideStream: Standby, Measurement. Default: Measurement
Compensate Method:
MainStream: General/O2/N2O/DES/ALL， SideStream: General/O2/N2O/DES/ALL
Default Methods: General.
Pump Rate: 100 – 200 ml/min. Default: 100 ml/min，Unit: mmHg/kPa.，Default: mmHg
Waveform Sweep: 25.0/12.5/6.25 (mm/s) Default: 25.0 mm/s
Waveform Scale: LOW/HIGH Default: LOW
Besides, for alarm function of CO2 module, refer to Chapter Alarm, for its recording function, refer to Chapter Recording, and for information about alarm event review, graphic and tabular trend of CO2 parameters, refer to Chapter Trend and Event.

11.3 Alarm Information and Prompt

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

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during CO2 measurement.

Physiological alarms:

Message	Cause	Alarm Level
CO2 TOO HIGH OR LOW	EtCO2 measuring value is above upper alarm or below lower limit.	User-selectable
INS TOO HIGH	InsCO2 measuring value is above alarm limits.	User-selectable
AWRR TOO HIGH OR LOW	AwRR measuring value is above upper or below lower alarm limit.	User-selectable
CO2 APNEA	In specific time interval, no RESP can be detected using CO2 module.	HIGH

Technical alarms:

Message	Cause	Alarm Level	Remedy
CO2 SENSOR OFF	Mainstream sensor is not properly connected or has fallen off.	LOW	Make sure that mainstream sensor is properly connected.
CO2 NO WATERTRAP	Sidestream water trap is not properly connected or has fallen off.	LOW	Make sure that sidestream water trap is soundly connected.
CO2 WATERTRAP OCCLUDE	Sidestream water trap is occluded.	LOW	Make sure that sidestream water trap functions smoothly.
CO2 SIGNAL LOW OR TOO LOW	Measuring module technical failure	LOW	If necessary, re-start the monitor. If failure persists, stop using measuring function of CO2 module, notify biomedical engineer or Our service staff.
CO2 BAROMTRC TOO LARGE		MED	
CO2 PNEUMATIC LEAK		MED	
CO2 SIGNAL NOISY OR SATURATE		LOW	
CO2 CALCULATION ERR		HIGH	
CO2 SENSOR FAULT		HIGH	
CO2 SENSOR TEMP HIGH OR LOW		HIGH	
CO2 WATCHDOG TIMEOUT		HIGH	
CO2 OTHER INFORMATION ERR		HIGH	
CO2 COMM ERR	CO2 module communication failure	HIGH	Stop using measuring function of CO2 module, notify biomedical engineer or Our service staff.

CO2 INIT ERR	CO2 module is not properly connected or failed.	HIGH	Stop using measuring function of CO2 module, notify biomedical engineer or Our service staff.
CO2 COMM STOP	Measuring module failure or communication failure.	HIGH	
CO2 ALM LMT ERR	Functional safety failure	HIGH	Stop using measuring function of CO2 module, notify biomedical engineer or Our service staff.
INS ALM LMT ERR	Functional safety failure	HIGH	
AWRR ALM LMT ERR	Functional safety failure	HIGH	

Prompt message:

Message	Cause	Alarm Level
CO2 STANDBY STATUS	Turn from measuring mode to standby mode, making the module in energy-saving status.	No alarm
CO2 WARM UP	Shows that the sensor is in warming-up stage.	No alarm
CO2 SENSOR START UP	Shows that the sensor has just entering start-up stage.	No alarm

11.4 Maintenance and Cleaning

■ Care and Maintenance

1. Sample line is for one-off use in SideStream module. Do not sterilize or clean for reuse on another patient.

2. Airway adapter is for one-off use in MainStream module. Do not sterilize or clean for reuse on another patient.

3. When the sample system of Sidestream module occurring occlusion, first check kinks for sampling line. If no kinks are found, then check water trap after disconnecting sample line from the Watertrap. If the occlusion message on the screen disappears, the sampling line must be replaced. If the occlusion message on the screen remains, the Watertrap must be replaced.

4. No routine calibration required in both Mainstream and Sidestream CO2 module.

⚠ **Note** ⚠

- **Please dry the water filter in a ventilated place after single use, and be sure to have 2 water filters to interchangeably in use, it should be change new water fileter when the cumulative use time is 50 hours. Or else it would make damage to the module's pump and block the inner air tube.**
- **If the CO2 waveform (capnograph) appears abnormal, inspect the water filter, sample tube and replace if needed.**
- **Periodically check the water filter for excessive moisture or secretion buildup, at any time water in the water filter can be poured out.**
- **Regular replacement of consumables can prolong the lifetime of the module.**

Chapter 12 Appendix Product Specification

12.1 ECG

Lead Mode: 5 Leads (R, L, F, N, C or RA, LA, LL, RL,V)
Lead selection: I, II, III, avR, avL, avF, V,
Waveform: 3 ch
Lead mode: 3 Leads (R, L, F or RA, LA, LL)
Lead selection: I, II, III,
Waveform: 1 ch
Gain: ×2.5mm/mV, ×5.0mm/mV, ×10mm/mV, ×20mm/mV, auto
HR and Alarm
Range：Adult:15 ~ 300 bpm Neo/Ped:15 ~ 350 bpm
Accuracy: ± 1% or ± 1bpm,which great
Resolution: 1 bpm
Sensitivity: > 200 (uV_{P-P})
Differential Input Impedance: > 5 MΩ
CMRR: Monitor: > 105 dB Operation: > 105 dB Diagnosis: > 85 dB
Electrode offset potential：±300mV
Leakage Current:< 10 uA
Baseline Recovery: < 3 S After Defi.
ECG Signal Range: ±8 m V (Vp-p)
Bandwidth: Surgery 1 ~ 15 Hz，Monitor 0.5 ~ 35 Hz，Diagnostic 0.05 ~ 100 Hz
Calibration Signal:1 (mV_{p-p}), Accuracy ：±5%
ST Segment Monitoring Range
Measure and Alarm -2.0 ~ +2.0 mV
ARR Detecting
Type:ASYSTOLE, VFIB/VTAC, COUPLET, BIGEMINY, TRIGEMINY, R ON T, VT>2, PVC, TACHY, BRADY, MISSED BEATS, PNP, PNC
Alarm: Available
Review：Available

12.2 RESPARATION

Method: Impedance between R-F(RA-LL)
Differential Input Impedance: >2.5 MΩ
Measuring Impedance Range: 0.3~5.0 Ω
Base line Impedance Range:0 – 2.5 KΩ
Bandwidth: 0.3 ~ 2.5 Hz
Resp. Rate
Measuring and Alarm Range: Adult:0 ~ 120 rpm Neo/Ped: 0 ~ 150 rpm
Resolution:1 rpm
Accuracy:±2 rpm
Apean Alarm: 10 ~ 40 S

12.3 NIBP

Method: Oscillometric

Mode: Manual, Auto, STAT
Measuring Interval in AUTO Mode
1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240,480 (Min)
Measuring Period in STAT Mode 5 Min
Pulse Rate Range:40 ~ 240 bpm
Alarm Type；SYS, DIA, MEAN
Measuring and alarm range：
Adult Mode：SYS:40 ~ 270 mmHg，DIA:10 ~ 215 mmHg，MEAN:20 ~ 235 mmHg
Pediatric Mode:SYS:40 ~ 200 mmHg，DIA:10 ~ 150 mmHg，MEAN:20 ~ 165 mmHg
Neonatal Mode:SYS:40 ~ 135 mmHg，DIA:10 ~ 100 mmHg，MEAN:20 ~ 110 mmHg
Resolution:Pressure 1mmHg
Accuracy:Pressure
Maximum Mean error:±5mmHg
Maximum Standard deviation:±8mmHg
Overpressure Protection
Adult Mode:297±3 mmHg
Pediatric Mode: 240±3 mmHg
Neonatal Mode: 147±3 mmHg

12.4 SpO2

Measuring Range:0 ~ 100 %
Alarm Range：0 ~ 100 %
Resolution:1 %
Accuracy:70% ~ 100% ±2 % ， 0% ~ 69% unspecified
Actualization interval:about 1 Sec.
Alarm Delay:10 Sec.
Pulse Rate
Measuring and Alarm Range: 0~254bpm
Resolution:1bpm
Accuracy :±2bpm

12.5 TEMPERATURE

Channel：1
Measuring and Alarm Range:0 ~ 50 ℃
Resolution:0.1℃
Accuracy:±0.1℃
Actualization interval:about 1 Sec.
Average Time Constant:< 10 Sec.

Contact Information:

Manufacturer:Shanxi Jerry Medical Instrument Co., Ltd.

Room701/702, Dasheng Tech. Blg., 303Changzhi Road, Taiyuan City, Shanxi Province 030006, China

European Representative: Well Kang Limited

Enterprise Hub, NW Business Complex,1 Beraghmore Rd., Derry, BT48 8SE, Northern Ireland,UK

Notified Body:MEDCERT GmbH

Notified Body Address: Pilatuspool 2, 20355 Hamburg

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