AM-2000 Series User Manual

Patient Monitor

Contents

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Responsibility on the manufacturer party

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

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

NOTE
This equipment is not intended for family usage.

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

Warranty

Workmanship & Materials topplor

Guarantee 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 the 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

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

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

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

- 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:

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

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

Preface

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.

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** ⚠

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

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

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.

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

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=110VA
FUSE T 1.6A

General instruction:

Portable 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 IBP. 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.

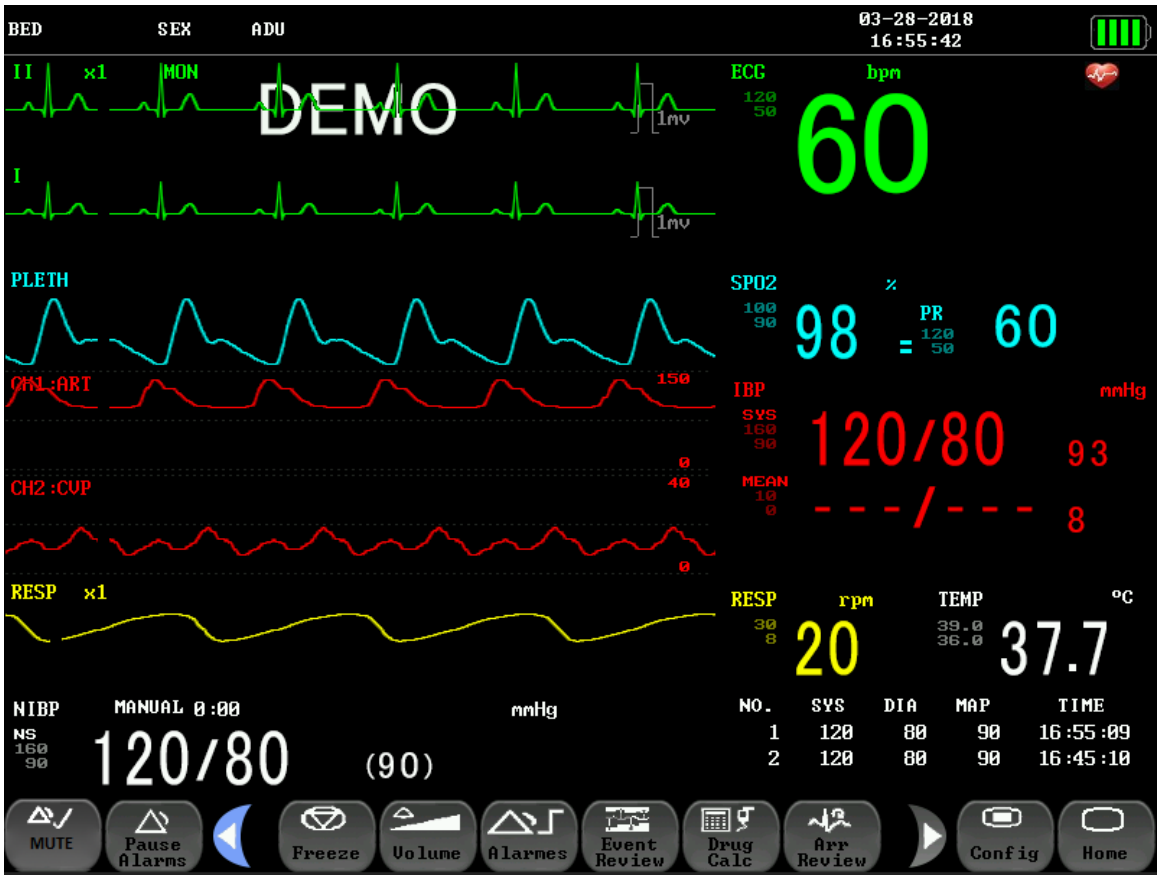


Figure 1-1 Portable Patient Monitor

Portable Patient Monitor performs monitoring of:

ECG	Heart Rate (HR)
	2-channel ECG waveforms
	S-T segment analysis
	Arrhythmia （optional）
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
IBP	IBP DATA
CO2	CO2 DATA

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.

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 is a TFT color screen. The patient parameters, waveforms, alarm messages, bed number, date, system status and error messages can be reflected from the screen.

The screen is divided into 5 areas (See Figure 1-2):

Message area;

Waveform area;

Parameter area;

NIBP review list;

Menu bar on the bottom.

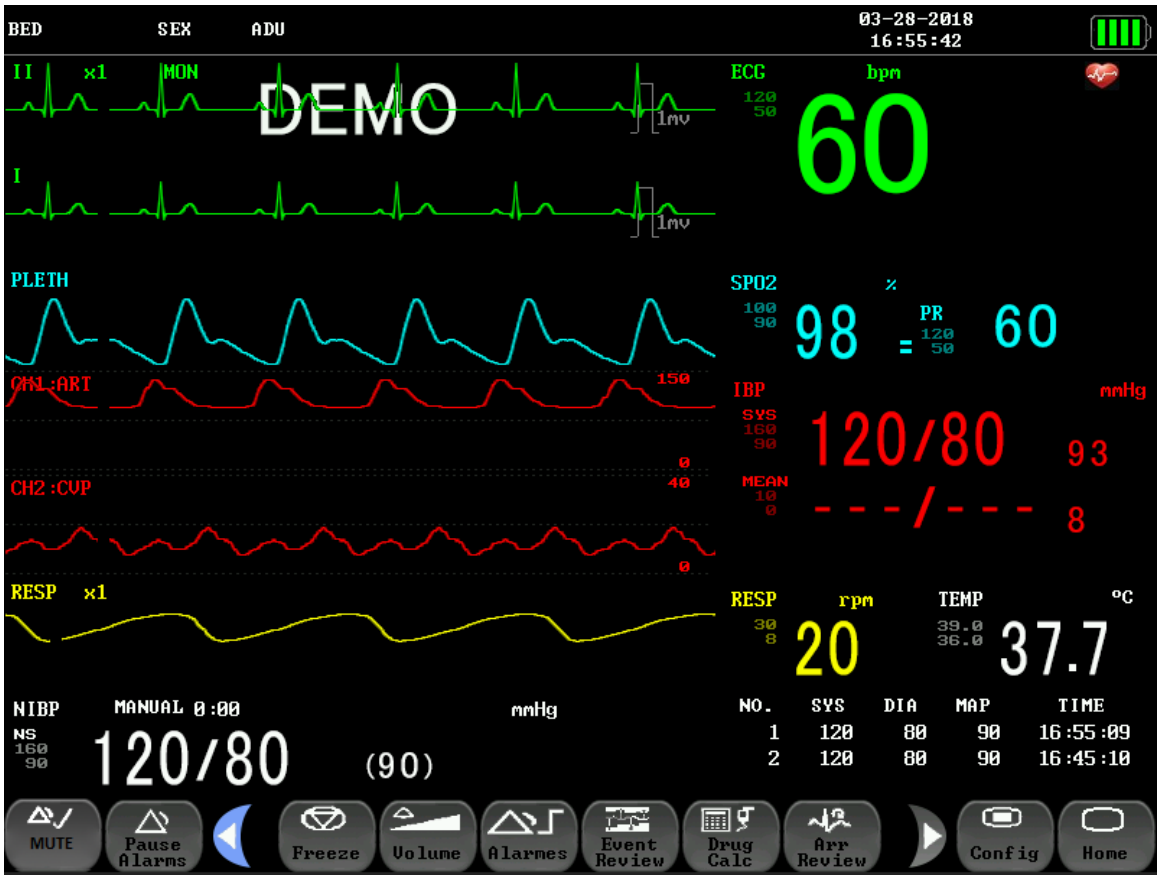


Figure 1-2 Main Display

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:

BED NO	Bed number of the monitored patient
SEX	Patient gender
ADU	Type of patient
03-28-2018	Current date
16:55:42	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 SILENCE button is pressed for more than 1 second.
- "  " 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 cannot 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

Four 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.

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.

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.

ECG:

- Heart Rate (Unit: BMP)
- ST-segment analysis of Channel 1 & 2 (Unit: mv)

NIBP
(From left to right) Systolic, Mean, Diastolic (Unit: mmHg or kPa)

SpO2:

- SpO2 (Unit: %)

RESP

- Respiration Rate (Unit: breath/min)

TEMP

- Temperature (Unit:℃ or ℉)

EtCO2

- CO2 concentration (Unit: kPa or mmHg)

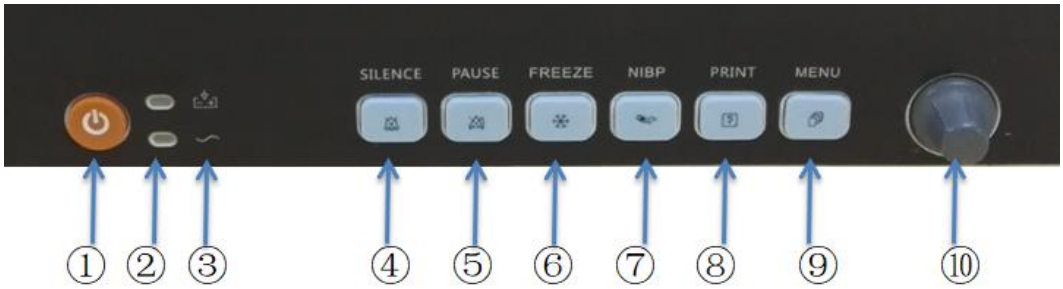
The above monitoring results are displayed in the Parameter Area.
The parameters refresh every second, except that NIBP values refresh each time the measurement is over.

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

Alarm indicator:

In the normal mode, no indicator is lights.
In alarm mode, the alarm indicator lights or flashes.

1.3 Button Function



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

1) Power key: key to turning on and turning off of the power;
2) AC led: when connect the AC power, the led will be lighted.
3) Battery led: when battery supplied, the led will be lighted.
4) Alarm silence key: With this key pressed down, sound of the alarm will shut down, also the "ALARM SILENCE" will be displayed in the information section, and other sounds (key sound, palpitation sound and so on) will not be affected. Pressing down the key again will restore all the alarms.
5) Alarm pausing key: With this key pressed down, the alarm may hang up for 2 minutes ("1 minute", "2 minutes" and "3 minutes" are optional), and the "ALARM PAUSE" will be demonstrated in the information section. All the alarm will be restored after this key is pressed again.
6) Freezing key: In the normal mode, all the waveforms on the screen will be frozen with this key pressed down. Pressing down this key once again will release the frozen waveforms;
7) Blood pressure key: Pressing down this key will start to charge the cuff with gas, and to measure the blood pressure. Pressing down the key once again can cancel the measurement;
8) Record/Stop key: If the monitor has a recorder, pressing down this key will start recording the real-time waveforms. Pressing the key again may stop recording;
9) Main menu key: press this key to returning to the main menu;
10) Knob key: With this key, the user may enter the menus and windows and change the monitor settings.

1.4 Interfaces

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

At the left side is the recorder

At the right side are the connectors to patient cables and the sensors, as shown in Figure 1-3.

① ECG: Socket for ECG cable
② NIBP: Socket for NIBP Cuff
③ SpO2: Socket for SPO2 Sensor
④ CO2: Socket for EtO2 Sensor (Optional)
⑤ TEMP1\TEMP2: Socket for TEMP probe
⑥ IBP1\IBP2:Socket for IBP transducer (Optional)

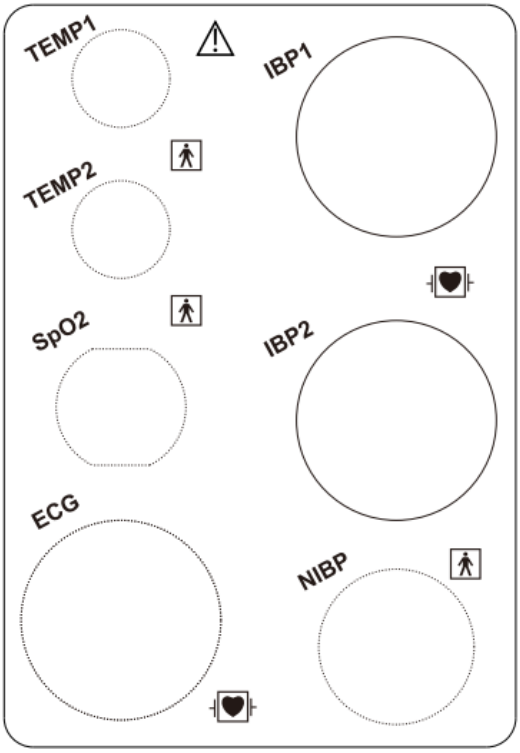


Figure 1-3 Right Side

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**.

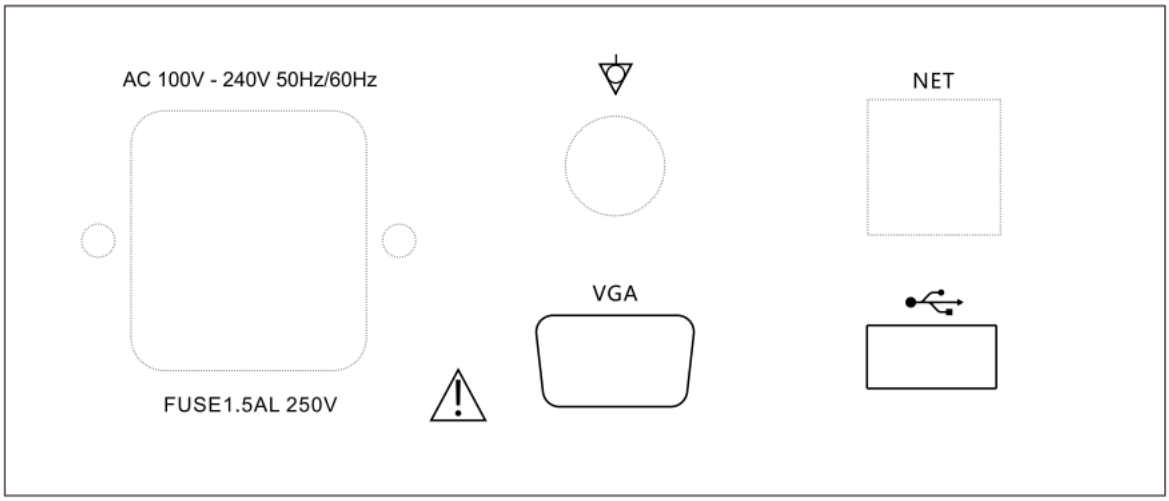


Figure 1-4 Rear Panel

On the rear panel are the following sockets, shown in Figure 1-4

Power Supply: 100~240 (VAC), 50/60 (Hz)

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

FUSE: 250V 1.5A fuse

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

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

Portable 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】

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

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

【NOTE】

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.

【NOTE】

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】

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

【NOTE】

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

【NOTE】

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

⚠ **Warning** ⚠

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

Service Center immediately.

【NOTE】

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

2.4 Connect Patient Sensors

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

2.5 Check the Recorder

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

Chapter 3 System Menu

Portable 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 “MONITOR SETUP”. The configuration is realized through operations on the MONITOR SETUP, as shown below.

Figure 3-1 SYSTEM MENU

- MONITOR SETUP
- MAINTENANCE
- MONITOR INFORMATION
- DEFAULT
- DRUG CALCULATION
- DEMO
- Recording
- New patient enrolment

The monitor can be set up using the Knob key to select the bottom menu bar as following Figure 3-2, 3-3, 3-4

Figure 3-2 SYSTEM MENU ON THE BUTTOM

Figure 3-3 SYSTEM MENU ON THE BUTTOM

Figure 3-4 SYSTEM MENU ON THE BUTTOM

3.1 Patient Information Setup

【NOTE】

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

Press the Knob key to select “PATIENT” from the bottom menu to call up the following menu.

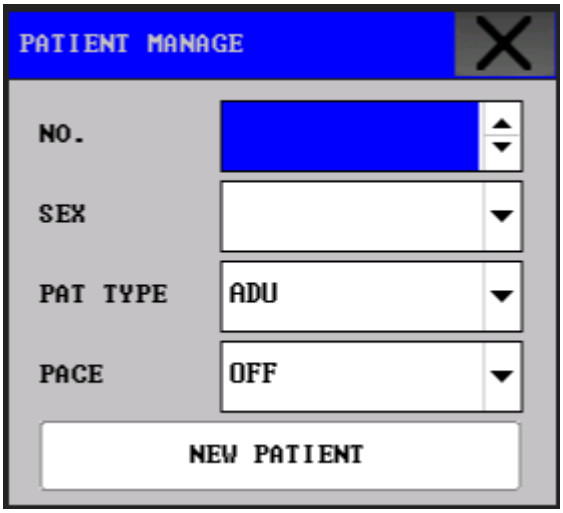


Figure 3-5 PATIENT SETUP

You can setup the following patient record:

NO	Patient bed number (Range: 1-200)
SEX	Patient gender (Available options: "F" for Female, "M" for Male)
PAT TYPE	Patient type (Available options: ADU, PED, and NEO)
PACE	Pace ON or OFF
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.

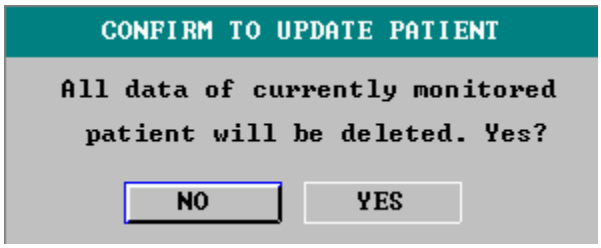


Figure 3-6 NEW PATIENT Menu

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:

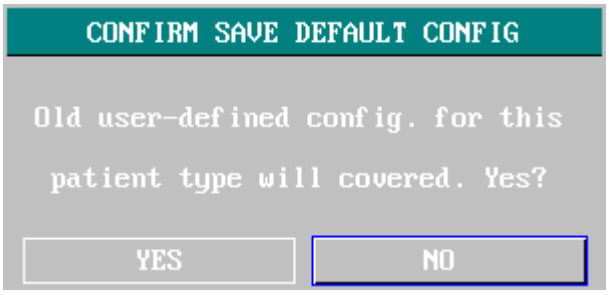


Figure 3-7 CONFIRM SAVE DEFAULT CONFIG

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.

NIBP Recall

The monitor can review the latest 400 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.

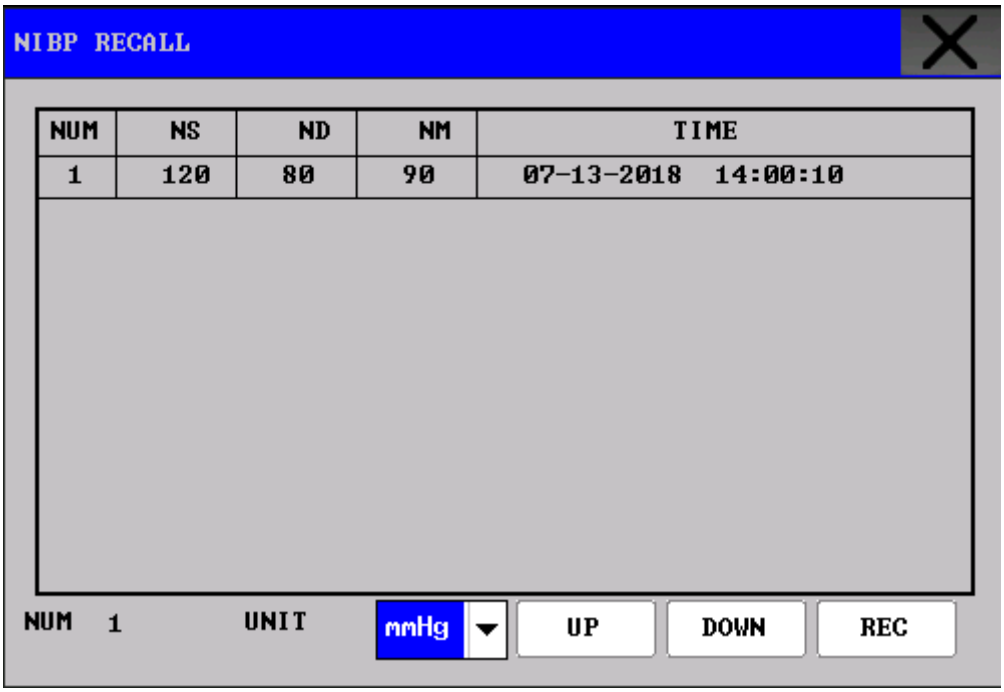


Figure 3-8 NIBP RECALL

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 400 results. Pick REC to print out all measurement data of NIBP RECALL.

3.3 Monitor Information

Select the "INFO" item from the "SYSTEM MENU" to know the software version of the monitor.

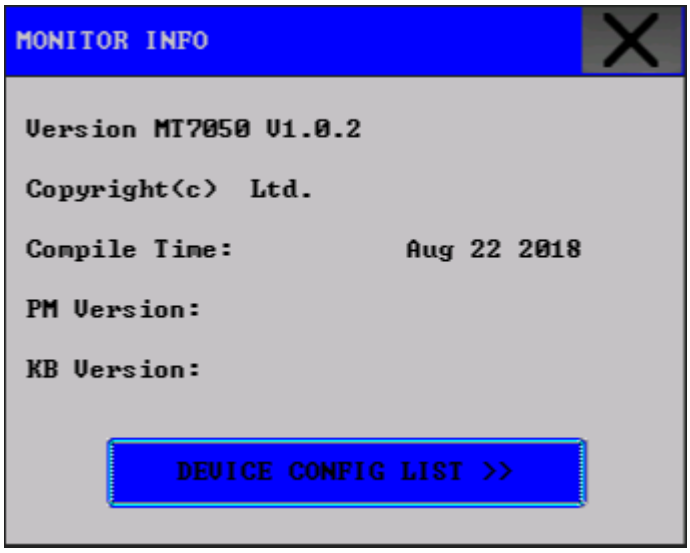


Figure 3-9 Version

Select the [DEVICE CONFIG LIST] to know the configuration of the monitor.

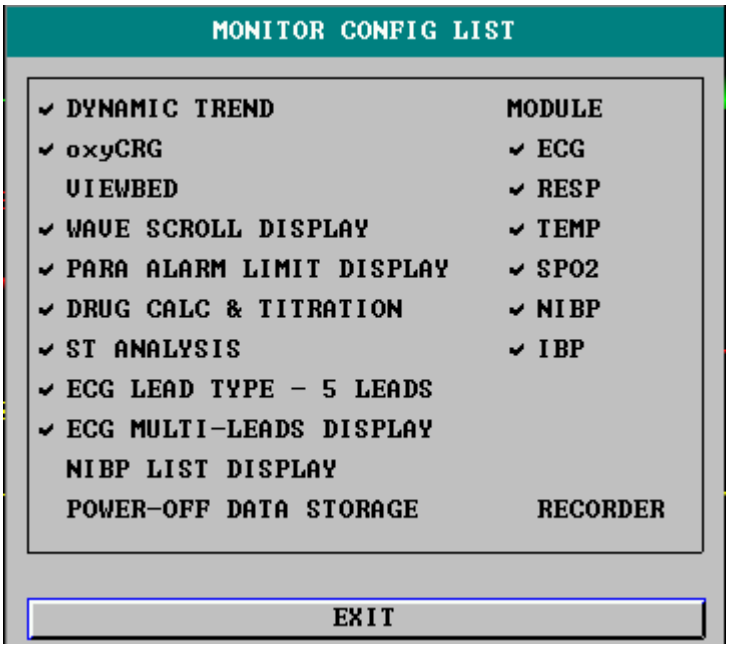


Figure 3-10 Monitor Info

3.4 Monitor Setup

Select the “MONITOR” item from the “SYSTEM MENU” to know below

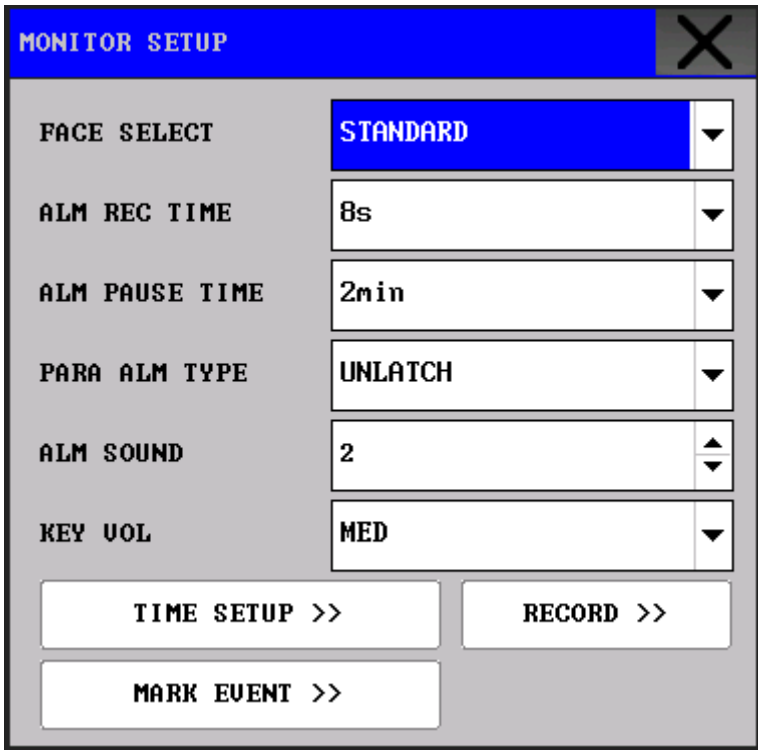


Figure 3-11 Monitor Setup

3.5.1 Alarm Limit

The system can display the alarm limit. The method is:
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 press "×" in the top right corner to return to the previous menu.

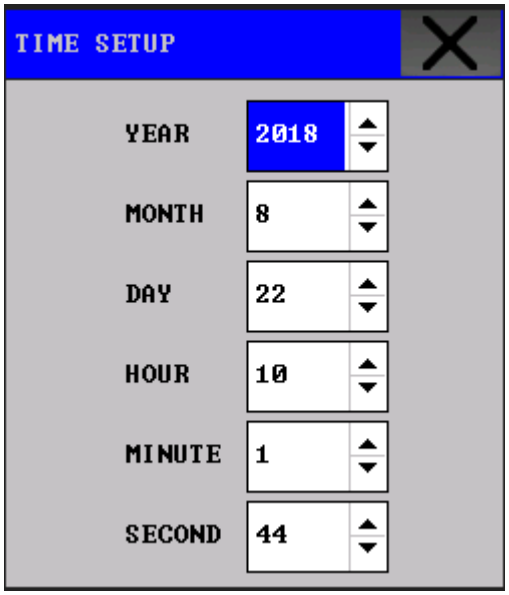


Figure 3-12 TIME SETUP

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 press "×" in the top right corner 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 (For optional)

Select "RECORD" in “MONITOR SETUP” menu to call up the following menu:

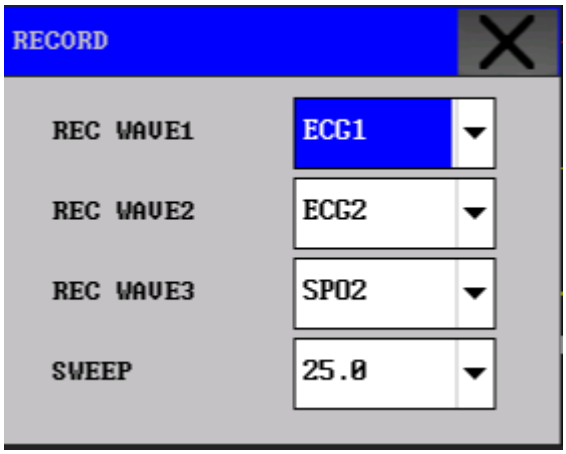


Figure 3-14 RECORD Menu

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

ECG1-ECG2

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.

IBP The IBP waveform on the screen (This item cannot be picked if no IBP waveform displaying on the screen.).

RESP RESP waveform (This item cannot be picked if no RESP waveform displaying on the screen.)

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】

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.

【NOTE】
The recorder is an optional part.

【NOTE】
If two same waveforms are selected, one of them is switched to a different waveform automatically.

3.6 Maintenance

Select “MAINTAIN” item in “MONITOR SETUP” 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.

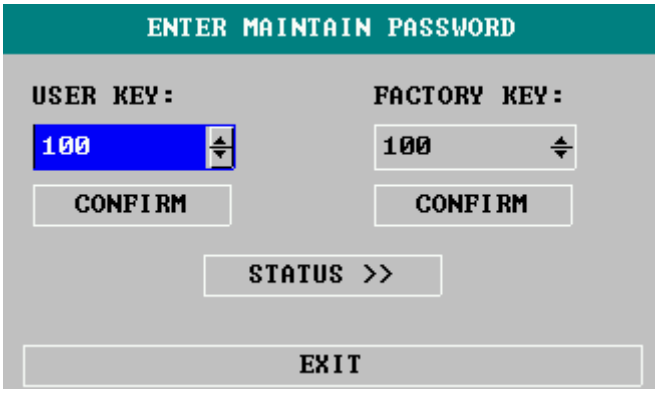


Figure 3-15 ENTER MAINTAIN PASSWORD

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 startup 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.

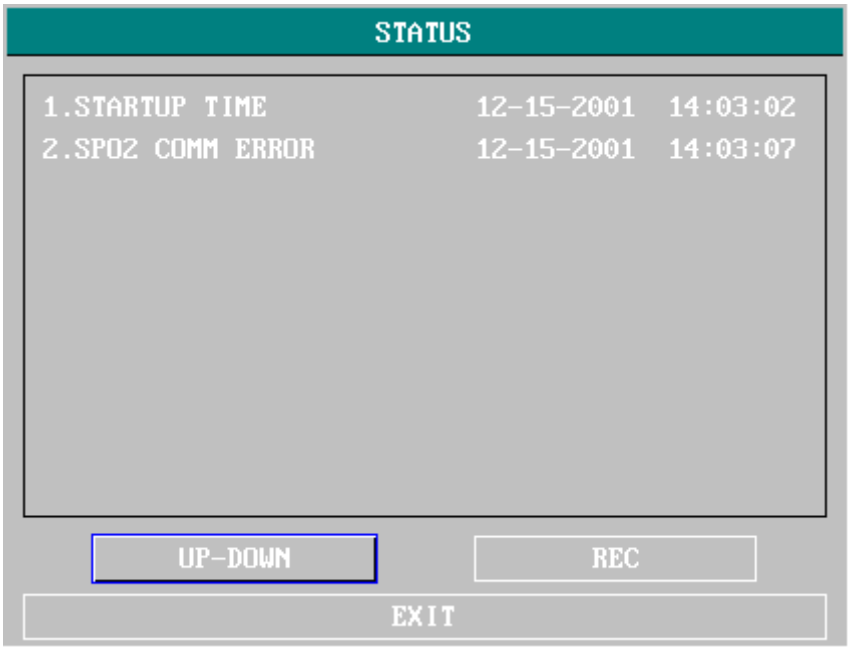


Figure 3-16 STATUS

For user default, enter the user key (105) 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

- 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.

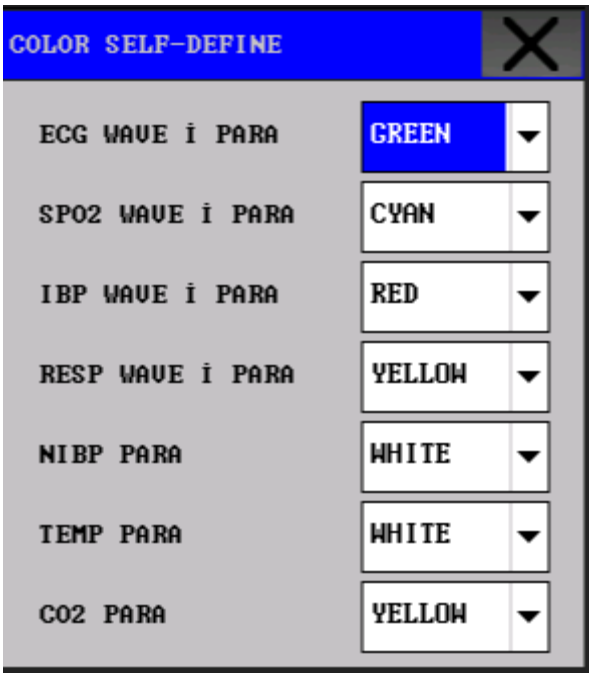


Figure 3-18 COLOR SELF-DEFINE

3.7 DEMO function

Select the “DEMO” item in the “MONITOR SETUP” to call up the “ENTER DEMO PASSWORD”. After entering the password (101), the system enters DEMO status.

The purpose of waveform demonstration is only to demonstrate the machine performance, and for training purpose. In clinical application, this function is 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.

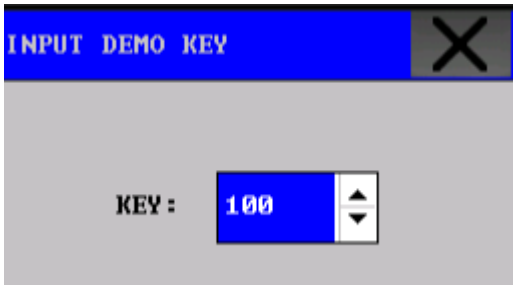


Figure 3-19 Input Demo Key

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 high frequency electricity knife. If the correct electrodes are used and applied in accordance with the manufacturer instructions, the screen display will recover within 10 seconds after 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 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 Portable Patient Monitor must be grounded. Accordingly, the 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 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 INSTRUMENT 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 ⚠

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.

⚠ Warning ⚠

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

Explanation of Symbols in the Monitor

 This symbol means 'BE CAREFUL '. Refer to the manual.

 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.

 This symbol indicates that the instrument is Type BF 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 Type BF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part.

 Equipotential grounding system

Protective earth ground

 On/Off

Chapter 5Care / 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 the MEDICAL INSTRUMENT 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** ⚠

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.

⚠ **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.

⚠ **Warning** ⚠

Refer the battery replacement only to our service technician.

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.**

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** ⚠

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

⚠ **Note** ⚠

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 leads, SpO2 sensor, blood pressure cuff, TEMP probe, IBP sensor and CO cables 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 cannot by changed once defined by the system. Alarms in 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 cannot be categorized into these two cases but still need to pay some attention.
has preset the alarm level for the parameters. You can also modify the alarm level using the method described in this chapter.

Alarm level of the System Error Message (technical alarm) is pre-set in the system.
All technical alarm level and general alarm level, some of the physiological alarm level are pre-set in the system and cannot be changed by user.

6.1.2 Alarm Modes

When alarm occurs, 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 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】

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.

【NOTE】

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

【NOTE】

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

Press the “MONITOR” button on the MONITOR SETUP menu as shown below, the user may set up the information about common alarm setup:

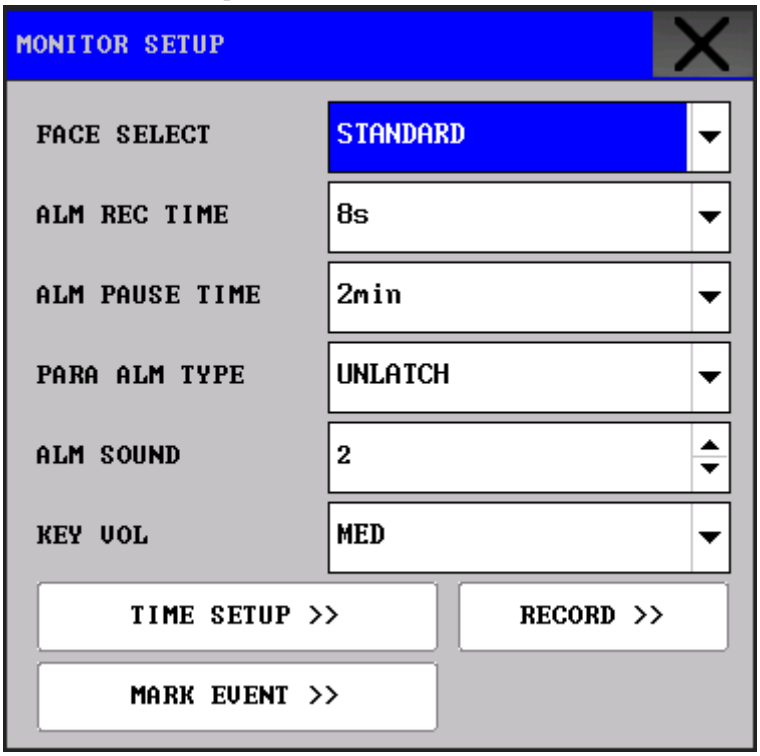


Figure 6-1 ALARM SETUP

- **COMMON ALM SETUP**
- 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: 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.
- ALM SOUND: 0,1,2,3,4
- **Alarm setup of each parameter**

The alarm setup of each parameter like HR, ST, PVC, SPO2, NIBP, IBP, RESP and TEMP can be realized in the “ALARM” menu from the bottom menu as following:

Figure 6-2 ALARM SETUP

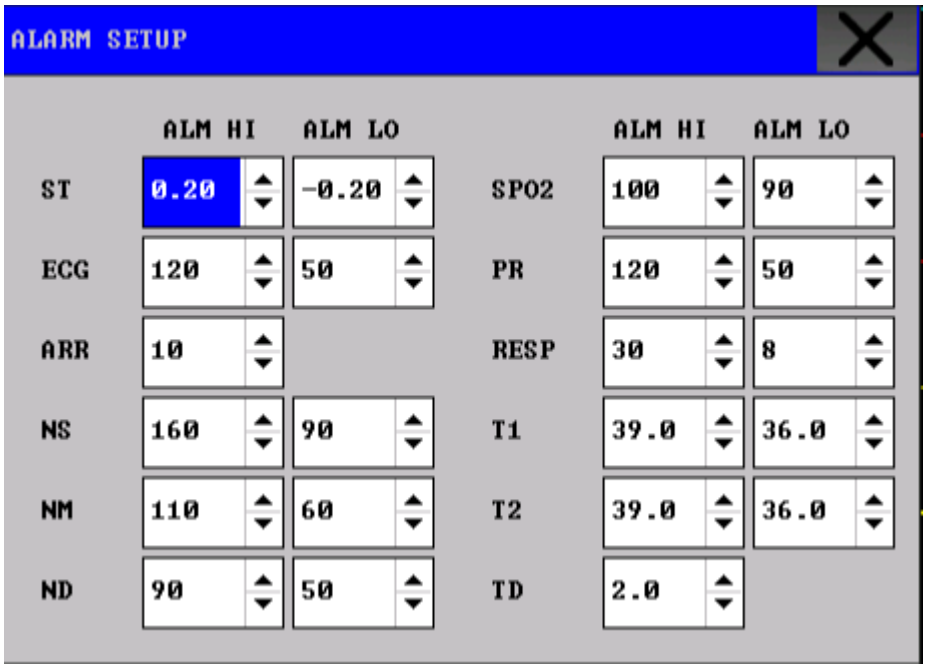


Figure 6-3 ALARM SETUP

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.

Chapter 7Recording (Optional)

- General information on recording
- Instructions for configuring and recording
- Recording messages

7.1 General Information on Recording

A thermal dot matrices recorder with 48mm wide printout paper is used for Portable Patient Monitor.

Performance of the Recorder

- Waveform record is printed out at a rate of 25 or 50 mm/s.
- It can record up to 2 waveforms.
- Output with grid selectable.
- English / Chinese printout.
- The real time recording time and waveform are user-configurable.
- Auto recording interval is set by the user, the waveform is in accordance with the real time recording.
- The alarm recording waveform is automatically selected by the monitor.

7.2 Recording Type

It provides several stripe recording types:

- Continuous real-time recording
- 8 second real-time recording
- Auto 8 second recording
- Alarm recording
- Waveform freeze recording
- Trend graph/table recording
- ARR events review recording
- Alarm event recording
- NIBP review recording
- Monitor information recording
- Drug calculation titration recording
- OxyCRG recording

Real-time Recording

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

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

In RECORD menu, the user can choose two waveforms to be printed out. The User can setup one waveform off. Thus, the real time record will print out one waveform. If two waveforms are off, the real time record will print out measure parameters only.

NOTE

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

7.3.1 Auto recording

The monitor starts the recorder for 8 seconds according to interval time set in the “TIMING REC TIME” of the “RECORDER ” menu.

7.3.2 Alarm Recording

1. Parameter Alarm

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

When parameter alarm occurs, two recorded waveforms can be printed out.

In order to avoid repeated printout of alarm waveforms:

- If more than two parameter alarms are switched on and triggered simultaneously, the recorder will print out those of the highest level. If of the same alarm level, the latest alarm will be printed out.
- If an alarm occurs during the alarm of another parameter, it will be printed out after the current recording is finished.
- If many alarms occur at the same time, some of waveforms will be stored for printout in turn.

2. 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.

3. 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.

7.3.3 Freeze Waveform Recording

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

7.3.4 Trend Graph / Table Recording

The monitor can print out the trend graph and table in the current TREND GRAPH or TREND TABLE window.

7.3.5 Arrhythmia Review Recording

The monitor can print out the alarm Arrhythmia event in the current ARR RECALL window.

7.3.6 Alarm Review Recording

The monitor can print out the alarm events include waves and parameters in the current ALARM RECALL window.

7.3.7 NIBP Review Recording

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

7.3.8 Monitor Information

The monitor can print out messages in the current STATUS window.

7.3.9 Titration Table

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

7.3.10 Notes on Recording

- Recording texts:
  Real time Report
  Periodic Report
  Para Alarm Report: XXX (name of the alarm parameter)
  Arrhythmia Report: XXX (Arrhythmia type)
  Freeze Wave Report
  Trend Graph
  Trend Table
  Para Alarm Review
  NIBP Test Review
  Status Report
  Titration Table

- Alarm parameters, alarm time and freeze time.
- Patient bed number, name, sex, height, weight, date of birth, admission date.
- Parameter name and value
- Recording time
- Waveform name
- Waveform scale (for ECG waveform)
- ECG lead, scale, filter mode, (if having ECG waveforms, it will be printed out within the first second or when changing the lead, gain and filter mode during real-time recording.)
- IBP scale (the first second of IBP waveform)
- Date and time
- Company name

7.3 Recording Startup

You can start the recording in the following ways:

Continuous real-time recording	Press REC/STOP to start/stop the recording.
8 second real-time recording	Press REC/STOP to start recording. It will automatically stop in 8 seconds.
Auto recording	Record the two waveforms selected in RECORD menu according to the setup time interval in RECORD menu.
Alarm recording	When alarm recording is set ON, it automatically starts when alarm occurs.
Frozen waveform recording	---After accessing FREEZE menu, use knob to select two waveforms to be output. Then press REC button in the menu to print out the waveforms.  If two waveforms are off, the measure parameters in frozen are printed out only.
Trend graph recording	Pick “REC” button in the “TREND GRAPH” menu when viewing the trend graph to print out the currently displayed trend graph.
Trend table recording	Pick “REC” button in the “TREND TABLE” menu when viewing the trend table to printout the currently displayed trend table.
Arrhythmia review recording	Access ARR RECALL window from ARR ANALYSIS of ECG SETUP menu and Pick “WAVE” button to access “ARR

	WAVE RECALL" window. Then press "REC" button to output the Arr. waveform and related information currently displayed on the screen.
Alarm review recording	Access the "ALARM RECALL" window from "ALARM RECALL CONDITION" menu from "SYSTEM MENU" and pick "REC" button to print out the alarm review waveform and related information currently displayed in the "ALARM RECALL" window.
NIBP review recording	Access the "NIBP RECALL" window from "SYSTEM MENU" and pick "REC" button to print out the NIBP information currently displayed in the window.
Monitor information recording	Access the "ENTER MAINTAIN PASSWORD" menu from the "MAINTAIN" menu. Then pick the "STATUS" button to access the "STATUS" window. Pick "REC" button to print out the status monitor information currently displayed in the window.
Titration table recording	Access the "DRUG CALC" menu from the "SYSTEM MENU" menu. Pick the "TITRATION" button in the menu to access the "TITRATION" window. Pick the "REC" button to print out the titration currently displayed in the window.
Oxy CRG recording	In oxy CRG screen, pick the "RED" button to put out the oxy CRG currently displayed in the window.

【NOTE】

You can press REC/STOP button on the recorder to stop the current recording process.

Access the "RECORD" menu from the "MONITOR SETUP" menu. Then pick the "CLEAR REC TASK" button to stop all recording tasks.

7.4 Recorder Operations and Status Messages

Record Paper Requirement

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

Function Properly

- When the recorder is working, the record paper goes out steadily. Do not pull the paper, or the recorder will be damaged.

- Do not operate the recorder without record paper.

Paper Out

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

Inserting Paper

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

【NOTE】

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

Removing Paper Jam

Please open the recorder catch to check for a paper jam when the recorder functions or sounds improperly, removing the paper jam in the following way:

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

Chapter 8 ECG/RESP Monitoring

8.1 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, 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.

8.2 Precautions during ECG Monitoring

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

Use only the original ECG cable for monitoring.

⚠ **Warning** ⚠

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

【 NOTE 】

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

8.3 Monitoring Procedure

8.3.1 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** ⚠

Check every day whether there is skin irritation resulted from the ECG electrodes. If so, replace electrodes every 24 hours or change their sites.

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

⚠ **Warning** ⚠

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.

8.3.2 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

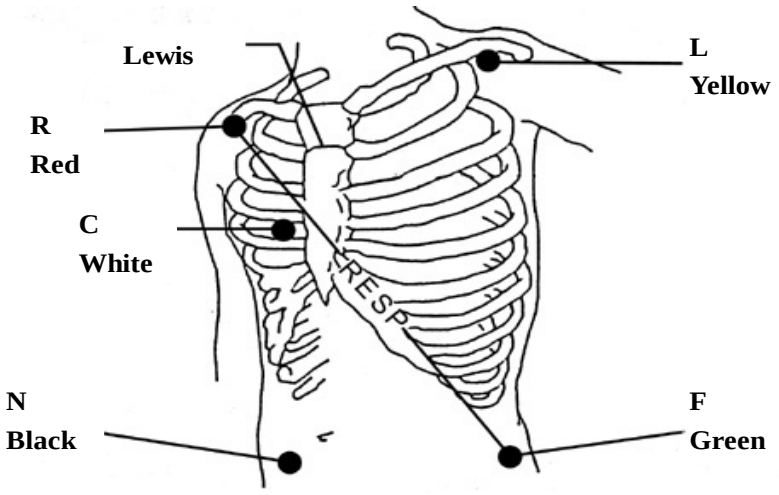


Figure 8-2 Electrode placement for 5-lead set

【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 (Figure 8-3):

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

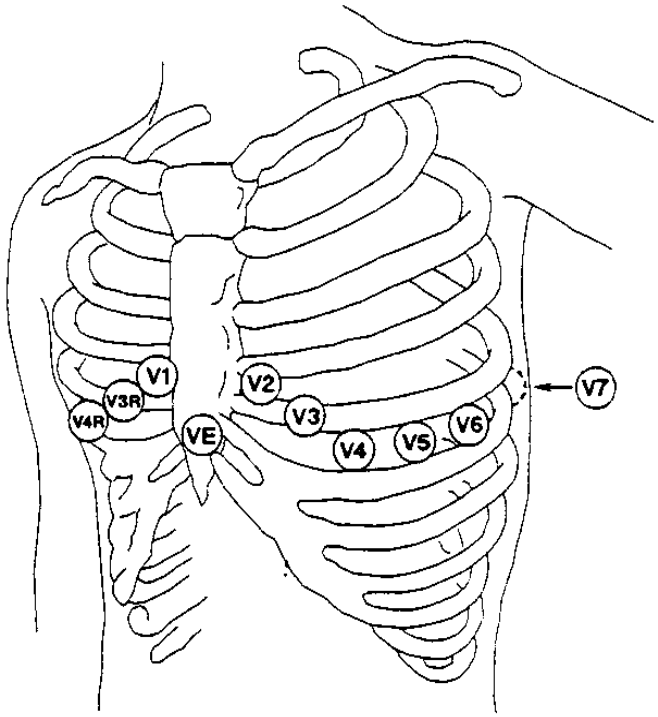


Figure 8-3 C-electrode placement for 5-lead set

Recommended ECG Lead Placement for Surgical Patients

⚠ **Warning** ⚠

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.

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)

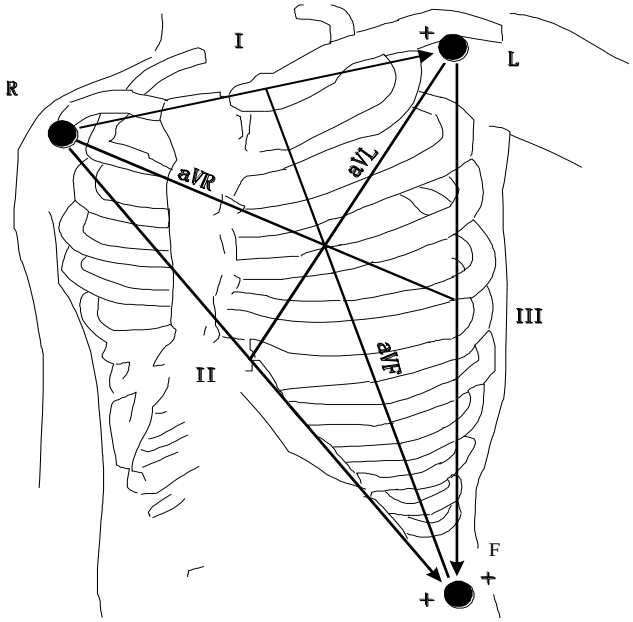


Figure 8-4 ECG lead

【 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.

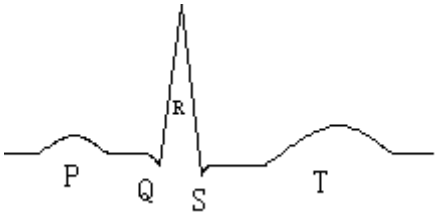


Figure 8-5 Standard ECG Waveform

⚠ **Warning** ⚠

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

8.4 ECG Menu

ECG SETUP Menu

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

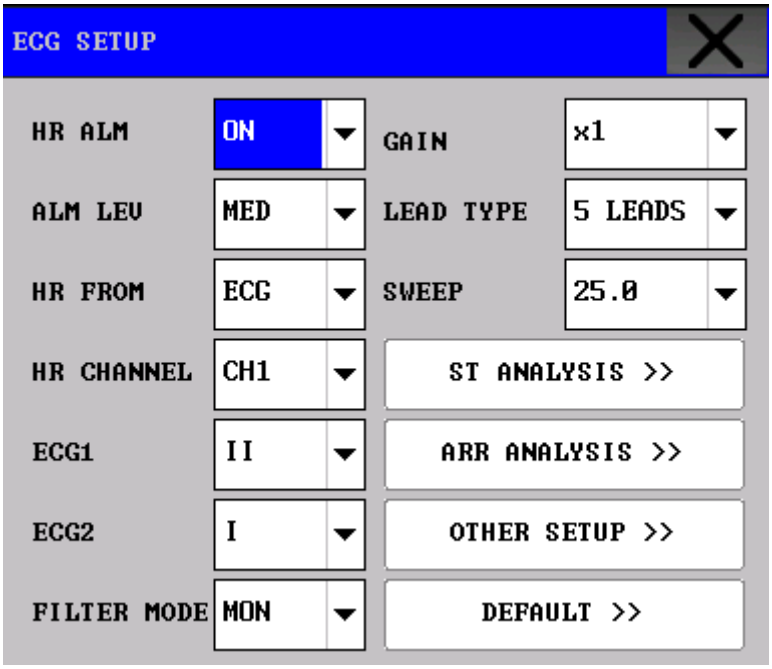


Figure 8-6 ECG SETUP menu

- 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.
  - 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
  - ECG1: Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V
  - ECG2: Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V
  - FILTER MODE: MON, SUR, DIA
  - LED TYPE: 3 LEADS, 5 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:

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

ECG alarm limits:

	Max. ALM HI	Min. ALM LO	Step
HR ADU	300	15	1
HR PED	350	15	1
HR NEO	350	15	1

【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.

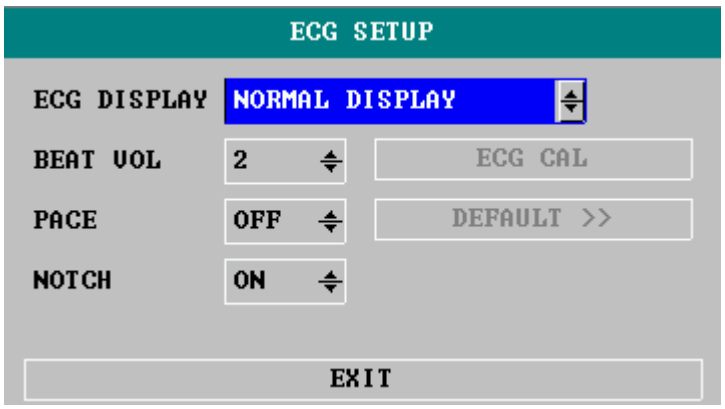


Figure 8-7 ECG SETUP menu

In the sub-menu, following functions are available:

- ECG DISPLAY

  Select NORMAL DISPLAY to display 2 ECG waveforms for 5-lead (for 3-lead, only 1 ECG waveform is displayed.). Select MULTI-LEADS DISPLAY, the waveform area on the screen displays 7 ECG waveforms, and is occupied 7 waveforms position. Select HALF-SCAN MUTTI-LEADS, there are 7 ECG waveforms are displayed on the screen，they occupy 4 waveforms position.

  Note: If 3 LEADS is selected in the ECG SETUP menu, only NORMAL DISPLAY can be selected for ECG DISPLAY item in the sub-menu.

- 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.

8.5 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	HR measuring value is above the upper alarm limit	User-selectable
HR TOO LOW	HR measuring value is below the lower 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 V LEAD OFF or ECG C LEAD OFF			
ECG LL LEAD OFF or ECG F LEAD OFF			
ECG LA LEAD OFF or ECG L LEAD OFF			
ECG RA LEAD OFF or ECG R LEAD OFF			
ECG INIT ERR	ECG module failure	HIGH	Stop using measuring function provided by ECG module, notifies bioMEDICAL INSTRUMENT engineer or service staff.
ECG INIT ERR1			
ECG INIT ERR2			
ECG INIT ERR3			
ECG INIT ERR4			
ECG INIT ERR5			
ECG INIT ERR6			
ECG INIT ERR7			
ECG INIT ERR8			
ECG COMM STOP	Occasional communication failure	HIGH	If failure persists, notify bioMEDICAL INSTRUMENT engineer or service staff.
ECG COMM ERR	Occasional communication failure	HIGH	If failure persists, notify bioMEDICAL INSTRUMENT engineer or service staff.
HR ALM LMT ERR	Functional safety failure	HIGH	Stop using HR alarm function, notify bioMEDICAL INSTRUMENT engineer or service staff.

ECG NOISE	ECG measuring signal is greatly interfered.	LOW	Make sure the patient is quiet, the electrodes are properly connected and AC power system is well grounded.

Prompt messages (include general alerts):

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

8.6 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.

8.6.1 ST ANALYSIS menu

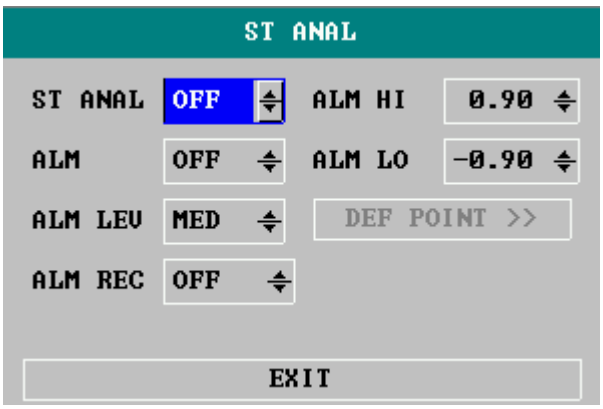


Figure 8-8 ST ANALYSIS menu

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.

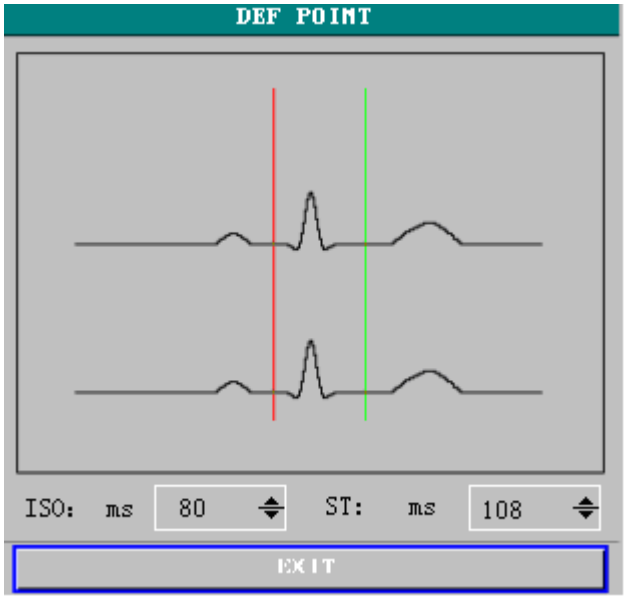


Figure 8-9 DEF POINT window

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).

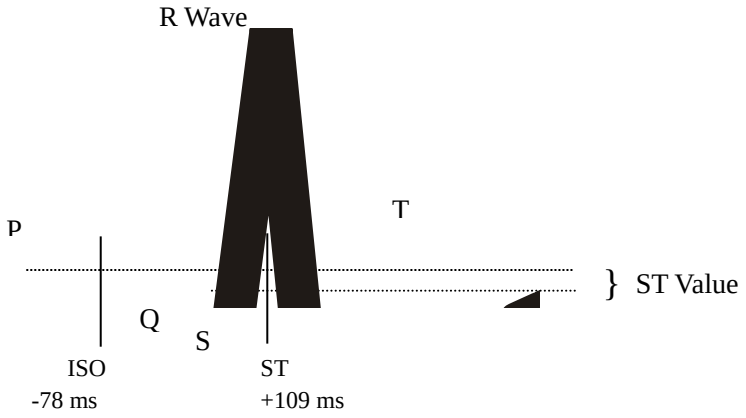


Figure 8-10 DEF Point

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.

8.6.2 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
ST1 TOO HIGH	ST measuring value of channel 1 is above the upper alarm limit.	User-selectable
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 bioMEDICAL INSTRUMENT 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

8.7 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.

8.7.1 ARR ANALYSIS Menu

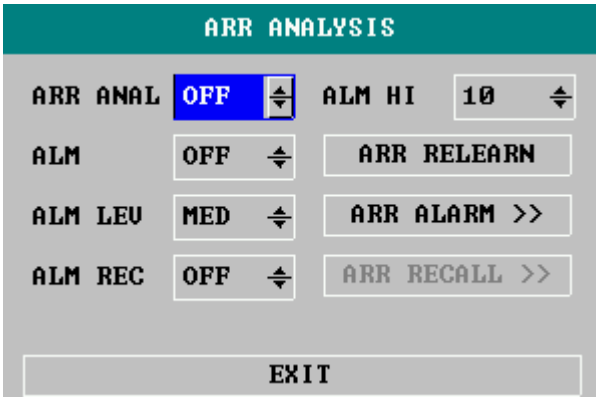


Figure 8-11 ARR ANALYSIS Menu

- 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.

Figure 8-12 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.

■ ARR RECALL Pick this item to review and edit the ARR analysis result.

The latest arrhythmia events (up to 60) are displayed.

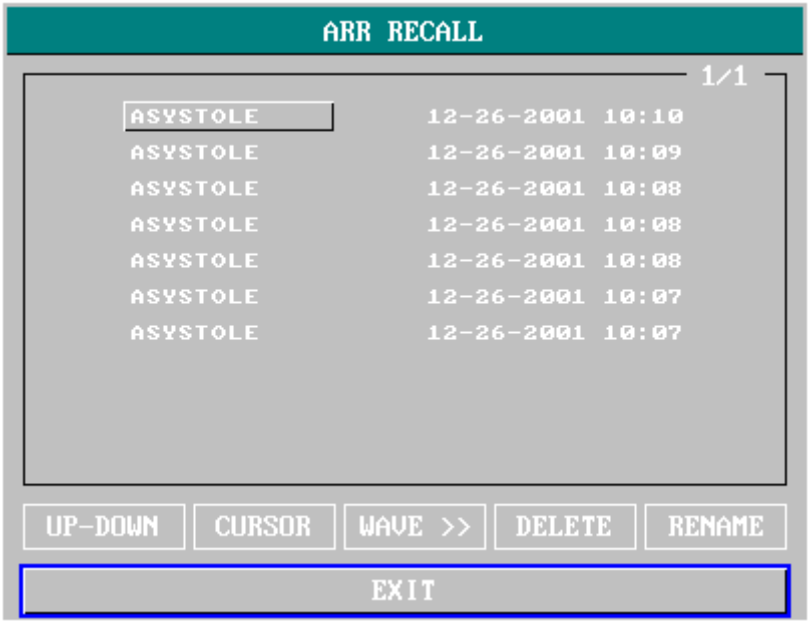


Figure 8-13 ARR RECALL Menu

- UP-DOWN Observe other event lists of other page.
- CURSOR Select the Arr. event, whose name is displayed in a protruding frame.
- DELETE Delete the selected Arr. event.
- RENAME Rename the selected Arr. event, whose name is displayed in a sunken frame.
  Switch the knob until the name you want appears.
- WAVE To display the Arrhythmia waveform, time and parameter value.
  - UP-DOWN To observe waveforms of other Arrhythmia events.
  - L_RIGHT To observe 8-second waveform of Arrhythmia events.
  - REC To print out displayed Arrhythmia event.
  - EXIT To return to ARR RECALL menu of Arrhythmia event.

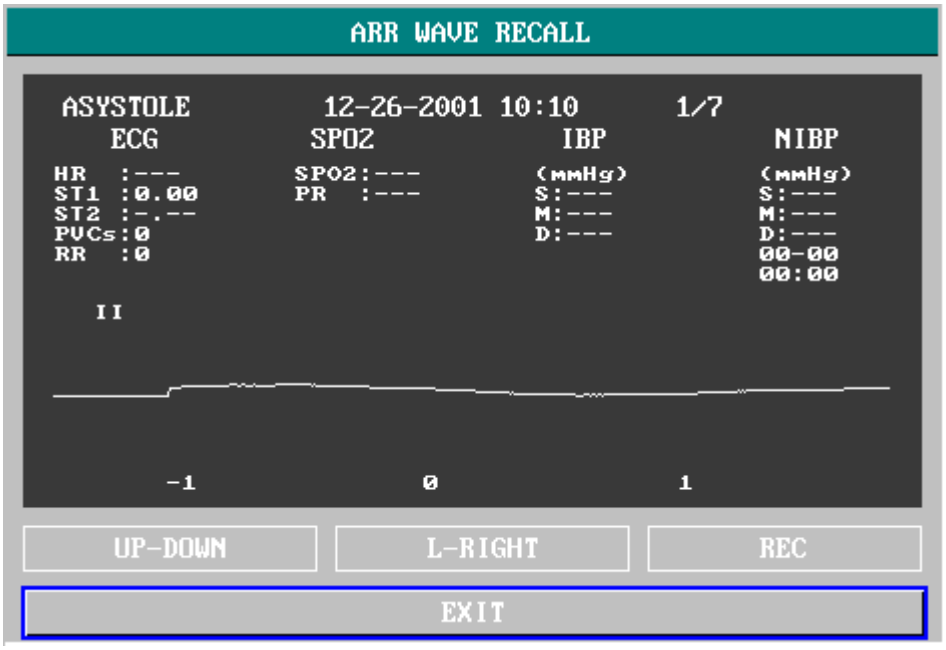


Figure 8-14 ARR WAVE RECALL Menu

【NOTE】

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

8.7.2 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-selectable

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-selectable

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.

8.8 Measuring RESP

8.8.1 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.

8.8.2 Setting Up RESP measurement

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

Some patients, due to their clinical condition, expand their chest laterally, causing a negative

intrathoracic pressure. In these cases it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of breathing movement to optimize the respiratory waveform.

【NOTE】

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

Checklist for RESP Monitoring

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

8.8.3 Installing electrode for RESP measurement

Placing the Electrodes for Respiratory Monitoring

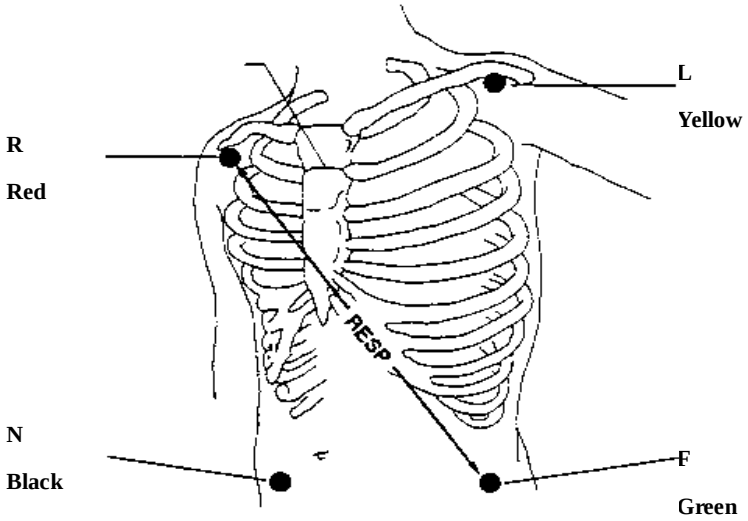


Figure 8-15 Electrodes placement (5-lead)

【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.

8.8.4 RESP menu

RESP SETUP Menu

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

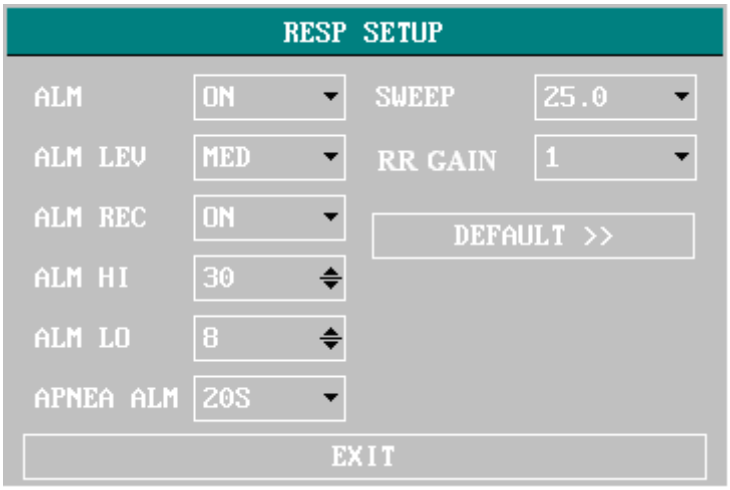


Figure 8-16 RESP SETUP Menu

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.
- ALM LEV: selectable from HIGH, MED and LOW. Level HIGH represents the most serious case.
- ALM HI: used to set up the upper alarm limit.
- ALM LO: used to set up the lower alarm limit.
  RESP alarm is activated when the respiration rate exceeds set ALM HI value or falls below ALM LO value.

RESP alarm limits:

	Max. RR HI	Min. RR LO	Step
RESP ADU	120	0	1
RESP NEO/PED	150	0	1

- 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 bioMEDICAL INSTRUMENT engineer or service staff.

Prompt message (general alerts):

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

8.9 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.

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.

■ Cleaning
Use fine-hair cloth moistened in mild soap liquid or cleaning agent containing 70% ethanol to clean the equipment.

■ 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: 70% alcohol, 70% isopropanol
- Acetaldehyde

■ 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.

Chapter 9SpO2 Monitoring

9.1 What is SpO_2 Monitoring

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

9.1.1 How the SpO_2 / 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 SpO_2 value and the PLETH waveform can be displayed on the main screen.

⚠ **Warning** ⚠

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

9.1.1 SpO_2 / Pulse Monitoring

⚠ **Warning** ⚠

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

⚠ **Warning** ⚠

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

【Note】

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

9.2 Precautions during SpO_2/Pulse Monitoring

【Note】

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

【Note】

SpO_2 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】

SpO_2 waveform is not proportional to the pulse volume.

⚠ **Warning** ⚠

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

⚠ Warning ⚠

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

⚠ **Warning** ⚠

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.

9.3 Monitoring Procedure

SpO_2 plethysmogram measurement

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

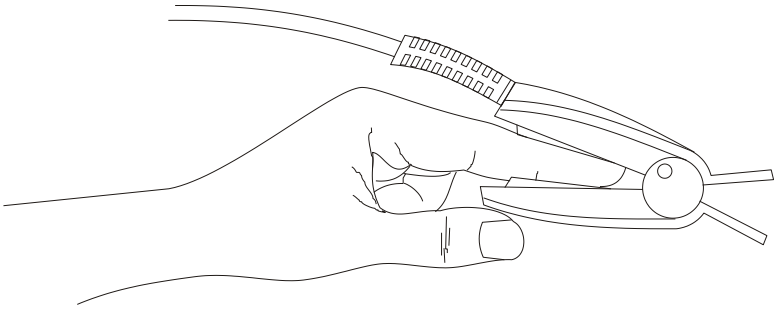


Figure 9-17 mounting of the sensor

9.4 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 SpO_2 sensors described in chapter Accessories and Ordering Information.**

9.5 SpO_2 Menu

SPO2 SETUP Menu

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

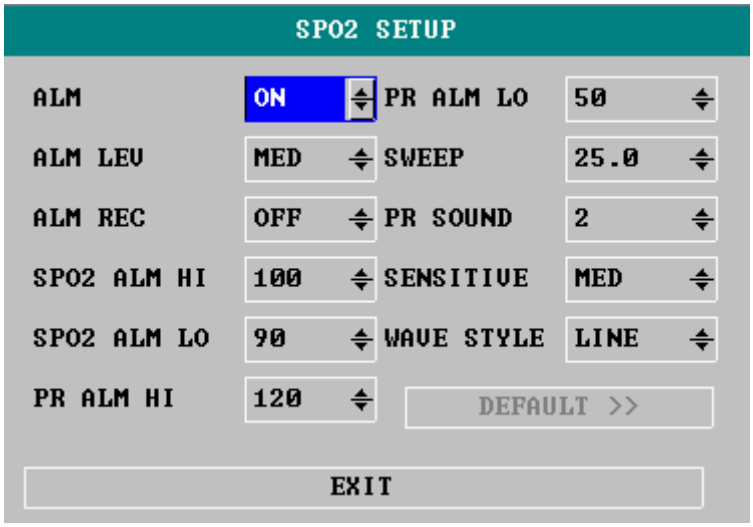


Figure 9-18 SPO2 SETUP menu

⚠ **Warning** ⚠

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

- SpO_2 alarm setting
  - ALM: pick "ON" to enable prompt message and data record during the SpO_2 alarm;

    pick "OFF" to disable the alarm function, and there will be a  beside "SpO_2".
  - ALM REC: pick "ON" to enable report printing upon SpO_2 alarm.
  - ALM LEV: used to set up alarm level, selectable from HIGH, MED and LOW. HIGH represents the most serious case.
  - SPO2 ALM HI and SPO2 ALM LO:SpO2 alarm is activated when the result exceeds set SPO2 ALM HI value or falls below SPO2 ALM LO value. Use the knob to pick the SPO2 ALM HI or SPO2 ALM LO item and turn the knob to select the desired alarm limit.
  - PR ALM HI and PR ALM LO: PR alarm is activated when the pulse rate exceeds set PR ALM HI value or falls below PR ALM LO value. Use the knob to pick the PR ALM HI or PR ALM LO item and turn the knob to select the desired alarm limit.

SpO2 and PR alarm limits:

	Max. Upper Limit	Min. Lower Limit	Step

SpO2	100	0	1
PR	254	0	1

- 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 SpO_2 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.

9.6 Alarm Description and Prompt

SpO_2 Alarm Message

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

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

Physiological alarm:

Message	Cause	Alarm Level
SPO2TOO HIGH	SpO2 measuring value is above 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	Al arm 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.
SPO2 INIT ERR	SpO2 module failure	HIGH	Stop using the measuring function of SpO2 module, notify bioMEDICAL INSTRUMENT engineer or service staff.
SPO2 COMM STOP	SpO2 module failure or communication error	HIGH	Stop using the measuring function of SpO2 module, notify bioMEDICAL INSTRUMENT engineer or service staff.
SPO2 COMM ERR	SpO2 module failure or communication error	HIGH	Stop using the measuring function of SpO2 module, notify bioMEDICAL INSTRUMENT engineer or service staff.
SPO2 ALM LMT ERR	Functional safety failure	HIGH	Stop using the measuring function of SpO2 module, notify bioMEDICAL INSTRUMENT engineer or service staff.
PR ALM LMT ERR	Functional safety failure	HIGH	Stop using the measuring function of SpO2 module, notify bioMEDICAL INSTRUMENT engineer or service staff.

Prompt message (include general alerts):

Message	Cause	Alarm Level
SPO2 EXCEED	SpO2 measuring value exceeds the range.	HIGH
PR EXCEED	PR measuring value exceeds the range.	HIGH
SEARCH PULSE	SpO2 module is searching for pulse.	No alarm
NO PULSE	SpO2 module cannot detect SpO2 signal for a long time.	HIGH

9.7 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.

⚠ **Warning** ⚠

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 10TEMP Monitoring

10.1 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** ⚠

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

【Note】
Disposable TEMP probe can only be used once for one patient.

⚠ **Warning** ⚠

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.

⚠ **Warning** ⚠

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】

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.

10.2 TEMP SETUP Menu

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

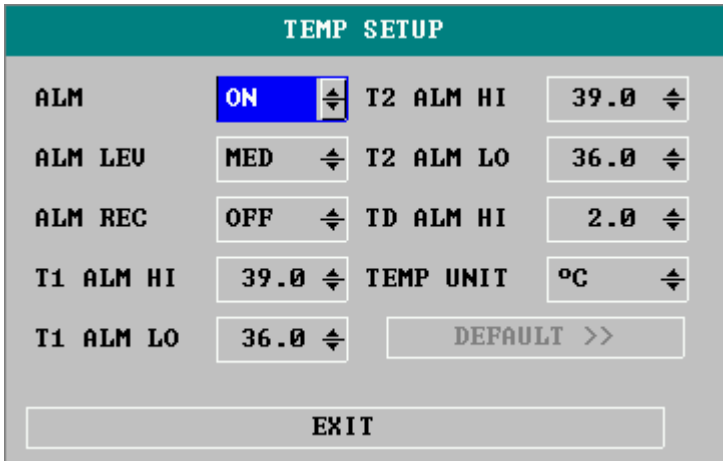


Figure 10-19 TEMP SETUP Menu

- 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.

10.3 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 bioMEDICAL INSTRUMENT engineer or service staff.

Prompt message:

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

10.4 Care and Cleaning

⚠ **Warning** ⚠

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

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 The probe must not be sterilized in steam.
3 Only detergents containing no alcohol can be used for disaffection.
4 The rectal probes should be used, if possible, in conjunction with a protective rubber cover.
5 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.

Note

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

Note

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

Chapter 11 NIBP Monitoring

11.1 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.**

11.2 NIBP Measuring

11.2.1 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.**

⚠ **Warning** ⚠

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 11-20).

■ 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.

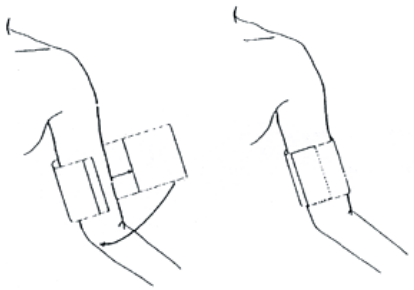


Figure 11-20 Applying Cuff

□ 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**

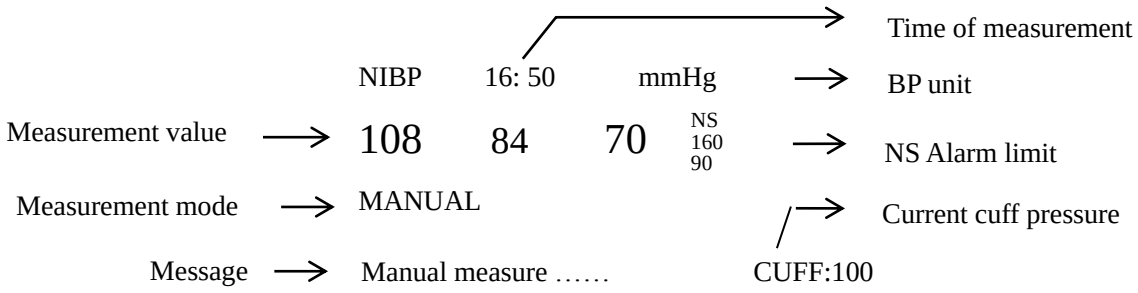
If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

- **Heart Rate Extremes**

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

11.2.2 NIBP monitoring screen

NIBP measurement result and corresponding message are displayed as follows:



11.3 NIBP SETUP menu

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

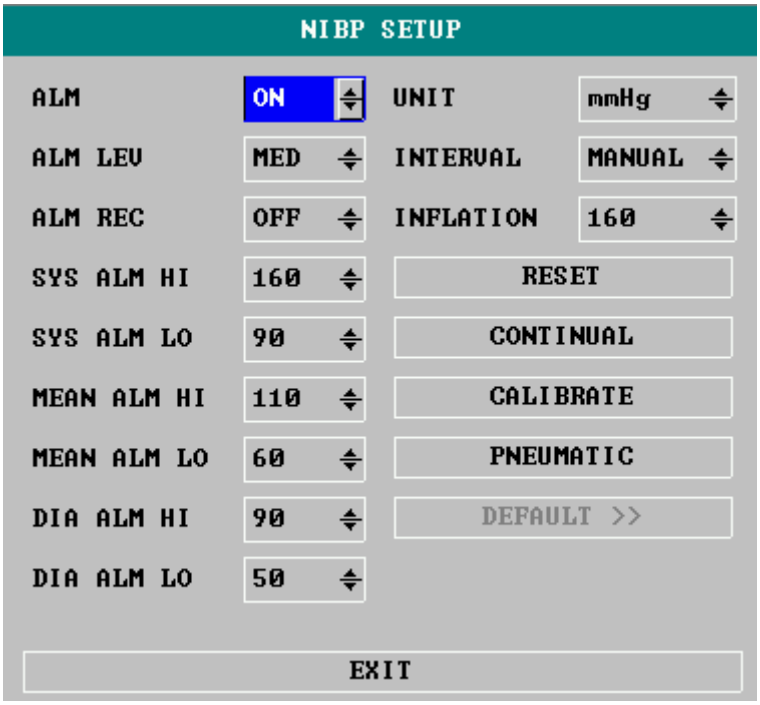


Figure 11-21 NIBP SETUP Menu

- 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.

11.4 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 12 IBP Monitoring(Optional)

12.1 Introduction

The Monitor measures direct blood pressure (SYS, DIA and MAP) of one selected blood vessel through two channels, and displays two BP waveforms measures direct blood pressure (SYS, DIA and MAP).

The available pressure labels are:

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

12.2 Precautions during IBP Monitoring

⚠ **Warning** ⚠

The operator should avoid contact with the conductive parts of the appurtenance when being connected or applied.

⚠ **Warning** ⚠

When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided conductive connection to the HF equipment to protect against burns to the patient.

⚠ **Warning** ⚠

Disposable IBP transducer or domes should not be reused.

⚠ **Note** ⚠

Use only the pressure transducer listed in the Chapter Accessories and Ordering Information.

The specified transducer is designed to have the special ability to protect against the electricity shock (especially for the leak current allowed), and it is protected against the effects of a discharge of a cardiac defibrillator. It can be used in the surgical operation. When the patient is in the defibrillation, the waveform of the pressure maybe distorted temporarily. After the defibrillation, the monitoring will go on normally, the operation mode and the user configuration are not affected.

⚠ **Warning** ⚠

Verify transducer cables fault detection before beginning of monitoring phase. Unplug the transducer of the channel 1 from the socket, the screen will display the error message "IBP: SENSOR 1 OFF" and the audible alarm is activated. The other channel is the same.

⚠ **Note** ⚠

Calibrate the instrument either whenever a new transducer is used, or as frequently as dictated by your Hospital Procedures Policy.

⚠ **Warning** ⚠

If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or may enter the transducer or the monitor, contact the Hospital Service Center immediately.

12.3 Monitoring Procedure

Preparatory steps for IBP measurement:

1. Plug the pressure cable into corresponding socket and check that the monitor is switched on.
2. Prepare the pressure line and transducer by flushing through the system with normal saline solution. Ensure that the system is free of air bubbles.
3. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.

⚠ **Warning** ⚠

If there are air bubbles in the pressure line or the transducer, you should flush the system with the solution to be infused.

4. Position the transducer so that it is at the same level with the patient's heart, approximately mid-axillary line.

5. Check if you have selected the correct label name. See the next section for details.
6. Zero the transducer. See the next section for details.

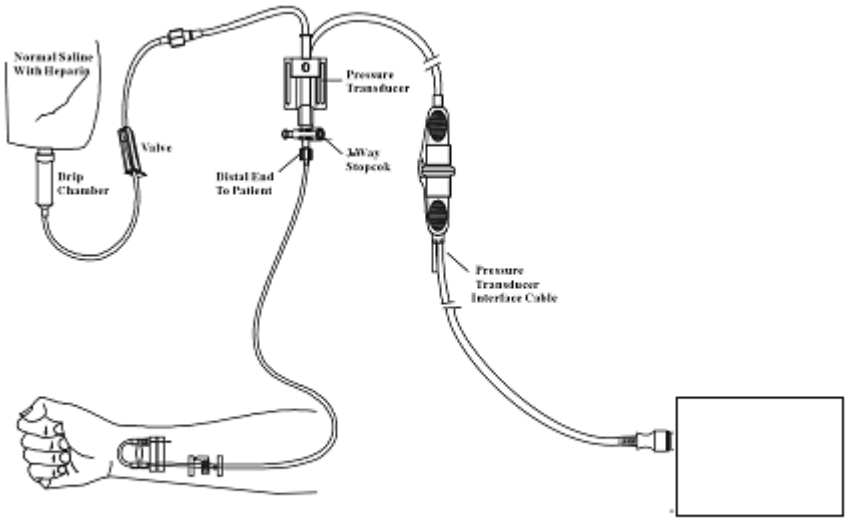


Figure 12-22 IBP Monitoring

12.4 IBP Menu

Pick the IBP hot key on the screen to access the IBP SELECT menu shown as following:

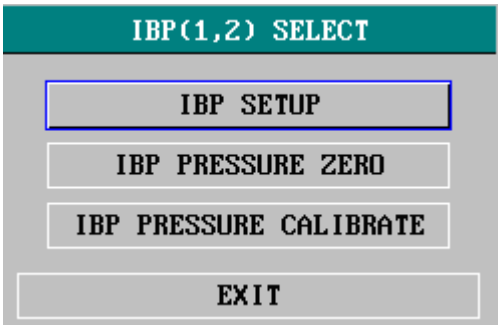


Figure 12-23 IBP SELECT Menu

Pick the IBP SETUP item to call up the IBP SETUP menu as following:

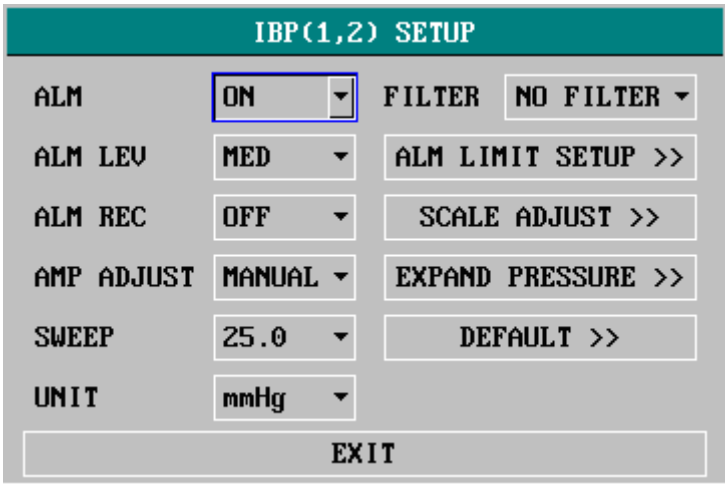


Figure 12-24 IBP SETUP Menu

The items to be set up in the menu include:

- ALM: Select “ON” to enable alarm prompt and data storage during IBP alarm. Select “OFF” to disable audio alarm and prompt the symbol beside “IBP” numeric.
- ALM LEV: used to set up the alarm level. Three levels are available: HIGH, MED, LOW.
- ALM REC: Select “ON” to enable recording during the IBP alarm or to OFF to disable the alarm recording function.
- AMP ADJUST: used to adjust waveform amplitude. Two selections are available: MANUAL, AUTO. Set it to AUTO, the pressure names of IBP become P1 and P2 (or P3, P4), and the IBP scale is adjusted by system automatically. Set it to MANUAL, the pressure names of IBP can choose one of ART, PA, CVP, RAP, LAP, ICP, P1, P2, and the IBP scale is adjusted by the user via SCALE ADJUST item.
- SWEEP: used to select the scanning speed of the IBP wave. Two selections are available: 12.5 mm/s or 25 mm/s.
- UNIT: used to select the pressure unit (mmHg or kPa).
- FILTER: used to select the filtering way to be adopted by the system. Three selections are available: NORMAL (filtering the waveform in 16Hz frequency), SMOOTH (filtering the waveform in 8Hz frequency) and NO FILTER (display the original waveform). The default value is NO FILTER.
- ALM LIMIT SETUP: used to access the sub-menu of IBP ALM LIMIT SETUP, in which the user may set up the upper and lower alarm limit of systolic pressure, diastolic pressure and mean pressure respectively for channel 1 and channel 2.
- SCALE ADJUST: used to access the sub-menu of IBP SCALE ADJUST, in which the user may adjust the position of the high, reference and low scales for the two waveforms displayed on the screen.
- EXPAND PRESSURE: used to access the sub-menu of IBP EXPAND PRESSURE, in which the user may select the pressure name to be represented by P1, P2.
- DEFAULT: pick this item to access the IBP 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.
- EXIT: used to exit the menu and return to the main screen.

⚠ **Warning** ⚠

Before set the alarm limits, confirm to choose the correct label.

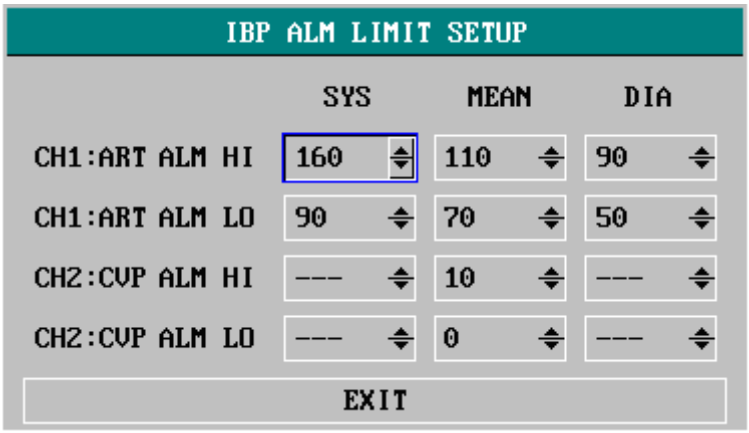


Figure 12-25 IBP ALM LIMIT SETUP

The alarm occurs when the value exceeds the set limits.

IBP alarm limits:

Pressure Label	Max. Alarm High (mmHg)	Min. Alarm Low (mmHg)	Step (mmHg)
ART	300	0	1
PA	120	-6	1
CVP	40	-10	1
RAP	40	-10	1
LAP	40	-10	1
ICP	40	-10	1

IBP Transducer Zero

Press the IBP PRESSURE ZERO button on the IBP SELECT menu to call up IBP PRESSURE ZERO menu as shown below:

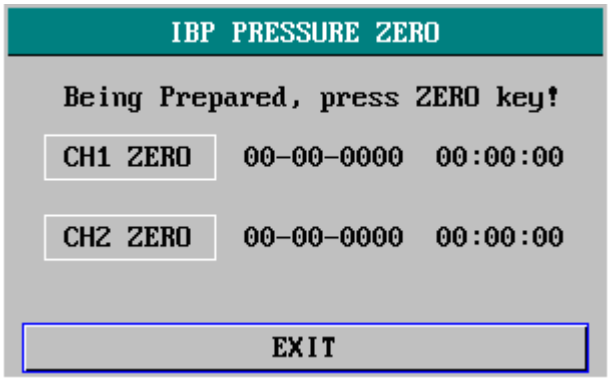


Figure 12-26 IBP PRESSURE ZERO

【Note】

It is the responsibility of the user to ensure that a zero procedure has recently been done on the transducer, otherwise there will be no recent, valid zero value for the instrument to use, which may result in inaccurate measurement results.

Zero Calibration of Transducer

Select CH1, the system will zero IBP1. Select CH2, the system will zero IBP2.

Cautions:

- Turn off patient stopcock before you start the zero procedure.
- The transducer must be vented to atmospheric pressure before the zero procedure.
- The transducer should be placed at the same height level with the heart, approximately mid-axially line.
- Zero procedure should be performed before starting the monitoring and at least once a day after each disconnect-and-connect of the cable.

The prompt information related to zero, take CH1 for example.

- "SENSOR OFF, FAIL"
  Make sure that transducer is not off, then proceed zeroing.
- "IN DEMO FAIL"
  Make sure that the monitor is not in DEMO mode. Contact service technician if necessary.
- "PRESSURE OVER RANGE, FALL"

Make sure that the stopcock is vented to atmosphere. If the problem persists, contact service technician.

- "PULSATILE PRESSURE, FALL"
  Make sure that the transducer is not attached to the patient and that the stopcock is vented to atmosphere. If the problem persists, contact service technician.

IBP Calibration

Press the IBP PRESSURE CALIBRATION button on the IBP SELECT menu to call up the IBP PRESSURE CALIBRATE menu as shown below:

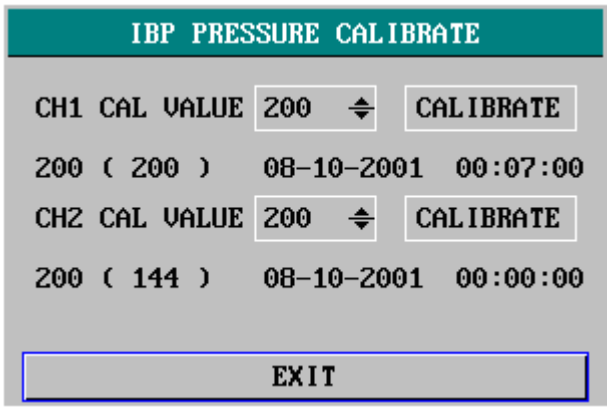


Figure 12-27 IBP Calibration Menu

Calibrate the transducer:

Turn the knob to select the item CH1 CAL VALUE, press and turn the knob to select the pressure value to be calibrated for channel 1. Then turn the knob to select the item CALIBRATE to start calibrating channel 1.

Turn the knob to select the item CH2 CAL VALUE, press and turn the knob to select the pressure value to be calibrated for channel 2. Then turn the knob to select the item CALIBRATE to start calibrating channel 2.

- The pressure calibration of the monitor

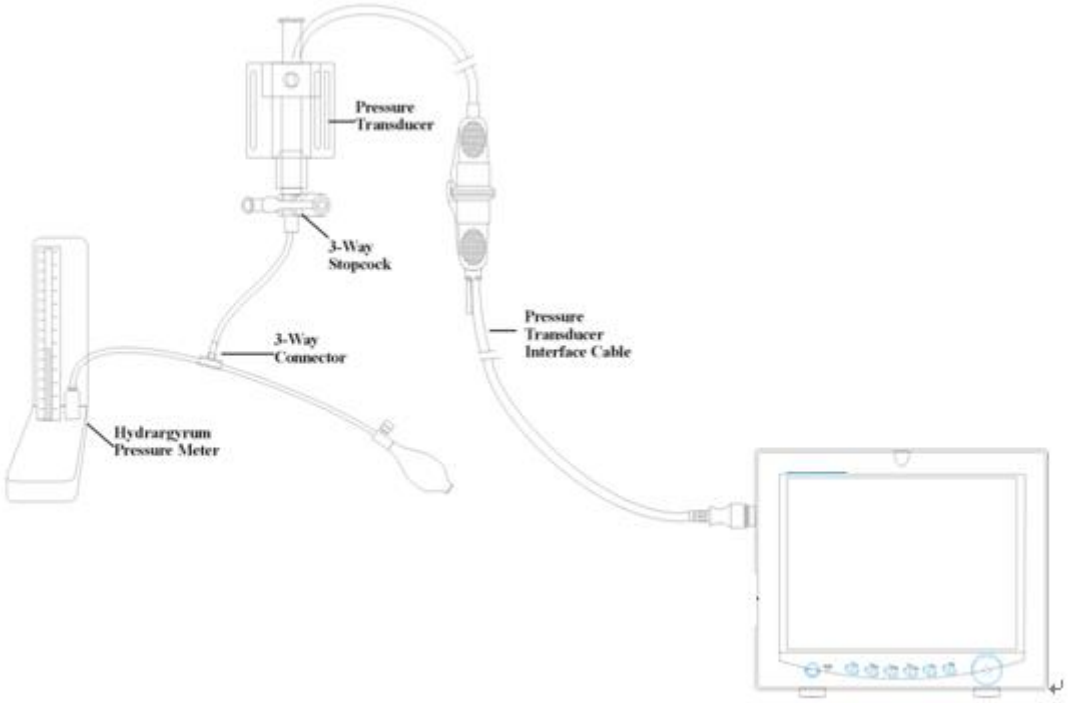


Figure 12-28 IBP Calibration

Caution:

- Mercury calibration should be performed by the biomedical engineering department either whenever a new transducer is used, or as frequently as dictated by your Hospital Procedures Policy.
- The purpose of the calibration is to ensure that the system gives you accurate measurements.
- Before starting a mercury calibration, a zero procedure must be performed.
- If you need to perform this procedure yourself you will need the following pieces of equipment:

- Standard sphygmomanometer
- 3-way stopcock
- Tubing approximately 25 cm long

The Calibration Procedure: (SEE Figure 12-28)

⚠ **Warning** ⚠

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

1. Close the stopcock that was open to atmospheric pressure for the zero calibration.
2. Attach the tubing to the sphygmomanometer.
3. Ensure that connection that would lead to patient is off.
4. Connect the 3-way connector to the 3-way stopcock that is not connected to the patient catheter.
5. Open the port of the 3-way stopcock to the sphygmomanometer.
6. Select the channel to be calibrated in the menu and select the pressure value to which the IBP

is to be adjusted.

7. Inflate to make the mercury bar rise to the setup pressure value.
8. Adjust repeatedly until the value in the menu is equal to the pressure value shown by the mercury calibration.
9. Press the Start button, the device will begin calibrating.
10. Wait for the calibrated result. You should take corresponding measures based on the prompt information.
11. After calibration, disassemble the blood pressure tubing and the attached 3-way valve.

If the following messages prompt up, refer to relevant instructions (take channel-1 for instance):

- "SENSOR OFF , FALL"
  Make sure that sensor is not off, then proceed calibration.
- "IN DEMO, FAIL"
  Make sure that the monitor is not in DEMO mode. Contact service technician if necessary.
- "PRESSURE OVER RANGE, FAIL"
  Make sure that you have selected transducer value in IBP CAL, then proceed calibration.

Changing the Label

■ IBP SCALE ADJUST submenu:

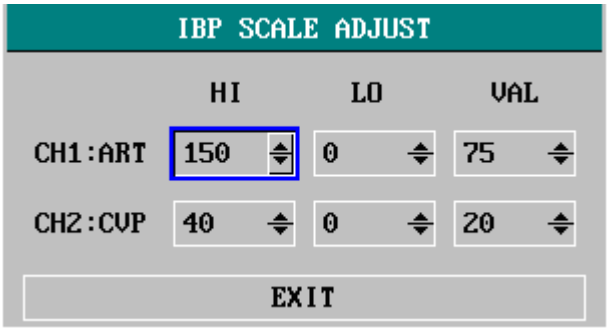


Figure 12-29 IBP SCALE ADJUST Menu

The waveform and corresponding scale appears in the IBP Waveform Area with 3 dotted lines representing High Limit Scale, Reference Scale, and Low Limit Scale from the top to the bottom. Values of the three scales can be user-set according to the instruction given below.

- IBP label: selectable from ART, PA, CVP, RAP, LAP, ICP, P1, P2;
- HI: IBP value of High Limit scale, the range is the measuring range of the current pressure

【NOTE】
The HI value must be higher than the LO value.

- LO: IBP value of Low Limit scale, the range is the measuring range of the current pressure.

【NOTE】
The LO value must be lower than the HI value.

- VAL: IBP value of Reference scale (between HI and LO).

.

【NOTE】

When change HI scale, Low scale or Reference scale of IBP waveform and the corresponding IBP waveforms are displayed under the menu window, the waveform will come penetratingly through the menu window for observing.

12.5 Alarm Information and Prompts

Alarm Messages

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

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

Physiological alarms:

Message	Cause	Alarm Level
IS1 TOO HIGH	SYS measuring value of channel 1 is above upper alarm limit.	User-selectable
IS1 TOO LOW	SYS measuring value of channel 1 is below lower alarm limit.	User-selectable
ID1 TOO HIGH	DIA measuring value of channel 1 is above upper alarm limit.	User-selectable
ID1 TOO LOW	DIA measuring value of channel 1 is below lower alarm limit.	User-selectable
IM1 TOO HIGH	MAP measuring value of channel 1 is above upper alarm limit.	User-selectable

IM1 TOO LOW	MAP measuring value of channel 1 is below lower alarm limit.	User-selectable
IS2 TOO HIGH	SYS measuring value of channel 2 is above upper alarm limit.	User-selectable
IS2 TOO LOW	SYS measuring value of channel 2 is below lower alarm limit.	User-selectable
ID2 TOO HIGH	DIA measuring value of channel 2 is above upper alarm limit.	User-selectable
ID2 TOO LOW	DIA measuring value of channel 2 is below lower alarm limit.	User-selectable
IM2 TOO HIGH	MAP measuring value of channel 2 is above upper alarm limit.	User-selectable
IM2 TOO LOW	MAP measuring value of channel 2 is below lower alarm limit.	User-selectable

Technical alarms:

Message	Cause	Alarm Level	Remedy
IBP1 SENSOR OFF	IBP cable of channel 1 falls off from monitor.	LOW	Make sure that cable is properly connected.
IBP2 SENSOR OFF	IBP cable of channel 2 falls off from monitor.	LOW	Make sure that cable is properly connected.
IBP(1,2) INIT ERR	IBP module failure	HIGH	Stop using measuring function of IBP module, notify biomedical engineer or Our service staff.
IBP(1,2) INIT ERR1			
IBP(1,2) INIT ERR2			
IBP(1,2) INIT ERR3			
IBP(1,2) INIT ERR4			
IBP(1,2) INIT ERR5			
IBP(1,2) INIT ERR6			
IBP(1,2) INIT ERR7			
IBP(1,2) INIT ERR8			
IBP(1,2) COMM STOP	IBP(1,2) module failure or communication failure	HIGH	Stop using measuring function of IBP module, notify biomedical engineer or Our service staff.

IBP(1,2) COMM ERR	IBP(1,2) communication error	HIGH	Stop using measuring function of IBP module, notify biomedical engineer or Our service staff.
IBP1 ALM LMT ERR	Functional safety failure	HIGH	Stop using measuring function of IBP module, notify biomedical engineer or Our service staff.
IBP2 ALM LMT ERR	Functional safety failure	HIGH	Stop using measuring function of IBP module, notify biomedical engineer or Our service staff.

Prompt message (general alerts):

Message	Cause	Alarm Level
IBP1 SYS EXCEED	Systolic measuring value of channel 1 is beyond measurement range.	HIGH
IBP1 DIA EXCEED	Diastolic measuring value of channel 1 is beyond measurement range.	HIGH
IBP1 MEAN EXCEED	Mean measuring value of channel 1 is beyond measurement range.	HIGH
IBP2 SYS EXCEED	Systolic measuring value of channel 2 is beyond measurement range.	HIGH
IBP2 DIA EXCEED	Diastolic measuring value of channel 2 is beyond measurement range.	HIGH
IBP2 MEAN EXCEED	Mean measuring value of channel 2 is beyond measurement range.	HIGH
IBP1 NEED ZERO-CAL	Zero calibrating must be done before measuring in IBP channel 1.	LOW
IBP2 NEED ZERO-CAL	Zero calibrating must be done before measuring in IBP channel2.	LOW

12.6 Maintenance and Cleaning

Care and Cleaning

⚠ **Warning** ⚠

Before cleaning the monitor or the transducer, make sure that the equipment is switched off

and disconnected from the power line.

Cleaning of IBP Transducer (Reusable)

After the IBP monitoring operation is completed, remove the tubing and the dome from the transducer and wipe the transducer diaphragm with water. Soaking and/or wiping with soap can clean the transducer and cable and water or cleaning agents such as those listed below:

Cetylcide
Wavicide-01
Wescodyne
Cidex
Lysol
Vesphene

Do not immerse the connector in any liquid. After cleaning, dry the transducer thoroughly before storing. Slight discoloration or temporary increase of surface stickiness of the cable should not be considered abnormal If adhesive tape residue must be removed from the transducer cable, double seal tape remover is effective and will cause a minimum of damage to the cable if used sparingly. Acetone, Alcohol, Ammonia and Chloroform, or other strong solvents are not recommended because over time the vinyl cabling will be damaged by these agents.

Note
The disposable transducers or domes must not be re-sterilized or re-used.

Note
For protecting environment, the disposable transducers or domes must be recycled or disposed of properly.

Sterilization

- Liquid Chemical Sterilization
  Remove obvious contamination by using the cleaning procedure described previously. Select a sterilant that your hospital or institution has found to be effective for liquid chemical sterilization of operating room equipment. Buffered gluteraldehyed (e.g. Cidex or Hospisept) has been found to be effective. Do not use quaternary cationic detergents such as zephiran chloride. If the whole unit is to be sterilized, immerse the transducer but not the electrical connector into the sterilant for the recommended sterilizing period. Be sure that the dome is removed. Then rinse all transducer parts except the electrical connector with sterilized water or saline. The transducer must be thoroughly dried before storing.
- Gas Sterilization
  For more complete asepsis, use gas sterilization.
  Remove obvious contamination by using the cleaning procedure described previously. To inhibit the formation of ethylene glycol when ethylene oxide gas is used as the disinfectant, the transducer should be completely dry.
  Follow the operating instructions provided by the manufacturer of the gas disinfectant.

⚠ **Warning** ⚠

The sterilize temperature must not exceed 70°C (158°F). Plastics in the pressure transducer may deform or melt above this temperature.

Chapter 13 CO2 Monitoring

13.1 Abstract

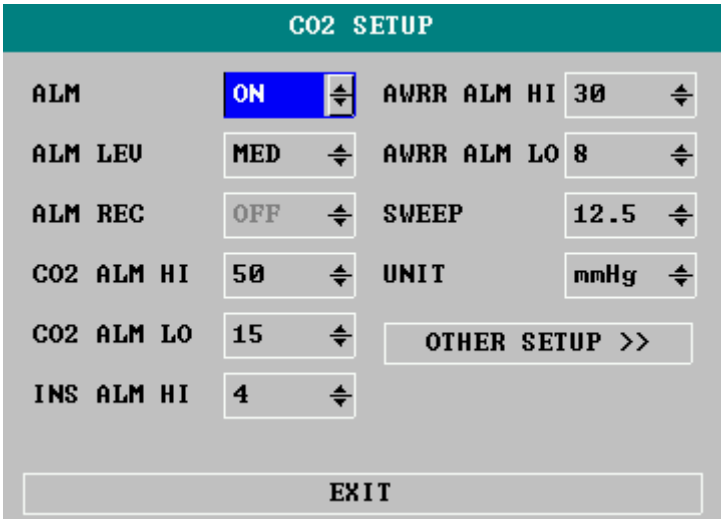
This monitor is capable of measuring Patients' Gas Circuit CO2 pressure, show one channel CO2 waveform and EtCO2 (End Tidal CO_2), FiCO2 (Fraction of Inspired CO_2), AwRR (Air Way Respiration Rate)。

13.2 Test Procedure

1) Fix Water Trap on the right place of monitor;
2) If CO2 Module in Stand By model,Enter"CO2 OTHER SETUP" Menu, set "work mode" as: "Work"
3) After starting, monitor will display waveform and value.

13.3 CO_2 Setting

Turn Knob, Move Cursor to "CO2 Hot Key" on the screen, Press knob,enter"CO2 Setting" as following picture 12-1:



Picture 12-1

■ CO2 Alarm Setting

◆ Alarm Switch: Select "ON" will alarm and storage when End tidal parameter alarming. otherwise, select will not alarm ,only show  on the screen。

◆ Alarm Level: "High, MED, Low" High indicated serious alarm

◆ Alarm Record: Unused

◆ End tidal parameter alarm work base on value limit had been set. w hen valve exceeds "high limit" or less than "Low limit", monitor alarm

End-tidal alarm high & low limit range as follow:

EtCO Parameter 0 ～ 99 (%)

FiCO₂Parameter: 0 ～ 99 (%)

AwRR Parameter: 0 ～ 100

■ Waveform Sweep Speed

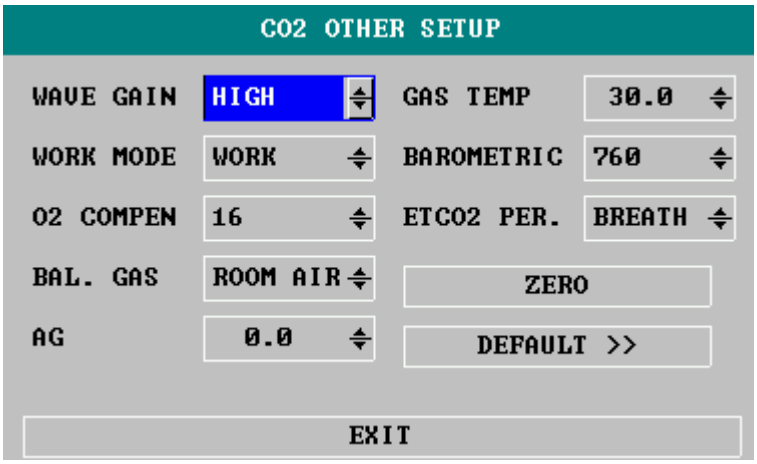
Option: 6.25mm/s, 12.5mm/s, 25.0mm/s

■ Presure resolution

mmHg、kPa、%，Three resolution exchange as following:
CO Partial Pressure and CO_2concentration exchange ：
CO_2partial（mmHg）= CO_2concentration（%）×Pbaro（Environment Pressure mmHg）/100
CO_2Partial Pressure（kPa）= CO_2Partial Pressure（mmHg）/7.5

13.4 CO_2 OTHER SETUP

By selecting “Other SETUP of “CO2 Setting” ,enter following 12-2 picture



picture12-2

■ Wave Gain

Optional: “High” and “Low”

■ Work Mode

2 mode :” work”, ”Stand By”。When set as :”Stand By”，CO_2pump and infrared light power would be closed，save consumption，lifelong use of pump and all CO2 module；When CO_2 Monitoring，set” work mode” as “work”.

■ CO2 Initial Settings

◆ O2 Compensation: Range 0 ～ 100 (%)

◆ Balance Gas: 3 option: Room air, CO2, N2. default as room air.

◆ Anesthetic Gas: Range 0.0 ～ 20.0 (%)

◆ Gas Temp: Range 0.0 ～ 50.0

◆ Atmospheric pressure: Range 400 ～ 850

◆ Calculate Cycle: "1 breath", "10seconds", "20seconds" 3 option, default as "1 breath"。

13.5 CO_2 Zero

By Select "CO2 Zero" from "Other Setup" menu, enter CO2 calibration.(set work mode as "work" before calibration, as folloing12-3 picture

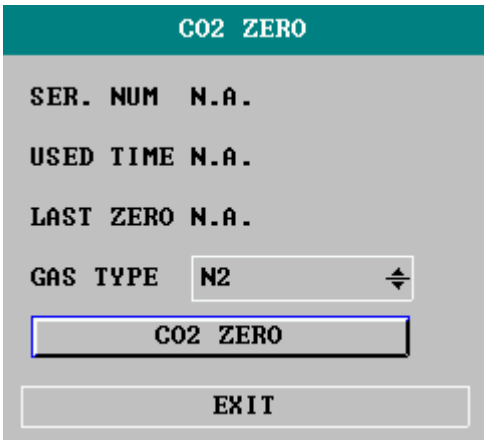


图 12-3

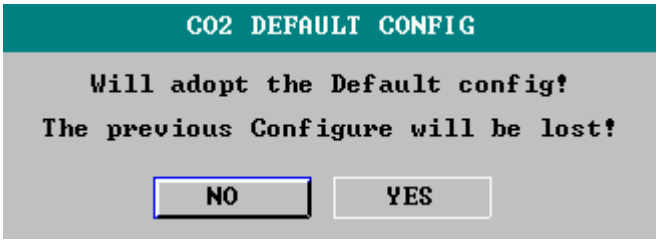
■ Gas Type: With "N2", "Room air" option, default as N2。

■ Zero: Select "CO2 Zero", user can zero CO_2 module。During zero period,Co2 waveform would be higher than former, It would automatically down after zero

13.6 CO_2 Default Config

By select "CO_2 Default Config" enter CO_2 Default Config menu

As following picture 12-4



Picture 12-4

■ CO2Fefault Config: Select "Yes" make all parameter about CO2 as default value, select" NO" exit menu.

Chapter 14 IoC Monitoring

Discription

The index of cerebral (IoC) has been designed to be used in the monitoring of the level of consciousness of a person during the application of general anaesthesia or in intensive care. This is accomplished by registering the electroencephalographic signal (EEG) bymeans of surface electrodes which is then analyzed by a digital process.

As a result of the applied calculation, an index "IoC" is obtained, which serves as guidance to the experts who use it to determine the level of consciousness of the patient during surgery.

IoC	Clinical state
90-100	Awake
80-90	Drowsy
60-80	Light anaesthesia
40-60	Range consider as adequate for surgical anaesthesia
10-40	Deep anaesthesia, in most cases accompanied by BS (Burst Suppression)
0-10	Close to coma. BS greater than 75. When CSI is below 3, the EEG is practically iso-electric

⚠ Warning ⚠

1) Not to be used in the presence of flammable gases; explosion risk.
2) When used with High Frequency(HF) surgery please note the positioning of the sensors. In order to reduce the hazard of burns the sensors should not be located between the surgical site and the electro-surgical unit return sensor.
3) Pay attension if the monitor is connected to a patient connected to other equipment. The total of leakage current may exceed the allowable llimit and cause a possible hazard to the patient.
4) The conductive parts of sensors and ther connectors, incuding the neutral sensor, should not contact other conductive parts including earth.
5) The monitor will not accurate readings when used on patients with severe neurological disordersand patients under 2 years of age.
6) The use of pacemakers might cause either long periods of artifacts or elevated IoC values.

⚠ Cautions ⚠

1) The monitor should be used in conjuction with other patient monitoring parameters and clinical signs. This will ensure the optimum balance of the anaesthesia/sedation administration.
2) Do not use IoC monitor when cardiac defibrillator is used.
3) Patient cable are not protected against defibrillation.

The patient cable

The patient cable in figure 14.1 is connected to the monitor at the patient cable connector;

while the other end with three leads (red, yellow and green) is connected to the electrodes on the skin of the patient, see figure 14.2.

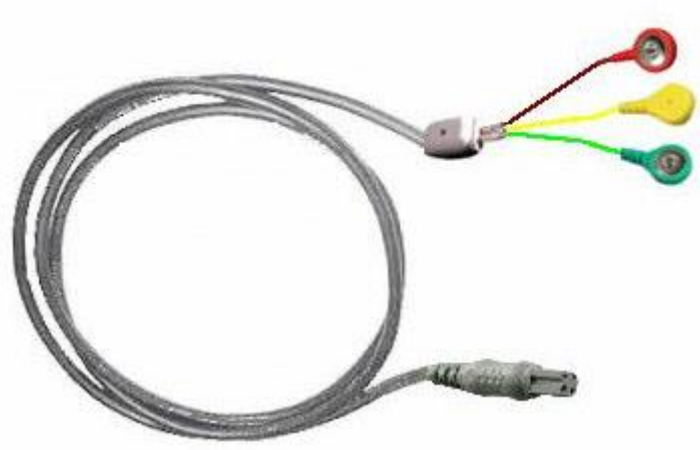


Figure 0-1 patient cable

The cable is of a design especially prepared for measuring the EEG with low levels of interference. Among its characteristics are accentuated:

1) Each lead of the cable is shielded individually until the yoke.
2) Short terminals that permit better rejection of both capacitive and inductive interference.
3) Long main cable.

The connections have different colors to assist in the correct placement. Care should be taken when positioning the electrodes as they are identical except for the colors. The device will not work properly if the electrode leads are interchanged.

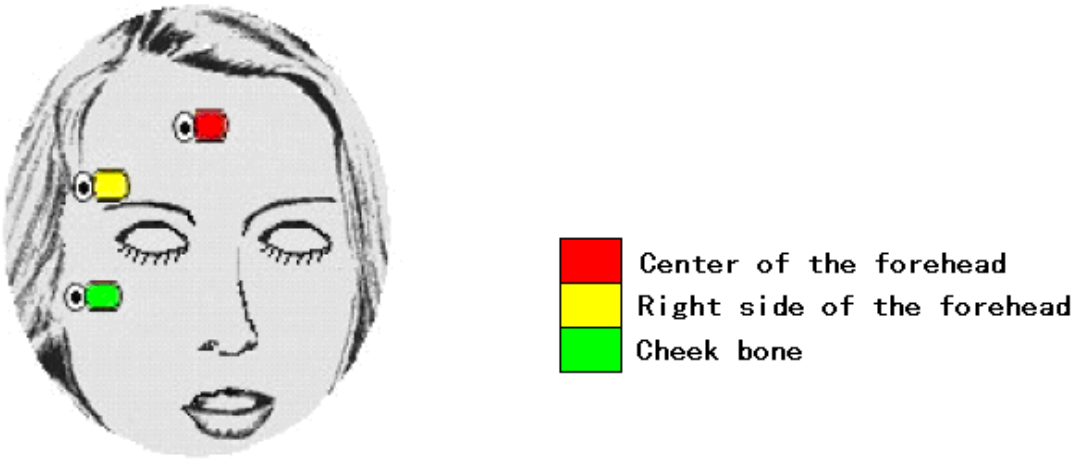


Figure 0-2– Application of the electrodes

Skin preparation and connections

In order to obtain a correct measurement of the EEG signal, it is especially recommended to prepare the skin in order to reduce the contact impedance that exists in normal conditions. For this purpose, it is advised to use fine sandpaper dedicated to remove the surface layers of the skin in the areas where the electrodes are to be placed.

3.3.1. Application of the electrodes

The patient-cable possesses three connections that should be connected to the

electrodes placed on the surface of the patient's previously prepared skin. The three electrodes should be placed as indicated in figure 3. The coloured spots correspond to the colours of the ends of the patient cable, red (+), yellow (reference) and green (-). Always follow the instructions provided by the manufacturer of the electrodes.

⚠ **Warning** ⚠

1) If skin rash or other unusual symptoms develop, remove sensors from patient.
2) It is important to take specially care of patients with skin problems.
3) Do not place the electrodes on wounds

IoC module

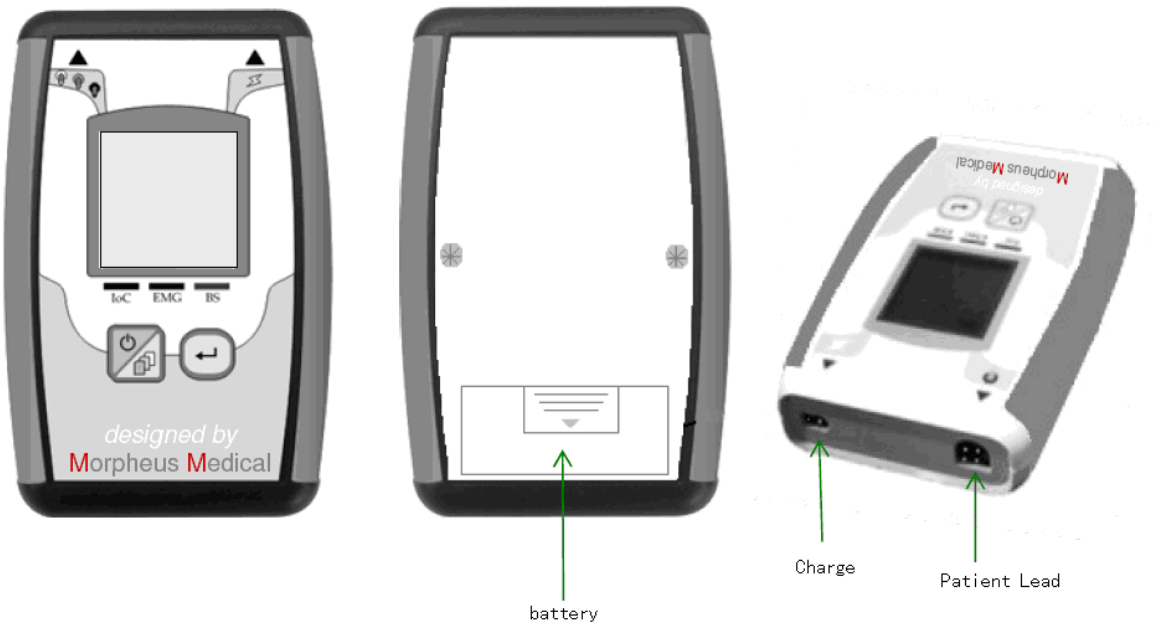


Figure 0-3 IoC module

There are 2 buttons on IoC-View module:

Button 1(On-off /Change screen):

this button on the left side of the monitor is generally used to turn on, turn off, enter the Main Menu and exit from all other menus. Press the button during 3 seconds will switch on the IoC-view.

Button 2 (Confirm value):

this button on the right side of the monitor is used to move from one selection to another inside the same screen or to another menu. It is also used for certain procedures, such as the sensor check and confirms the different options.

Graphic user interface

When the user switches on the IoC-View module, the screen of welcome will be displayed, figure 7. After the device has been turned on for three seconds the electrodes test screen appears. This shows the estimation of the impedance of every electrode.

There are three different screens showing the clinical information, see fig 14.7, 14.8 and 14.9; each one will be described below. To change between them press button 2, as in the upper part of figure 10. In the same figure pressing 1C leads to the main menu. The procedure to change between windows or choose the main menu is shown in figure 14.4.

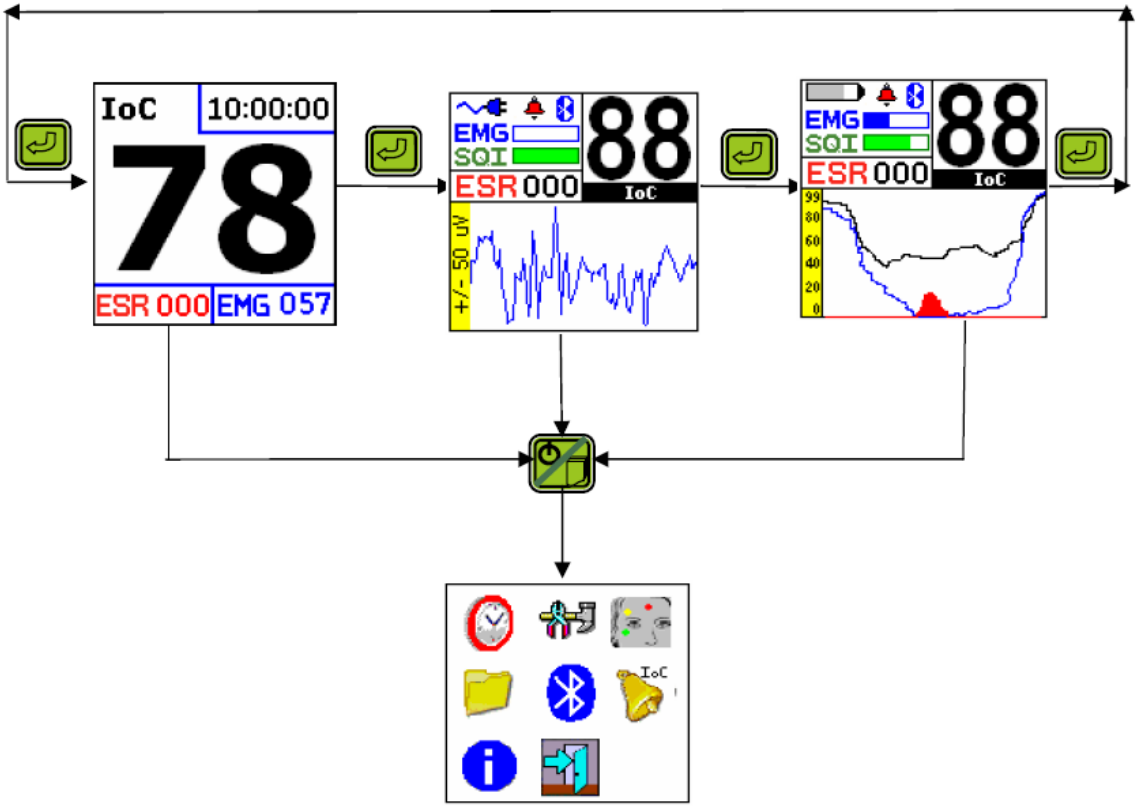


Figure 0-4 IoC Mainscreens

Display mode (A) – Welcome screen

When the monitor is turned on the welcome screen (figure 7) is shown for 2 seconds; after that the electrodes test screen is shown (figure 8).

Figure 0-5 Welcome screen

Display mode (B)- Electrode test

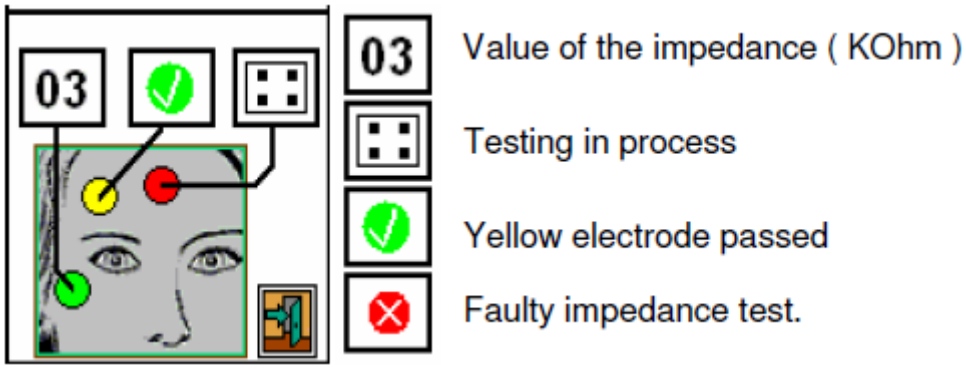


Figure 0-6 Electrode test screen

Display mode (C1) –main screen1

Figure 0-7 Main screen1

Display mode (C2) –main screen2

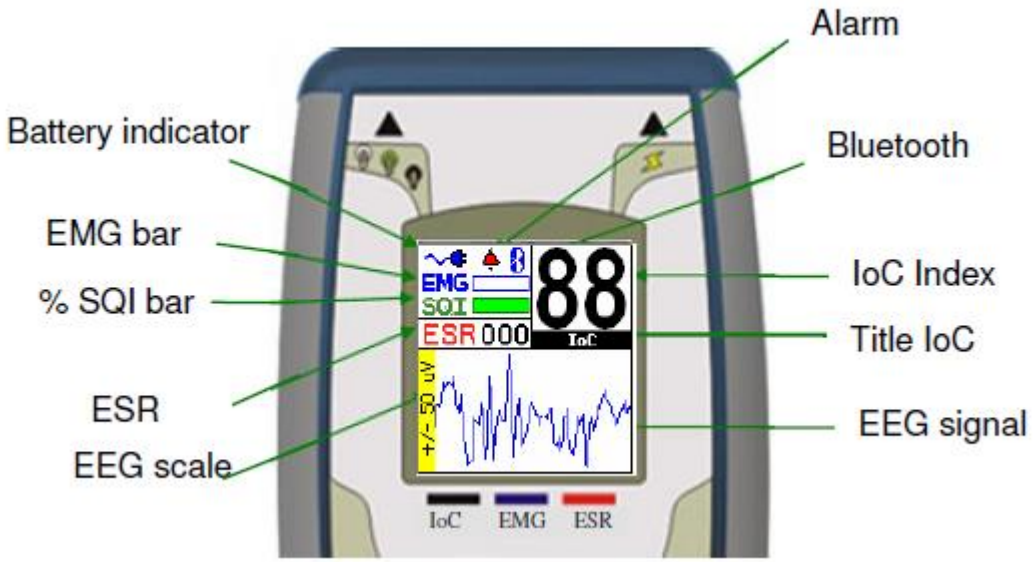


Figure 0-8 Main screen2

Display mode (C3) –main screen3

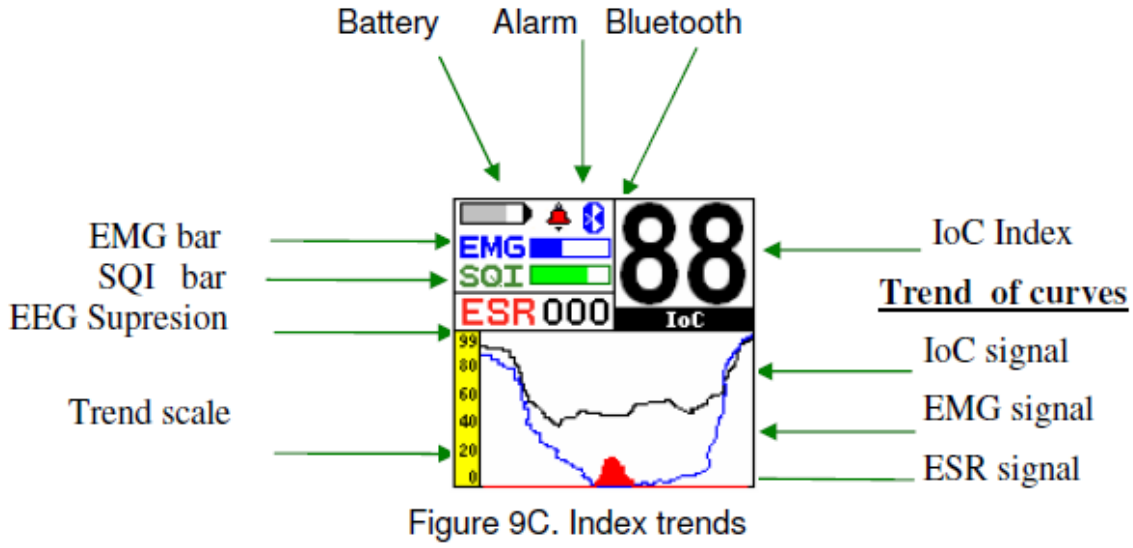


Figure 9C. Index trends

Figure 0-9 Main screen3

Patient monitor screen

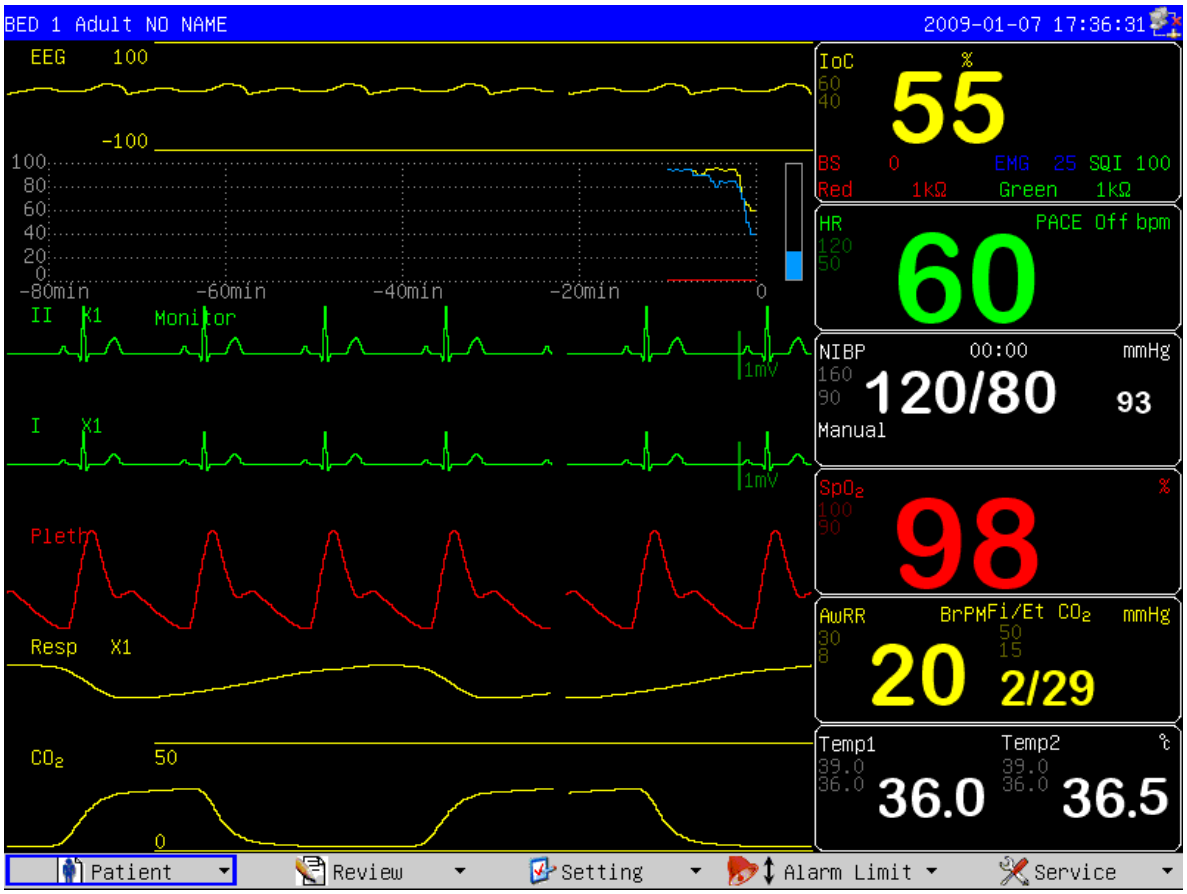


Figure 0-10 Patient monitor screen

EEG and 4 IoC trend waves (include IoC, SQI, BS, EMG) are displayed on wave area; 4 IoC parameters (include IoC, SQI, BS, EMG) and white lead, black lead value are displayed on parameter area.

IoC setting

■ Choose “IoC Setting” in “Setting” menu will enter “IoC Setting” dialog:

■

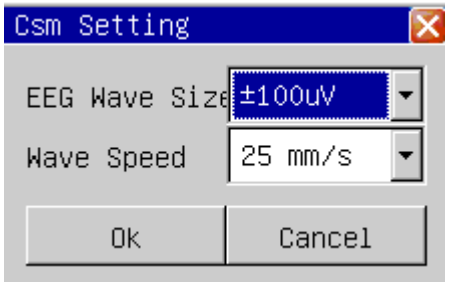


Figure 0-11 IoC setting

1) EEG Wave Size：±10uV、±20uV、±40uV、±80uV、±100uV、±150uV、±200uV.
2) Wave Speed：6.25mm/s，12.5mm/s，25.0mm/s.

Appendix I

Product Specification

Ⅰ. 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	2 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

I.2 RESPARATION

Method Impedance between R-F(RA-LL)

Differential Input Impedance >2.5 MΩ

Measuring Impedance Range:0.3~5.0Ω

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

I.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

I.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

I.5 TEMPERATURE

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

I.6 IBP

Label	ART, PA, CVP, RAP, LAP, ICP, P1, P2

Measuring and alarm range

ART	0 ~ 300 mmHg
PA	-6 ~ 120 mmHg
CVP/RAP/LAP/ICP	-10 ~ 40 mmHg
P1/P2	-10 ~ 300 mmHg

Press Sensor

Sensitivity	5 uV/V/mmHg
Impedance	300-3000 Ω

Resolution	1 mmHg
Accuracy	±2% or ±1mmHg, which great
Actualization interval	about 1 Sec.

I.7 CO2 Specification

I.7.1 Monitoring range

0% ~ 13%

I.7.2 Resolution

1 mmHg

I.7.3 Accuracy

2 mmHg @ < 5.0% CO_2 (at ATPS)

I.7.4 Respiration Rate

3 - 150 bpm