EDAN INSTRUMENTS, INC.

CE 0123

M8B
Multi-Parameter
Patient Monitor

User Manual

EC Conformity Information

Manufacturer: EDAN Instruments, Inc.

Addr: 3/F-B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, shekou, Nanshan Shenzhen, 518067 P.R. China

European Representative: Shanghai International Holding Corp. GmbH (Europe)

Addr: Eiffestrasse 80 D-20537 Hamburg Germany

Product: Patient Monitor

Model: M8B

Classification (MDD, Annex IX): IIb

We herewith declare that the above mentioned product(s) meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices-as amended by Directive 98/79/EC on in vitro diagnostic medical devices.

All supporting documentation is retained at the premises of the manufacturer.

DIRECTIVES

General Applicable Directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards applied: EN60601-1:1990+A1:1993+A2:1995, IEC60601-1-2:2001, EN60601-2-27:1994, IEC60601-2-30:1999, EN60601-2-34:2000, IEC60601-2-49:2001, ISO9919:2005, EN12470-4:2001, EN1060-1:1995, EN1060-3:1997, ANSI/AAMI SP-10:2002, ISO9001:2000, ISO13485:2003, EN ISO14971:2000, IEC 60601-1:1988, BS EN60601-1-4:1997, ISO 21647:2004, ANSI/AAMI SP-10-2002, EN1041:1998, IEC/TR60878-2003, EN980:2003, EN 60417-2-2000, EN475:1995, EN540:1993, ISO1000:1998, EN ISO780:1999.

Notified Body: TüV SüD Product Service GmbH, Ridlerstr 65, D-80339 München, Germany.

Identification number   CE 0123

Copyright

Statement

Responsibility of the Manufacturer

This company 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 EDAN 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.

Using This Label Guide

This guide is designed to give key concepts on safety precautions.

⚠ **WARNING** ⚠

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

◈ **CAUTION** ◈

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE: A **NOTE** provides useful information regarding a function or procedure.

Warranty

Workmanship & Materials

EDAN guarantees new equipment other than accessories to be free from defects in workmanship and materials for a period of one year (six months for multi-site probes and SpO_2 sensor) from date of shipment under normal use and service. This company's obligation under this warranty is limited to repairing, at this company's option, any part which upon this company's examination proves defective.

Exemptions

This company's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the

substitution upon it of parts or accessories not approved by this company or repaired by anyone other than this company authorized representative.

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

Safety, Reliability and Performance

This company is not responsible for the effects on safety, reliability and performance of the Multi-parameter Patient Monitor if:

■ Assembly operations, extensions, re-adjusts, modifications or repairs are carried out by persons other than those authorized by this company.

■ The Multi-parameter Patient Monitor is not used in accordance with the instructions.

Return Policy

Return Procedure

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

1) Obtain return authorization. Contact EDAN Service Department and obtain a Customer Service Authorization number. The Company number must appear on the outside of the shipping container. Return shipments will not be accepted if the Company 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 EDAN for service (this includes customs charges).

Revision History

This user manual shall be revised whenever changes in regulatory requirements dictate.

Date	ECO	Version	Revision history
21st, Jan. 2008		V1.0	1st edition
8th, Apr. 2008	ECO-MPM-8005	V1.1	Add CE information; add 3-channel recording.

Contents

1 Introduction

1.1 General Information

M8B Multi-parameter patient monitor monitors parameters such as ECG, RESP, SpO$_2$, NIBP, dual-TEMP and dual-IBP (optional). It is adaptable to adult, pediatric, and neonatal usage. The user can select different parameter configuration according to different requirements.

It centralizes the function of parameter measurement module, display, record and output to compose a compact, portable device. Its built-in replaceable battery provides convenience for patient movement. On the high-resolution display screen, 7 waveforms and all the monitoring parameters can be displayed clearly.

The POWER switch is on the left of the front panel (Figure 1-1①). The POWER indicator lights when the monitor is powered on (Figure 1-1②). The CHARGE indicator shows the charging status (Figure 1-1③). The ALARM indicator flashes when the alarm is triggered (Figure 1-1④). The sockets of various sensors are on the left panel. Other sockets and power plug-in are on the rear panel. The recorder is on the right panel.

M8B Multi-parameter patient monitor is a user-friendly device with operations conducted by a few buttons and rotary knob on the front panel (Figure 1-1⑤⑥). Refer to **Button Functions.**
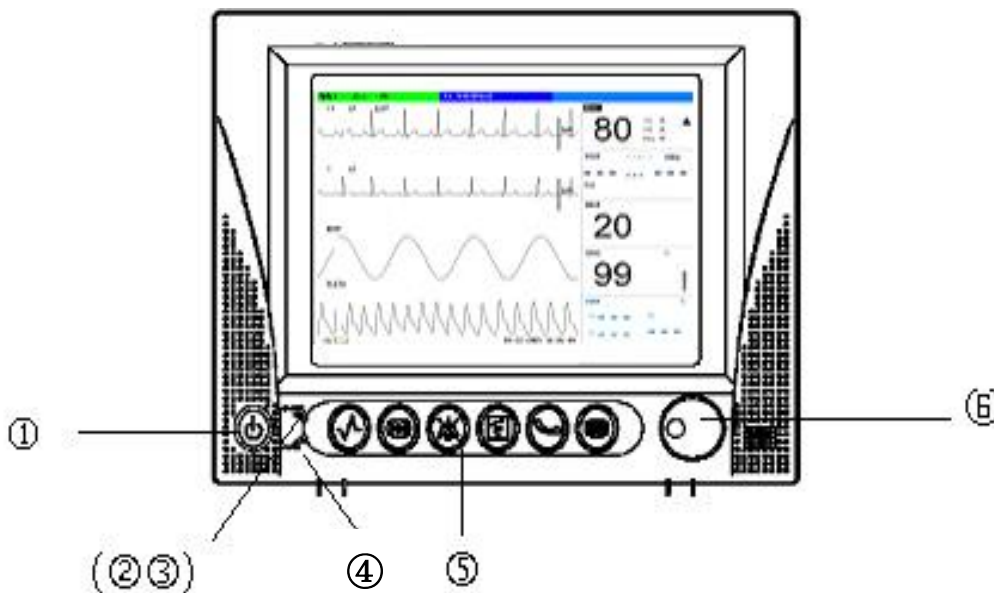
Figure 1-1 Button Functions of M8B
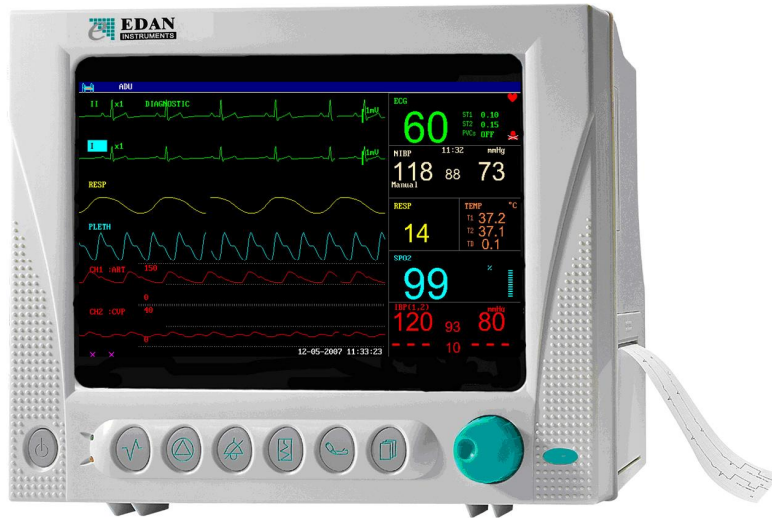
Figure 1-2 M8B Multi-parameter Patient Monitor

M8B Multi-parameter patient monitor can monitor:

ECG: Heart Rate (HR),

2-channel ECG waveform,

Arrhythmia and ST-segment analysis (optional);

RESP: Respiration Rate (RR),

Respiration Waveform;

SpO_2:   Oxygen Saturation (SpO_2), Pulse Rate (PR),

SpO_2 Plethysmogram;

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

TEMP: Channel-1 Temperature (T1), Channel-2 Temperature (T2),

Temperature Difference between two channels (TD);

IBP: Channel-1   SYS, DIA, MAP,

Channel-2   SYS, DIA, MAP,

Dual-IBP waveforms;

M8B Multi-parameter patient monitor provides extensive functions as visual & audible alarm, storage for trend data, NIBP measurements, alarm events, and drug dose calculation and so on.

1.2 Screen Display

M8B Multi-parameter patient monitor is equipped with a high-resolution multicolor TFT LCD screen. The patient parameters, waveforms, alarm messages, bed number, time, monitor status and other data can be reflected from the screen.

The screen is divided into three areas: 1 Information Area; 2 Waveform Area; 3 Parameter Area.
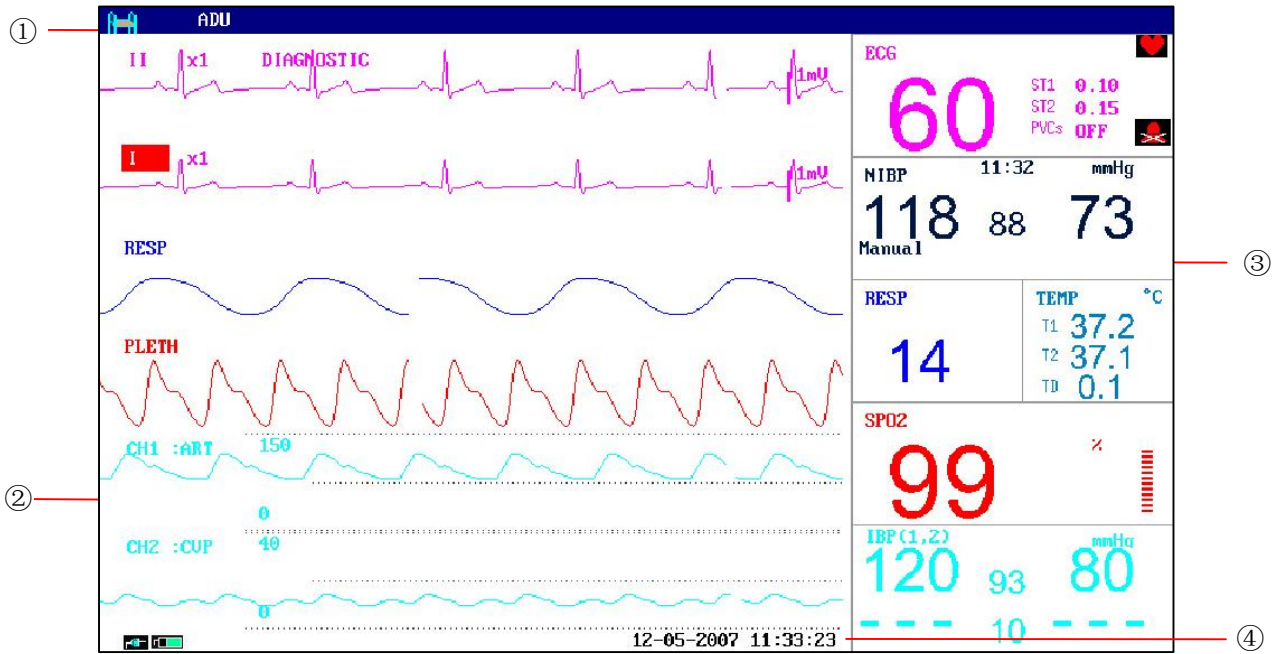
Figure 1-3 Main Interface of M8B

Information Area (① ④)

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

The information area contains following data:

	Bed number of the monitored patient
ADU	Type of patient. Three options: Adult, Pediatric, Neonate
Name	Name of the monitored patient. When the user input patient's name, this name will be displayed on the right side of the Patient type. If the user does not input patient name, this position will be vacant.
"12-05-2007"	Current date
"11:33:23"	Current time
	Indicates the status of mains power supply

 means the mains power supply is on,

 means the mains power supply is off.

 Indicates the battery and its capacity in the monitor

 means there is a battery in the monitor, and the green part indicates the battery's charge.

 means there is no battery is equipped in the monitor.

 Indicates the audio alarm is turned off.

Indicates the audio alarm is paused.

Indicates the alarm for parameters is turned off.

Other information of the Information 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 patient name.

Alarm message is displayed at the right most area.

"FREEZE" appears when the waveforms are frozen.

Waveform Area (②)

Seven waveforms can be displayed at the same time. The sequence of waveforms can be adjusted. Under the maximum configuration, the system can display 2 ECG waveforms, SpO_2 waveform, Respiration waveform (can be from ECG module), 2 IBP waveforms.

In the "**TRACE SETUP**"menu, all the waveforms are listed. The user can select the waveform to be displayed, and adjust the display position. Refer to "**Waveform Sequence Selection**" for details.

The name of the waveform is displayed on the upper left part of the waveform. The name of ECG is user-selectable. Gain and filter way of this channel are displayed as well. A 1mv scale is marked on the right of ECG waveform. The IBP waveform scale can also be selected according to the actual requirement. Its range is described in the part: IBP Monitoring. In the IBP waveform area, the waveform scale is displayed. The three dotted lines for each IBP waveform from up to down represent respectively the upper limit scale, reference scale and lower limit scale. The values of these three scales can be set. The specific method is given in the part: IBP Monitoring.

When a certain menu is displayed, some waveforms become invisible. Main display is restored when you exit the menu.

The user may set up the rate to refresh the waveform. The method to adjust the refreshing rate of each waveform is discussed in the setup description of each parameter.

Parameter Area(③)

Parameter area is on the right of Waveform area, and parameters are displayed corresponding to waveforms basically. They are:

ECG:

— Heart Rate (Unit: bpm)

— ST-segment analysis of Channel 1 & 2 – ST1, ST2 (Unit: mV)

— PVCs (Premature Ventricular Contraction) events (Unit: event/min)

Oxygen Saturation (SpO_2):

— SpO_2 (Unit: %)

NIBP:

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

TEMP:

— Temperature of channel1 and channel2 and their temperature difference: T1, T2, TD (Unit: °C or °F)

RESP:

— Respiration Rate (Unit: breath/min)

IBP:

— The blood pressure of channel 1 and 2. From left to right, there are Systolic pressure, Mean pressure and Diastolic pressure（unit: mmHg or kPa）

Alarm Indicator and Alarm Status

Under normal status, the alarm indicator does not light.

When alarming, the alarm indicator lights or flashes. The color of light represents the alarm level. Refer to "**Alarm Functions**" for details.

Refer to relative content of parameter for Alarm information and prompt.

Charge Indicator and Charge Status

The light can indicate the status of charging. When the battery is charged, the light color will turn to orange.

1.3 Button Functions

All the operations to M8B Multi-parameter patient monitor can be finished by several buttons and a knob. They are:

Figure 1-4 Buttons

①　Menu	Press to call up the SYSTEM MENU. Refer to Chapter **System Menu** and Chapter **Trend and Event** for details.
②　Start	Press to fill gas into cuff and start blood-measuring. During the measuring process, press the button to stop measuring and deflating.
③　Record	Press to start a real time recording. The recording time is set in RT REC TIME of RECORD submenu.
④　Silence	When the SYSTEM MENU→ MAINTAIN→ USER MAINTAIN → ALARM SETUP is set ON，Press this button to enter the status of ALARM SILENCE. All the alarm audio will be closed. At the same time, "Alarm Pause ×× s" and will be displayed in the interface. When repress it or the pause time is over, the system will stop pausing, and resume the normal monitoring status, and "Alarm Pause ×× s" and icon will vanish. Press this button and hold for more than 3 seconds can turn off the audio alarm. displays on interface. Press or hold the button again can resume the alarm. **NOTE:** Whether an alarm will be reset depends on the status of the alarm cause. But by pressing SILENCE button (suspend alarm) can permanently shut off audio sound of the Lead Off or Sensor Off alarms. So the user can exit the Alarm Silence Status by Technical Alarm.
⑤　Freeze	When in normal mode, press this button to freeze all the waveforms on the screen. When in FREEZE mode, press to restore the waveform refreshing.
⑥　Main	Press to return to the main interface.
⑦　Rotary Knob	The user may use the rotary knob to select the menu item and modify the setup. It can be rotated clockwise or anticlockwise and pressed like other buttons. The user may use the knob to realize the operations on the screen and in the system menu and parameter menu.

Method to Use the Knob to Operate on the Screen:

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

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

Operating method:

- Move the cursor to the item where the operation is wanted.
- Press the knob.
- One of the following four situations may appear:
    1. The cursor with background color may become into the frame without background color, which implies that the content in the frame can change with the rotation of the knob.
    2. Menu or measuring window may appear on the screen, or the original menu is replaced by the new menu.
    3. A check mark "√" appears at the position, indicating that the item is confirmed.
    4. The system immediately executes a certain function.

1.4 Interfaces

For the convenience of operator, interfaces of different function are in different sites of the monitor.

Right Side of the Monitor

At the right side of the monitor, there is the bracket of hydrophobic bottle from the recorder's paper inlet cover (①).
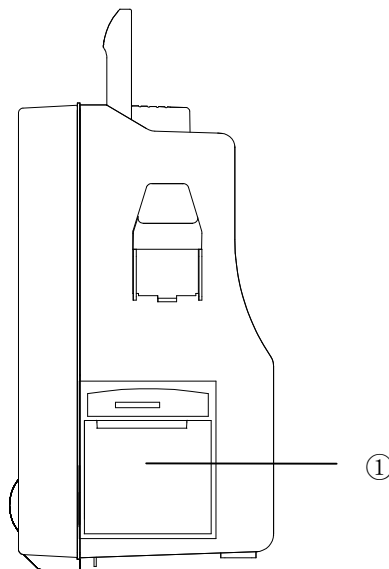
Figure 1-5 Right panel

Left Side of the Monitor

Connectors for cables and sensors are as shown in Figure 1-6.

① TEMP1 probe connector

② TEMP2 probe connector

③ IBP2 transducer connector

④ IBP1 transducer connector

⑤ ECG cable connector

⑥ NIBP cuff connector

⑦ SpO$_2$ sensor connector
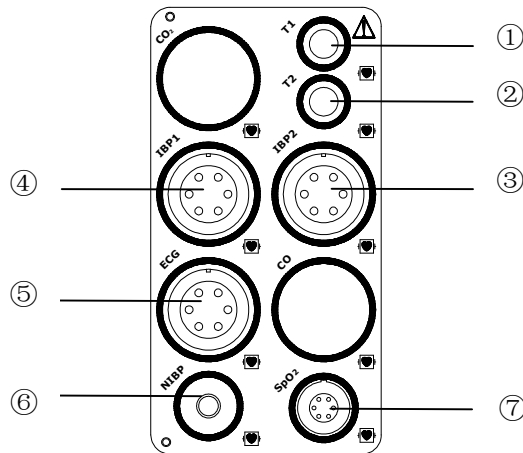
Figure1-6 Left Panel

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

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.

Rear Panel

Figure 1-7 Rear panel of M8B

Sockets on the rear panel are shown in Figure 1-7.

① Network Interface (reserved): Standard RJ45 Socket, for connecting to MFM-CMS of EDAN.

② Equipotential grounding terminal for connection with the hospital's grounding system.

③ Fuse box, used to put fuse in.

④ Power supply socket: AC100-240 V, 50/60 Hz.

1.5 Built-in Chargeable Battery

M8B Multi-parameter Patient Monitor is equipped with a built-in chargeable battery. When switch on AC power supply, the battery will be charged automatically until full electric energy. There is a sign "　　　" in the lower left corner of screen to show the charging status, and the green part is the electric energy of battery. When the monitor is not equipped with battery, the battery status will be showed as the sign "　　　", which means no battery.

One battery can support the working of monitor. Under the cable connectors is the cover of battery slot. See figure1-8 Battery Slot cover.

The charging time for battery resume to 90% quantity of electric charge needs 6 hours.
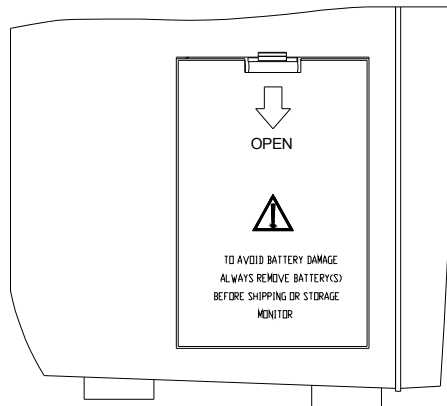
Figure 1-8 Battery Slot Cover

Replace Battery

When the lifespan of battery is over, or foul odor and leakage has been detected, please contact with manufacturer or local distributor for replacement of battery.

⚠ **WARNING** ⚠

Do not unplug the battery when monitoring.
The unexpected power off can not impact the device normal working, for it has battery for standby.

⚠ **WARNING** ⚠

Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.

⚠ **WARNING** ⚠

Make sure the device is used in the appointed range of voltage, the effect of power supply can be not noticeable.

2 Installation of Monitor

■ Open the package and check
■ Install wall mount for M8B
■ 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 **Safety Guidance**, 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 Install Wall Mount for M8B (Optional)
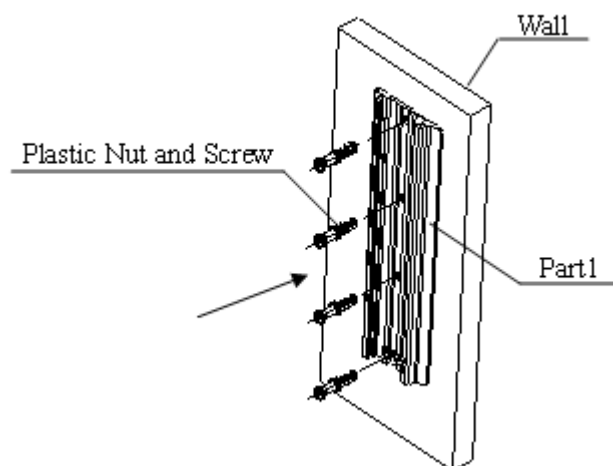
Figure 2-1
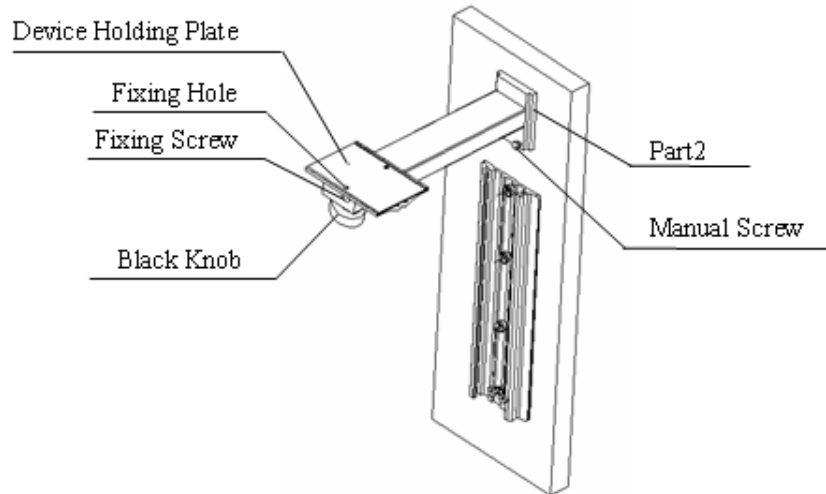
Figure 2-2
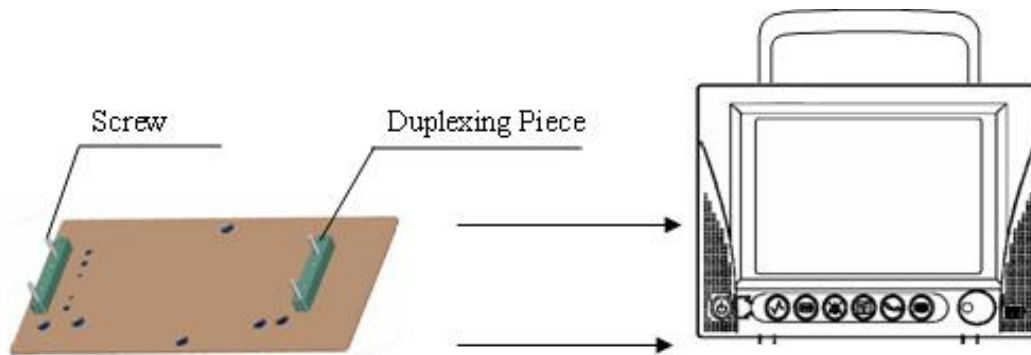
Figure 2-3

Installation Steps:
1. Outline along the part 1 edge against the wall with the desired location.
2. Drill 4 holes of 6 mm diameter in the wall, and knock the plastic nuts in the holes completely.
3. Knock 4 screws in the plastic nuts, when tighten them, secure the channel (part1) at the desired location of the wall (as shown in Figure 2-1).
4. Slide the arm (part2) into channel (part1) as Figure2-2 shown to the desired location.
5. Tighten the manual screw and secure the arm (part2) at the desired position within the channel (part1).
6. Face the side with duplexing piece of the device holding plate to the underside of the M8B, fix it with M4×25mm screw (as shown in Figure 2-3).
7. Pull out the fixing screw from the fixing hole.
8. At the same time, put the arm (part2) into the M8B with the device holding plate, and secure the fixing screw totally through the fixing hole.
9. The M8B can be adjusted maximum 15 degrees by rotating the black knob.

2.3 Connect the Power Cables

Connection procedure of the AC power line:

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

Apply the power line provided with the monitor. Plug the power line to INPUT interface of the monitor (Socket ④ in Figure 1-7). 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 **Safety Guidance** for details.

NOTE:

When the battery configuration is provided, after the device is transported or stored, the battery must be charged. Powering on without connecting AC power supply may cause the device out of work. Switch on AC power supply can charge the battery no matter if the monitor is powered on.

2.4 Power on the Monitor

Power on, LOGO information will be displayed on the screen.

NOTE:

Check all the functions that may be used to monitor and make sure that the M8B is in good status.

NOTE:

If chargeable battery is provided, charge it after using the device every time to ensure the electric power is enough.

⚠ WARNING ⚠

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

NOTE:

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

NOTE:
After continuous 360-hour runtime, please restart the M8B to ensure the monitor's steady performance and long lifespan.

2.5 Connect Patient Sensors

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

NOTE:
For information on correct connection, refer to related chapters.

2.6 Check the Recorder

If your M8B is equipped with a recorder, open the recorder door to check if paper is properly installed in the slot. If no paper is present, refer to Chapter **Recording** for details.

3 System Menu

M8B Multi-parameter 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 output content.

Press the MENU button on the front panel to call up "SYSTEM MENU" menu. You can perform following operations in this menu.
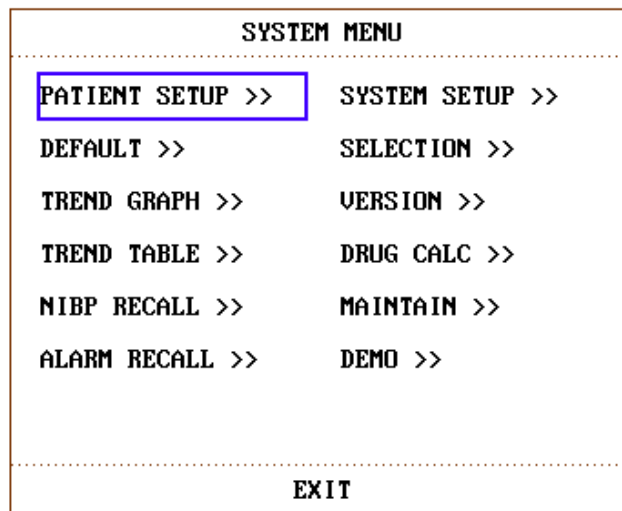
Figure 3-1 System Memu

Review of trend graphs/tables and NIBP measurements will be described in Chapter **Trend and Event**.

3.1 Patient Information Setup

NOTE:
To clear current patient data, refer to New Patient for details.

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

Figure 3-2 Patient Setup

You can setup the following patient information:

DEPT.	Department in which the patient receives treatment.
PAT NO	Patient No.
BED NO	Patient bed number (Range: 1~254)
DOCTOR	Name of the doctor.
NAME	Patient name (Valid characters: A~Z, 0~9; Max. length: 12 characters)
SEX	Patient gender (Available options: "F" for Female, "M" for Male)
PAT TYPE	Patient type (Available options: ADU, PED, and NEO)
ADMIT	Hospitalization starting date (format: year\month\day)
BIRTH	Patient date of birth (format: year\month\day)
HEIGHT(cm/inch)	Patient height (Increase/decrease by 0.5 cm or 0.5 inch per switch)
WEIGHT(kg/lb)	Patient weight (Increase/decrease by 0.5 kg or 0.5 lb per switch)
BLOOD	Patient blood type (Pick A, B, O, AB, or N. "N" represents unknown blood type)
NEW PATIENT	Admission of new patient

Also in this menu, the user may select "NEW PATIENT" item to access "CONFIRM TO UPDATE

PATIENT" dialog box as shown below, in which the user decide whether to monitor a new patient.
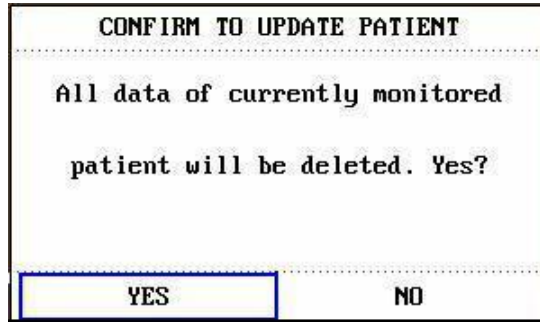
Figure 3-3 Confirm to Update Patient

Pick YES to delete all information of the patient being currently monitored and exit the menu.
Pick NO to give up updating the patient and the system will keep the information of the current patient 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.
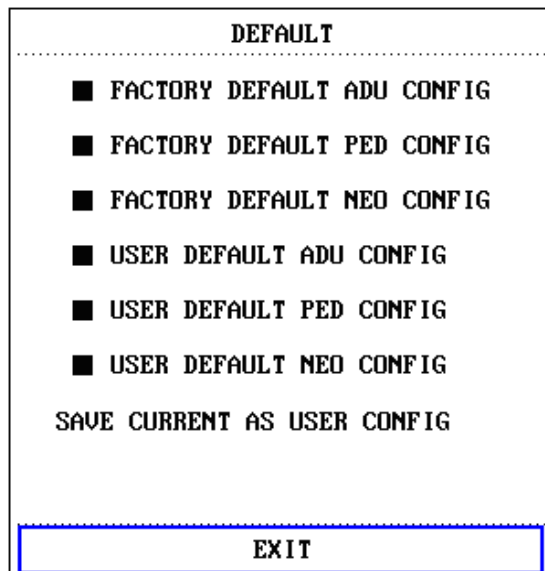
Figure 3-4 Default Menu

In this sub-menu, you can select both the factory default and the user-defined default. Also in this

sub-menu, you can save the current configuration as the user-defined default configuration. At this time, the system will automatically save all the setups in the parameter menu, ECG lead, gain and filter way as the user-defined default configuration according to the patient type. And the dialog box as shown below will pop up.

```
CONFIRM SAVE DEFAULT CONFIG
..............................................

Old user-defined config. For this

patient type will covered. Yes?

..............................................
       YES      |      NO
```
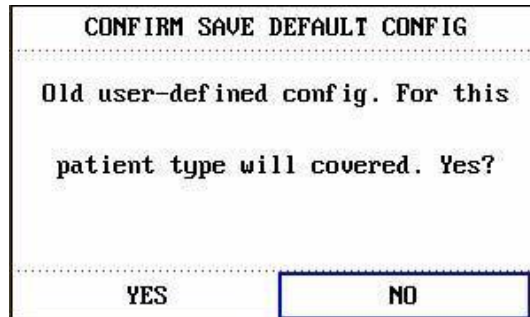
Figure 3-5 Confirm Save Default Config

Pick YES to save the current patient type config as user default configuration.

Pick NO to give up the operation.

3.3 Mark Event

There are four types of events that you can define.
Select "MARK EVENT" item in "SYSTEM SETUP" to call up the following menu:

```
          SYSTEM MARK
..............................................
           EVENT A
           EVENT B
           EVENT C
           EVENT D

..............................................
            EXIT
```
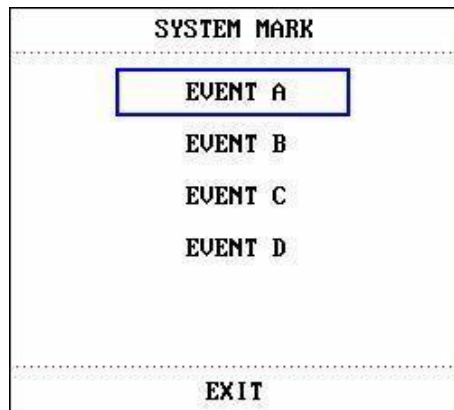
Figure 3-6 Mark Event

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

The point of using event function:
To differentiate the patient events that have impact on parameter monitoring, such as dose taking,

injection, therapy status, etc.

Event will be displayed on the Trend Graph, Trend Table to assist to analyse patient parameter of the time event happened.

3.4 Face Select

Select "FACE SELECT" item in "SYSTEM SETUP" menu to access "FACE SELECT" dialog box as shown below, in which five selections are available: STANDARD SCREEN, TREND SCREEN, oxyCRG SCREEN, VIEWBED SCREEN and LARGE FONT SCREEN. Only one selection can be chosen for each time.
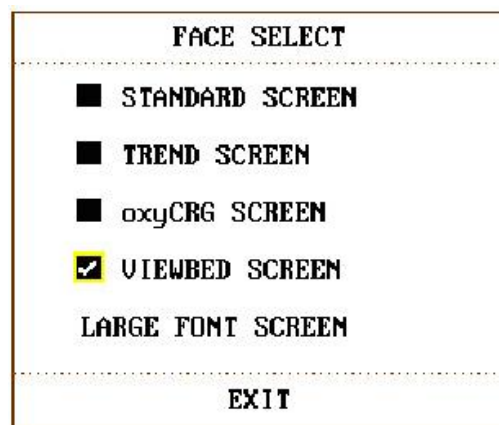
Figure 3-7 Face Select

Enter LARGE FONT SCREEN can select three modes, see as follows:
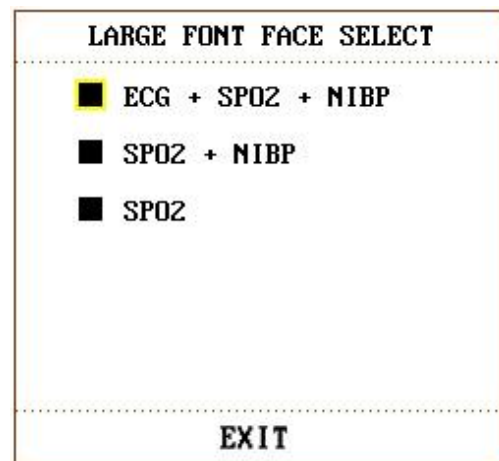
Figure 3-8 Large Font Face Select

3.5 Time Setup

Select "TIME SETUP" item in "SYSTEM 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. Select "EXIT" item to return to the previous

menu.

Figure 3-9 Time Setup

3.6 Recorder Setup

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

Figure 3-10 Record

In the sub-menu, the user may select the "REC WAVE1", "REC WAVE2" or "REC WAVE3" items, maximum 3 waveforms can be printed out.

The output waveforms can be selected for the following items:

ECG1, ECG2	ECG1 waveform and ECG2 waveform. (There will be 7 ECG waveforms on the screen when Full-Lead display). If no ECG waveform is currently displayed on the screen, this item cannot be picked.
SpO_2	SpO_2 Plethysmogram. (If no SpO_2 waveform is currently displayed on the screen, this item cannot be picked. But under ECG Full-Lead display mode, this item can be picked, although no SpO_2 waveform is currently displayed on the screen.)
RESP	RESP waveform. (If no RESP waveform is currently displayed on the screen, this item cannot be picked. But under ECG Full-Lead display mode, this item can be picked, although no RESP waveform is currently displayed on the screen.)
IBP1, IBP2	IBP1 waveform and IBP2 waveform. (If no IBP waveform is currently displayed on the screen, this item cannot be picked. But under ECG Full-Lead display mode, this item can be picked, although no IBP waveform is currently displayed 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 "Record" button on the front panel, the recorder will continuously print out the waveform or parameter until the "Record" button 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:
REC TIME has the priority compared with TIMING REC TIME.

REC RATE: 25.0 mm/s or 50.0 mm/s..
CLEAR REC TASK can be used by the user to stop recorder from printing out too many tasks.

NOTE:
The recorder is an optional part.

NOTE:
If two same waveforms are selected, one of them is switched to a different waveform

automatically.

NOTE:
When ECG waveforms are selected for printing, with gain of ×1, ×0.5 or ×0.25, 3-channel waveform can be printed out; however, with gain of ×2, only 2-channel waveform can be printed out to avoid overlapping of waveforms, and the third waveform will be omitted.
The 3-channel waveform can be printed only in real-time recording, while it is not available in other recording modes, such as alarm review recording, alarm triggered recording.

3.7 Module Setup

Select "MODULE SETUP" item in "SYSTEM SETUP" menu to call up the following menu:

Figure 3-11 Module Setup

You can choose the parameter you want to monitor from this menu, so that you can enhance the display efficiency, and avoid interference from other messages.

3.8 Tracing Waveforms Selection

Select "TRACE SETUP" item in "SYSTEM SETUP" menu to call up the following menu:
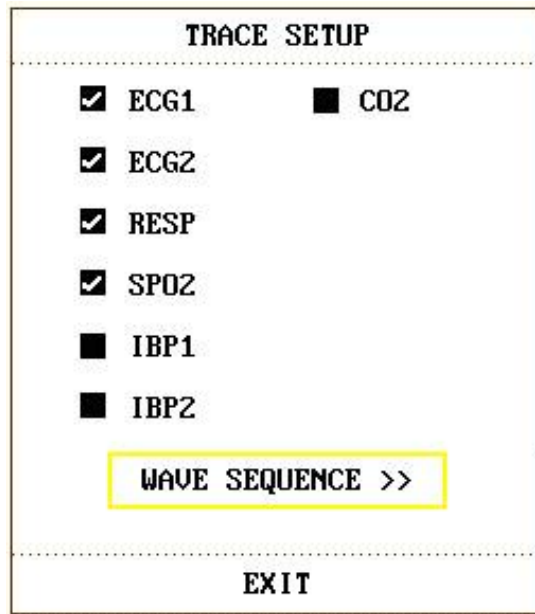
Figure 3-12 Trace Setup

You can define the traces displayed on the screen in this menu. The waveforms available for selection are those whose modules have been selected in "MODULE SETUP" menu.

3.9 Monitor Version

Pick VERSION to show the software version information of this monitor.

3.10 Alarm Volume

The system provides five levels of alarm volume and an alarm silence function. The system will give audio alarm prompt (including no alarm sound) based on the selection.

The user may select different level of volume as per clinical requirement. The method is listed below:

Press "ALARM SETUP" item in "SYSTEM SETUP" menu to call up "ALARM SETUP" sub-menu as shown below, in which the user may set up the alarm volume and other alarm information. Refer to Chapter **Alarm** for details.

```
              ALARM SETUP
..............................................................
  ALM SEL   ┌──────────────────────────┐
            │ COMMON ALM SETUP         │
            └──────────────────────────┘

     ALARM VOL        3
     ALM REC TIME     8S




..............................................................
              EXIT
```
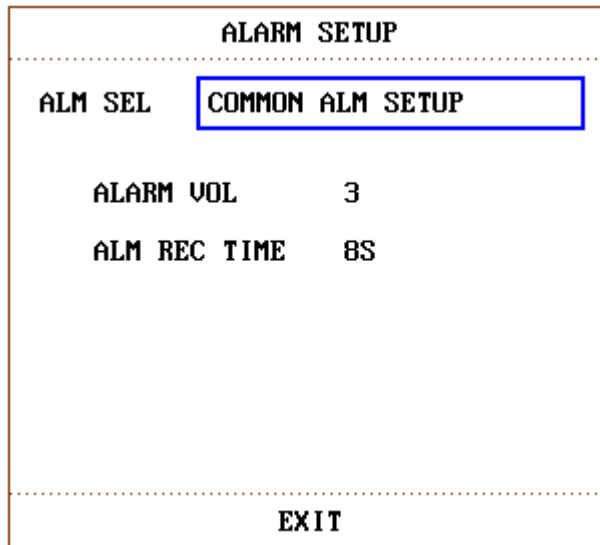
Figure 3-13 Alarm Setup

Pick ALARM VOL to set the volume of alarm sounds by turning the knob. The selections are "1~5".

You can also set alarm parameters in MAINTAIN →USER MAINTAIN →ALARM SETUP. Refer to Chapter5 Alarm for details.

⚠ **WARNING** ⚠

If the alarm volume is off, when there is alarm, the M8B can not give audio alarm prompt, so the user should use this function cautiously.

3.11 Key Volume

Select "SELECTION" item in "SYSTEM SETUP" menu to call up "SELECTION" sub-menu as shown below. Select "KEY VOL" item and set the volume. The selections are "OFF, LOW, MED, HIGH".

```
              SELECTION
..............................................................
   KEY VOL    ┌────────────┐
              │ MED        │
              └────────────┘



..............................................................
              EXIT
```
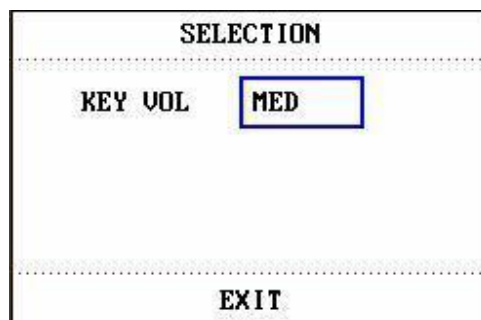
Figure 3-14 Selection

3.12 Drug Calculation

The M8B provide drug calculation and titration table display functions for fifteen different drugs. For details, please refer to the Chapter: **Drug Calculation and Titration Table.**

3.13 Waveform Demonstration

Select "DEMO" item in "SYSTEM MENU" to call up "INPUT DEMO KEY". After entering the password, the system enters the Demonstration Waveform status.

The purpose of waveform demonstration is only to demonstrate the machine performance, and for training purpose. In clinical application, this function is not recommended because the DEMO will mislead the hospital workers to treat the waveform and parameter as actual data of the patient, which may result in delay of treatment or mistreatment.

3.14 Maintenance

Select "MAINTAIN" item in "SYSTEM MENU" to call up "ENTER MAINTAIN PASSWORD" dialog box as shown below, in which you can enter password and then customize maintenance settings. User can not execute factory maintenance function, which is only available for the service engineers of EDAN or local representative authorized by EDAN.

Figure 3-15 Enter Maintain Password

User Maintain

Input the password into the "ENTER MAINTAIN PASSWORD" box and press "CONFIRM", the "USER MAINTAIN" menu will pop up, in which you can set up following items.

```
USER MAINTAIN
..........................................................
LANGUAGE                ENGLISH
Note:Please Restart To Change Language!
LEAD NAMING             AHA
LOCAL NET NO            1
 ALARM SETUP>>
 OTHER SETUP>>
SERVER IP               202   114   4     119
SERVER PORT             Auto
 CO2 CHECK >>
 GAS CALIBRATE >>
..........................................................
                   EXIT
```

Figure 3-16 User Maintain

LANGUAGE: You can set one of the eight interface languages, which are "CHINESE", "ENGLISH", "RUSSIAN", "ITALIAN", "SPANISH", "FRENCH", "POLISH" and "GERMAN".

NOTE:
Please restart the monitor after changing the language.

LEAD NAMING: You can select "AHA" or "EURO". To know the difference between these two styles, refer to Chapter **ECG/RESP Monitoring.**

LOCAL NET NO: Physical No. of monitor.

ALM SETUP>>: You can set up parameters of alarm. For more details refer to Chapter **Alarm**:

Figure 3-17 Alarm Setup

OTHER SETUP>>: you can setup some parameters, such as module type. See as follows:

Figure 3-18 Other Setup

NURSE CALL: turn on or off nurse call. When a new alarm of physiological parameter occurs, it gives 3-second NURSE CALL alarm; if the system alarm or the audio alarm is turned off, the NURSE CALL is unavailable. It is connected to RJ45 socket, the same port as connected to Ethernet. NURSE CALL occupies the 7th and 8th pins of RJ45. When alarm occurs, the 7th and 8th pins are in short circuit, otherwise they are disconnected.

SERVER IP: Setup server IP.

SERVER PORT: Setup server port.

CO_2 CHECK>>: For calibrating CO_2. Unavailable for M8B.

GAS CALIBRATION>>: For calibrationing gas for AG monitoring. Unavailable for M8B.

Factory Maintain

Factory maintenance function is only available for the service engineers of EDAN or representative authorized by EDAN.

1. Enter factory maintain through password.
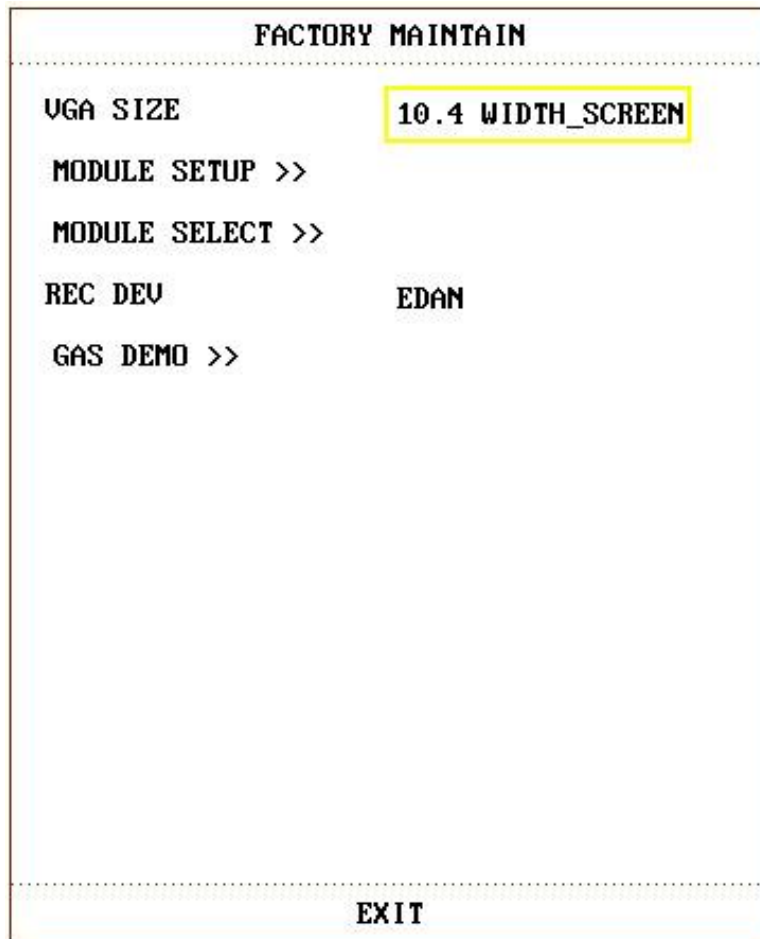
Figure 3-19 Factory Maintain

VGA SIZE: set this item to 10.4' WIDTH_SCREEN.

MODULE SELECT:

Figure3-20 Select Module

NOTE:

For M8B, the AG, CO_2 functions are unavailable.

2. **Enter representative maintain through password.**

Figure 3-21 Representative Maintain

SELECT MODULE:

Figure3-22 Select Module

For changing password:

Figure 3-23 Change Password Interface

Prompts for changing password:

Figure 3-24 Save Failure

Figure 3-25 Save Successfully

4 Face Select

The M8B has five different operating screens, which are "Standard Screen", "Trend Screen", "oxyCRG Screen", "VIEWBED SCREEN"and "Large Font Screen". When required, you can select different operating screen for necessary information. Let's probe into these four operating screens one by one.

4.1 Select Operating Screen

Select "FACE SELECT" item in "SYSTEM SETUP" menu to access "FACE SELECT" dialog box as shown below, in which five selections are available: STANDARD SCREEN, TREND SCREEN, oxyCRG SCREEN, VIEWBED SCREEN and LARGE FONT SCREEN. Only one selection can be chosen for each time.
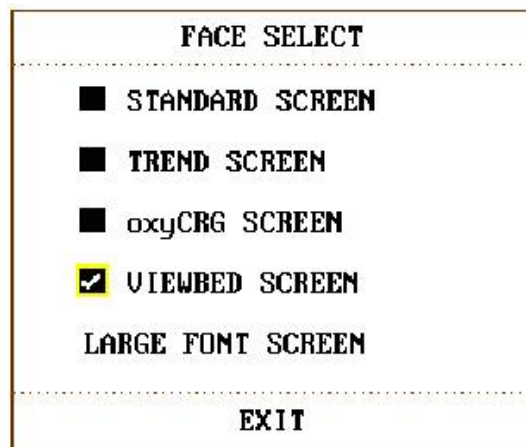
Figure 4-1 Face Select

4.2 Standard Screen

In the "FACE SELECT" menu, select the "STANDARD SCREEN" option to enter the Standard Screen. The Standard Screen displays to us the parameters in the Parameter area and the waveforms being monitored. This screen is the basic operating screen of the monitor.
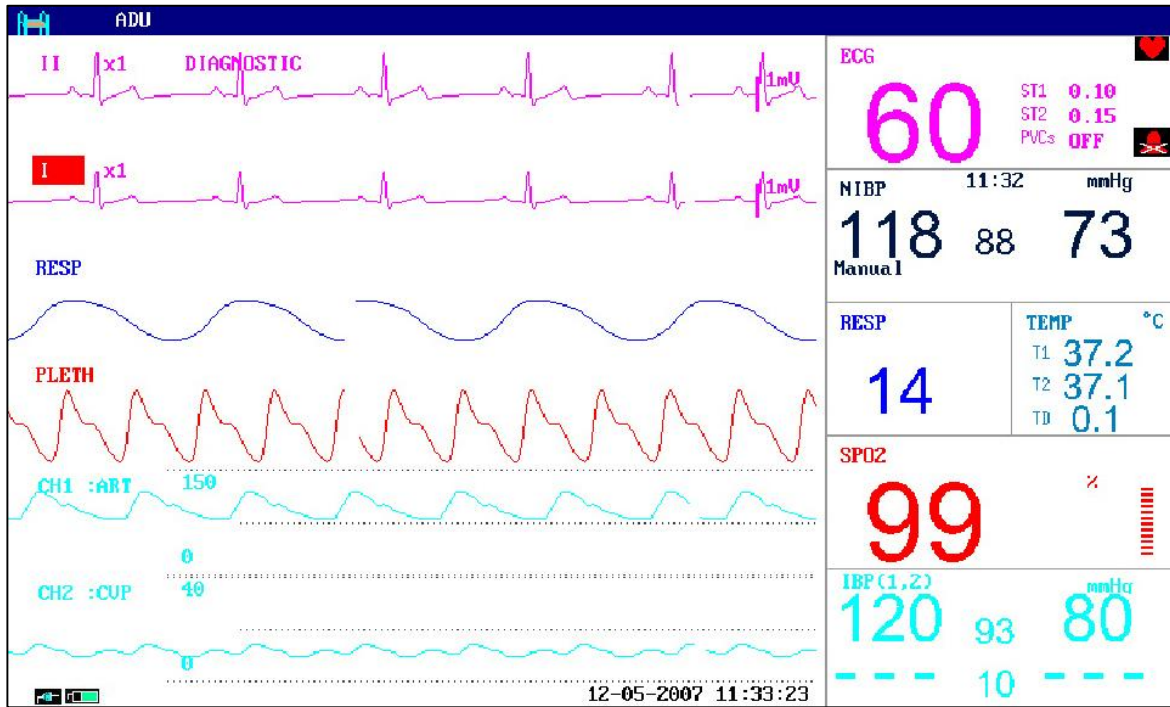
Figure 4-2 Standard Screen

4.3 Trend Screen

Enter TREND SCREEN

In the "FACE SELECT" menu, select the "TREND SCREEN" option to enter the Trend Screen.
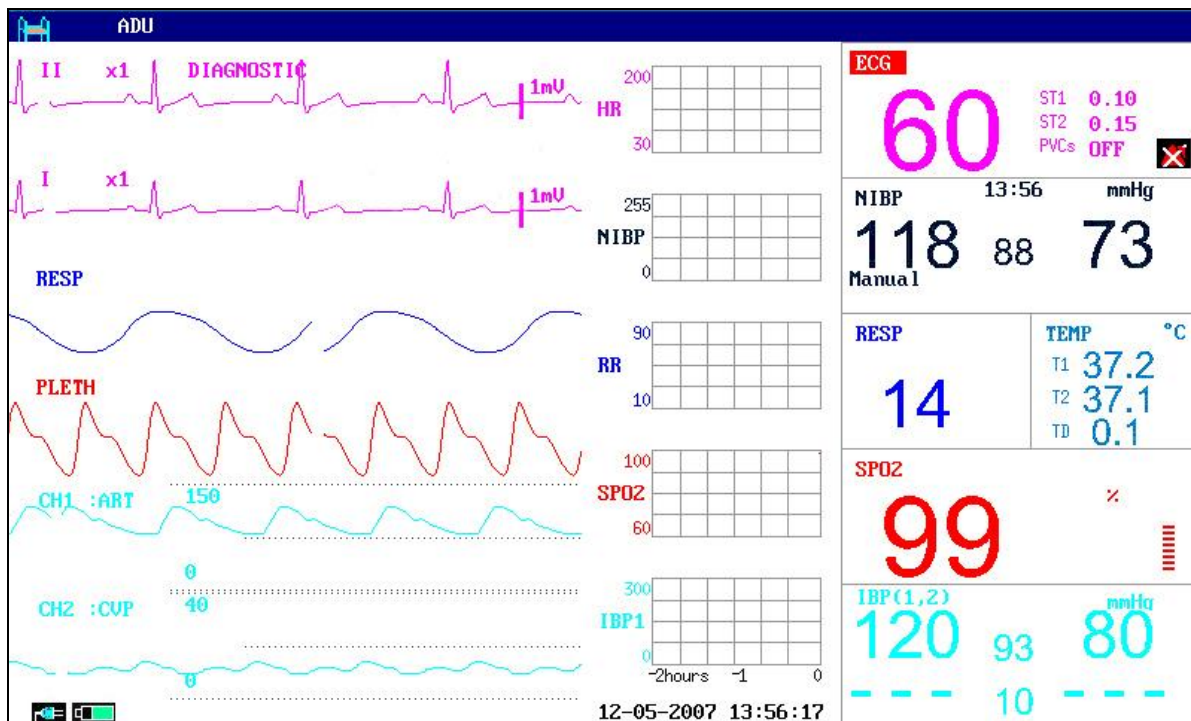
Figure 4-3 Trend Screen

Position of trend graph

Trend graph is located to the right of the corresponding waveform in the Waveform area. Its color is the same as that of the corresponding parameter.

Trend length

Dynamic trend length is 2 hours. On the trend graph, the scale of the right end of the X-axis is 0 hour while the left end is 2-hour.

Select trend parameter

If M8B are located at the same position on the trend graph, by selecting the corresponding hot key of a parameter on the trend graph, you can have the trend graph of this parameter displayed on the screen. For example, in ECG trend graph, you can select hot keys such as HR, ST or PVCs, then the system will display their corresponding trend graphs respectively.

Close trend screen

In the "FACE SELECT" menu, select options of other operating screens to close the Trend Screen.

4.4 oxyCRG Screen

Enter oxyCRG SCREEN

In the "FACE SELECT" menu, select the "oxyCRG SCREEN" option to enter the oxyCRG Screen.
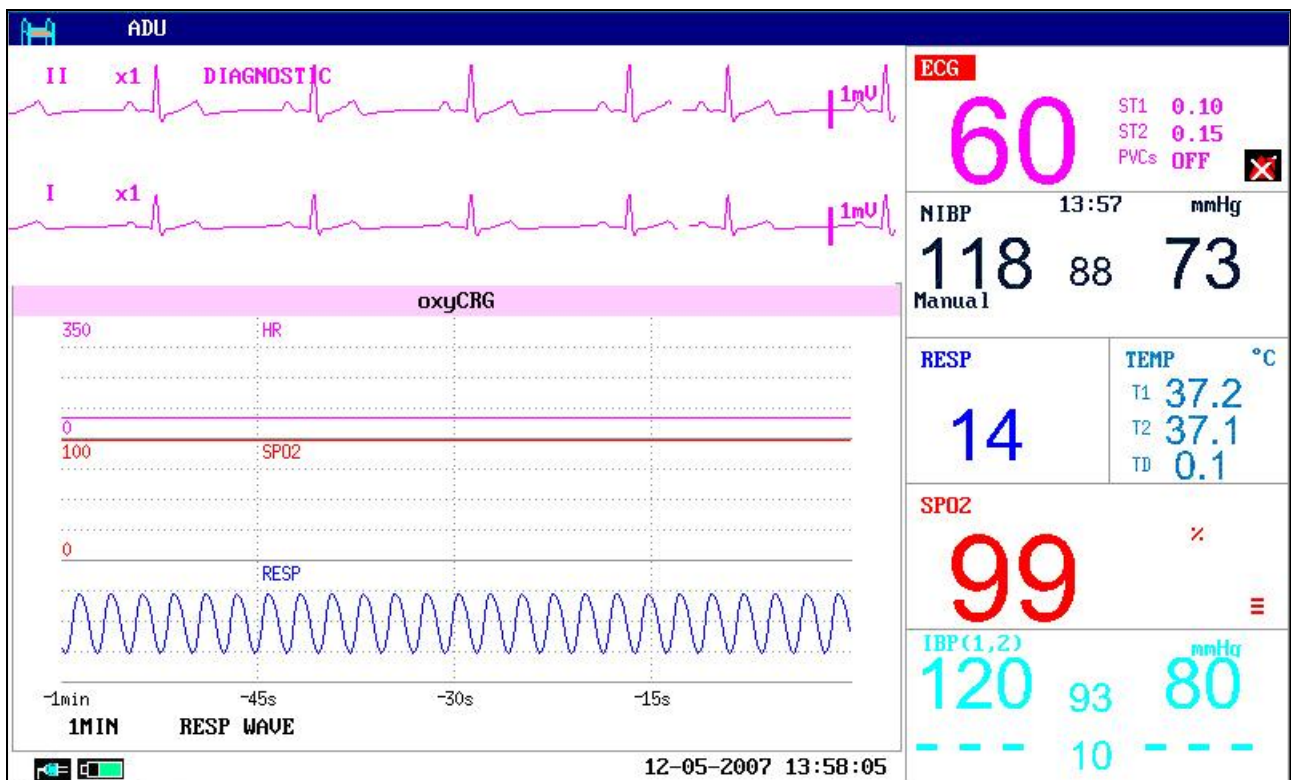
Figure 4-4 oxyCRG Screen

Trend graph of oxyCRG screen

Located at the lower part of the screen, oxyCRG screen consists of three trends: HR Trend, SpO$_2$ Trend and RR Trend or Compressed Resp. Waveform.

Select oxyCRG trend length

There are two hot keys at the bottom part of the oxyCRG Screen, which are 4MIN/2MIN/1MIN, RR/RESP WAVE.

By using hot keys for trend time, you may select to display trend graphs of three different lengths, i.e., 1 min, 2 min and 4 min.

Select RR trend or Compressed Resp. Waveform

By using the hot keys for RR/RESP WAVE, you may select either RR trend graph or compressed Resp. Wave. They occupy the same position. Therefore, if you select "RR", the position displays the dynamic trend of RR. If you select "RESP WAVE", the position displays the compressed Resp. Wave.

Close oxyCRG

In the FACE SELECT menu, select other options of operating screen to close the oxyCRG Screen.

4.5 Viewbed Screen

If another monitor is connected on the same LAN of this monitor, you can use this monitor to view any measured waveform and information about all measured parameters from another monitor.

Enter Viewbed Screen

Select the "VIEWBED SCREEN" option in the "FACE SELECT" menu. Viewbed Screen window occupies the space of the bottom four waveforms.
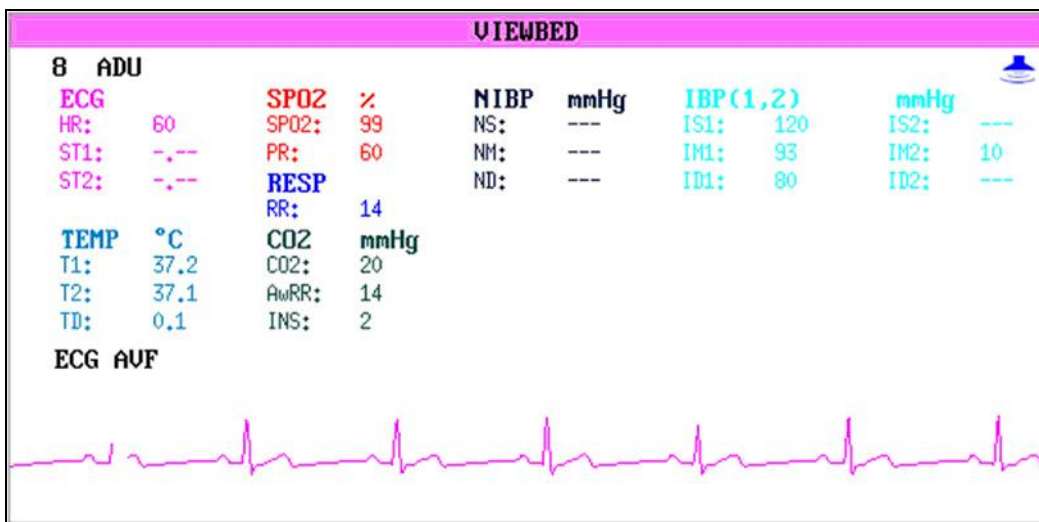
Figure 4-5 Viewbed Screen

Hot key of Viewbed

There are two hot keys in the Viewbed Screen: Select Bed Number and Select Waveform.

The hot key of Select Bed Number displays the bed numbers and patient names of other monitors currently connected on the LAN. You can select a monitor to be monitored according to the patient name and bed number. If at this time no other monitors are connected on the same LAN of this monitor, the hot key of Bed Number will therefore display "N/A". After you use this hot key to select a monitor to be viewed, the system will toggle to the display of the selected monitor for your view. The selected waveform is one of those listed in the hot key of Select Waveform.

The hot key of Select Waveform is used to select a waveform generated by the monitor being viewed. If the hot key of Select Waveform displays "N/A", it indicates that the bedside monitor being viewed has no waveforms. You can use this hot key to select and therefore view different waveforms of the monitor being viewed.

Alarm indicator of Viewbed

On the upper right side of the Viewbed Screen, there is an Alarm Indicator used to tell the alarm status of the monitor being viewed. The activity of this alarm indicator is identical with that of the alarm lamp on the panel of the monitor being viewed. That is to say, if the monitor being viewed occurs medium/low level alarm, this alarm indicator illuminates yellow; if it occurs high level alarm, this alarm indicator illuminates red. If the monitor being viewed has no alarm or the alarm is screened, the icon for this alarm indicator will not be displayed.

Parameter area of Viewbed Screen

Under the hot key of Select Bed Number is the Parameter area, in which parameters of all monitors being viewed are displayed.

Waveform area of Viewbed Screen

Under the hot key of Select Waveform is the Waveform area. The Sweep manner (refreshing or scrolling) of the waveform is identical with that of this monitor. The feature description of the displayed waveform is given above the waveform. Sweep speed is also identical with that set up for the same waveform on this monitor.

Close Viewbed Screen

In the FACE SELECT menu, select options of other operating screens to close the Viewbed Screen.

Rules for automatically selecting monitor to be viewed and waveform

When you turn on the monitor or enter Viewbed Screen, the system will automatically select a networked bedside monitor and a waveform of this monitor for you to view. If the monitor being currently viewed is disconnected, the viewed monitor will automatically close, clear displays of all alarms, parameters and waveforms. However in this situation, the Viewbed Screen still displays. If you want to view another monitor, you must select again through using hot keys.

If a measure module of the viewed monitor is plugged out or closed, its corresponding waveform will disappear and the waveform in the Waveform area will not be refreshed. Instead this Waveform area will display empty. At this time, if you want to view other waveforms of this monitor, you need to select again.

4.6 Large Font Screen

Large Font Screen is a kind of operating screen, just like Standard Screen, Trend Screen and other operating screens. It is used by customer to meet different display requirements in monitoring.

Enter Large Font Screen

Choose LARGE FONT SCREEN in FACE SELECT menu to enter LARGE FONT FACE SELECT. There are three modes, see as follows:
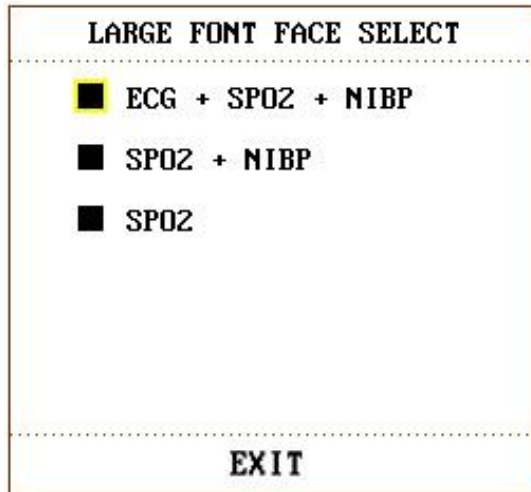
Figure 4-6 Large Font Face Select

Three display modes

1. ECG+SpO$_2$+NIBP display mode:
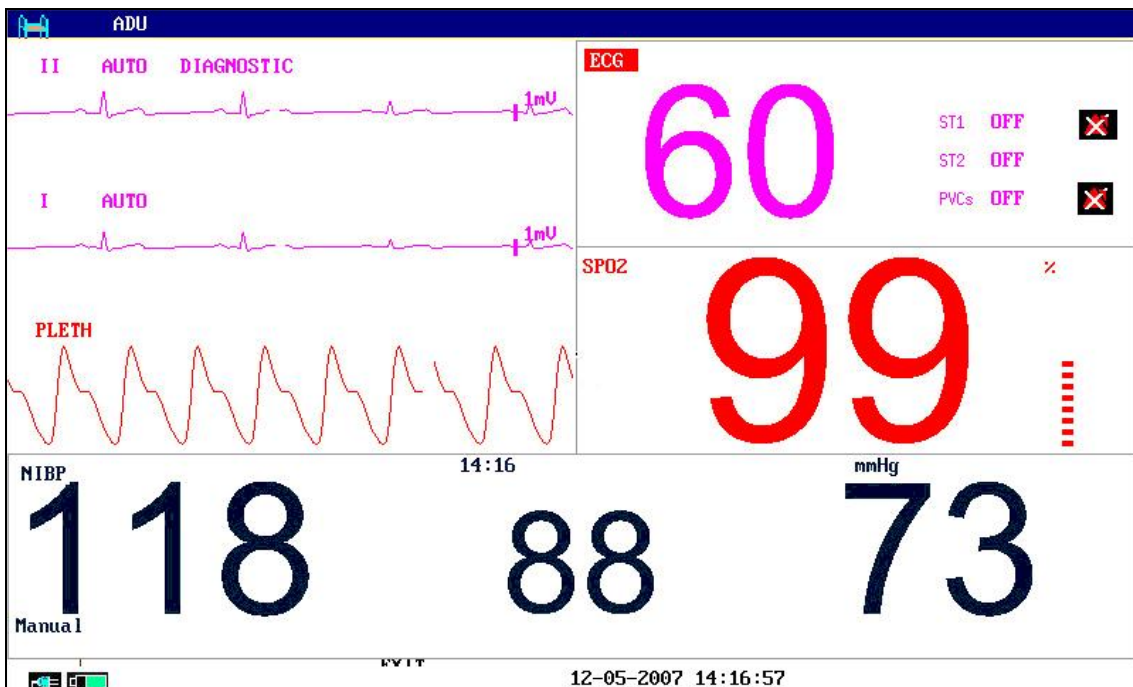
Figure 4-7 ECG+SpO$_2$+NIBP display mode

2. SpO$_2$+NIBP display mode:
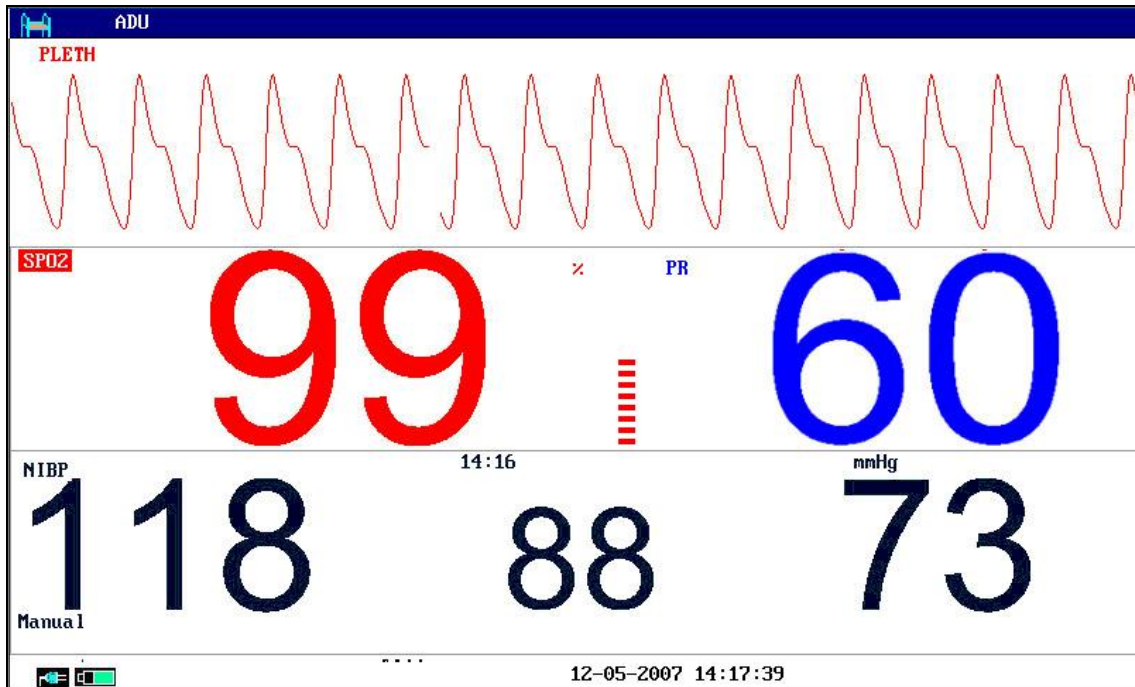
Figure 4-8 SpO$_2$+NIBP display mode

3. SpO$_2$ display mode:
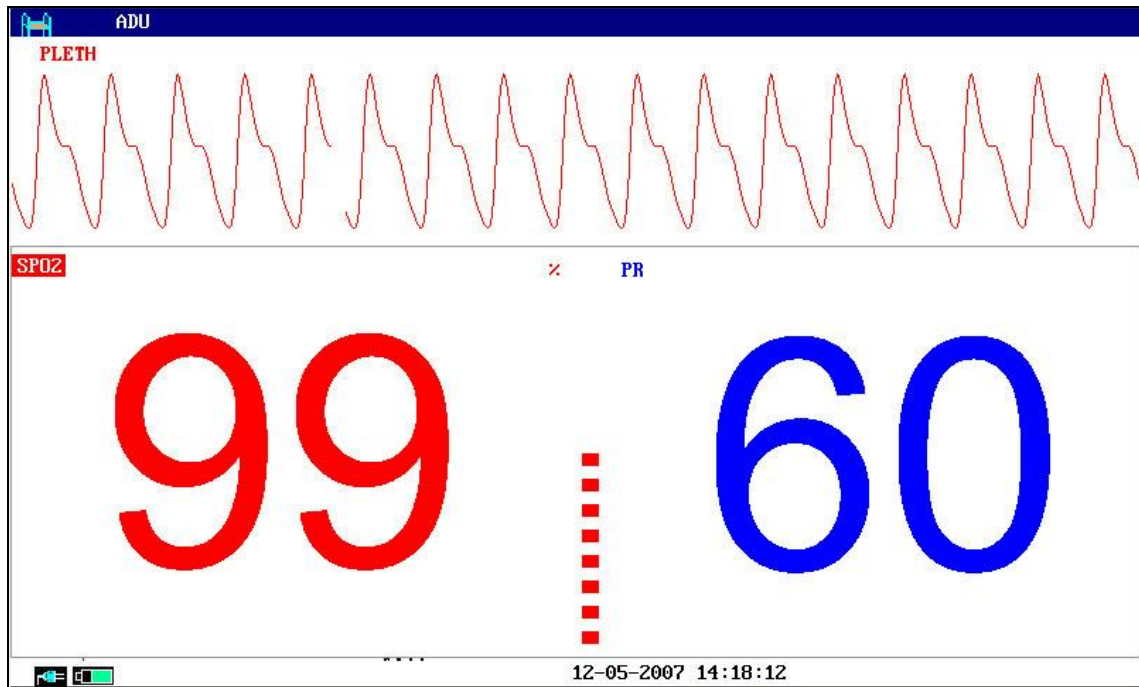
Figure 4-9 SpO$_2$ display mode

Exit Large Font Screen

In the LARGE FONT FACE SELECT menu, choose EXIT to return to FACE SELECT screen.

5 Alarm

This chapter gives general information about the alarm and measures to be taken accordingly. Alarm setup and prompt messages are provided in respective parameter setup sections.

5.1 Alarm Modes

5.1.1 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 various ways. Some alarm's level can be set by the user via software. Others can not be changed once defined by the system. Alarms in M8B are divided into three levels which are high, medium and low.

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

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

M8B Multi-parameter patient monitor 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 preset in the system.
All technical alarm level and general alarm level, some of the physiological alarm levels are preset in the system and can not be changed by user.

5.1.2 Alarm Modes

When alarm occurs, M8B Multi-parameter patient monitor 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 M8B is connected to the external alarm prompt system (e.g. the alarm speaker and indicator connected onto the rear panel of the monitor), when alarm occurs, the external alarm prompt system responds in the same way as the the monitor.

NOTE:

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

How to indicate that the measured parameter has exceeded its alarm limits:

When physiological alarm of the monitored parameter exceeds the alarm limit, besides using the above-mentioned three ways to give the alarm prompt, the M8B gives alarm by making the monitored parameter flash in the frequency of 1Hz.

Screen Display

When the measured parameter exceeds its alarm limits and triggers a physiological alarm, the corresponding parameter value will flash. "*" 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 orange with low frequency.
Low	Alarm indicator lights on in orange.

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 10 seconds.
Medium	Mode is "DO-DO-DO", which is triggered once every 25 seconds.
Low	Mode is "DO-", which is triggered once every 30 seconds.

NOTE:

When alarms of different levels occur at the same time, the M8B prompts the one of the highest level.

5.1.3 Alarm Setup

Setup alarm in the ALARM SETUP menu

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

```
                ALARM SETUP
..................................................

ALM SEL    ┌─────────────────────────┐
           │ COMMON ALM SETUP        │
           └─────────────────────────┘

    ALARM VOL       3

    ALM REC TIME    8S





..................................................
                 EXIT
```
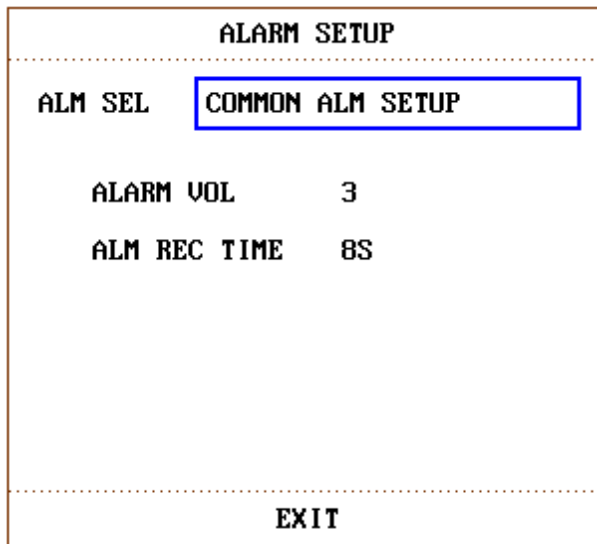
Figure 5-1 Alarm Setup

COMMON ALM SETUP

Select "COMMON ALM SETUP" selection in "ALM SEL" item. This operation may call up the dialog box as the default one.
ALARM VOL: have five selections: 1, 2, 3, 4 and 5.
ALM REC TIME: which has three selections: 8S, 16S, 32S.

Alarm setup of each parameter

In the "ALARM SETUP" menu, select the "ALM SEL" item to set up the alarm information for following parameters. They are HR, ST, PVCs, SpO$_2$, NIBP, IBP (1, 2), RESP, TEMP, CO$_2$, CO and AG. For example:

Method to set up HR alarm information:

Step 1: Select the "HR ALM SETUP" option in the "ALM SEL" item. Then the menu only displays HR setup items.

Step 2: You can set up five items in this menu, which are HR ALM (on/off of the alarm switch), ALM LEV (alarm level), ALM REC (alarm recording switch), ALM HI (higher limit of HR alarm), ALM LO (lower limit of HR alarm). You can move the cursor onto the item to be setup by using the knob and press the knob to make the setup.

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

Setup alarm in the User Maintain menu

You can also setup alarm parameters in SYSTEM MENU→ MAINTAIN→ USER MAINTAIN → ALARM SETUP. See as follows:
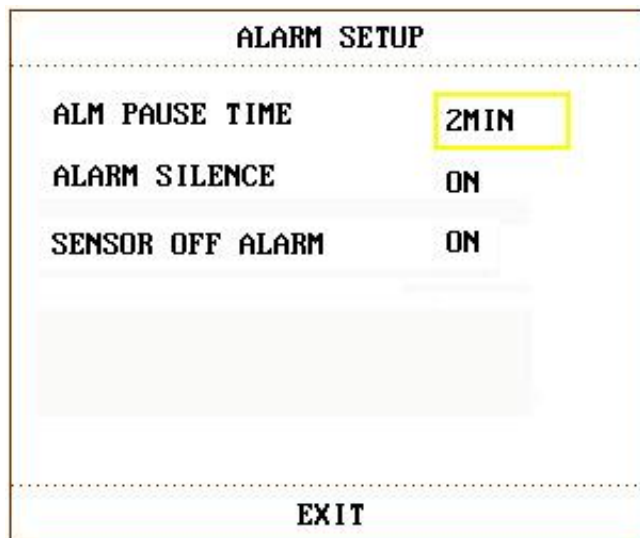
Figure 5-2 Alarm Setup in User Maintain

ALM PAUSE TIME: set up the duration of Alarm Pause status. Three options are available, 1 minute, 2 minutes and 3 minutes.

ALARM SILENCE: when it set to ON, hold the Silence button on front panel for 3 seconds, the alarm will be silenced. During the silence, the monitor gives Low alarm for alarm silenced state per 3 minutes. Press this button again to turn on the alarm system.

SENSOR OFF ALARM: turn on or off the sensor off alarm. When this item is set ON, press Silence button on front panel can pauze the audio alarm. And press again to resume the audio alarm; at the alarm paused state, it will give alarm if sensor off alarm occurs.

5.2 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.

C. General alert

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

5.3 SILENCE

SILENCE

Enter SYSTEM MENU→ MAINTAIN→ USER MAINTAIN → ALARM SETUP, if the ALARM SILENCE is set to ON, press Silence button to turn off the audio alarm or paused it.

1. Audio alarm paused icon

When the ALARM SILENCE is ON, press Silence button on front panel, then the audio alarm is paused. And the paused time can be set in ALARM SETUP menu, see figure 5-2. The audio alarm paused icon displays in Information area. Press Silence button again can resume the audio alarm.

2. Audio alarm off icon

Press the Silence button for more than 3 seconds, the audio alarm is turned off. Then press Silence button again or hold it for few seconds can turn on the audio alarm. At the audio alarm off state, the monitor gives a Low alarm beep per 3 minutes to prompt that the alarm is turned off.

NOTE:
Whether an alarm will be reset depends on the status of the alarm cause.

5.4 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.

5.5 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. Identify which parameter is alarming or which alarm is happening.
4. When cause of alarm has been over, check that the alarm is working properly.

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

6 Freeze

General
Freeze & Unfreeze
Review Frozen Waveforms

6.1 General

When monitoring a patient, you may freeze the waveforms of interest so as to view them carefully. Generally you can review maximally 120 seconds of a frozen waveform. The Freeze function of this monitor has following features:

Freeze status can be activated on any operating screen;
At the same time of entering the Freeze status, the system exits all other operating menus. Besides, the system freezes all waveforms in the Waveform area of the Basic Screen, and also freezes Full Lead ECG waveforms and extra waveforms in the Full Lead ECG interface(if have). Nevertheless the Parameter area refreshes normally.
The frozen waveforms can be reviewed.

6.2 Enter/Exit Freeze Status

Enter Freeze Status

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

Exit Freeze Status

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

Select the "EXIT" option on the "FROZEN" menu;
Press the "Freeze" button on the control panel again;
Press the non-immediate-to-execute button (such as a button once pressed, a menu will pop up for you to further select an option) on the front panel and system buttons of Menu and Main;
Execute any operation that may trigger the adjustment of the screen or display of a new menu.

After exiting the Freeze status, the system will discharge the Freeze status, clear screen waveforms and resume display real-time waveforms. In the Screen Refresh mode, the system will sweep the waveforms from the left to right in the Waveform Area.

6.3 FROZEN Menu

Press the "FREEZE" button on the control panel, the FROZEN menu will appear on the bottom part of the screen. At the same time, the system enters the Freeze status.
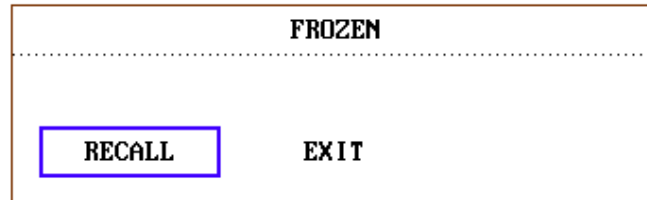
Figure 6-1 Frozen

RECALL: used to review frozen waveforms.
EXIT: after pressed, the system closes the FROZEN menu and exits the Freeze status.

NOTE:
Pressing the "Freeze" button repeatedly in short time may result in discontinuous waveforms on the screen.

6.4 Reviewing Frozen Waveform

By moving the waveform, you may review a waveform of 120 seconds before the moment when it is frozen. For a waveform less than 120 seconds, the remaining part is displayed as a straight line. Use the rotary snob on the control panel to move the cursor to the "RECALL" option on the FROZEN menu. Press the knob. By turning the knob left or right, frozen waveforms on the screen will move left or right correspondingly. There is an arrow indicating upward under the right side of the last waveform. There is also a time scale beside the arrow. "-0S" is used to mark the moment when waveforms are frozen. With waveforms moving right, this time mark will in turn change into -1S, -2S, -3S… These time marks are applied to all waveforms on the screen.

7 Recording (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 M8B Multi-parameter Patient Monitor.

Performance of the Recorder

Waveform record is printed out at the rate of 25 mm/s or 50 mm/s.

It can record up to 3 waveforms.

English printout.

User-selectable real-time recording time and waveform.

Auto recording interval is set by the user, the waveform is in accordance with the real time recording.

7.2 Recording Type

M8B Multi-parameter patient monitor provides several stripe recording types:

Continuous real-time recording

8 second real-time recording

Auto 8 second recording

Alarm recording

Frozen waveform recording

Trend graph, trend table recording

Arrhythmia review recording

Drug calculation titration recording

NIBP review recording

Alarm review recording

oxyCRG recording

NOTE:
When ECG waveforms are selected for printing, with gain of ×1, ×0.5 or ×0.25, 3-channel waveform can be printed out; however, with gain of ×2, only 2-channel waveform can be printed out to avoid overlapping of waveforms, and the third waveform will be omitted.
The 3-channel waveform can be printed only in real-time recording, while it is not available

in other recording modes, such as alarm review recording, alarm triggered recording.

Real-time Recording

Real-time recording starts as you press the "Record" 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 three 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 three waveforms to be printed out. The User can setup one or two waveforms off. Thus, the real time record will print out one or two waveforms. If three waveforms are off, the real time record will print out measure parameters only.

NOTE:
When the system is executing a recording task, the system can start executing next alarm recording task only when the current one is finished.

Auto Recording

The monitor starts the recorder for 8 seconds according to interval time set in the "TIMING REC TIME" of the "RECORD" menu. Refer to Chapter **Recorder Setup** for details.

Alarm Recording

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:

① 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.

② If an alarm occurs during the alarm of another parameter, it will be printed out after the current recording is finished.

③ If many alarms occur at the same time, some of waveforms will be stored for printout in turn.

ST Segment Alarm

The M8B 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.

Arrhythgmia Alarm

The M8B records 2-channel ECG waveforms 4, 8, or 16 seconds prior to and after the alarm (totally 8, 16 or 32 seconds). All measurement results during the alarm will also be recorded.

Titration Table

The M8B can print out the message in the current TITRATION window.

Notes on Recording

Recording types:

Real time Report

Periodic Report

Para Alarm Report

Titration Table

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.

7.3 Recording Startup

You can start the recording in the following ways:

Continuous real-time recording	Press the "Record" button to start/stop the recording.
8 second real-time recording	Press the "Record" button to start recording. It will automatically stop in 8 seconds.
Auto recording	Record the three waveforms selected in RECORD menu according to the setup time interval in RECORD menu. It will automatically stop in 8 seconds.
Alarm recording	When alarm recording is set ON, it automatically starts when alarm occurs.

Trend graph recording	Access the "TREND GRAPH" menu, then press the "Record" button to start recording.
Trend table recording	Access the "TREND TABLE" menu, then press the "Record" button to start recording.
Arrhythmia review recording	Enter the "ECG SETUP" menu via hot key, select "ARR ANALYSIS"→"ARR RECALL", then press the "Record" button to start recording.
Alarm review recording	Access the "ALARM RECALL" menu, then press the "Record" button to start recording.
NIBP review recording	Access the "NIBP RECALL" menu, then press the "Record" button to start recording.
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.

NOTE:

You can press the "Record" button on the control panel to stop the current recording process.

Access the "RECORD" menu from the "SYSTEM 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 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.

Proper Operation

■ When the recorder is working, the record paper goes out steadily. Do not pull the paper outward with force, otherwise the recorder may be damaged.
■ Do not operate the recorder without record paper.

Paper Out

When "RECORDER OUT OF PAPER" alarm is displayed, the recorder can not start. Please insert

record paper properly.

Inserting Paper

■　Place fingers under the two sides flange of the recorder casing, pull outwards directly to release the casing.

■　Insert a new roll of paper into the paper cassette, printing side facing upwards.

■　Ensure proper position and tidy margin.

■　Pull about 2 cm of the paper out, and close the recorder casing.

NOTE:

Be careful when inserting paper. Avoid damaging the thermo-sensitive print head. Unless when inserting paper or shooting troubles, do not leave the recorder catch open.

Removing Paper Jam

When the recorder functions or sounds improperly, you should open the recorder casing to check if there is a paper jam. Removing the paper jam in the following way:

■　Cut the record paper from the feeding edge.

■　Open the recorder casing.

■　Re-insert the paper.

8 Trend and Event

M8B Multi-parameter patient monitor provides 96-hour trend data of all parameters, storage of 500 NIBP measurement results and 60 alarm events. This chapter gives detailed instruction for review of all data.

8.1 Trend Graph

■ The latest 1-hour trend is displayed every 1 or 5 seconds;
■ The latest 96-hour trend is displayed every 1, 5 or 10 minutes;

Pick "TREND GRAPH" in the SYSTEM MENU to call up the following menu:
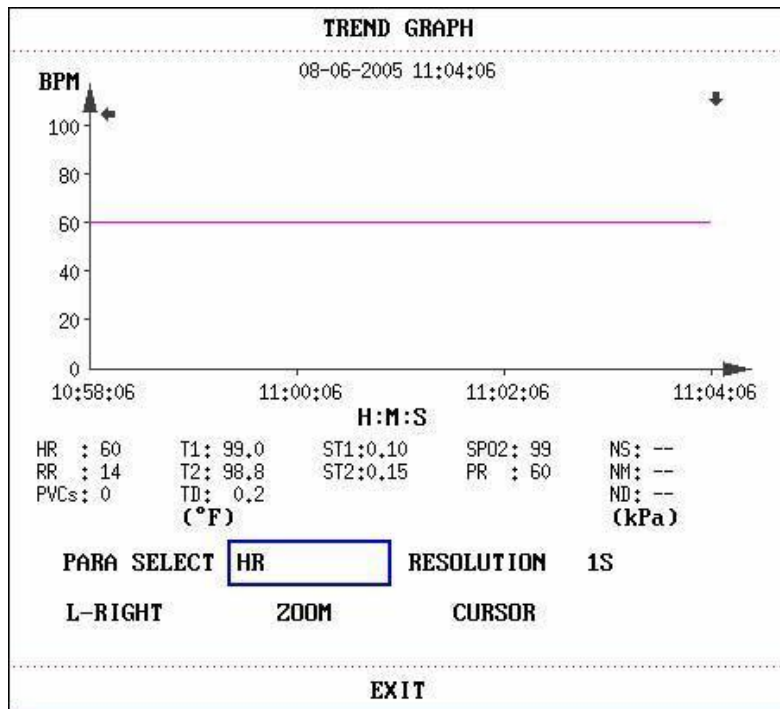
Figure 8-1 Trend Graph Menu

In the trend graph, the Y-axis stands for the measured value and X-axis time. "⬇" is the cursor of the trend graph, the parameter value of the position pointed by the cursor is displayed below the trend graph and the corresponding time is displayed above the trend graph. Other trends except NIBP trend are displayed as continuous curves. In NIBP trend graph, "▼" indicates systolic value, "▲" indicates diastolic value, and "*" indicates mean value.

To select trend graph of a specific parameter

Pick PARA SELECT item and select a requested parameter name by turning the knob.

To select 1-hour or 96- hour trend graph

Pick RESOLUTION item, choose 1 or 5 sec for 1-hour trend graph and 1, 5 or 10 min for 96-hour trend graph.

To view other trend curves

When " ➤ " appears on the right part of the screen, pick "L-RIGHT", turn the knob clockwise to view later trend curves. When " ◀ " appears on the left part of the screen, pick the same item, turn the knob counterclockwise to view earlier trend curve.

To change the display scale

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

To obtain trend data of a specific time

The time to which the cursor points will change as the knob is turned. Parameter at this time is displayed below the X-axis. When " ➤ " appears on the right part of the screen, the trend graph pages down for later trend curve as the cursor moves here. When " ◀ " appears on the left part of the screen, the trend graph pages up for earlier trend curve as the cursor moves here.

Mark Event

If an event is marked A, B, C, or D, then the corresponding event type will display on the axis time of the trend graph，such as Ⓐ, Ⓑ, Ⓒ or Ⓓ.

Operation Example

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

Pick the Menu button on the lower right of the screen.
Pick TREND GRAPH item in the SYSTEM MENU.
Select parameter: pick the PARA item and turn the knob until NIBP appears.
Select 1S or 5S in the RESOLUTION item.
Pick the L-Right button and turn the knob to view changes of the trend graph time and trend curve.
Stop at requested trend time section for careful review. Pick the ZOOM button to adjust the display scale if necessary.
For measurement result of a specific time, pick CURSOR to move the cursor to the point, corresponding time and value will display on above and below respectively.
Pick EXIT to return to trend graph display.

8.2 Trend Table

The latest 96-trend table data can be displayed at every 1, 5, 10, 30, or 60 minutes.

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

```
                        TREND TABLE
........................................................

                         HR        PVCs
      TIME     EVENT                             →
                         BPM       /min
   (06)11:04             60          0
   (06)11:03             60          0
   (06)11:02             60          0
   (06)11:01             60          0
   (06)11:00             60          0
   (06)10:59             60          0
   (06)10:58             60          0
   (06)10:57             60          0
   (06)10:56             60          0
   (06)10:55             60          0
   (06)10:54             60          0
   (06)10:53 ↓           60          0

   RESOLUTION   1MIN      UP-DOWN    L-RIGHT



........................................................
                         EXIT
```

Figure 8-2 Trend Table

Time in response to each group of trend data is displayed at the leftmost list with date in bracket. Marked event corresponds to marking time. Trend data of each parameter is divided into 8 groups.

        HR, PVC

        ST1, ST2

        RR

        T1, T2, TD

        SpO_2, PR

        NIBP NS/NM/ND

        IBP1, IBP2

To choose trend table of different resolution

Pick the RESOLUTION item and turn the knob to change its content so as to change the time interval of trend data.

To view other trend data

When " ⬆ " appears on the upper part of the screen, pick UP-DOWN button and turn the knob counterclockwise to view later trend data. When " ⬇ " appears on the lower part of the screen, pick the same item and turn the knob clockwise to view earlier trend data.

To obtain trend data of different parameter

Pick L-RIGHT to select one from the 8 groups of parameters. A "➤" by the rightmost item indicates following page available. A "◄" by the leftmost item indicates previous page available.

Mark Event

If an event is marked A, B, C, or D, the corresponding event type will display on the axis time of the trend table.

Operation Example

To view a NIBP trend table:
    Pick the Menu button on the lower right of the screen to access "SYSTEM MENU".
    Pick TREND TABLE.
    Pick L-RIGHT and switch to NIBP by turning the knob.
    Pick RESOLUTION to select requested time interval.
    Pick UP-DOWN and turn the knob to view NIBP trend data of different time.
    Pick EXIT to return to SYSTEM MENU.

8.3 NIBP Recall

M8B Multi-parameter patient monitor can review the latest 500 NIBP measurement data.
Pick NIBP RECALL in the SYSTEM MENU to invoke the result and time of the latest 15 measurements, as shown in the figure below.

Figure 8-3 NIBP Recall

Data is listed chronologically from the latest to the earliest. 15 measurements can be displayed in one screen. Pick UP-DOWN to view other trend curve up to 500 results. When you press the "RECORD" button, the recorder will pint out the metrical data of current window.

8.4 Alarm Event Recall

M8B Multi-parameter patient monitor can display the latest 60 alarm events.

Select "ALARM RECALL" in the SYSTEM MENU to access ALARM RECALL CONDITION menu as shown below.

Figure 8-4 ALARM RECALL CONDITION

In this menu, the user may select the conditions for alarm review, including:

1. Start and End time of review:

   The user may select the start time of review in the item of START.

   Then the user may select the end time of review. Two selections are available: current time and the user-defined time.

   For user-defined end time, the user can use the knob to select.

2. ALARM RECALL EVENT

   In the pull-down list of ALARM RECALL EVENT, the user can select the parameter whose alarm events he wants to review. The selections include ALL (alarm events of all parameters), ECG, REST, SpO$_2$, NIBP, IBP, TEMP, HR_H>180 (the value of HR is higher than the upper alarm limit), HR_L<60 (the value of HR is below the lower alarm limit), SpO$_2$<90%, IBP_H>200mmHg, IBP_L<40mmHg, RR_H>40, RR_L<10, TEMP_H>40ºC, TEMP_L<34ºC. After setting up all the review conditions, press the "ALARM RECALL" button to access "ALARM RECALL" window.

ALARM RECALL

The ALARM RECALL window is as shown below, in which following data are displayed:

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

② Event type.

③ Serial number (Format: NO. ×× of ××).

④ The value at the time of alarm. NIBP result is with time.

⑤ Two 8/16/32-second waveforms.
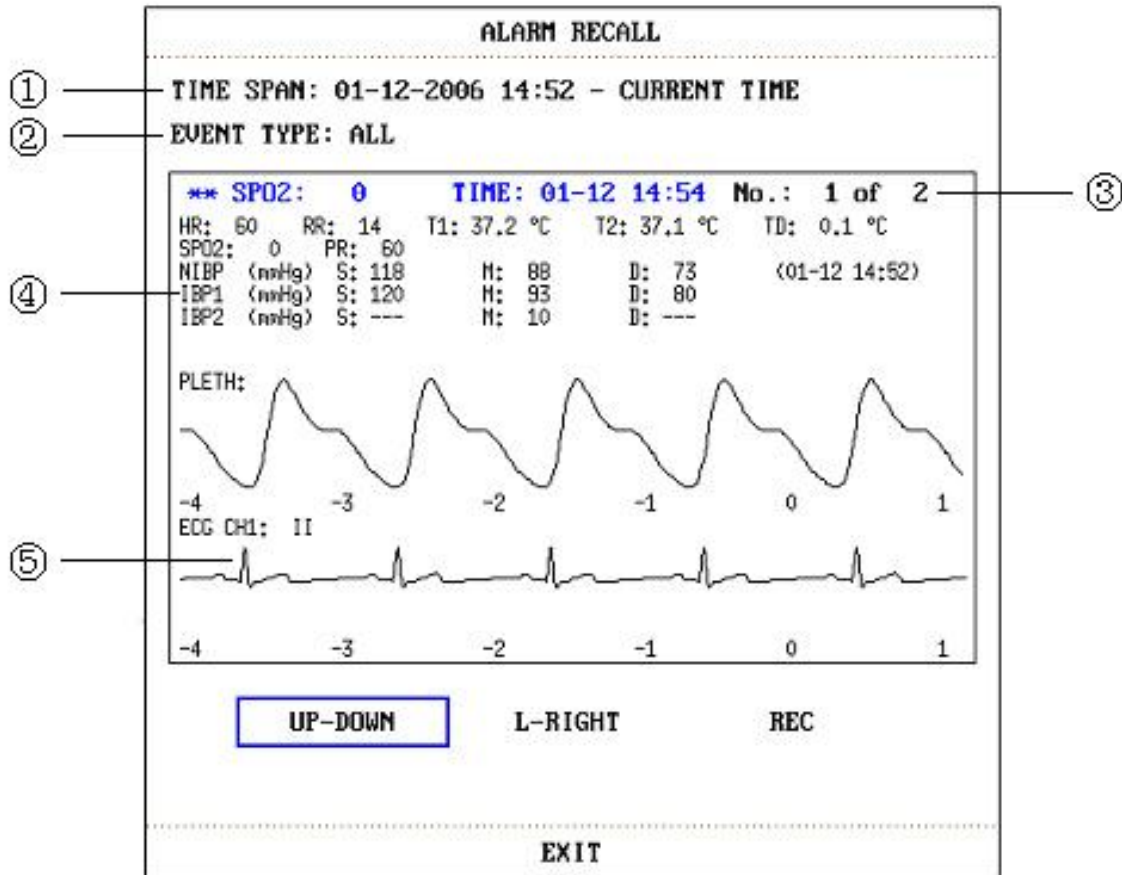
Figure 8-5 ALARM RECALL Menu

To view all waveforms during the alarming process

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

To view other alarm events

Events of up to 60 are listed chronologically from the latese to the earliest. Pick UP-DOWN button and turn the knob to view later or earlier events.

Recording

Pick REC to print our all data and waveform this event.

9 Drug Calculation and Titration Table (Optional)

M8B Multi-parameter patient monitor provides Drug calculation and titration table display functions for fifteen drugs and outputs the content of titration table on the recorder.

9.1 Drug Calculation

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

Select "DRUG CALC" in SYSTEM MENU, the following "DRUG CALC" display appears:

```
                        DRUG CALC
.....................................................................
  DRUG NAME   AMINOPHYLLINE     INF RATE   60.00     ml/hr

  WEIGHT      70.0        kg    DRIP RATE  20.00     GTT/min

  AMOUNT      500.00      mg    DROP SIZE  20.00     GTT/ml

  VOLUME      500.00      ml    DURATION   8.33      hr

  CONCENTRAT  1.00        mg/ml

  DOSE/min    1.00        mg    Please carefully verify

  DOSE/hr     60.00       mg    the input information!

  DOSE/kg/min 14.29       mcg

  DOSE/kg/hr  857.14      mcg   TITRATION >>

.....................................................................
                          EXIT
```

Figure 9-1 DRUG CALC

The following formulas are applied for dose calculation:

Concentrat   = Amount / Volume

INF Rate   = DOSE / Concentrat

Duration   = Amount / Dose

Dose   = Rate × Concentrat

DRIP Rate   = INF Rate / 60 × DROP Size

Operating Method:

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

Turn the knob to select the value of the item to be calculated. Turn the knob to change the value. When it is the required value, press the knob to view the calculation result. Each item has its calculation range. If the result exceeds the range, it displays "---.--".

NOTE:

For the drug calculation, the prerequisite is that the operator must enter the patient weight and drug name at first. The system first gives a group of random initial values, which can not be used by the operator as the calculation reference. Instead, he should enter a new group of values at the doctor's instruction.

NOTE:

Each drug has its fixed unit or unit series. Operator must select the proper unit at the doctor's instruction. If the result exceeds the system-defined range, it will display "---".

NOTE:

After entering a value, a conspicuous prompt will appear in the menu warning the operator to confirm the correctness of the entered value. The correct value is the guarantee for the reliability and safety of the calculated results.

NOTE:

For each entered value, the system will always give a dialog box asking for the user's confirmation. You must be careful when answering each box. The calculated result is reliable only after the entered value is confirmed to be correct.

Select the Drug Name:

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

NOTE:

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

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

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

"mEq" is fixedly used for drug E.

Patient Weight:

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

NOTE:

This drug calculation function acts only as a calculator. That means the patient's weight in Drug Calculation menu and Patient Information menu are independent on each other. When the Weight in "Drug Calculation" is changed, the Weight in "Patient Information" will not change. In this way, we can say, the Drug Calculation menu is independent on other menus in the system. Any change of it will not affect other information about the patient being currently monitored.

9.2 Titration Table

Access Titration Table:

Select TITRATION item in DRUG CALC menu to enter titration table display.

Titration table display for drug is as following:

Figure 9-2 TITRATION

Method to operate the titration table:

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

2. Then turn the knob to pick STEP item. Press and turn the knob to select step. 1 ~ 10 are available for selection with the increment being 1.

3. Turn the knob to pick DOSE TYPE item. Press and turn the knob to select the unit in the pull-down list.

4. Use UP-DOWN item in the table to view the data in previous or following pages.

5. Turn the knob to pick REC item. After pressing the knob, the recorder prints out the data displayed in tne current titration table.

6. Turn the knob to pick EXIT to return to DRUG CALC menu.

Total amount, dose, volume, INF rate, drip rate and patient weight and drug name are displayed on the top of the titration table. Meaning of each English identifier is:

AMOUNT: drug amount
VOLUME: liquid volume
DOSE/min: drug dose
INF RATE: flow rate
DRIP RATE: drop rate
WEIGHT: patient weight

10 Safety Guidance

The M8B Multi-parameter Patient Monitor is designed to comply with the International National Safety requirements for medical electrical equipment IEC60601-1, EN60601-2-27 and EN60601-2-30. This device has floating inputs and is protected against the effects of defibrillation and electrosurgery. If the correct electrodes are used and applied in accordance with the manufacturer instructions (see Chapter **ECG/RESP Monitoring**), the system can restore screen display within 10 seconds after defibrillation.

This symbol indicates that the instrument is 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.

Environment

Follow the instructions below to ensure a completely safe electrical installation. The environment where the M8B Multi-parameter patient monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

M8B Multi-parameter patient monitor operates within specifications at ambient temperatures between 5℃ 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 (5cms) clearance around the instrument for proper air circulation.

Power Source Requirements

Refer to **APPENDIX Ⅰ**.

Grounding the M8B

To protect the patient and hospital personnel, the cabinet of the M8B Multi-parameter patient monitor must be grounded. Accordingly, the M8B 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.

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 M8B 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 medically 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 M8B 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.

Safety Precautions

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the instrument.

⚠ **WARNING** ⚠

The M8B is provided for the use of qualified physicians or personnel professionally trained. And they should be familiar with the contents of this user manual before operation.

⚠ **WARNING** ⚠

Only qualified service engineers can install this equipment. And only service engineers authorized by EDAN can open the shell.

⚠ **WARNING** ⚠

EXPLOSION HAZARD-Do not use M8B in a flammable atmosphere where concentrations

of flammable anesthetics or other materials may occur.

⚠ **WARNING** ⚠

SHOCK HAZARD-The power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.

⚠ **WARNING** ⚠

SHOCK HAZARD-Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

⚠ **WARNING** ⚠

Accessory equipment connected to the analog and digital interfaces must be certified complying with the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult our technical service department or your local distributor.

⚠ **WARNING** ⚠

Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.

⚠ **WARNING** ⚠

Do not place battery in the M8B with the (+) and (-) in the wrong way around.

⚠ **WARNING** ⚠

Do not connect the positive (+) and negative (-) terminals with metal objects, and do not put the battery together with metal object, which can result in short circuit.

⚠ **WARNING** ⚠

Do not unplug the battery when monitoring.

⚠ **WARNING** ⚠

Do not heat or throw battery into fire.

⚠ **WARNING** ⚠

Do not use, leave battery close to fire or other places where temperature may be above 60℃.

⚠ **WARNING** ⚠

Do not immerse, throw, and wet battery in water/seawater.

⚠ **WARNING** ⚠

Do not destroy the battery: Do not pierce battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the battery.

⚠ **WARNING** ⚠

Use the battery only in the M8B. Do not connect battery directly to an electric outlet or cigarette lighter charger.

⚠ **WARNING** ⚠

Do not solder the leading wire and the battery terminal directly.

⚠ **WARNING** ⚠

If liquid leaking from the battery gets into your eyes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately.

⚠ **WARNING** ⚠

If liquid of the battery leaks onto your skin or clothes, wash well with fresh water immediately.

⚠ **WARNING** ⚠

Keep away from fire immediately when leakage or foul odor is detected.

⚠ **WARNING** ⚠

Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.

⚠ **WARNING** ⚠

Do not use a battery with serious scar or deformation.

⚠ **WARNING** ⚠

Only patient cable and other accessories supplied by EDAN can be used. Or else, the performance and electric shock protection can not be guaranteed.

⚠ **WARNING** ⚠

The user should check the monitor and accessories before use.

⚠ **WARNING** ⚠

Be sure that all electrodes have been connected to the patient correctly before operation.

⚠ **WARNING** ⚠

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

⚠ **WARNING** ⚠

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

⚠ **WARNING** ⚠

Please set the alarm according to the individual status of patient to avoid delaying treatment. Ensure there will be alarm audio prompt when alarming.

⚠ **WARNING** ⚠

Devices connecting with monitor should be equipotential.

⚠ **WARNING** ⚠

When the M8B and electrosurgical device are used together, the user (physician or nurse) should guarantee the safety of patient.

⚠ **WARNING** ⚠

The M8B will be damaged if the water level in the hydropohobic bottle reachs the bottom of drainpipe.

⚠ **WARNING** ⚠

Please replace the hydrophobic bottle if it is nearly full.

⚠ **WARNING** ⚠

Please sterilize and disinfect timely to prevent the cross infection between patients.

◊ **CAUTION** ◊

Electromagnetic Interference - Ensure that the environment in which the M8B is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.

◊ **CAUTION** ◊

The device is designed for continuous and is "ordinary" (i.e. no drip or splash-proof).

◊ **CAUTION** ◊

Keep the environment clean. Avoid vibration. Keep it far from corrosive medicine, dust area, high-temperature and humid environment.

◊ **CAUTION** ◊

Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.

◊ **CAUTION** ◊

Do not use autoclave or gas sterilizer to the M8B, recorder or any accessories.

◈ **CAUTION** ◈

The M8B and reusable accessories could be sent back to the manufacturer for recycling or proper disposal after their useful lives.

◈ **CAUTION** ◈

Remove a battery whose life cycle has expired from the monitor immediately.

◈ **CAUTION** ◈

Avoid liquid splash and excessive temperature. The temperature must be kept between 5℃ and 40℃ while working. And it should be kept between -20℃ and 55℃ during transportation and storage.

◈ **CAUTION** ◈

Before use, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.

Explanation of Symbols in the Monitor

⚠ This symbol means "BE CAREFUL". Refer to the user manual.

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

🗑 This symbol consisting of two parts, see below.

🗑

It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection after its useful life.

▬

It indicates that the equipment is put on the market after 13th August 2005.

SN   Serial number

$C\epsilon_{0123}$ CE Mark

EC | REP   Authorised representative in the European community
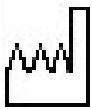
Manufacture date

Manufacturer

Equipotential grounding system

Standby. It designates that the switch or switch position which one part of the device has been switched on, while the device is at the status of stand-by.

11 Maintenance/Cleaning

11.1 System Check

Before using M8B, do the following:

■　Check if there is any mechanical damage;

■　Check if all the outer cables, inserted modules and accessories are in good condition;

■　Check all the functions of the M8B to make sure that the monitor is in good condition.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or 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 months, and each time after fixing up.

All the checks that need to open the M8B should be performed by qualified customer service technician. The safety and maintenance check can be conducted by persons from this company. You can obtain the material about the customer service contract from the local company's office.

⚠ **WARNING** ⚠

If the hospital or agency that is responding to using the M8B does not follow a satisfactory maintenance schedule, the M8B may become invalid, and the human health may be endangered.

NOTE:

To prolong the life of chargeable battery, charging it once every month at least is recommended, and it must be done after the electric energy is run out.

⚠ **WARNING** ⚠

Replace batteries according to the instruction of our servicing engineer.

11.2 General Cleaning

⚠ **WARNING** ⚠

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

M8B Multi-parameter patient 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.

◇ **CAUTION** ◇

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. Do not use the grinding material, such as steel wool etc.
4. Do not let the cleaning agent enter into the chassis of the system.
5. Do not leave the cleaning agents at any part of the equipment.

11.3 Cleaning Agents

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

■ Diluted Ammonia Water
■ Diluted Sodium Hypochlorite (Bleaching agent).

NOTE:
The diluted sodium hypochlorite from 500 ppm (1:100 diluted bleaching agent) to 5000 ppm (1:10 bleaching agents) is very effective. The concentration of the diluted sodium hypochlorite 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:
M8B and sensor surface can be cleaned with hospital -grade ethanol and dried in air or with crisp and clean cloth.

NOTE:
This 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.

11.4 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 relative chapters respectively.

⚠ **WARNING** ⚠

Please sterilize and disinfect timely to prevent the cross infection between patients.

◈ **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.

11.5 Disinfection

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

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

◈ **CAUTION** ◈

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

11.6 Replacement of Fuse

Unscrew the fuse cap anticlockwise, replace the fuse (protector tube) and screw down the fuse cap clockwise. Fuse size: Φ5x20, Rated value: T1.6AL/250V.

NOTE:
Switch off the power switch of the M8B before examining the fuse.

12 ECG/RESP Monitoring

12.1 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, The monitor provides display of 2-channel ECG waveforms.

■ The patient cable consists of 2 parts

   The cable that connects to the monitor,

   The lead set that connects to the patient.

■ Using a 3-lead set, one waveform is displayed on the screen. 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.

■ Lead off detecting, detect all the electrods, indicate the broken off leads.

■ Anti-electrotome function: if the monitor works with high-frequency electrotome, it will not be deadlock or restarting.

■ Every ECG channel has Pacing impulse rejection and Bandpass filter circuit.

■ Defibrillation protection (needs 1K resistance ECG cables in series) and hardware clampe function.

■ A 20 seconds monitor stabilization period shall be allowed before testing. The active noise suppression is less than $0.1\mu A$, has Tall T-wave rejection capability.

■ Response time of heart rate meter to change in heart rate is less than 10s.

   The type of averaging done to compute the minute heart rate, its updating interval is 1s.

■ Alarm for tachycardia with different plus is given within 10s.

NOTE:

In the default settings of the M8B, the ECG waveforms are the first two waveforms from top in the Waveform Area.

NOTE：

The monitor can only be used on one patient at the same time.

NOTE：

The defibrillator cables should be used in the ECG monitoring, it can avoid burned by high frequency.

12.2 Precautions during ECG Monitoring

⚠ **WARNING** ⚠

Do not come into contact with the patient, table, or the monitor 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 but not the conductive part or ground.

NOTE:

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

EN60601-1-2 (protection against radiation is 3v/m) specifies that the electrical field density exceeding 1v/m may cause measurement error in various frequencies. It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.

NOTE:

The simultaneous use of cardiac pacemaker or other patient-connected equipments does not cause safety hazard.

NOTE:
If the pacemaker signals are higher than the claimed range, the heart rate may be calculated incorrectly.

12.3 Monitoring Procedure

12.3.1 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 ⚠

Placed the electrode carefully and make sure contact good.

⚠ WARNING ⚠

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

⚠ WARNING ⚠

Check if the lead connection is correct before monitoring. Unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm is activated.

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

12.3.2 Installing ECG Lead

Placing the Electrodes for ECG Monitoring

Electrode placement for 3-lead set (Figure 12-1)

■ 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.

■ Green (F) electrode - Be placed on the left hypogastrium.

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

America		Europe	
Lead names	Color	Lead names	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
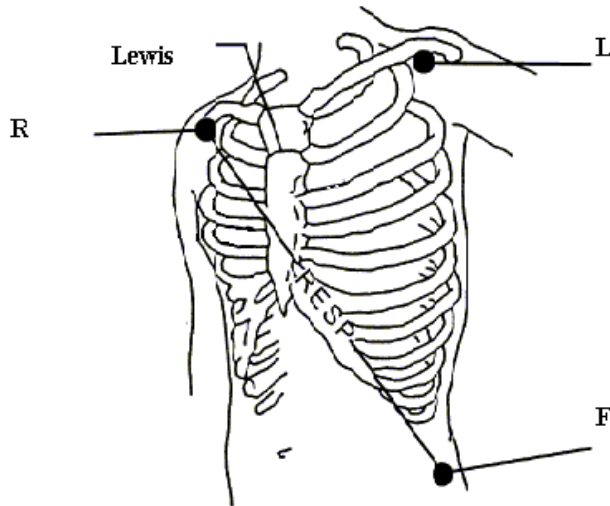
Figure 12-1 Electrode Placement for 3-lead Set

Electrode placement for 5-lead set (Figure 12-2)

■ 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 Figure 12-3.

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
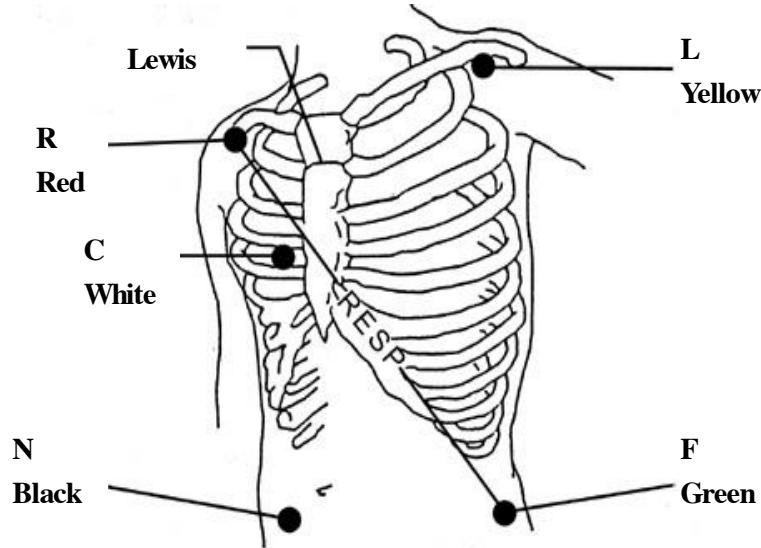
Figure 12-2 Electrode Placement for 5-lead Set

NOTE:

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

For 5-lead set, attach the C (V)-electrode to one of the indicated positions as below (Figure 12-3):

- 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.
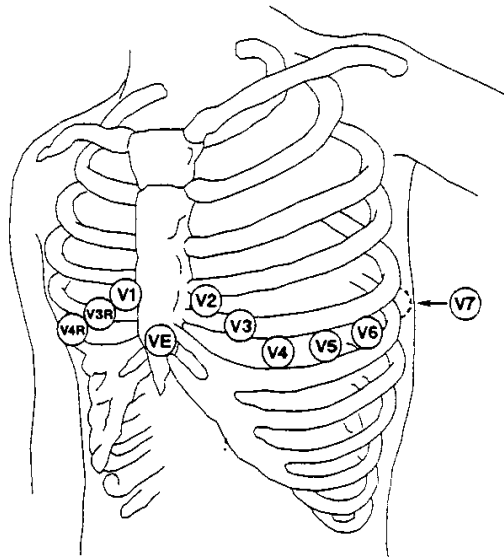
Figure 12-3 C-electrode Placement for 5-lead Set

Recommended ECG Lead Placement for Surgical Patients

⚠ **WARNING** ⚠

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

Monitoring ECG leads are mainly used for monitoring the patient's vital signs. When using the M8B with other Electrosurgery equipments, we advice to use the counteracting defibrillation ECG lead.

The placement 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 may 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 abdomen, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arm, otherwise the ECG waveform will be too small.

⚠ **WARNING** ⚠

When using the M8B with the defibrillator or other high frequency equipments, counteracting defibrillation ECG lead should be used to avoid cautery.

⚠ **WARNING** ⚠

When using Electrosurgery (ES) equipment, do not 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

You can set the leads on ECG CH1 and ECG CH2 according your needs. The lead label is displayed on the upper left part of the waveform. You can set them corresponding 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 12- 4)
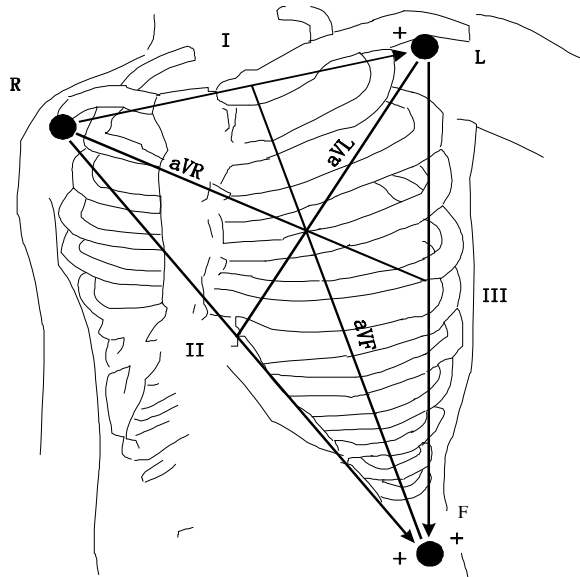
Figure 12-4 ECG Lead

NOTE:

If an 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 pacemakr 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.
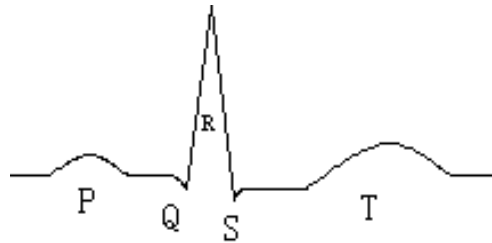
Figure 12-5 Standard ECG Waveform

12.4 ECG Screen Hot Keys
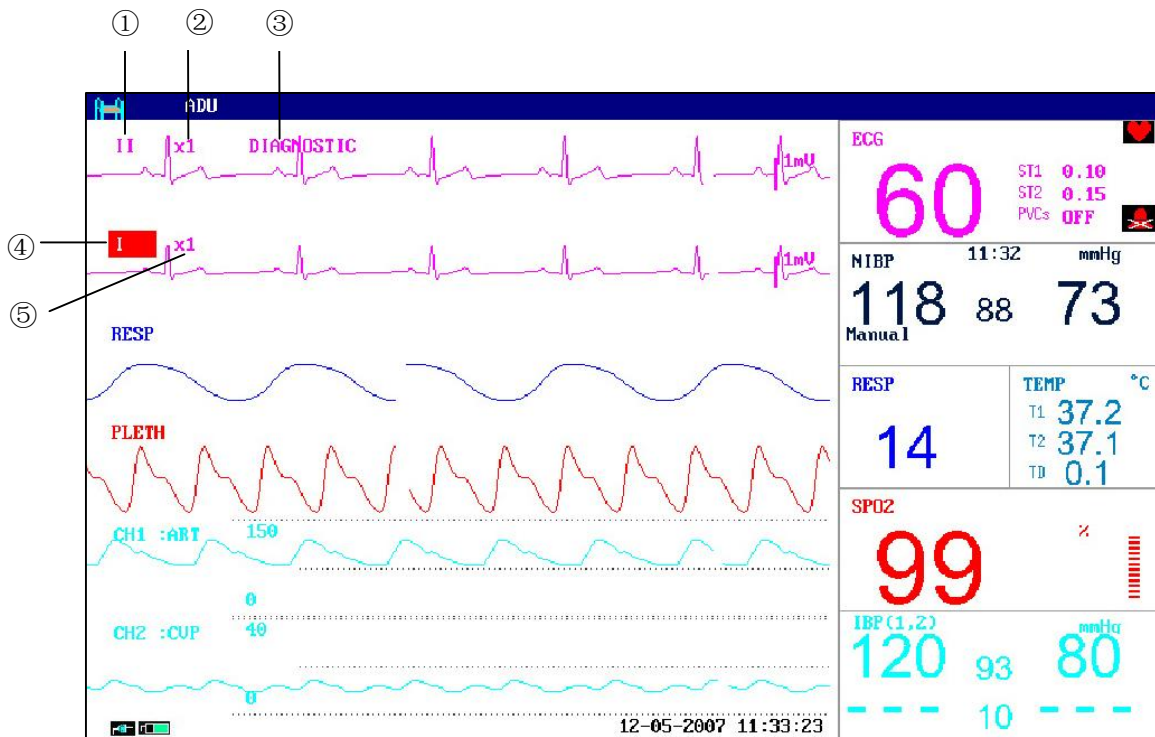
Figure 12-6 Hot Key for ECG

① Leads of channel 1:

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

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

3）Leads on the ECG wave must not have the same name. Otherwise, the system will automatically change the ECG waveform name that has the same name as the waveform being currently adjusted to another name.

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

Signal amplification and collection of Channel 1 ECG (12 bits, 500Hz), it can collect plus value

for each channel setting as ×0.25, ×0.5, ×1, ×2, or AUTO mode. Under "AUTO" mode, the monitor chooses an appropriate level automatically. A 1mv scale displays on each ECG channel's right side. The height of 1mV bar is directly proportional to the waveform amplitude.

NOTE:

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

③ Filter method: used for displaying clearer and more detailed waveform
There are three filter modes for selection. DIAGNOSTIC, MONITOR and SURGERY modes may reduce perturbance and interference from Electrosurgery equipment. The filter method is the item applicable for both channels, which is always displayed at the waveform place of the channel 1 ECG waveform.

NOTE:

Only in Diagnosis mode, the system can provide non-processed real signals. In M8B or Sugery mode, ECG waveforms may have distortion of different extent. In either of the latter two modes, the system can only show the basic ECG and the results of ST analysis may also be greatly affected. In Surgery mode, results of ARR analysis may be somewhat affected. Therefore, it is suggested that in the environment having relative small interference, you'd better monitor a patient in Diagnosis mode.

④ Leads of channel 2: refer to ① for detailed information.
⑤ Waveform gain of channel 2: refer to ② for detailed information.

NOTE:

Pacemaking signal detected is marked by a " | " above the ECG waveform.

12.5 ECG Menu

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

```
ECG SETUP

HR ALM      ON           HR CHANNEL   CH1

ALM LEV     MED          LEAD TYPE    5 LEADS

ALM REC     OFF          SWEEP        25.0

ALM HI      120          ST ANALYSIS >>

ALM LO      50           ARR ANALYSIS >>

HR FROM     ECG          OTHER SETUP >>


                    EXIT
```

Figure 12-7 ECG Setup

■ **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 ![X icon] beside "ECG".

⚠ **WARNING** ⚠

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ALM LEV: selectable from HIGH, MED, LOW. Level HIGH represents the most serious case.
- ALM REC: pick "ON" to enable report printing upon ECG alarm.
- ALM HI: used to set up the upper limit of ECG alarm.
- ALM LO: used to set up the lower limit of ECG alarm.

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

The adjusting range of ECG alarm limits is: 15~350.

ECG alarm limits for default:

	ALM HI	ALM LO	Step
HR ADU	120	50	1
HR PED	160	75	1
HR NEO	200	100	1

The adjusting range of 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 beats per minute higher than the patient's heart rate.

⚠ **WARNING** ⚠

Response time for heart rate meter to change in heart rate calculation is less than 10s. The updating interval of averaging type done to compute the heart rate per minute is 1s.

■ **HR FROM**

ECG, SpO_2, AUTO and BOTH may detect heart rate. AUTO distinguishes heart rate source according to the quality of signal. When the quality of ECG signal and SpO_2 signal is the same, ECG takes priority over SpO_2. By picking ECG, the monitor prompts HR and activates HR beep. By picking SpO_2, 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 SpO_2. 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

■ **LEAD TYPE:** used to select either 5 LEADS or 3 LEADS.

■ **SWEEP**

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

■ **ST ANALYSIS**

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

■ **ARR ANALYSIS**

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

■ **OTHER SETUP**

Pick this item to access ECG SETUP menu as shown below:
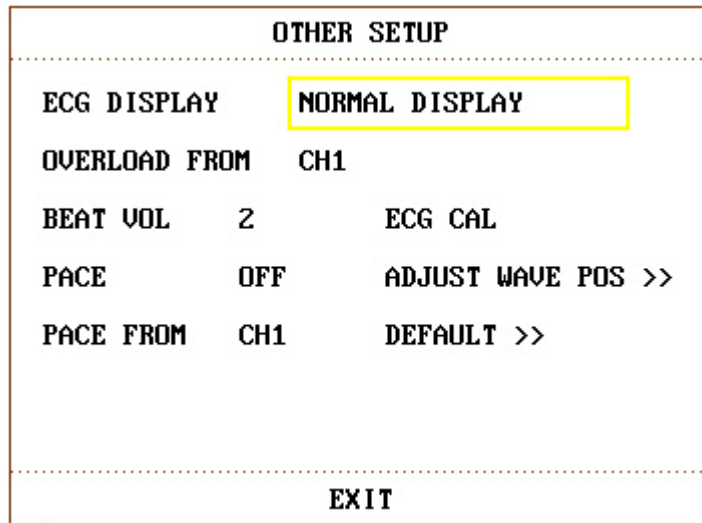
Figure 12-8 ECG Setup

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 only displays 7 ECG waveforms，occupying the area of 7 waveforms. Select HALF-SCAN MULTI-LEADS, those 7 ECG waveforms are displayed on the screen, occupying the area of 4 waveforms.
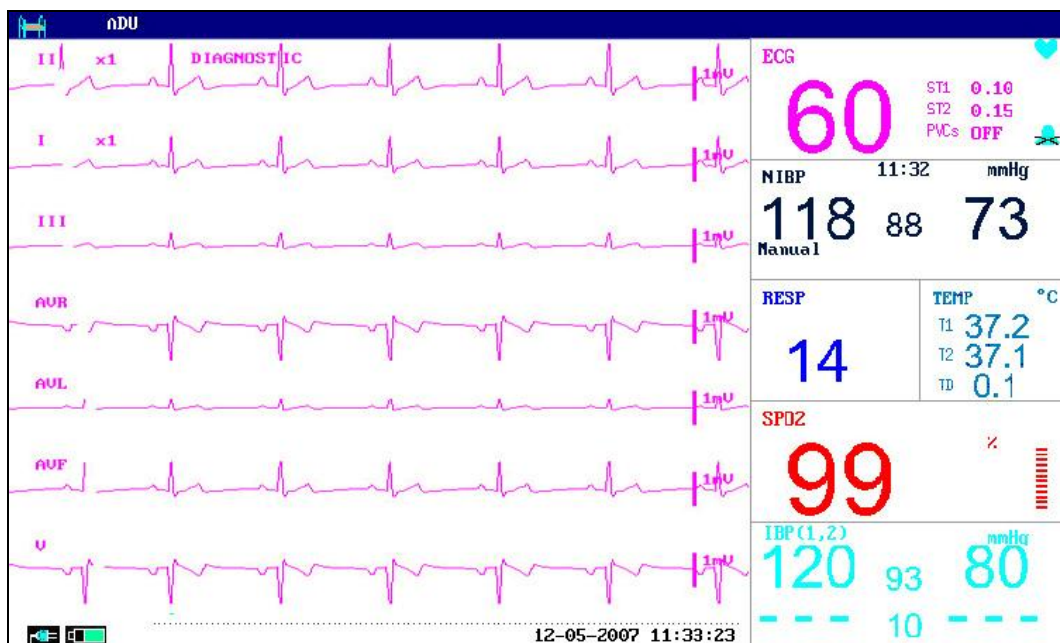
Figure 12-9 MULTI-LEADS DISPLAY

- 84 -
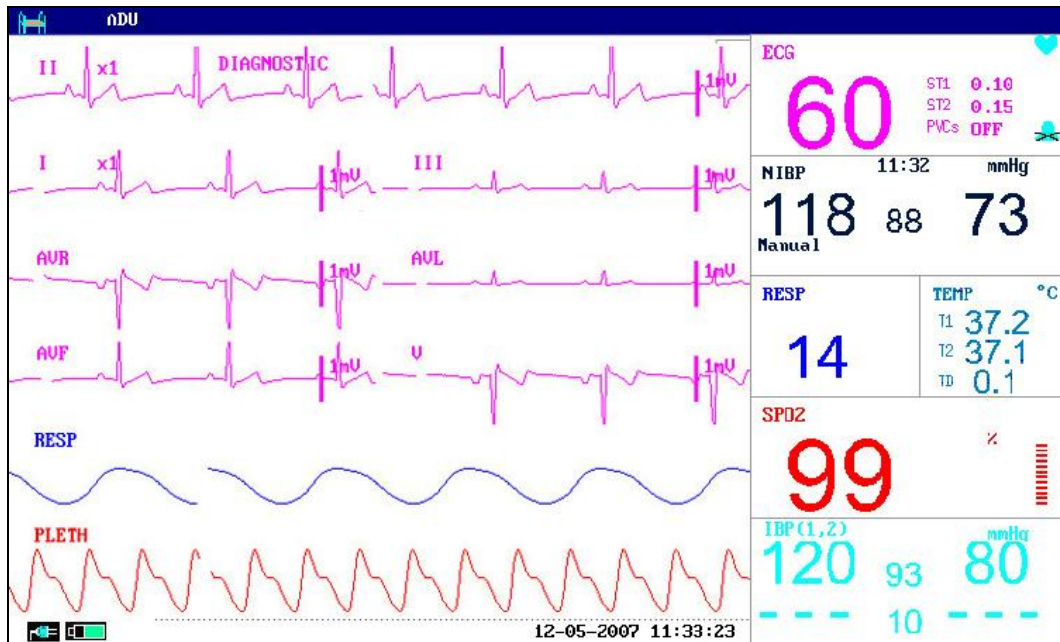
Figure 12-10 HALF-SCAN MULTI-LEADS display

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

Six selections are available: 0, 1, 2, 3, 4, 5. "5" indicates maximum volume. "0" 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.

PACE FROM: to set ON or OFF PACE FROM which means all the ECG waveforms occupy 2 channels waveform area. It functions only when the ECG DISPLAY is set to NORMAL DISPLAY.

ECG CAL

Pick this item to start ECG calibrating process. Picking this item again or change lead name on the screen can end calibrating process.

It can use Standardizing voltage to set the display width for 1mV signal, such as X1 is for

10mm, X2 is for 20mm.

ADJUST WAVE POS

Pick this item to call up the ADJUST WAVE POS dialog box and adjust the position of ECG waveforms on the screen. The user may use CH NAME item to select the channel to be adjusted, UP-DOWN to adjust the position of the selected channel on the screen, BACK TO DEFAULT to let the waveform go back to the default position on the screen.

```
┌─────────────────────────────────────┐
│         ADJUST WAVE POS             │
│ ....................................│
│                                     │
│   CH NAME   CH1                     │
│                                     │
│   UP&DOWN                           │
│                                     │
│   BACK TO DEFAULT                   │
│                                     │
│                                     │
│ ┌─────────────────────────────────┐ │
│ │            EXIT                 │ │
│ └─────────────────────────────────┘ │
└─────────────────────────────────────┘
```
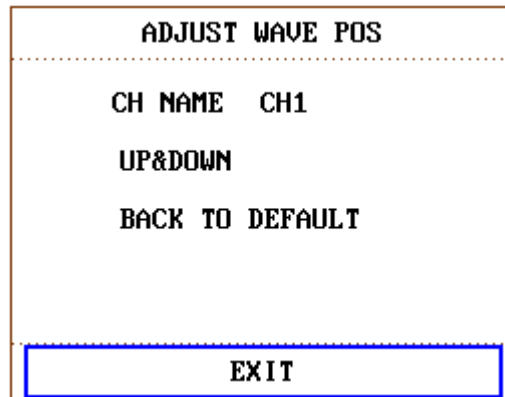
Figure 12-11 ADJUST WAVE POS Menu

DEFAULT

Pick the DEFAULT item to call up the ECG DEFAULT CONFIG dialog box, in which you can select the FACTORY DEFAULT CONFIG or the USER DEFAULT CONFIG item. After selecting any of the items and exiting the dialog box, the system will pop up a dialog box asking for your confirmation.

```
┌─────────────────────────────────────┐
│        ECG  DEFAULT  CONFIG         │
│ ....................................│
│   ■ FACTORY DEFAULT CONFIG          │
│                                     │
│   ■ USER DEFAULT CONFIG             │
│                                     │
│ ....................................│
│            EXIT                     │
└─────────────────────────────────────┘
```
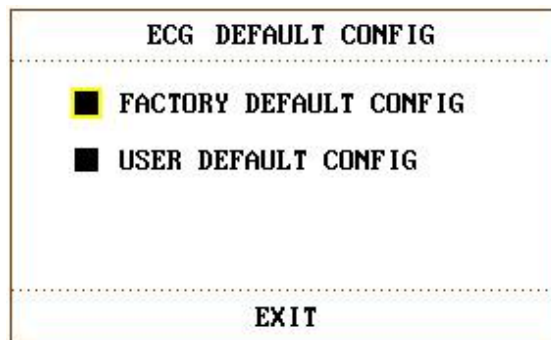
Figure 12-12 ECG Default Configure

⚠ **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 detection.

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.

If the monitor can do ST segment monitoring and Arrhythmia monitoring, please refer to section 12.7 and 12.8.

12.6 ECG Alarm Information

12.6.1 Alarm Message

Alarms occurring in the process of ECG measurement contain two types: physiological alarm and technical alarm. For the audio and visual features during the appearance of these alarms in the process of ECG measurement, please refer to the related description in Chapter **Alarm**. In the screen, physiological alarm messages are displayed in the Physiological Alarm area. Technical alarms messages are displayed in the Technical Alarm area.This section does not describe the content about Arr. and ST analysis.

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

Physiological alarms:

Message	Cause	Alarm level
ECG SIGNAL WEAK	Can not detect the signal in designated time period.	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: (take American Standard for example)

Message	Cause	Alarm level	Remedy
ECG LEAD OFF	More than one 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 C LEAD OFF	ECG electrode C falls off the skin or ECG cables fall off the monitor.	Low	

ECG V LEAD OFF	ECG electrode V falls off the skin or ECG cables fall off.	Low	
ECG Ⅰ LEAD OFF	ECG electrode Ⅰ falls off the skin or ECG cables fall off the monitor.	Low	
ECG Ⅱ LEAD OFF	ECG electrode Ⅱ falls off the skin or ECG cables fall off the monitor.	Low	
ECG **F** LEAD OFF	ECG electrode **F** falls off the skin or ECG cables fall off the monitor.	Low	
ECG L LEAD OFF	ECG electrode L falls off the skin or ECG cables fall off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG R LEAD OFF	ECG electrode R falls off the skin or ECG cables fall off the monitor.	Low	
ECG LL LEAD OFF	ECG electrode LL falls off the skin or ECG cables fall off the monitor.	Low	
ECG LA LEAD OFF	ECG electrode LA falls off the skin or ECG cables fall off the monitor.	Low	
ECG RA LEAD OFF	ECG electrode RA falls off the skin or ECG cables fall off the monitor.	Low	

ECG EXCEED	ECG measuring value is beyond measuring range.	High	Check lead connection and patient condition
ECG INIT ERR	ECG module failure	High	Stop using measuring function of ECG module, notify biomedical engineer or Manufacturer's service staff.
ECG INIT ERR 1	ECG module failure	High	Stop using measuring function of ECG module, notify biomedical engineer or Manufacturer's service staff.
ECG INIT ERR 2			
ECG INIT ERR 3			
ECG INIT ERR 4			
ECG INIT ERR 5			
ECG INIT ERR 6			
ECG INIT ERR 7			
ECG INIT ERR 8			
ECG COMM STOP	ECG module failure or communication failure	High	Stop using measuring function of ECG module, notify biomedical engineer or Manufacturer's service staff.
ECG COMM ERR			
HR ALM LMT ERR	Functional safety failure	High	Stop using HR alarm function, notify biomedical engineer or Manufacturer's service staff.
ECG NOISE	ECG measuring signal is greatly interfered.	Low	Check lead connection and patient condition
HR EXCEED	HR measuring value is beyond measuring range.	High	Check lead connection and patient condition

12.7 ST Segment Monitoring (Optional)

ST Segment Monitoring (Optional)

■ 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.

NOTE:

ECG/RESP monitoring need select "DIAGNOSTIC" mode.

■ 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.

ST ANALYSIS Menu

```
                    ST ANALYSIS
..................................................
  ST ANAL   OFF        ALM HI     0.20

  ST ALM    ON         ALM LO    -0.20

  ALM LEV   MED         DEF POINT >>

  ALM REC   OFF



..................................................
|                    EXIT                        |
```

Figure 12-13 ST Analysis

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 ![X] beside ST. ST alarm is activated when the result exceeds set ST HI value or falls below ST LO value.

⚠ **WARNING** ⚠

In order to avoid endangering the patient's life, the user should use this function cautiously.

■ 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 must be 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 maximum lower limit must be 0.2 lower than the set higher limit.

ST analysis alarm limits for default:

	ST HI	ST LO	Step
ST	0.2 mv	-0.2 mv	0.1 mv

The adjusting range of ST analysis alarm limits:

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

■ 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 80 ms.
　ST　　Measurement point. Default is 108 ms.
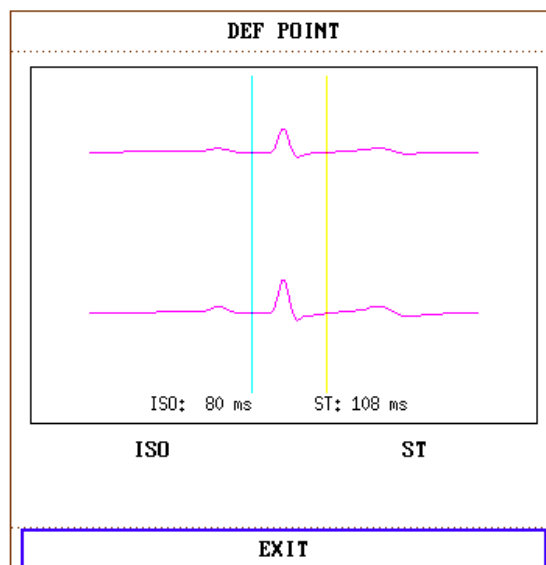
Figure 12-14 DEF POINT Window

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

Set the reference point of ST measurement point to be peak point of R-wave (see Figure 12-13).
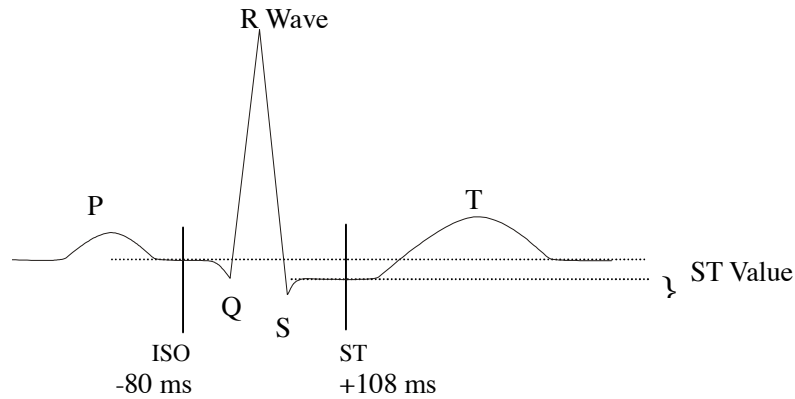
Figure 12-15 DEF POINT

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 system displays the QRS complex template in the window.It is adjustable of the highlight bar in the window. You may select ISO or ST, then switch the knob left or right to move the cursor line. When the cursor is at the required position, you may select the base point or the measurement point.

NOTE:

Abnormal QRS complex is not considered in ST segment analysis.

ST Alarm Message

NOTE:

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

Tables below describe the possible physiological alarms.

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

12.8 Arr. Monitoring (Optional)

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 11 different arrhythmia analyses.
  Pick the item ARR ANALYSIS in ECG SETUP menu to access the ARR ANALYSIS sub-menu.

Every ECG channel has Pacing impulse rejection and Band pass filter circuit. Pacing rate >320mV/s (RTT).

⚠ **WARNING** ⚠

This device is not intended for treatment.

NOTE:
ECG**/**RESP monitoring need select "DIAGNOSTIC" mode.

ARR ANALYSIS Menu

```
┌─────────────────────────────────────────┐
│              ARR ANALYSIS                │
│ ......................................   │
│                                          │
│  ARR ANAL  ┌OFF ┐    ALM HI     10       │
│            └────┘                        │
│  PVCs ALM   ON       ARR RELEARN         │
│                                          │
│  ALM LEV    MED      ARR ALARM >>        │
│                                          │
│  ALM REC    OFF      ARR RECALL >>       │
│                                          │
│                                          │
│                                          │
│ ......................................   │
│                 EXIT                     │
└─────────────────────────────────────────┘
```
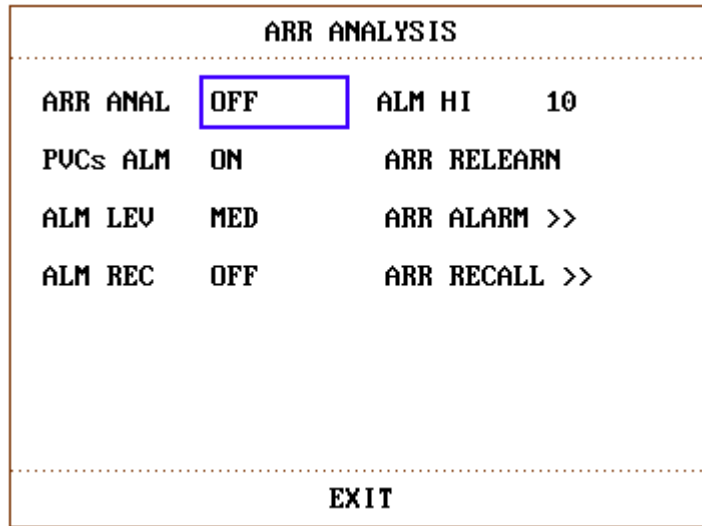
Figure 12-16 ARR Analysis

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

⚠ WARNING ⚠

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ■ 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.
- ■ 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:

Tables below describe the possible physiological alarms occurring during pvcs measurement.
Physiological alarms:

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

- ■ 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.

```
                          ARR ALARM
..........................................................
                 ALM      LEV      REC

  ASYSTOLE       ON       MED      OFF

  VFIB/VTAC      ON       MED      OFF
                                        ALL ALM ON
  R ON T         ON       MED      OFF

  VT>2           ON       MED      OFF
                                        ALL ALM OFF
  COUPLET        ON       MED      OFF

  PVC            ON       MED      OFF
                                        ALL REC ON
  BIGEMINY       ON       MED      OFF

  TRIGEMINY      ON       MED      OFF
                                        ALL REC OFF
  TACHY          ON       MED      OFF

  BRADY          ON       MED      OFF    ALM LEV

  MISSED BEATS   ON       MED      OFF    MED



..........................................................
                          EXIT
```

Figure 12-17 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.
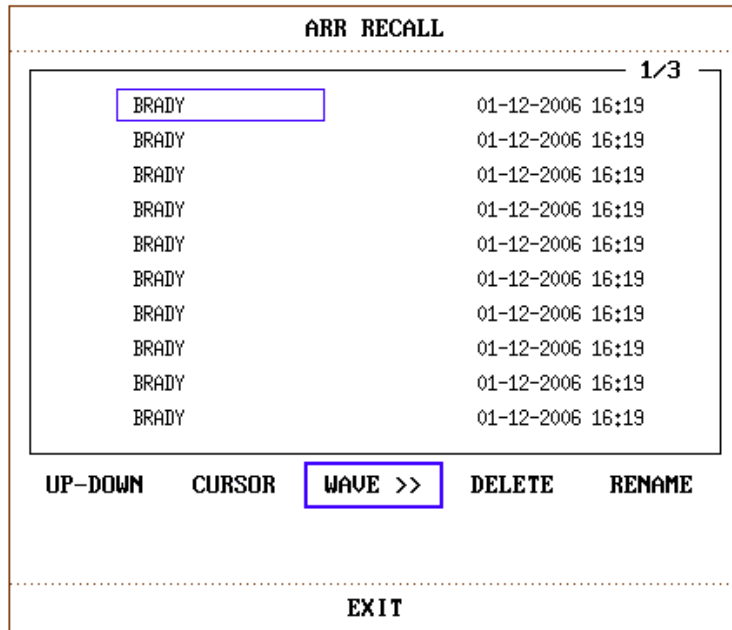
Figure 12-18 ARR Recall

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.
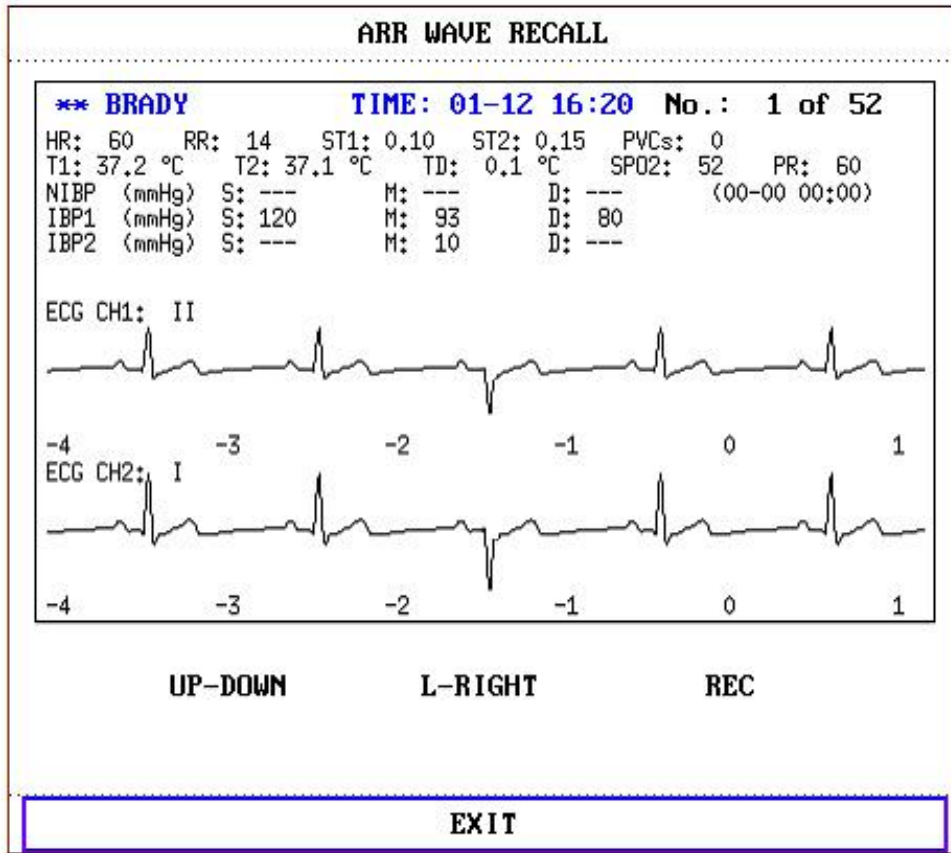
Figure 12-19 ARR Wave Recall

ARR ALARM

The alarm is triggered when an Arrhythmia occurs. If the ALM is ON, the alarm sounds and the alarm indicator flashes.

Physiological alarms:

Prompt	Applicable Patient Type	Occurring Condition	Alarm Level
ASYSTOLE	All patients	No QRS is detected for 4 consecutive seconds	User-selectable
VFIB /VTAC	Without pacemaker	Fibrillation 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.	User-selectable
VT>2	Without pacemaker	$3 \leq$ the number of cluster PVCs < 5	User-selectable

COUPLET	Without pacemaker	2 consecutive PVCs	User-selectable
BIGEMINY	Without pacemaker	Vent Bigeminy	User-selectable
TRIGEMINY	Without pacemaker	Vent Trigeminy	User-selectable
R ON T	Without pacemaker	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).	User-selectable
PVC	Without pacemaker	Single PVCs not belonging to the type of above mentioned PVCs.	User-selectable
TACHY	All patients	5 consecutive QRS complex, RR interval is less than 0.5s.	User-selectable
BRADY	All patients	5 consecutive QRS complex, RR interval is longer than 1.5s.	User-selectable
MISSED BEATS	Without pacemaker	When HR is less than 100 beats/min., no heart beat is tested during the period 1.75 times of the average RR interval; or When HR is larger than 100 beats per min., no beat is tested with 1 second.	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.

12.9 Measuring RESP

12.9.1 How to Measure RESP?

The M8B 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.

12.9.2 Setting up RESP Measurement

For RESP monitoring, it is not necessary for additional electrodes, however, it is very important to attach the electrodes to the correct positions.

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

NOTE:

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

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.

12.9.3 Installing Electrode for RESP Measurement

Placing the Electrodes for Respiratory Monitoring
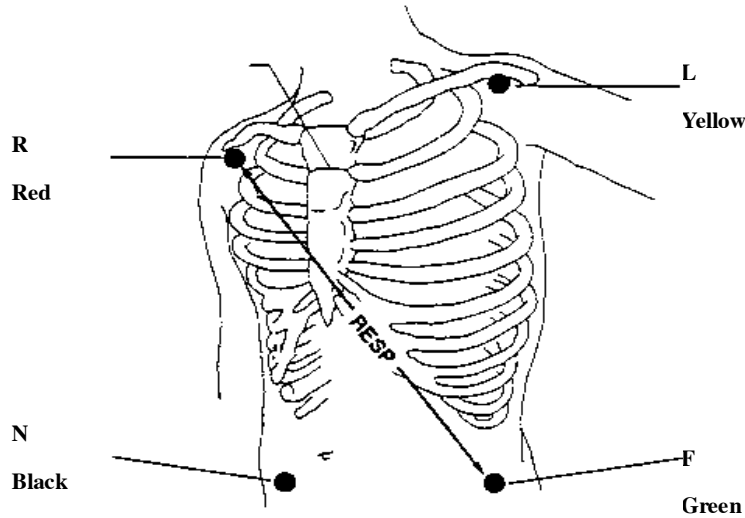
Figure 12-20 Electrodes Placement (5-lead)

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.

12.9.4 RESP Menu

RESP SETUP Menu

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

Figure 12-21 RESP Setup

RESP alarm setting

• ALM: pick "ON" to enable prompt message during the RESP alarm; pick "OFF" to disable the alarm function, and there will be a beside "RESP".

⚠ **WARNING** ⚠

In order to avoid endangering the patient's life, the user should use this function cautiously.

• ALM LEV: selectable from HIGH, MED and LOW. Level HIGH represents the most serious case.
• ALM REC: pick "ON" to enable report printing upon RESP alarm.
• 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 for default:

	RR HI	RR LO	Step
RESP ADU	30	8	1
RESP PED	30	8	1
RESP NEO	100	30	1

The adjusting range of RESP alarm limits:

	Max. RR HI	Min. RR LO	Step
RESP ADU	120	0	1
RESP PED	150	0	1
RESP NEO	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.
• RESP LEAD: set the lead type for respiration.
• SWEEP: Available options for RESP SWEEP 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 Auto, 0.5, 1, 2, 4.
• HOLD TYPE: can set to AUTO or MANUAL. When it is set to AUTO mode, the HOLD HI and HOLD LO are unavailable, the monitor can calculate the respiration rate automatically. When it is at MANUAL mode, you can adjust the broken lines in RESP area by the HOLD HI and HOLD LO items.
• HOLD HI/LO: when the HOLD TYPE is MANUAL, you can adjust the broken lines for higher

or lower limit of the respiration rate.

• 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 DEFAULT CONFIG
..........................................
  ■ FACTORY DEFAULT CONFIG
  ■ USER DEFAULT CONFIG


..........................................
           EXIT
```
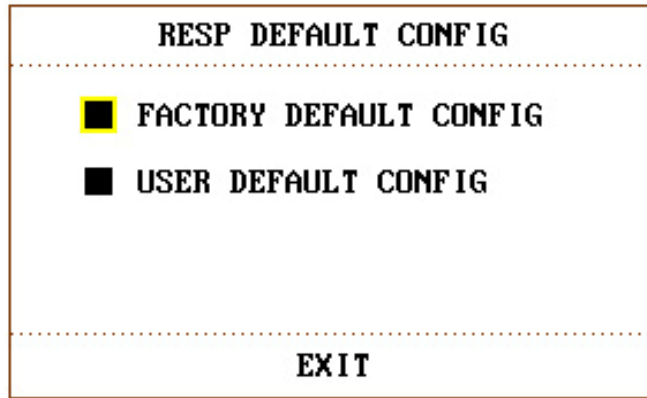
Figure 12-22 RESP default configuration

⚠ WARNING ⚠

The respiration sensitivity will descend after using the defibrillation cable, and the "4" mode
is recommended in the WAVE AMP.

12.9.5 RESP Alarm Message

Tables below describe the possible physiological alarms 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

12.10 Maintenance and Cleaning

Care and Cleaning

⚠ **WARNING** ⚠

Before cleaning the M8B 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.

13 SpO$_2$ Monitoring

13.1 What is SpO$_2$ Monitoring

SpO$_2$ Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO$_2$ oxygen saturation of 97%. The SpO$_2$ numeric on the monitor will read 97%. The SpO$_2$ numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO$_2$/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

How the SpO$_2$/PLETH Parameter Works

■ Arterial oxygen saturation is measured by a method called pulse 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 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 interface.

⚠ **WARNING** ⚠

Pulse oximetry can overestimate the SpO$_2$ value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.

SpO$_2$/Pulse Monitoring

⚠ **WARNING** ⚠

ES (Electrosurgery) equipment wire and SpO$_2$ 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.

13.2 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.

Hand should not be too cold when measuring, and the nail polish should be cleaned before measuring, or the data accuracy may be affected.

NOTE:

SpO$_2$ value always displays at the same position. Pulse Rate will display when HR FROM is set at "SpO$_2$", No ECG signal when HR FROM is set at "Auto".

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 "SpO$_2$ SENSOR OFF" and the audible alarm is activated.

⚠ **WARNING** ⚠

If the SpO$_2$ sensor can not work properly, please reconnect the sensor or change a new one.

⚠ **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. More frequent examinations may be required for different patients.

⚠ **WARNING** ⚠

When using the reusable SpO_2 sensor, change the examine position not more than 4 hours every time (neonate SpO_2 sensor can only be used when it requires to, no more than 20 min at a time).

⚠ **WARNING** ⚠

The sensor's applicable wavelengths are 660nm of red light and 895nm of infrared light.

⚠ **WARNING** ⚠

The sensor accords with the ISO 10993-3 for biological compatibility.

13.3 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 SpO_2 module.
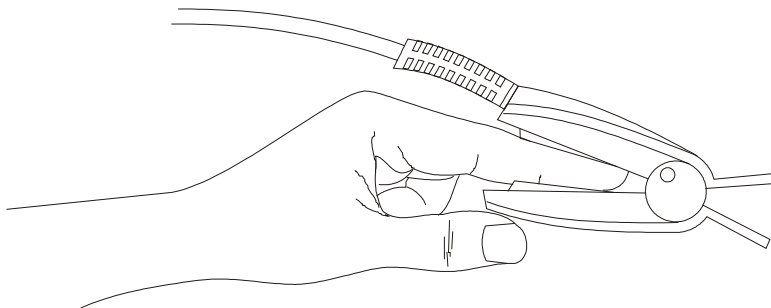
Figure 13 -1 Mounting of the Sensor

13.4 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.

Intravenous dye

Excessive patient movement

Outside ray radiation

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 concentration of dysfunctional hemoglobin, such as carboxyhemog- lobin and methemoglobin

Low SpO_2

Circular perfusion is not well for test part

It is recommended to use SpO_2 sensors described in chapter **Accessories and Ordering Information**.

The dissipation power is less than 50μW, when the sensor temperature is higher than 41℃, you should shorten the measuring time.

13.5 SpO$_2$ Menu

SpO$_2$ SETUP Menu

Pick the SpO_2 hot key on the screen to call up the SpO_2 SETUP menu as shown below.

```
                    SPO2 SETUP
 ...........................................................
  ALM          ON        PR ALM LO    50

  ALM LEV      MED        SWEEP        12.5

  ALM REC      OFF        PR SOUND     2

  SPO2 ALM HI  100        AVG TIME     4S

  SPO2 ALM LO  90         PITCH TONE   OFF

  PR ALM HI    120        DEFAULT >>
 ...........................................................
                    EXIT
```

Figure 13-2 SpO$_2$ Setup

⚠ **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 during the SpO$_2$ alarm; pick "OFF" to disable the alarm function, and there will be a ☒ beside "SpO$_2$".

⚠ **WARNING** ⚠

In order to avoid endangering the patient's life, the user should use this function cautiously.

- ALM LEV: used to set up alarm level, selectable from HIGH, MED and LOW. HIGH represents the most serious case.
- ALM REC: pick "ON" to enable report printing upon SpO$_2$ alarm.
- SpO$_2$ alarm is activated when the result exceeds set SpO$_2$ ALM HI value or falls below SpO$_2$ ALM LO value. Use the knob to pick the SpO$_2$ ALM HI or SpO$_2$ ALM LOW item and turn the knob to select the desired alarm limit.
- 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 LOW item and turn the knob to select the desired alarm limit.

The adjusting range of SpO_2 alarm limits is: 0~100

SpO_2 alarm limits for default:

	Max. Upper Limit	Min. Lower Limit	Step
ADU	100	90	1
PED	100	90	1
NEO	95	80	1

The adjusting range of PR alarm limits is: 0~254.

PR alarm limits for default:

	Max. Upper Limit	Min. Lower Limit	Step
ADU	120	50	1
PED	160	75	1
NEO	200	100	1

■ SWEEP

Available options for SpO_2 SWEEP are 6.25, 12.5 and 25.0 mm/s.

■ PR SOUND

Pulse beep volume. Options are "0~5".

■ AVG TIME

4S, 8S, 16S represent times that SpO_2 average value is counted.

■ PITCH TONE

When ON is enabled, the system will provide prompt sound with different tone for clinic under complex monitoring environment, basing on the variance of SpO_2 value.

■ DEFAULT

Pick this item to access the SpO_2 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.

13.6 Alarm Description

SpO_2 Alarm Message

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

When there is no SpO_2 or PR, it prompts for signal weak.

Physiological alarm:

Message	Cause	Alarm Level
SpO$_2$ TOO HIGH	SpO$_2$ measuring value is above upper alarm limit.	User-selectable
SpO$_2$ TOO LOW	SpO$_2$ measuring value is below lower alarm limit.	User-selectable
PR TOO HIGH	PR measuring value is above upper alarm limit.	User-selectable
PR TOO LOW	PR measuring value is below lower alarm limit.	User-selectable

Technical alarms:

Message	Cause	Alarm Level	Remedy
SpO$_2$ SENSOR OFF	SpO$_2$ 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.
SpO$_2$ NOISE	SpO$_2$ measuring signal is greatly interfered.	Low	
SEARCH PULSE	SpO$_2$ sensor may be disconnected from the patient or the monitor.	Low	
SpO$_2$ SIGNAL WEAK	Cannot detect signal during setup time period	High	Check the lead connection and patient condition
SpO$_2$ INIT ERR	SpO$_2$ module failure	High	Stop using measuring function of SpO$_2$ module, notify biomedical engineer or Manufacturer's service staff.
SpO$_2$ COMM STOP	SpO$_2$ module failure or communication failure	High	Stop using measuring function of SpO$_2$ module, notify biomedical engineer or Manufacturer's service staff.
SpO$_2$ COMM ERR	SpO$_2$ module failure or communication failure	High	

13.7 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.

14 NIBP Monitoring

14.1 Introduction

■ 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 two modes of measurement available: manual, automatic. 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 CONTINUAL mode, the system executes NIBP measurement continuously within 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.

NOTE:
The equipment is suitable for use in the presence of electrosurgery.

NOTE:
The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT.

NOTE:
The equipment can protect against the effects of the discharge of a defibrillator.

NOTE:
The continuous measuring and calibration can not be operated on neonate and pediatric patient, they also can not be operated on AUTO measuring.

14.2 NIBP Monitoring

14.2.1 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 14 -1).
■   Ensure that the cuff is completely deflated.
■   Apply the appropriate size cuff to the patient, and make sure that the symbol "Φ" is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.
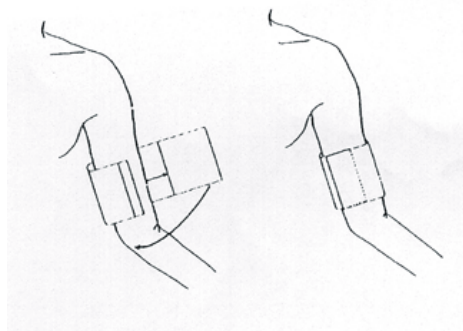
Figure 14-1 Applying Cuff

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

Size of reusable cuff for neonate/children/adult:

Patient Type	Limb perimeter	Cuff width	Hose
Infant	10 ~19 cm	8 cm	
Child	18 ~ 26 cm	10.6 cm	
Adult	25 ~ 35 cm	14 cm	1.5 m or 3 m
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	

The lifespan of cuff is: 480mmHg/20000 times; 300mmHg/50000 times.

■ 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 "Start" 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 the "Start" buttonon 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 the "Start" 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 "Start" button on the front panel to start a manual measurement.

   During the idle period of auto measuring process, press the "Start" button on the front panel at any time to start a manual measurement. Then press the "Start" button on the front panel 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 the "Start" button on the front panel.

5. To stop a manual measuring

   Repress the "Start" button on the front panel again.

6. To start a continuous measuring:

   Access the NIBP SETUP menu and pick the CONTINUAL item to start a continuous measurement. The continuous measurement will last 5 minutes.

7. To stop continuous measuring:

   During continuous measuring press the "Start" 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.

14.2.2 NIBP Parameter Setup and Adjustment

NIBP measurement result and corresponding message are displayed as follows:

Measurement Time

NIBP   16: 50   mmHg   →   BP unit

Measurement value →   108   84   70

Measurement mode →   MANUAL
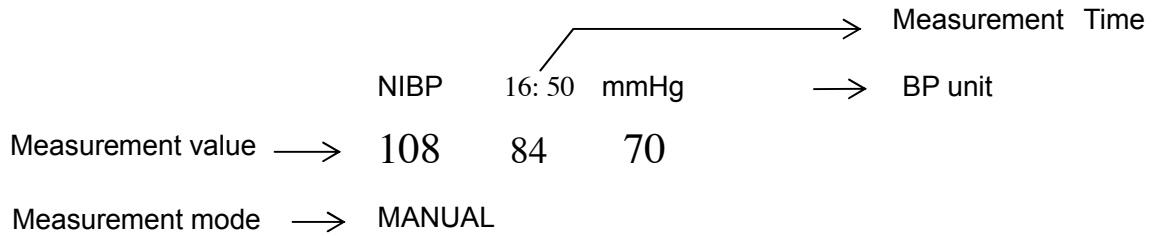
14.3 NIBP SETUP menu

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

```
                    NIBP SETUP
..........................................................
ALM            ON        UNIT        mmHg

ALM LEV        MED       INTERVAL    Manual

ALM REC        OFF       RESET

SYS ALM HI     160       CONTINUAL

SYS ALM LO      90       CALIBRATE

MEAN ALM HI    110       PNEUMATIC

MEAN ALM LO     60       DEFAULT >>

DIA ALM HI      90

DIA ALM LO      50


..........................................................
                     EXIT
```

Figure 14-2 NIBP Setup

NIBP alarm setting

- ALM: pick "ON" to enable prompt message during the NIBP alarm; pick "OFF" to disable

  the alarm function, and there will be a ❎ beside "NIBP".

⚠ **WARNING** ⚠

In order to avoid endangering the patient's life, the user should use this function cautiously.

- 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, MAP ALM HI, MAP 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.

The adjusting range of NIBP alarm limits is: 10 ~ 300mmHg

NIBP alarm limits for default:

	ADU		PED		NEO	
	Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
SYS	90	160	70	120	40	90
DIA	50	90	40	70	20	60
MAP	60	110	50	90	25	70

The adjusting range of NIBP alarm limits:

Adult Mode
>   SYS   40 ~ 270 mmHg
>   DIA   10 ~ 215 mmHg
>   MAP   20 ~ 235 mmHg

Pediatric Mode
>   SYS   40 ~ 200 mmHg
>   DIA   10 ~ 150 mmHg
>   MAP   20 ~ 165 mmHg

Neonatal Mode
>   SYS   40 ~ 135 mmHg
>   DIA   10 ~ 100 mmHg
>   MAP   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.

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.

⚠ **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.
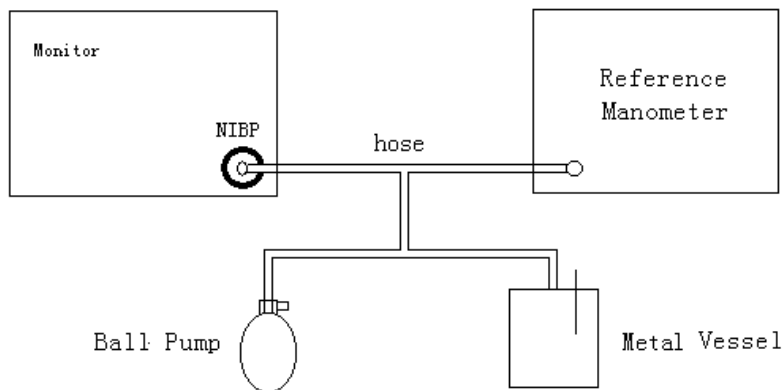
Figure 14-3 Diagram of NIBP Calibration

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 PENUM, 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 180 mmHg.

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.
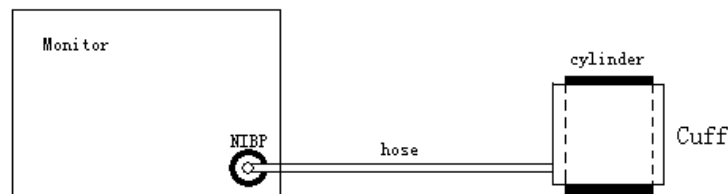
Figure 14-4 Diagram of NIBP Air Leakage Test

INTERVAL

Interval time for automatic measuring. Available selection:

1/2/3/4/5/10/15/30/60/90/120/180/240/480 minutes.

Press START button to start the first auto measuring.

Pick MANUAL selection in INTERVAL item to set up the measuring mode to MANUAL.

14.4 NIBP Alarm Message and Prompt Message

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

Physiological alarms:

Message	Cause	Alarm Level
NS TOO HIGH	NIBP SYS measuring value is above upper alarm limit.	User-selectable
NS TOO LOW	NIBP SYS measuring value is below lower alarm limit.	User-selectable
ND TOO HIGH	NIBP DIA measuring value is above upper alarm limit.	User-selectable
ND TOO LOW	NIBP DIA measuring value is below lower alarm limit.	User-selectable
NM TOO HIGN	NIBP MAP measuring value is above upper alarm limit.	User-selectable
NM TOO LOW	NIBP MAP measuring value is below lower alarm limit.	User-selectable

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

Message	Cause	Alarm Level	Remedy
NIBP COMM STOP	NIBP module failure or communication failure	High	Stop using measuring function of NIBP module, notify biomedical engineer or Manufacturer's service staff.
NIBP COMM ERR	NIBP module failure or communication failure	High	Stop using measuring function of NIBP module, notify biomedical engineer or Manufacturer's service staff.
NM ALM LMT ERR	Functional safety failure	High	Stop using NIBP alarm function, notify biomedical engineer or Manufacturer's service staff.
ND ALM LMT ERR	Functional safety failure	High	Stop using NIBP alarm function, notify biomedical engineer or Manufacturer's service staff.
LOOSE CUFF	Cuff is no properly wrapped or no cuff exists.	Low	Properly wrap the cuff

AIR LEAK	Cuff, hose or connector is damaged.	Low	Check and replace the leaking parts, if required, notify biomedical engineer or manufacturer's service staff.
WEAK SIGNAL	Cuff is too loose or patient pulse is too weak.	Low	Use other method to measure blood pressure.
EXCESSIVE MOTION	After by arm motion, signal noise is too large or pulse rate is not regular.	Low	Make sure that the patient under monitoring is motionless.
OVER PRESSURE	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
SIGNAL SATURATED	Excessive motion.	Low	Stop the patient from moving.
PNEUMATIC LEAK	During pneumatic test, leak is detected.	Low	Check and replace the leaking parts, if required, notify biomedical engineer or manufacturer's service staff.
CUFF TYPE ERR	Cuff type does not comply with the patient type.	Low	Select appropriate cuff type.
NIBP TIME OUT	Measuring time has exceeded 120 seconds (adult) or 90 seconds (neonatal).	Low	Measure again or use other measuring method.

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

Message	Cause	Alarm Level
Manual measuring…	During manual measuring mode.	No alarm
Auto measuring…	During automatic measuring mode.	
Measurement over	Measurement over	

Calibrating…	During calibrating	No alarm
Calibration over	Calibration over	
Pneum testing…	During pneumatic test	
Pneum test over	pneumatic test over	
Resetting...	NIBP module in resetting	
Reset failed	NIBP module reset failed	

14.5 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.
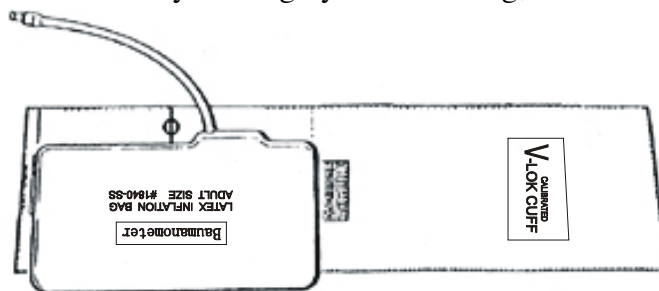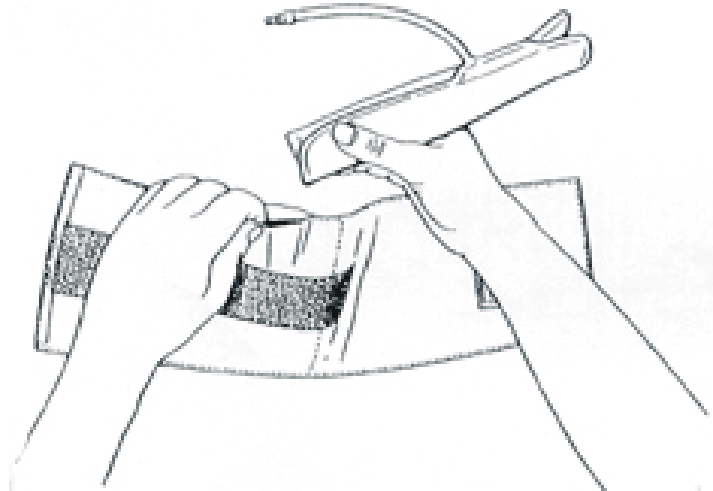
Figure 14-5 Replace Rubber Bag in Cuff

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.

15 TEMP Monitoring

15.1 TEMP Monitoring

Two TEMP probes can be used simultaneously to measure two TEMP datas, and get the temperature difference. The standard configuration is axilla sensor for adult.

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.
The stabilization time for body temperature needs 2-3 min.

⚠ **WARNING** ⚠

Verify probe cables fault detection before beginning of monitoring phase. Unplug the temperature probe cable of the channe1 from the socket, the screen will display the error message "TEMP1 SENSOR OFF" and the audible alarm is activated. The other channel is the same.

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** ⚠

Take the TEMP probe and cable carefully. If not use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.

⚠ **WARNING** ⚠

The TEMP module shall be calibrated once every two years (or as required by your

hospital's regulation). When calibration is required, contact the manufacture please.

15.2 TEMP SETUP Menu

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

```
                    TEMP SETUP

    ALM         ON        T2 ALM HI    39.0

    ALM LEV     MED       T2 ALM LO    36.0

    ALM REC     OFF       TD ALM HI     2.0

    T1 ALM HI   39.0      TEMP UNIT    °C

    T1 ALM LO   36.0      DEFAULT >>



                      EXIT
```

Figure 15-1 TEMP Setup

ALM: pick "ON" to enable prompt message during the TEMP alarm; pick "OFF" to disable the alarm function, and prompt the [X] symbol beside TEMP numeric.

⚠ WARNING ⚠

In order to avoid endangering the patient's life, the user should use this function cautiously.

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 T1, T2, TD occurs when the measured temperature exceeds set alarm high limit or falls below alarm low limit.

T1 represents the TEMP of Channel1, T2 represents the TEMP of Channel2, TD represents the TEMP difference of T1 and T2.
The adjusting range of T1,T2 和 TD alarm limits is: 0~50ºC
T1 and T2 alarm limits for default:

	TEMP HI	TEMP LO	Step
ADU/PED/NEO	39ºC	36ºC	0.1

TD alarm limits for default:

	TEMP HI	Step
ADU/PED/NEO	2ºC	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.

15.3 TEMP Alarm Message

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

Physiological alarms:

Message	Cause	Alarm Level
T1 TOO HIGH	Measuring value of T1 channel is above upper alarm limit.	User-selectable
T1 TOO LOW	Measuring value of T1 channel is below lower alarm limit.	User-selectable
T2 TOO HIGH	Measuring value of T2 channel is above upper alarm limit.	User-selectable
T2 TOO LOW	Measuring value of T2 channel is below lower alarm limit.	User-selectable
TD TOO HIGH	Temperature difference of T1 and T2 is above upper temperature difference limit.	User-selectable

Technical alarms:

Alarm Message	Cause	Alarm Level	Remedy
TEMP SENSOR OFF	Temperature cable of TEMP channe may be disconnected from the monitor.	Low	Make sure that the cable is properly connected
T1 SENSOR OFF	Temperature cable of TEMP channe1 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected

T2 SENSOR OFF	Temperature cable of TEMP channe2 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected.
T1 EXCEED	TEMP1 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
T2 EXCEED	TEMP2 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
TEMP COMM STOP	TEMP module failure or communication failure	High	Stop using measuring function of TEMP module, notify biomedical engineer or Manufacturer's service staff.

15.4 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:
Wash the probe with clean water after disinfecting and sterilizing to remove any remaining solution. The probe can only be reused after being dried thoroughly.

NOTE:

Do not disinfect the probe with the means of water boiled.

NOTE:

The product has not been disinfected at the factory.

NOTE:

Any residue should be removed from the probe before being disinfected and sterilized, and avoid contacting corrosive solvent. Dip the cable into alcohol or alkalescent solvent for a long time, may reduce the flexibility of the scarfskin of the cable. Also, the connector should not be dipped.

NOTE:

After monitoring, disinfect the probe according to the instruction described in the user manual.

NOTE:

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

NOTE:

Cavity temperature probe only suggested to be used inside the recta. Recommend to use the disposable cannula to prevent cross infection.

NOTE:

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

NOTE:

Do not force the cavity temperature probe against resistance when inserted into human body. Also it is not recommended to use it in bleeding part and cankerous part of human body.

16 IBP Monitoring (Optional)

16.1 Introduction

M8B Multi-parameter patient 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 Artery Pressure
CVP	Center Arterial Pressure
RAP	Right Arterial Pressure
LAP	Left Arterial Pressure
ICP	Intracranial Pressure
P1-P2	Expand Pressure

16.2 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 "IBP1 SENSOR 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.

16.3 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.
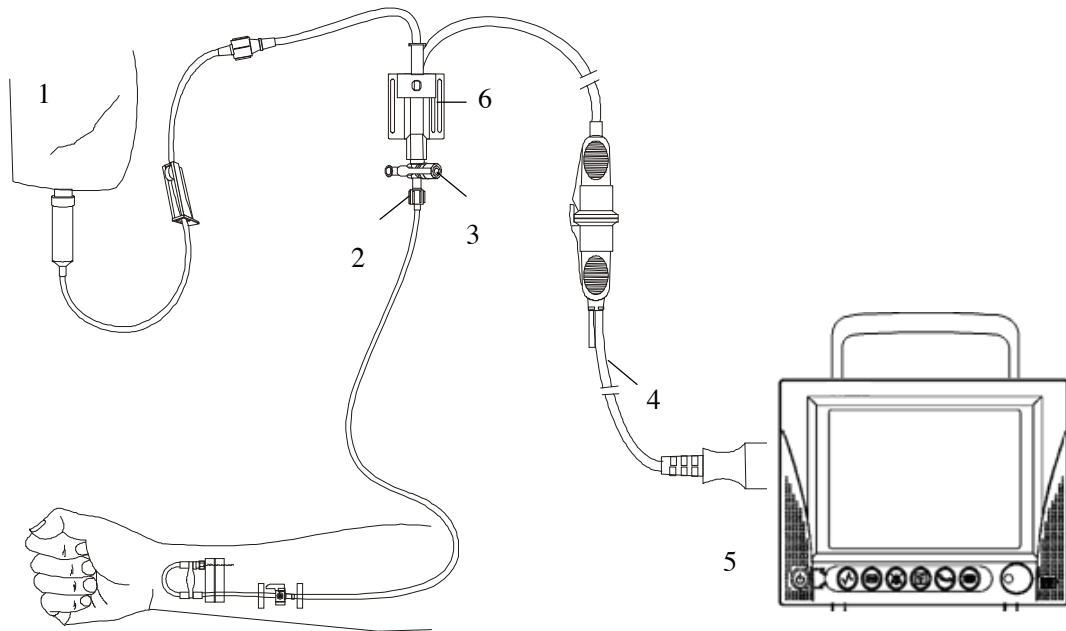
1: Normal Saline with Heparin; 2: Distal end to patient; 3: 3-way stopcok; 4: Pressure transducer interface cable; 5: Monitor; 6: Pressure transducer.

Figure 16-1 IBP Monitoring

16.4 IBP Menu

Pick the IBP hot key on the screen to access the IBP SELECT menu shown as following:
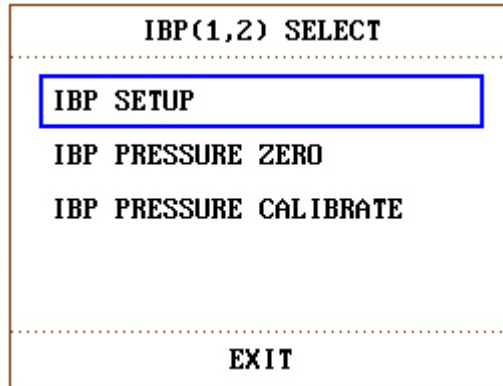
Figure 16-2 IBP SELECT Menu

Pick the IBP SETUP item to call up the IBP SETUP menu as following:
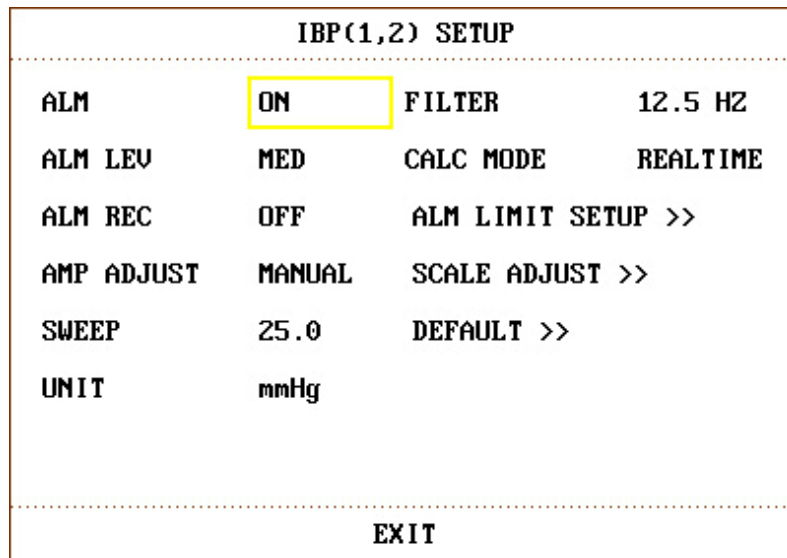
Figure 16-3 IBP SETUP Menu

The items to be set up in the menu include:

■ ALM: select "ON" to enable alarm prompt during IBP alarm. Select "OFF" to disable audio

alarm and prompt the symbol beside "IBP" numeric.

⚠ **WARNING** ⚠

In order to avoid endangering the patient's life, the user should use this function cautiously.

■ 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, 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: set the filter frequency to 12.5Hz or 40.0 Hz.

■ 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.

■ 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 interface.

⚠ **WARNING** ⚠

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

```
         IBP ALM LIMIT SETUP
......................................................
                     SYS      MAP      DIA

   CH1:ART ALM HI     160      110      90

   CH1:ART ALM LO      90       70      50

   CH2:CVP ALM HI     ---       10     ---

   CH2:CVP ALM LO     ---        0     ---



..................................................
                     EXIT
```

Figure 16-4 IBP ALM LIMIT SETUP

The alarm occurs when the value exceeds the set limits.

IBP alarm limits for default:
  P1:
      SYS 90 ~ 160 mmHg

     DIA   50 ~ 90 mmHg

     MAP   70 ~ 110 mmHg

P2:

     SYS   90 ~ 160 mmHg

     DIA   50 ~ 90 mmHg

     MAP   70 ~ 110 mmHg

ART:

     SYS   90 ~ 160 mmHg

     DIA   50 ~ 90 mmHg

     MAP   70 ~ 110 mmHg

PA:

     SYS   10 ~ 35 mmHg

     DIA   0 ~ 16 mmHg

     MAP   0 ~ 20 mmHg

CVP, RAP, LAP, ICP:

     MAP   0 ~ 10 mmHg

The adjusting range of NIBP 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
P1	300	-10	1
P2	300	-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:

```
┌─────────────────────────────────────────────┐
│            IBP PRESSURE ZERO                  │
│ ..........................................    │
│     Being Prepared,Press ZERO key!            │
│  ┌─────────────────┐                          │
│  │ CH1 ZERO        │   00-00-0000 00:00:00    │
│  └─────────────────┘                          │
│                                               │
│    CH2 ZERO          00-00-0000 00:00:00      │
│                                               │
│                                               │
│ ..........................................    │
│                  EXIT                         │
└─────────────────────────────────────────────┘
```
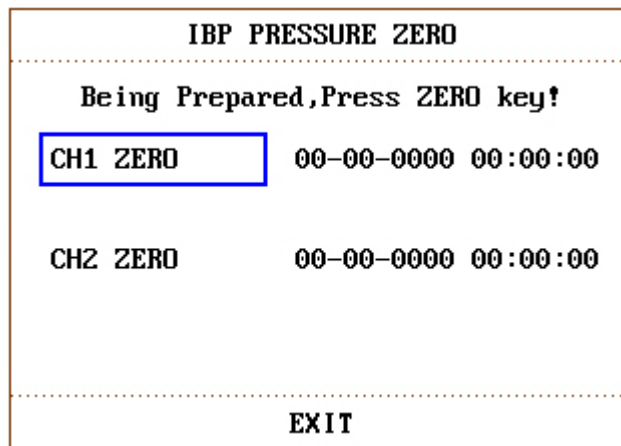
Figure 16-5 IBP PRESSURE ZERO

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, IBP1 return to zero. Select CH2, IBP2 return to zero.

◈ **CAUTION** ◈

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 calibration, take CH1 for example.

■ "CH1 ZERO SUCCESS!"

Indicate that zero calibration is over，so you can turn off the stopcock that was open to atmospheric pressure，and turn on the patient stopcock.

■ "CH1 ZERO FAIL!"

Make sure that the transducer is not attached to the patient.

■ "CH1 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, FAIL!"

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

IBP Calibration

Press the IBP PRESSURE CALIBRATE button on the IBP (1, 2) SELECT menu to call up the IBP PRESSURE CALIBRATE menu as shown below:

```
                IBP  PRESSURE  CALIBRATE
........................................................
  CH1 CAL VALUE       | 26.7 |   CALIBRATE
  0   ( 0   )    00-00-0000 00:00:00

  CH2 CAL VALUE          26.7     CALIBRATE
  0   ( 0   )    00-00-0000 00:00:00




........................................................
                      EXIT
```

Figure 16-6 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 CALIBRATE item 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 CALIBRATE item to start calibrating channel 2.

The pressure calibration of the portable M8B.
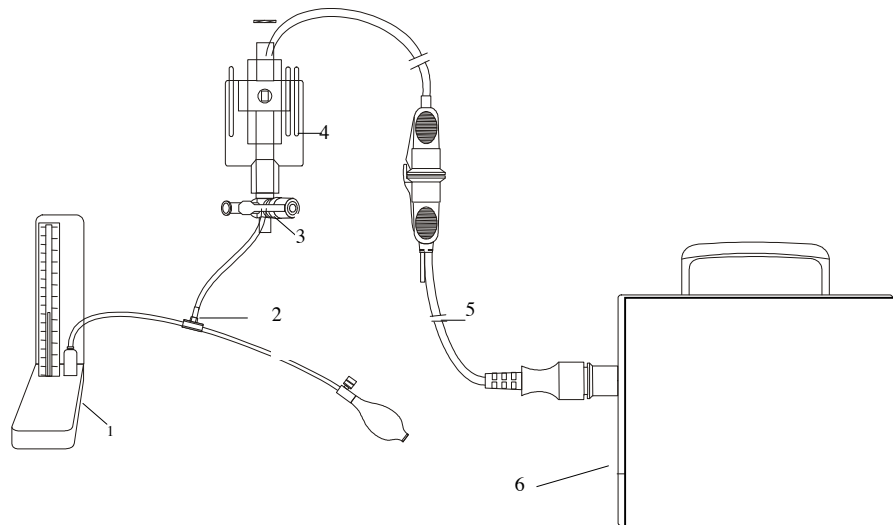
1: Hydrargyrum pressure meter; 2: 3-way connector; 3: 3-way stopcock; 4: Pressure transducer;

5: Pressure transducer interface cable; 6: Monitor

Figure 16-7 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 16-7)

⚠ **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.

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

■ "CH1 CAL SUCCESS!"

Indicate that CH1 works normally, you can use CH1 to monitor the patient.

■ "CH1 CAL FAIL!"

Make sure that pressure value shown by hydrargyrum pressure meter is change- less.

■ "CH1 SENSOR OFF, FAIL!"

Make sure that sensor is not off, then proceed calibration.

■ "IN DEMO, FAIL!"

Make surze 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.

IBP SCALE ADJUST Submenu

IBP SCALE ADJUST			
	HI	LO	VAL
CH1:ART	20.0	0.0	10.0
CH2:CVP	5.3	0.0	2.7
		EXIT	

Figure 16-8 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.

16.5 Alarm Information

Tables below describe the possible physiological alarms, technical alarms 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.

16.6 Maintenance 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.

17 Accessories and Ordering Information

The following accessories are recommended when using this monitor.

⚠ WARNING ⚠

The specification of accessories recommended is listed below. Using other accessories may damage the monitor.

NOTE:
For using neonatal disposable cuff, one NIBP Tube, one connecting tube and one neonatal disposable cuff are necessary.

Parts No.	Accessories
M15-40000	ECG Cable With 5-lead Wires（EUR Standard）
M15-40010	ECG Cable With 5-lead Wires（USA Standard）
M15-40060	ECG Cable With 5-Lead Wires（Defibrillation）(EUR Standard)
M15-40094	ECG Cable With 5-Lead Wires（Defibrillation）(USA Standard)
M15-40046	ECG Cable With 3-lead Wires（EUR Standard)
M15-40028	ECG Cable With 3-lead Wires（USA Standard）
M15-40090	ECG Electrodes (1pc)
M15-40024	Pediatric electrodes (1pc)
M15-040155	ECG Cable with 5-Lead Wires(clamp) （USA Standard）
M15-40109	Neonatal electrodes (3pcs/pack) match clamp
MS3-109069	EDAN SH1 Adult Reusable SpO_2 Sensor (Only compatible with EDAN SpO_2 module)
M15-40099	ENVITE Child Reusable SpO_2 Sensor (Only compatible with EDAN SpO_2 module)
M15-40125	ENVITE Neonate Disposable SpO_2 Sensor (Only compatible with

ENVITE SpO$_2$ Extension cable)

M13-36091	ENVITE SpO$_2$ Extension cable (Only compatible with ENVITE Neonate Disposable SpO$_2$ Sensor and EDAN SpO$_2$ module)
MS2-30043	Nellcor Reusable Adult SpO$_2$ Sensor (DS-100A OxiMax) (Only compatible with Nellcor SpO$_2$ Extension cable)
M15-40096	Nellcor Reusable Adult/Neonate SpO$_2$ Sensor (OXI-A/N OxiMax) (Only compatible with Nellcor SpO$_2$ Extension cable)
M15-40107	Silica gel SpO$_2$ Sensor/ Adult CRY036-260LB ENVITEC
M15-40108	Silica gel SpO$_2$ Sensor/ Pediatric CRYS-3212-260LB
MS1-30131	Nellcor SpO$_2$ Extension cable (Compatible with Nellcor Nell-3 OXI-Max SpO$_2$ module and Nellcor sersor)
M15-40029	Adult Cuff (25cm-35cm)
M15-40074	Large Adult Cuff (33-47cm)
M15-40043	Adult Thigh Cuff (46-66cm)
M15-40018	Child Cuff (18-26cm)
M15-40020	Infant Cuff (10-19cm)
M15-40097	Neonatal Disposable Cuff 5102 (About 6-9cm)
M15-40098	Neonatal Disposable Cuff 5104 (About 9-14cm)
M13-36036	NIBP Tube (3m)
MS1-30437	Connecting Tube for Neonatal Cuff
M15-40007	Skin Temperature Probe
MS0-18927	Rectal / Oral Temperature Probe
M13-36087	Pressure transducer interface cable
M15-40121	Disposable pressure transducer kit (BD DT-4812)
M50R-78035	Printing Paper

MS3-30493   Mounting system (Simple)

MS3-30164   Mounting system

M21-064089   Rechargeable Lithium-Ion Battery (14.8V, 2Ah)

M21-64044   Rechargeable Lithium-Ion Battery (14.8V, 4Ah)

MS9-100403   Rolling Stand

MS1R-100381   Multi-parameter Patient Monitor Service Manual

18 Service Information

If there is any question during use, please contact local distributor or the manufacturer to get help.

Manufacturer: EDAN INSTRUMENTS, INC.

Address: 3/F-B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, shekou, Nanshan Shenzhen, 518067 P.R. China

Zip code: 518067

Tel: +86-755-26882220

Fax: +86-755-26882223

Appendix Ⅰ

Product Specification

A1.1 Classification

Anti-electroshock type	Class Ⅰ equipment and internal powered equipment
EMC type	Class A
Anti-electroshock degree	ECG (RESP), TEMP, IBP CF
	SpO₂, NIBP BF
Harmful liquid proof degree	IPX1, Ordinary equipment (sealed equipment without liquid proof)
Disinfection/sterilizing method	Refer to **Chapter 12 ~ Chapter 16** for details.
Working system	Continuous running equipment

A1.2 Specifications

A1.2.1 Size and Weight

Size	318mm×152mm×264mm
Weight	5 kg

A1.2.2 Environment

Temperature
    Working   5 ~ 40 °C
    Transport and Storage   -20 ~ 55 °C
Humidity
    Working   25% ~ 80 %
    Transport and Storage   25% ~ 93 %（no coagulate）
Altitude
    Working   860hPa ~ 1060hPa
    Transport and Storage   700hPa ~ 1060hPa

Power Supply   100/240 VAC, 50/60 Hz,
     Pmax=80VA, FUSE T 1.6AL

A1.2.3 Display

Device
10. 2 inch width_screen, Multicolour TFT LCD,
Resolution 800 × 600, 1 LED
Messages

       11 Waveforms Maximum
       1 Power LED (Green)
       1 Alarm LED (Yellow/Red)
       1 Charge LED (Yellow)
       3 Sound Mode corresponding Alarm Mode

A1.2.4 Battery

2 Ah/4 Ah   14.8V chargeable Li battery
Under normal status, the working time with full electric energy is more than 120 minutes.

A1.2.5 Recorder (Optional)

Record Width	48 mm
Paper Speed	25mm/S, 50mm/S
Trace	3
Recording types:	

       Continuous real-time recording
       8 second real-time recording
       Auto 8 second recording
       Parameter alarm recording
       Drug Calculation and titration table recording

A1.2.6 Recall

Trend Recall	
Short	1 hrs, 1 Second Resolution
Long	96 hrs, 1 Min. Resolution
NIBP Measurement Recall	500 NIBP measurement data.

A1.2.7 ECG

Lead Mode   3 Leads (R, L, F or RA, LA, LL), 5 Leads (R, L, F, N, C

	or RA, LA, LL, RL, V)
Lead selection	3 Leads:I, II,III, drive leads change accordingly
	5 Leads: select 2 channels from I, II, III, avR, avL, avF
	and V. drive leads RL.
Waveform	3 Leads: 1 channel
	5 Leads: 2 channel
	7 waveforms display on screen
Analog channel setup	12 bits, 500Hz,
	4 selectable plus: ×0.25, ×0.5, ×1, ×2 cm/mV
Pacing impulse detection circuit	selecte one from I, II, III, avR, avL, avF, V
Pacing rate higher limit	>320 mV/s (RTI)
Pacing rejection (HR report has no error)	
Impulse amplitude	±2 ~ ±700 mV
Impulse width	0.1 ~ 2.0 ms
Ascending time	10μs ~ 100μs（less than 10％ of pulse width）
PACE detection	
Detection leads	7 selectable leads: I, II, III, avR, avL, avF, V
Can detect impulse as follows:	
Pulse amplitude	±2 ~ ±700mV
Pulse width	0.1 ~ 2.0 ms
Ascending time	10μs~ 100μs（less than 10％ of pulse width）
Defibrillation energy distributary	
Over-voltage	<5000V
Energy	<360J
Resume time	<5s
Energy absorption	<10%
Release charge	< 100 μC
Anti-electrotome signal resume time	<10s
Least detection signal	
Rate×2	Display accuracy 0.5mV/10mm
	Least detection signal 10μV
Rate×1	Display accuracy 1mV/10mm
	Least detection signal 20μV
Rate×0.5	Display accuracy 2mV/10mm
	Least detection signal 40μV
Rate×0.25	Display accuracy 4mV/10mm
	Least detection signal 80μV
Input voltage range	±8mV, polarized voltage: ±500mV

CMRR

Diagnosis	>100 dB (no 50Hz/60Hz software wave trap)
Monitor	>110 dB (has 50Hz/60Hz software wave trap)
Surgery	>100dB (50Hz/60Hz software wave trap)

Frequency response

Diagnosis	0.05Hz ~125Hz (-3dB)
Monitor	0.5Hz ~40Hz (-3dB), 50Hz/60Hz wave trap
Surgery	1Hz ~20Hz (-3dB), 50Hz/60Hz wave trap

System noise $<30\mu V$ p-p (RTI)

HR Measuring and Alarm Range

Adult/Ped	15 bpm ~ 300bpm
Neo	15 bpm ~ 350bpm

Accuracy	±1% or ±1bpm, which great
Resolution	1 bpm
Sensitivity	> 200 µV P-P
Differential Input Impedance	≥ 5 MΩ
Electrode offset potential	±300mVd.c.→ ± 600mVd.c.
Leakage Current	< 10 uA
Working Mode	
Monitor	
Surgery	
Diagnosis	
ECG Signal Range	±6 mV (Vp-p)
Amplitude-frequency Characteristic (Bandwidth)	
Monitor	0.5 ~ 40 Hz
Surgery	1 ~ 25 Hz
Diagnosis	0.05 ~ 120 Hz
ST Segment Monitoring Range	
Measure and Alarm	-2.0 ~ +2.0 mV

A1.2.8 RESPIRATION

Method	Impedance between R-F (RA-LL)
Measuring Sensitivity	0.2 ~3.0Ω
Base line Impedance Range	500~ 4000Ohms (excitation frequency 64.8kHz)
Resp. Rate:	

Measuring and Alarm Range

Adult	0 rpm ~120rpm
Neo/Ped	0 rpm ~150rpm
Resolution	1 rpm
Accuracy	±2 rpm
Gain Selection	×0.5, ×1, ×2, ×4, Auto

A1.2.9 NIBP

Method	Oscillometric
Mode	Manual, Auto, Continuous

Measuring Interval in AUTO Mode

1/2/3/4/5/10/15/30/60/90/120/240/480Min

Measuring Type

Systolic Pressure, Diastolic Pressure, Mean Pressure

Measuring Rang

Adult Mode

	SYS	30~270mmHg
	DIA	10~220mmHg
	MEAN	20~235mmHg

Pediatric Mode

	SYS	30~235mmHg
	DIA	10~220mmHg
	MEAN	20~225mmHg

Neonatal Mode

	SYS	30~135mmHg
	DIA	10~110mmHg
	MEAN	20~125mmHg

Cuff Pressure measuring Range	0~280mmHg
Pressure Resolution	1mmHg

Pressure Accuracy

Mean error	±5mmHg
Maximum Standard deviation	≤8mmHg
Entire Measuring Period	20~45s typical (depend on HR/motion disturbance)
Overvoltage protection	Dual Overvoltage protection

Adult	297±3mmHg
Pediatric	240±3mmHg
Neonatal	145±3mmHg

A1.2.10 SpO$_2$

Measuring Range	0 ~ 100 %
Alarm Range	0 ~ 100 %
Resolution	1 %
Accuracy	
Adult (including Pediatric)	±2 digits（70%~100% SpO$_2$）
	Undefined（0~70% SpO$_2$）
Neonate	±3 digits（70%~100% SpO$_2$）
	Undefined （0~70% SpO$_2$）
Pulse Rate	
Measuring and Alarm Range	15 ~ 254 bpm
Resolution	1 bpm
Accuracy	± 3bpm
	Under Motion Condition ±5 bpm
Anti-low-perfusion	Strong Anti-low-perfusion
Anti-motion Interference	Strong Anti-motion Interference,
	Anti-electrotome

Nellcor module (optional)

Measuring Range	1 ~ 100 %
Alarm Range	1 ~ 100 %
Resolution	1 %
Accuracy	
Adult and Low-perfusion	±2 digits（70%~100% SpO$_2$）
	Undefined （0~70% SpO$_2$）
Neonate	±3 digits（70%~100% SpO$_2$）
	Undefined （0~70% SpO$_2$）
Pulse Rate	
Measuring and Alarm Range	20~250bpm
Resolution	1bpm
Accuracy	±3 bpm
Low Perfusion	0.03 % ~ 20 %

A1.2.11 TEMPERATURE

Channel	2
Measuring Range	0 ~ 50 °C
Resolution	0.1°C

Accuracy	±0.1°C (20 ~ 45 °C)
	±0.2°C (other)
Refresh Time	Every1 ~ 2 Seconds
Selftest	Every about 5 ~ 10 Minutes

A1.2.12 IBP

Channel	2
Label	ART, PA, CVP, RAP, LAP, ICP, P1, P2
Pressure Sensor	
Sensitivity	5 (μV/V/mmHg)
Impedance	300-3000 (Ohm)
Static Pressure Measuring Range	-50~+300 mmHg（up to 350 mmHg）
Static Pressure Accuracy	±1% or 1mmHg which great (excluding probe)
	±4% or 4mmHg which great (including probe)
Dynamical Pressure Measuring Range	-50~+300 mmHg
Dynamical Pressure Accuracy	±4% or 4mmHg which great (including probe)
Frequency Response	D.C.~15 Hz
Measuring and Alarm Range	
ART	0 ~ 300 (mmHg)
PA	-10 ~ 120 (mmHg)
CVP/RAP/LAP/ICP	-10 ~ 40 (mmHg)
P1/P2	-10 ~ 300 (mmHg)
Resolution	1 (mmHg)
IBP Zero	2-channel 12 bits DAC Zero
Zero range:	-50~ +300 mmHg

Appendix Ⅱ

EMC Information- Guidance and Manufacture's Declaration

A2.1 Electromagnetic Emissions-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The M8B is intended for use in the electromagnetic environment specified below. The customer or the user of the *M8B* should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *M8B* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The *M8B* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

A2.2 Electromagnetic Immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *M8B* is intended for use in the electromagnetic environment specified below. The customer or the user of *M8B* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±1kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles \<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles \<5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *M8B* requires continued operation during power mains interruptions, it is recommended that the *M8B* be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.				

A2.3 Electromagnetic Immunity-for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The *M8B* is intended for use in the electromagnetic environment specified below. The customer or the user of *M8B* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the *M8B*, including cables, than the

			recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V$_{rms}$ 150 kHz to 80 MHz	3 V$_{rms}$	$d = \left[\dfrac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\dfrac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\dfrac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1   At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2   These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]   Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *M8B* is used exceeds the applicable RF compliance level above, the *M8B* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *M8B*.

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

A2.4 Recommended Separation Distances

Recommended separation distances between **portable and mobile RF communications equipment and the *M8B***
The *M8B* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *M8B* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *M8* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz $d = \left[\dfrac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\dfrac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\dfrac{7}{E_1}\right]\sqrt{P}$
0.01	**0.1167**	**0.1167**	**0.2334**
0.1	**0.3689**	**0.3689**	**0.7378**
1	**1.1667**	**1.1667**	**2.3334**
10	**3.6893**	**3.6893**	**7.3786**
100	**11.6667**	**11.6667**	**23.3334**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EDAN INSTRUMENTS, INC.

Addr: 3/F-B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, shekou,

Nanshan Shenzhen, 518067 P.R. China

TEL: +86-755-26882220 FAX: +86-755-26882223

EC REPRESENTATIVE

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, D-20537 Hamburg Germany

TEL: +49-40-2513175 FAX: +49-40-255726

E-mail: antonjin@yahoo.com.cn