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User Manual

EDANUSA

M3A

Vital Signs Monitor

Version 1.3

CE 0123

About this Manual

P/N: 01.54.112593-13

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

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

Terms Used in this Manual

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 a procedure.

Table of Contents

Chapter 1 Intended Use and Safety Guidance

1.1 Intended Use

The M3A Vital Signs Monitor (hereinafter called monitor) is intended to be used for non-invasive continuous monitoring of SpO_2 (oxygen saturation of arterial blood), NIBP (non-invasive blood pressure) and TEMP (temperature).

The monitor is intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in hospitals, hospital type facilities and intra-hospital moves.

The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

1.2 Safety Guidance

1.2.1 Environment

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

The 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 (5cm) clearance around the instrument for proper air circulation.

1.2.2 Power Source Requirements

Refer to *Appendix Ⅰ*.

1.2.3 Grounding the Monitor

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

Connect the grounding wire to the equipotential grounding terminal on the mains 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 an expert in the field, to ensure that the necessary safety of all instruments concerned will not be impaired by the proposed combination.

1.2.4 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 Monitor must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the rear panel of the instrument 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 monitor must be supplied by internal power only.

1.2.5 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.

1.2.6 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

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

2 The monitor is intended to be used by qualified physicians or personnel professionally trained. And they should be familiar with the contents of this user manual before operation.

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

4 **EXPLOSION HAZARD**-Do not use the monitor in a flammable atmosphere where anesthetics or other flammable materials may accumulate.

5 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

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

7 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN60950 for data processing equipment and IEC/EN60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN60601-1-1. 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/EN60601-1-1. If in doubt, consult our technical service department or your local distributor.

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

9 Do not unplug the battery when monitoring.

10 Make sure the monitor is used in the appointed range of voltage, the effect of power supply can be ignored.

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

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

13 Always keep the battery away from fire.

14 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.

15 Do not use a battery with serious scar or deformation.

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

17 Please set the alarm according to the individual condition of patient to avoid delaying treatment. Ensure there will be an alarm audio prompt when an alarm occurs.

18 Devices connecting with the monitor should be equipotential.

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

20 The monitor can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT.

WARNING

21 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.

22 Please disinfect timely to prevent cross infection between patients.

23 This monitor is not a device for treatment purposes.

24 Only NIBP and SpO_2 applied parts of the monitor are defibrillation-proof. When a defibrillator is applied, keep other accessories away from the patient. Otherwise, it may result in damaging the monitor or harming the patient.

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

26 During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off, and only the patient information and alarm settings can be saved. After reconnecting the power supply, the user should turn on the monitor for monitoring.

CAUTION

1 Federal law (U.S.) restricts this device to sale by or on the order of a physician.

2 **Electromagnetic Interference** – Ensure the environment in which the monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.

3 The monitor is designed for continuous operation and is “ordinary” (i.e. not drip or splash-proof).

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

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

6 Do not sterilize the monitor, recorder or any accessories.

7 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do not dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

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

CAUTION

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

10 The disposable accessories can not be reused.

11 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.

12 If the monitor gets damp, put it in dry circumstance to dry it until it can work normally. If liquid pours on the monitor, please contact the service personnel authorized by EDAN.

13 Setting alarm limits to extreme values can render the alarm system useless.

14 A potential hazard may exist if different alarm presets are used for the same or similar equipment in any single area.

NOTE:

1 Position the device in a location where the operator can easily see the screen and access the operating controls.

2 The monitor can only be used on one patient at a time.

3 The equipment is calibrated to display functional oxygen saturation.

4 This equipment is not intended for family usage.

5 If the device is discolored or damaged, then discontinue use of the device.

6 The pictures and interfaces in this manual are for reference only.

7 Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.

1.2.7 Explanation of Symbols on the Monitor

	This symbol indicates that the instrument is IEC/EN60601-1 Type BF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.

	This symbol indicates that the instrument is IEC/EN60601-1 Type BF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock. It is not suitable for use during defibrillation.
	This symbol indicates that the instrument is IEC/EN60601-1 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 not suitable for use during defibrillation.
	CAUTION
	Consult Instructions for Use
	Equipotentiality
	ON/OFF switch
	It indicates the port has Nurse Call or serial port function.
	Serial number
	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
	Authorized representative in the European community
	Date of manufacture
	Manufacturer

P/N	Part Number
	Recycle
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
Rx only	Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Chapter 2 Installation of Monitor

NOTE:
To ensure that the monitor works properly, please read *Chapter 1 Intended Use and Safety Guidance*, and follow the steps before using the monitor.

2.1 Opening the Package and Checking

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage. 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 manufacturer or local representative immediately.

2.2 Connecting the Power Cable

Connection procedure of the AC power line:

- Make sure the AC power supply complies with the following specification: 100V-240V ~, 50Hz/60Hz.
- Apply the power line provided with the monitor. Plug the power line to input interface of the monitor. Connect the other end of the power line to a grounded power output.

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

- Connect to the ground line if necessary. Refer to section *1.2 Safety Guidance* for details.

NOTE:
When the battery is provided, after the monitor is transported or stored, the battery must be recharged. Switching on AC power supply can recharge the battery no matter if the monitor is powered on.

2.3 Powering on the Monitor

Press the **ON/OFF** button on the front panel to power on the monitor, all the seven-segment displays are bright, and LOGO information is displayed on the screen.

WARNING

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

NOTE:

1 During POST, make sure all the seven segments are bright, which indicates the seven segments function well.

2 Check all the functions of the monitor and make sure that the monitor is in good condition.

3 If rechargeable batteries are provided, recharge them after using the monitor every time to ensure the electric power is enough.

4 The interval between double presses of the **ON/OFF** button should be more than 1 second.

5 After continuous 7 days' (168 hours') runtime, please restart the monitor to ensure the monitor's steady performance and long lifespan.

2.4 Connecting Sensor to Patient

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

NOTE:

For information on correct connection, refer to related chapters.

Chapter 3 Introduction

3.1 General Information

The monitor integrates the function of parameter measurement modules, display and output to compose a compact, portable device. Its built-in replaceable battery provides convenience for patient movement.

The monitor is a user-friendly device with operations conducted by a few buttons on the front panel. Refer to section *3.3 Button Functions* for more details.

M3A with the T2 TEMP module

M3A with the TH TEMP module

Figure 3-1 M3A Vital Signs Monitor

M3A Vital Signs Monitor can monitor:

SpO_2: Oxygen saturation of arterial blood (SpO_2);
Pulse Rate (PR);
SpO_2 PLETH (Plethysmogram);

NIBP: Systolic Pressure (SYS);
Diastolic Pressure (DIA);
Mean Pressure (MAP);
Pulse Rate (PR).

TEMP: Temperature.

The monitor provides extensive functions such as visual and audible alarms, storage for data, SpO_2/NIBP/TEMP measurements review, nurse call and so on.

3.2 Screen Display

The monitor is equipped with LCD. The patient parameters, waveforms, alarm messages, patient ID, time, monitor status and other information can be reflected from the screen.

If the monitor has SpO_2, NIBP and TEMP functions. As an option, the monitor can be configured to single SpO_2, single NIBP, NIBP+SpO_2, NIBP+TEMP or NIBP+SpO_2+TEMP.

The configuration is preset by the manufacturer, and it can not be changed by the user.

3.2.1 All Parameters Display

The screen is divided into three areas:

1 Parameter area ①

2 Waveform/ NIBP Multi-Group Review/ Trend list/ Trend Graph ②

3 Information area ③ ④

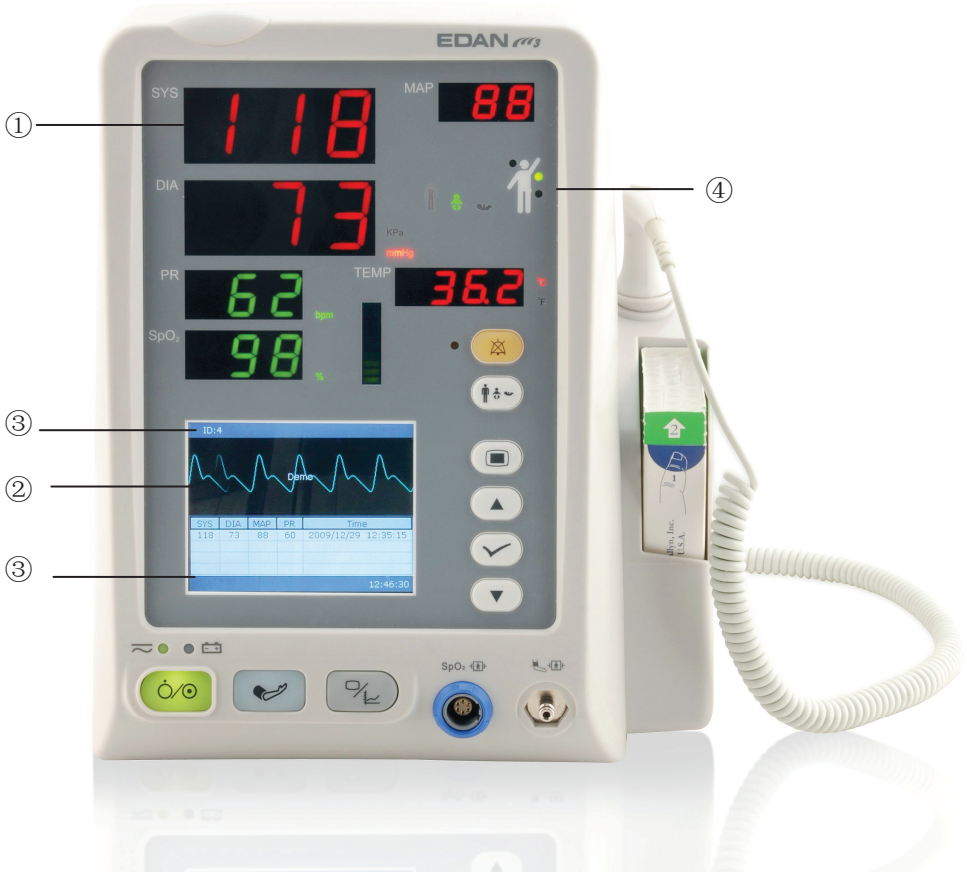


Figure 3-2 Main display

The NIBP multi-group Review and SpO_2 waveform area is displayed as follows:

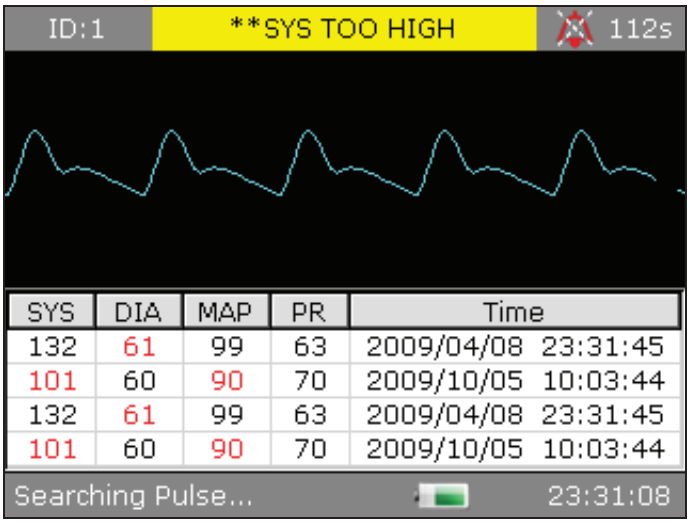


Figure 3-3 NIBP Multi-group Review

Change the display on the screen to Trend list as follows:

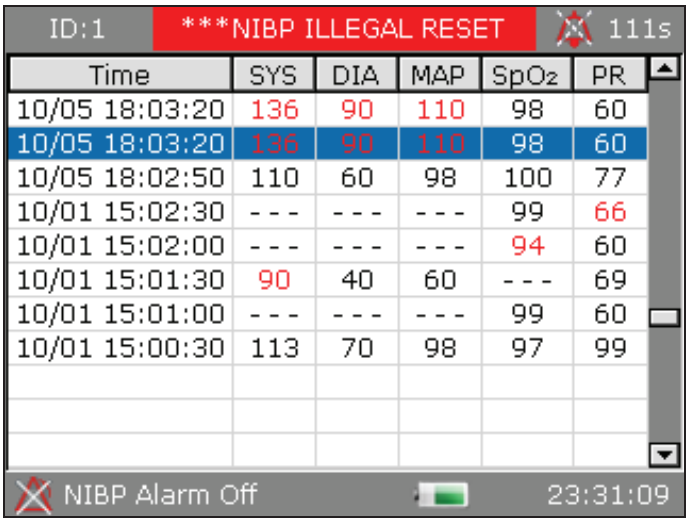


Figure 3-4 Display trend list

Change the display on the screen to Trend graph as follows:

Figure 3-5 Display SpO_2 trend graph

The icons on the interface and their meanings are as follows:

	Battery status indicator
	Connected to mains power supply
	Audio system off
	Audio alarm pause
	Parameter alarm off

	Indicates an error occurs	
	Note	
	Warning	
	Password protection	
	Patient type: ADU (adult)	
	Patient type: PED (pediatric)	
	Patient type: NEO (neonatal)	
	Measuring oral TEMP	For device with the T2 TEMP module only.
	Measuring axillary TEMP	
	Measuring rectal TEMP	
	Measuring ear TEMP	For device with the Intrared Ear Temperature module only.
ID	Current patient ID	
23：31：08	Current time	

Parameter Area (①)

Parameter area is on the upper part of main interface, and following parameters are displayed:

SpO_2:

— SpO_2 (Unit: %)

— PR (Pulse Rate, Unit: BPM).

NIBP:

— SYS, DIA, MAP (Unit: mmHg or kPa).

— Pulse Rate (Pulse Rate, Unit: BPM)

TEMP:

— Temperature (Unit: ℃ or ℉).

The PR signal from SpO_2 measuring takes priority to be displayed.

Waveform/Trend List (②)

It can display SpO_2 waveform, NIBP multi-group review, trend list or trend graph.

Information Area (③ ④)

The Information Area is at the right and bottom parts of the screen, displaying operating status of the monitor and condition of the patient.

The information area contains the following data:

— Patient type and ID;

— NIBP measuring mode;

— Signs indicating the battery or mains power supply status;

— Current time;

— Signs indicating the sensor or alarm status.

Alarm Indicator and Alarm Status

— In normal conditions, the alarm indicator does not light.

- When an alarm is generated, the alarm indicator lights or flashes. The color of light represents the alarm level. Refer to *Chapter 5 Alarm* for details.
- Refer to relevant content of parameters for Alarm information and prompt.

Charging Indicator and Charging Status

To indicate the status of charging: when the battery is being charged, the light turns to yellow; after the charge is finished, the light will be off.

3.2.2 Optional Displays

SpO_2 only measuring mode

Figure 3-6 Display in SpO_2 only mode

NIBP only measuring mode

In NIBP only measuring mode, the PR from NIBP measurement is also displayed on screen.

Figure 3-7 Display in NIBP only mode

3.3 Button Functions

Figure 3-8 Buttons

All the operations to the monitor can be finished by several buttons.

①	**ON/OFF** 	When the monitor is off, press this button to turn it on. When the monitor is on, press this button and hold for 2s to turn off the monitor; or press this button for less than 1s, the menu for entering Standby Mode is displayed.
②	**NIBP START/STOP** 	To inflate the cuff and start blood measuring. During the measuring process, press the button to stop measuring. (For the monitor with NIBP function).
	ALARM LIMIT 	For SpO_2 only monitor, the **NIBP STASRT/STOP** button is changed to **ALARM LIMIT** button. Press this button to set the alarm limits of the parameters of SpO_2.

③	**TREND/WAVEFORM** 	Press this button to switch among waveform display, trend list and trend graph display.
④	**SILENCE** 	Press this button for less than 2s to silence the audible alarm for a period; the icon  displays in the information area and the indicator beside the button flashes. When pressing it again or the pause time is over, the audible alarm will resume to the normal monitoring status, and the indicator is off. You can set the duration for silencing the audible alarm to 1 min, 2 min or 3 min. For more information, please refer to *4.9 Maintenance*. Press and hold this button for more than 2s to turn off the audio system including audio alarm, key volume and pulse tone. The icon  displays in the information area and the indicator is on during the alarm silence period until the button is pressed again.
⑤	**PATIENT TYPE** 	Press this button for 0.5s to change the patient type which is displayed on the front panel.
⑥	**MENU** 	Press to open the **Main Menu**. Refer to *Chapter 4 System Menu* for details.
⑦	 **UP**  **OK**  **DOWN**	Press **UP** or **DOWN** to select an item or to increase/ decrease a number. Confirm the selection by pressing **OK**.

The icons on the front panel:

⑧	 **CHARGE Indicator**	The LED beside this icon indicates the charging status. When the battery is being recharged, the LED is bright.

⑨	**POWER Indicator**	The LED beside this icon indicates the power condition. When the monitor connects to the mains power supply, the LED is bright.

3.4 Interfaces

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

Sensor port on the front panel

Figure 3-9 Sensor Connectors

Connectors for cables and sensors are as shown in Figure 3-9.

1. SpO_2 sensor connector ①

2. NIBP cuff connector ②

WARNING

Only connect the device to EDAN supplied or recommended accessories.

Rear Panel

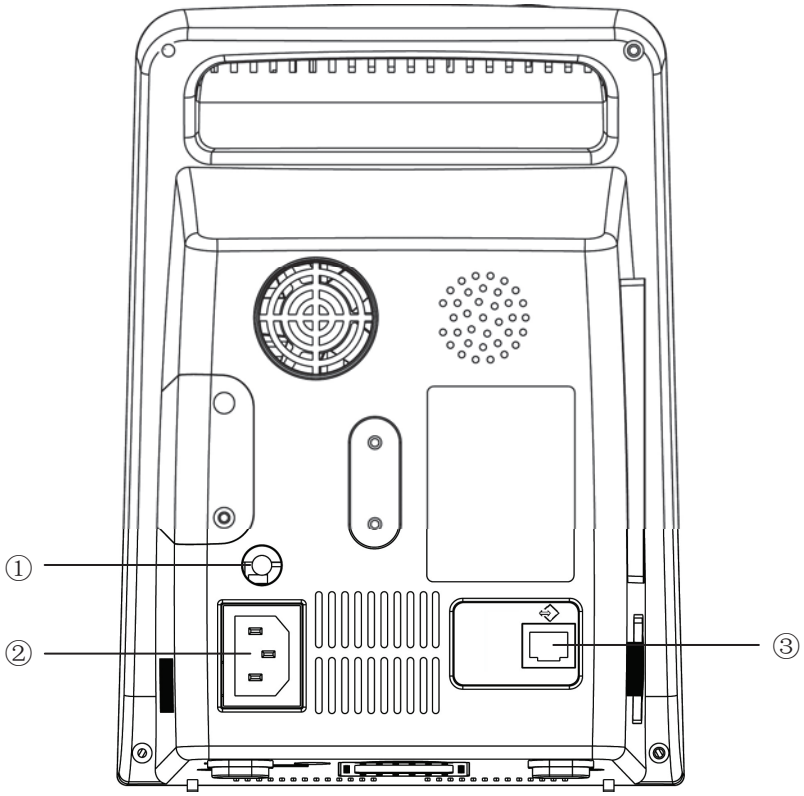


Figure 3-10 Rear Panel

Sockets on the rear panel are shown in the above figure:

① Equipotential grounding terminal for connecting to the hospital's grounding system.

② Power supply socket: 100V–240V ~, 50Hz/60Hz.

③ The port can be used as the Nurse Call connector and serial port (or as the interface to the Ethernet).

Bottom panel

There are battery compartment and fuse box on the bottom panel.

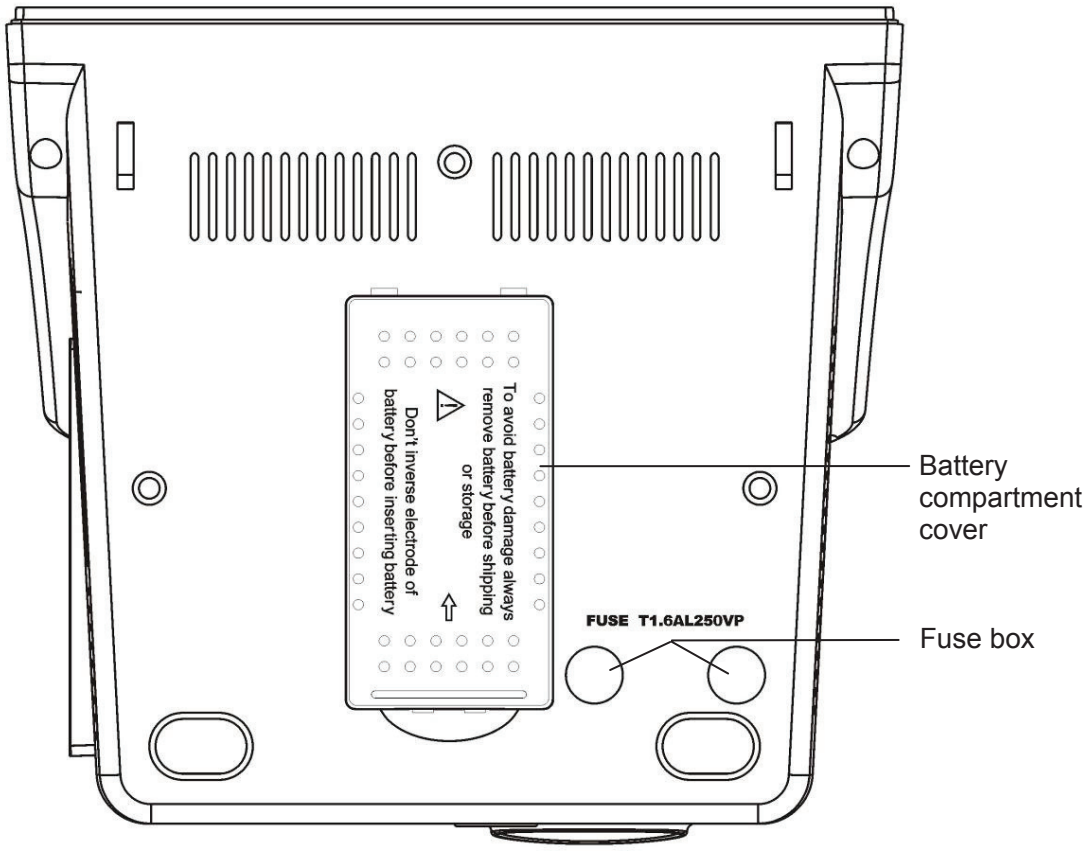


Figure 3-11 Bottom panel

3.5 Built-in Rechargeable Battery

The monitor is equipped with a built-in rechargeable battery. When switching on AC power supply, the battery will be recharged automatically until full electric energy. There is a sign  or  in the bottom right corner of screen.

- When the monitor is working with AC mains power, and it has no battery or the battery has full electric energy, it displays  ;
- When the monitor is working with AC mains power, and the battery is being recharged, it displays  ;
- When the monitor is working with battery, it displays  .

If the monitor is off, you can see recharging status from the charger indicator. The battery status indicator is light in yellow when being recharged, and off when full.

Replace Battery

In monitoring or communication state, the battery status indicator will flash when the battery is low or empty.

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

WARNING

1 Do not take off the battery when monitoring. The unexpected power supply off can not impact on the normal monitor working, if it has battery for standby.

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

3 Make sure the monitor is used in the appointed range of voltage, so the effect of power supply can be ignored.

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

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

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

7 Do not heat or throw battery into fire.

8 Do not use, leave battery close to fire or other places where temperature may be above +60℃. Do not immerse, throw, and wet battery in water/seawater.

9 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 to cause strong shock; do not disassemble or modify the battery.

10 Take out the battery before cleaning or storing the monitor for more than 1 month.

Chapter 4 System Menu

The monitor features in flexible configurations. You can configure various aspects of the monitor, including the parameters to be monitored, audio signal volume, and output content.

Press the **MENU** button on the front panel to open **Main Menu**. You can perform the following operations in this menu.

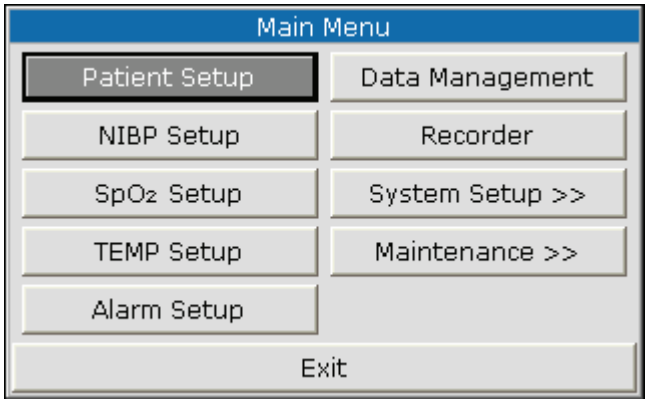


Figure 4-1 System Memu

4.1 Patient Setup

Click on **Patient Setup** in **Main Menu** to open the following menu.

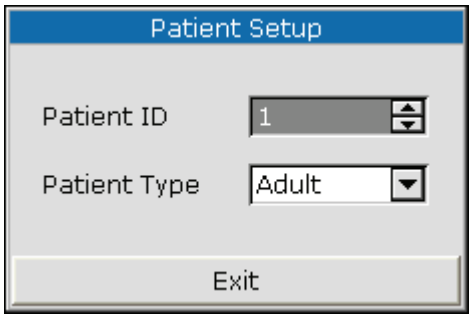


Figure 4-2 Patient Setup

You can set the following patient information:

- **Patient ID**: you can set the patient ID to 1 ~ 200.
- **Patient Type**: you can set the patient type to **Adult, Pediatry** or **Neonate.**

Press the **UP/DOWN** button on front panel to select the items, then press the **OK** button to confirm.

Select **Exit** to return to the previous menu.

4.2 NIBP Setup

Please refer to *10.3.1 NIBP Setup* for more information.

4.3 SpO_2 Setup

Please refer to *9.5.1 SpO_2 Setup* for more information.

4.4 TEMP Setup

Please refer to *11.1.3.1* or *11.2.3 TEMP Setup* for more information.

4.5 Alarm Setup

Select **Alarm Setup** in **Main Menu** to open submenu as shown below, in which the user may turn on or off alarm or set the upper alarm limit or lower alarm limit.

Set the item to **ON**, the alarm system is turned on. Pressing the **SILENCE** button on the front panel can stop the audio alarm or silence the audio system. If you set the item to **OFF** in this submenu, the monitor will not give an alarm when an alarm is activated.

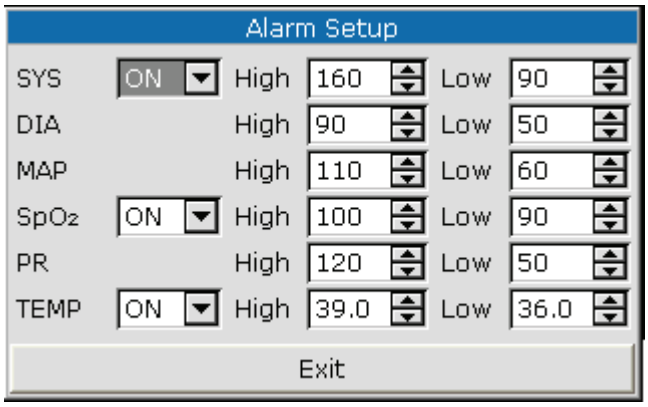


Figure 4-3 Alarm Setup

WARNING

1 If the user set alarm to **OFF**, the monitor will not give alarm prompts when an alarm is activated, the user should use this function cautiously.

2 The user should check the alarm limit to ensure it is proper for each patient.

4.6 Data Management

Select **Maintenance** in **Main Menu** to open the following menu.

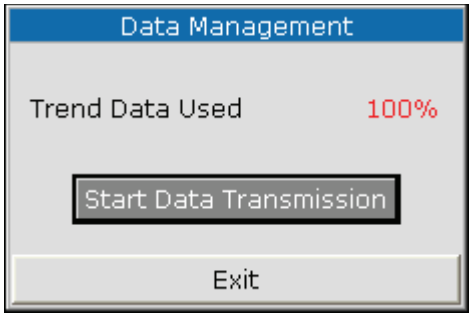


Figure 4-4 Data Management

- **Start Data Transmission:** select this item to start transmitting data from monitor to data management software.

4.7 Recorder

Select **Recorder** in **Main Menu** to open the following menu.

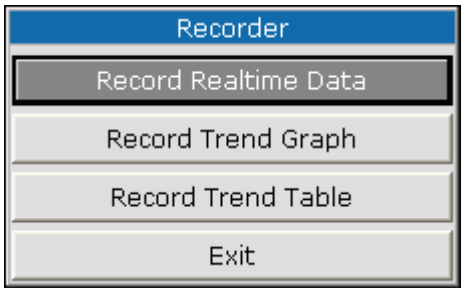


Figure 4-5 Recorder

- **Record Realtime Data**: Select it to output the real time data from the monitor.
- **Record Trend Graph**: Select it to output the trend graph.
- **Record Trend Table**: Select it to output the trend table.

Please refer to *Chapter 7 Recording* for more information.

4.8 System Setup

There are a few items to be set in this submenu, see as follows:

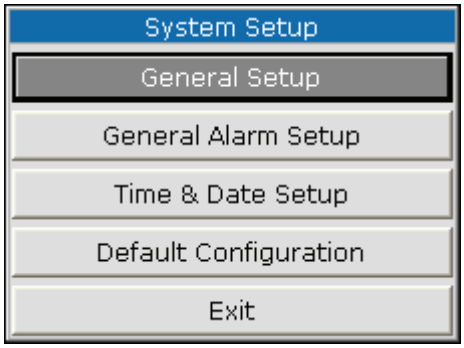


Figure 4-6 System Setup

4.8.1 General Setup

Select **General Setup** in **System Setup** to open submenu as shown below:

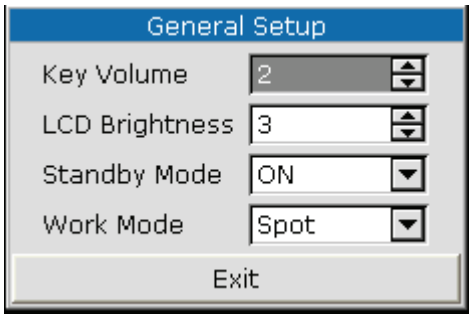


Figure 4-7 General Setup

- **Key Volume**: set key volume to level **0** ~ **5**.
- **LCD Brightness**: set LCD brightness to level **1** ~ **5**.
- **Standby Mode**: set to **ON** or **OFF**. If you set this item to **ON**, when pressing **ON/OFF** button for less than 1s, the monitor will enter Standby Mode. (Please refer to *4.10 Standby Mode* for more information.)
- **Work Mode**: set to **Spot** or **Monitor**.

4.8.2 General Alarm Setup

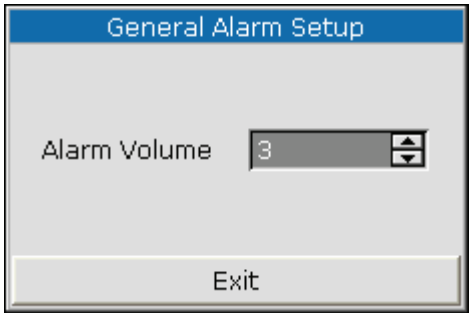


Figure 4-8 General Alarm Setup

- **Alarm Volume**: set alarm volume to level **1** ~ **5**.

4.8.3 Time & Date Setup

Select **Time & Date Setup** in **Main Menu** to access the submenu as shown below. System time is in format of **yy-mm-dd, mm-dd-yy** or **dd-mm-yy**. Users can set the year, month, day, hour, minute and second. Select the item you want to modify and confirm it by pressing **Confirm**. Select **Cancel** item to save the setup and return to the previous menu. If you want to exit the menu without saving it, press the **MENU** button on front panel.

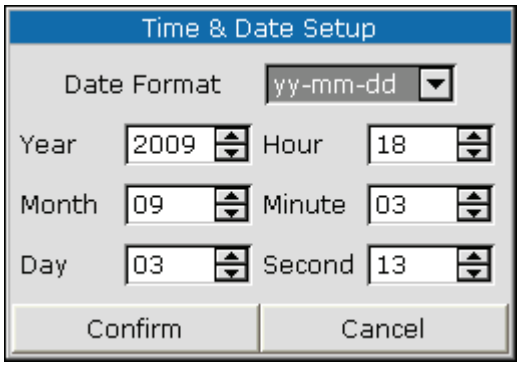


Figure 4-9 Time Setup

4.8.4 Default Configuration

NOTE:
Select any item in this submenu to cancel the current setup and use the selected default setup.

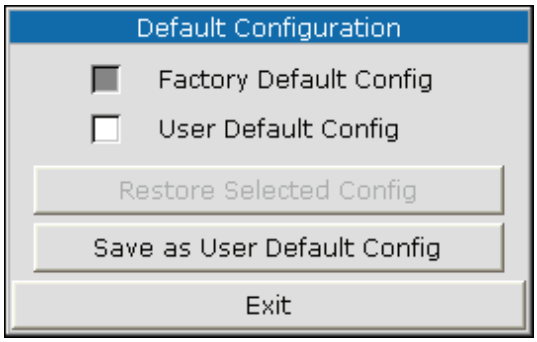


Figure 4-10 Default Configuration

- **Factory Default Config**: select the factory default configuration;
- **User Default Config**: select the user-defined default configuration;
- **Restore Selected Config**: select this item to restore the selected configuration;
- **Save as User Default Config**: save the current setup as the user default configuration;

4.9 Maintenance

Select **Maintenance** in **Main Menu** to open the following menu. **Factory Maintenance** is only available for the service engineers of EDAN or representatives authorized by EDAN.

Figure 4-11 Maintenance

User Maintenance

Input the user password **9 9 8 1** in the **Enter Password** box and press **Confirm**:

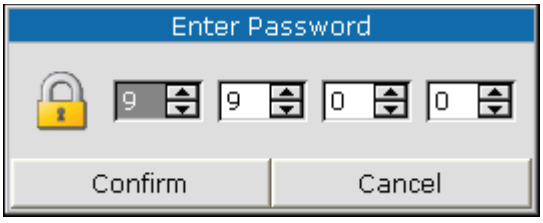


Figure 4-12 Enter the Password

User Maintenance menu will pop up, in which you can set the following items.

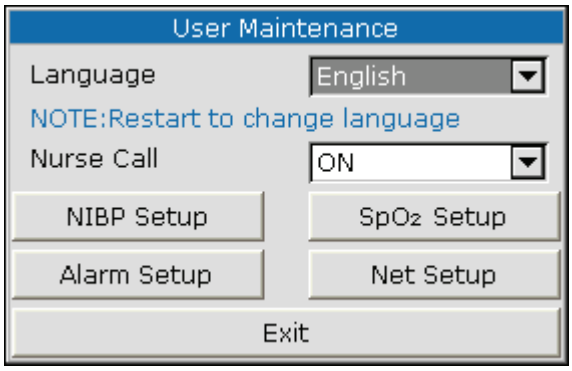


Figure 4-13 User Maintenance

- **Language**: Set the displaying language.

NOTE:

The user should restart the monitor after changing the displaying language.

- **Nurse Call**: Turn on or off the nurse call. When the parameter alarm occurs, the monitor gives a 3s nurse call alarm prompt; if the audio alarm or the audio system is off, the monitor can also give the nurse call alarm in abnormal condition.

  The relay contact between pin7 and pin8 of RJ45 is normally open. But it is closed when an alarm is audible.

- **NIBP Setup**

Access **NIBP Setup** and you can see the menu as follows:

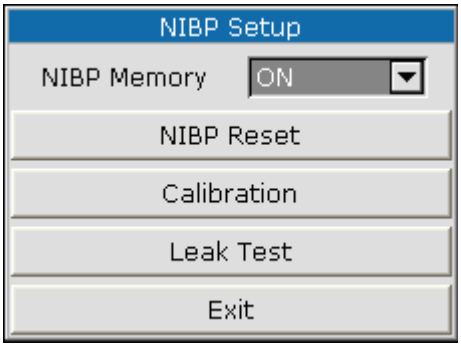


Figure 4-14 NIBP Setup

- **NIBP Memory**

  You can set this item to **ON** or **OFF**. If the item is **ON**, the monitor will automatically memorize the initial measurements of the patient when measuring his or her blood pressure. Then the monitor will inflate the cuff according to the previous memorized measurements. This function accelerates the measuring of the patient's blood pressure.

- **NIBP Reset**: select it to reset the NIBP module.
  - Restore measurement status.
  - Pick this item to restore initial settings of the pressure pump.
  - When the pressure pump 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.

- **Calibration**:

  Calibrate the cuff pressure reading with a calibrated reference manometer. Pick the **Calibration** 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 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 monitor with a rigid metal vessel with a capacity of (500 ± 25) ml. 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. Select **Calibration** in menu. Inflate the pneumatic system to 0 mmHg, 50 mmHg 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.

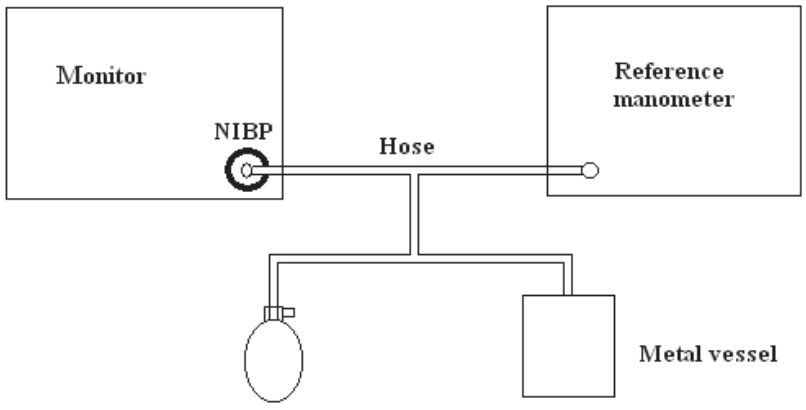


Figure 4-15 NIBP Calibration

- **Leak Test**

  This item is used for air leakage test. Press this item to start the air leakage test. Then the item will change into **Stop Leakage Test**. If it is picked again, the system will stop air leakage test.

WARNING

This leakage test other than being specified in the IEC/EN1060-1 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) Select the **Leakage Test** item by pressing the **UP/DOWN** button. It displays indicates **Leakage Test** on the bottom of the parameter area.
5) The system will automatically inflate the pneumatic system to about 180mmHg.
6) After 20s 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 status 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.

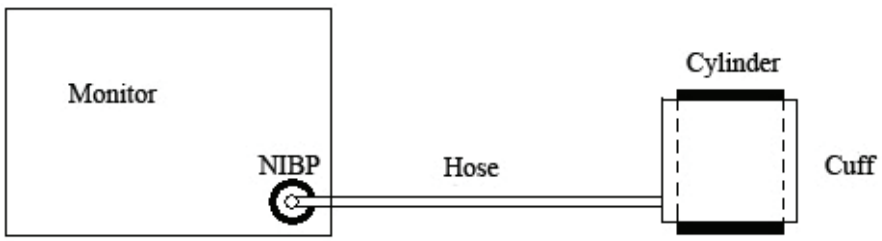


Figure 4-16 Diagram of NIBP Air Leakage Test

■ SpO_2 Setup

Access **SpO_2 Setup** and you can see the menu below:

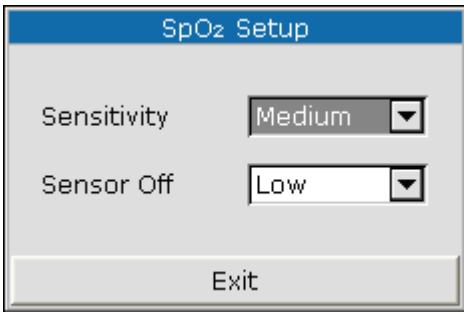


Figure 4-17 SpO_2 Setup

- **Sensitivity**

  The SpO_2 reading is the average of data collected within a specific time. You can set **Sensitivity** to **Low**, **Medium** or **High** via the menu. The higher the sensitivity is, the quicker the pulse oximeter responds to the changes in the patient's oxygen saturation level. Contrarily, the lower the sensitivity is, the slower the pulse oximeter responds to the changes in the patient's oxygen saturation level, but the measurement accuracy will be improved. When a critical patient is monitored, selecting high sensitivity will help to understand the patient's state.

- **Sensor Off**

  You can configure the alarm level for SpO_2 **Sensor Off** to **Low** or **High**.

■ **Alarm Setup**

Access **Alarm Setup** and you can see the menu below:

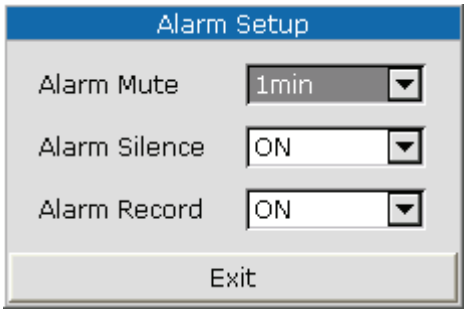


Figure 4-18 Alarm Setup (for monitor with recorder)

- **Alarm Mute**: Set the duration of silencing the audible alarm to **1 min**, **2 min** or **3 min**.

- **Alarm Silence**

  You can set this item to **ON** or **OFF**. If the item is **ON**, you can turn off the audio system by pressing the **SILENCE** button on the front panel for more than 2s. In this case, all sounds including the alarm sound, key sound and sphygmic sound coming from the monitor will be mute. If the item is **OFF**, the function mentioned above is unavailable.

- **Alarm Record** (only available for the monitor outfitted with a recorder)

  By configuring **Alarm Record**, the function of automatically outputting the alarm information in case of any physiological alarm can be enabled or disabled. If the item is **ON**, the monitor will automatically print out the alarm information once any physiological alarm is triggered. If the item is **OFF**, the monitor will not automatically output the alarm information.

■ **Net Setup**

Access **Net Setup** and you can see the menu below:

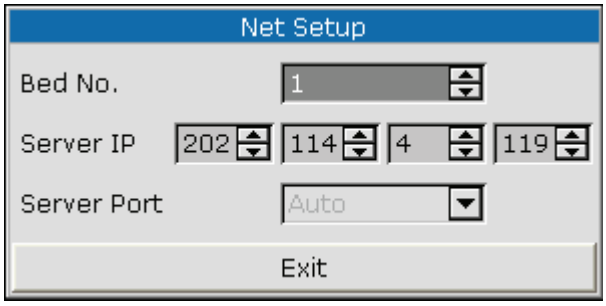


Figure 4-19 Net Setup

- **Bed No.**: Set the bedside monitor number to a value from 1~64.
- **Server IP**

  The default server IP is 202.114.4.119. It can be changed by the user according to the IP of PC installed with MFM-CMS of EDAN.
- **Server Port**: Set the server port.

■ **Exit**: Exit the menu.

Factory Maintenance

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

Version

Select **Main Menu** > **Maintenance** > **About** to check the version of the modules.

4.10 Standby Mode

Entering Standby Mode

When the monitor is on, press the **ON/OFF** button for less than 2 seconds, the dialog box displays as follows:

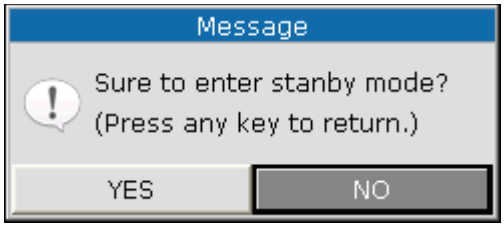


Figure 4-20 Enter Standby Mode

Select **YES** to enter the standby mode.

In the following two conditons, the monitor can not enter standby mode.

1. If the monitor is measuring, press the **ON/OFF** button for less than 2 seconds, the following dialog box displays:

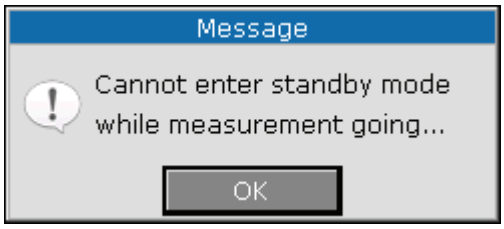


Figure 4-21

2. If the battery is low, press the **ON/OFF** button for less than 2 seconds, the following dialog box displays:

Figure 4-22

Quitting Standby Mode

In Standby Mode, press any button on the front panel to quit standby mode.

NOTE:

1 In the following situations, the monitor will return to normal monitoring mode automatically: The monitor receives physiological signal of SpO_2, and lasts for 5s; If the monitor is powered by battery, when the battery electric energy is low, it will enter normal monitoring mode, and indicates low battery alarm.

2 In DEMO mode, the monitor can not enter standby mode.

Chapter 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.

WARNING

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.

5.1 Alarm Modes

5.1.1 Alarm Level

Each alarm, either technical or physiological, has its own level. For an alarm of a higher level, when the alarm is activated, the system will give a prompt in various ways. The alarm's level can not be changed by the user once defined by the system. Alarms in the monitor are divided into three levels: High, Medium and Low.

High-level alarm indicates the patient's life is in danger or the monitor has serious technical problems. It is a 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 alarms refer to those alarms triggered by patient's physiological situation which could be considered dangerous to his or her life. Technical alarm refer to system failure which can make a 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 attention to.

The monitor has pre-set the alarm levels for the parameters.

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

All technical alarms, general alarms and some of the physiological alarms are preset in the system and can not be changed by the user.

5.1.2 Alarm Modes

When an alarm occurs, the monitor can raise the user's attention in at least three ways, which are audio prompt, visual prompt and description.

Audio and visual prompts are given by LCD display device, the speaker on the display device and the alarm indicator. Physiological alarm, technical Alarm or description is displayed in information area or beside the parameters at the bottom of the screen.

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

Screen display

When the measured parameter exceeds its alarm limits and triggers a physiological alarm, the alarm prompt will display on the screen of the monitor.
The description will display in Information area, such as "****SYS TOO HIGH**" to indicate the low-medium level alarm.

Technical alarm will not prompt * signal.

Alarm Level	Visual Prompt
High	*** displays in information area of LCD (Physiological alarm only)
Medium	** displays in information area of LCD (Physiological alarm only)
Low	* displays in information area of LCD (Physiological alarm only)

Lamp light

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

Alarm Level	Visual Prompt
High	Alarm indicator flashes in red with a high frequency.
Medium	Alarm indicator flashes in yellow with a low frequency.
Low	Alarm indicator lights on in cyan.

Alarm sound

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

Alarm Level	Audio Prompt
High	Mode is "beep-beep-beep------beep-beep, beep-beep-beep------beep-beep", which is triggered once every 5s.
Medium	Mode is "beep-beep-beep", which is triggered once every 20s.
Low	Mode is "beep-", which is triggered once every 25s.

The sound pressure of auditory alarm is in the range of 45dB ~ 85dB.

WARNING

Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

NOTE:

1 The monitor does not have alarm condition delay or alarm signal generation delay.

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

3 If the monitor is powered off and then turned on, the alarm setup can resume to the setup which is set before the power-off.

5.1.3 Alarm Setup

Set **Alarm Setup** in **Main Menu** to open the submenu as shown below. The user can turn **ON** or **OFF** the alarm for each parameter, and set the upper alarm limit and lower alarm limit for each parameter by **High** or **Low**.

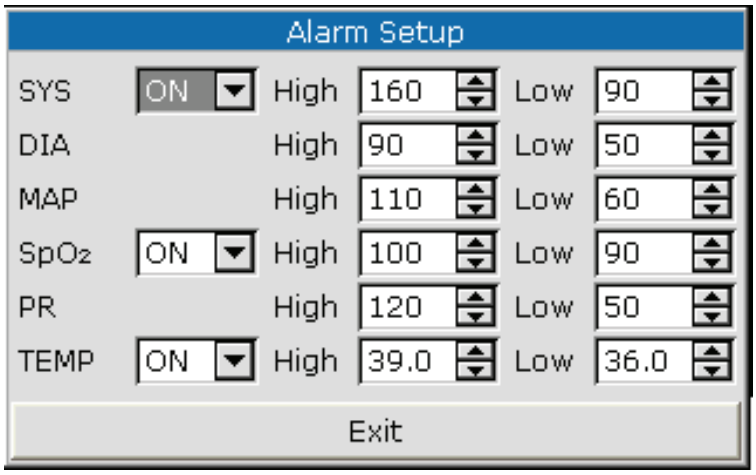


Figure 5-1 Alarm Setup

■ **Alarm setup of each parameter**

In the **Alarm Setup** menu, set the alarm limit for each parameter: **SYS, DIA, MAP, SpO_2, PR.**

For example: Method to set systolic blood pressure alarm limit for SYS alarm**:**

Step 1: Set **SYS** to **ON**;

Step 2: Set **High** (higher limit of **SYS** alarm) and **Low** (lower limit of **SYS** alarm).

The user can press the **UP/DOWN** and **OK** button to set the menu.

The method for setting the alarm limits of other parameters is the same as **SYS** alarm.

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:**

The measurement value exceeds the alarm limit and the alarm is set to **ON**. Alarms will not be activated if the alarm is set to **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 alarms in normal senses, we do not regard them as real patient health related items.

5.3 Silence

The user can press **SILENCE** on front panel to stop audio alarm or turn off the audio system. If an alarm occurs during this period, the monitor can still give alarm.

1. Audio alarm pause icon 

Press and hold the **SILENCE** button on front panel for less than 2s, then the audio alarm is stopped for 2 min, and the indicator beside the button flashes. The audio alarm pause icon displays. Pressing **SILENCE** again can resume the audio alarm.

2. Audio system off icon 

Press the **SILENCE** button for more than 2s, the audio system is turned off, including the audio alarm, key volume and pulse tone, at the same time the indicator beside the button is on. Pressing **SILENCE** again can turn on the audio system.

5.4 Parameter Alarm

WARNING

1 Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.
2 Setting alarm limits to extreme values may cause the alarm system to become ineffective.

In **Main Menu** > **Alarm Setup**, you can check and set the alarm limit or alarm status. The setup is isolated from each other.

When a parameter alarm is **OFF**, an icon  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 limits. 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 in Information area of the screen. 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 the cause of the alarm is cleared, check that the alarm is working properly.

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

5.6 Testing Alarms

When you switch the monitor on, a selftest is started. You must check that the alarm indicator lights and that you hear a single tone. This indicates that the visible and audible alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

Chapter 6 Trend

The monitor provides 100-hour trend data of all parameters (SYS, MAP, DIA, PR, SpO_2, TEMP), 2-hour trend graph of NIBP/SpO_2/PR/TEMP, storage data of 12, 000 NIBP measurement results and 200 Patient IDs.

6.1 Trend List

The NIBP Multi-Group list is displayed as follows:

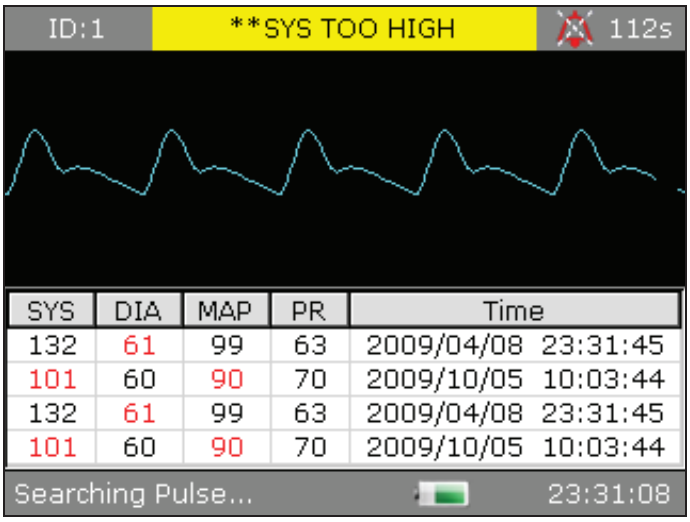


Figure 6-1 NIBP Multi-Group Review

Press **TREND/WAVEFORM** button to change the waveform to trend list as follows:

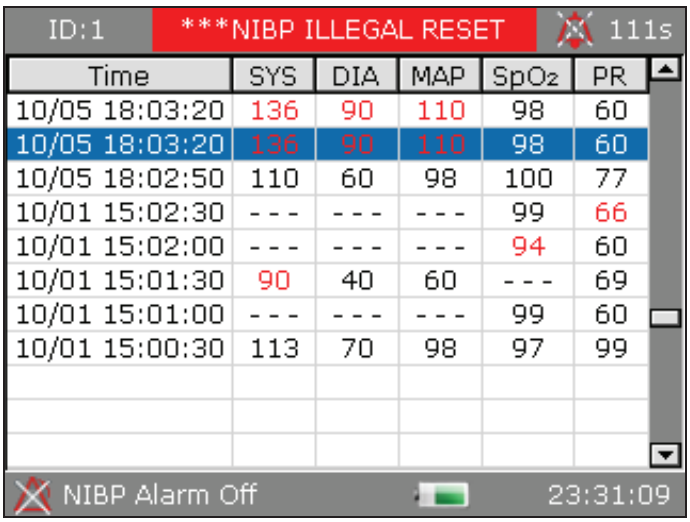


Figure 6-2 Trend List

Select one data file and press the **OK** button, the following menu and deleting process are displayed:

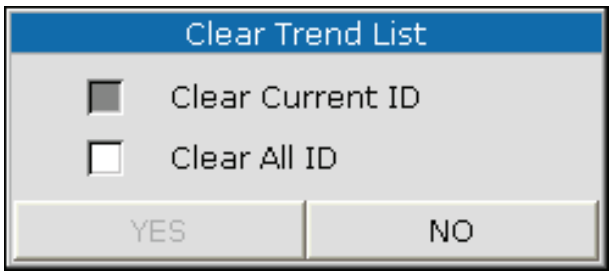


Figure 6-3 Delete Data in Trend List

When deleting data, the process bar is diaplayed:

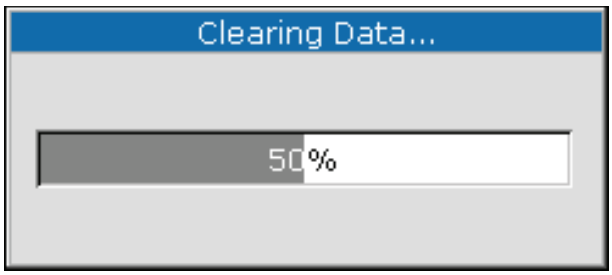


Figure 6-4 Deleting process

6.2 Trend Graph

Press the **TREND/WAVEFORM** button to change the displaying list to trend graph of NIBP/SpO_2/PR as follows:

Figure 6-5 SpO_2 Trend Graph

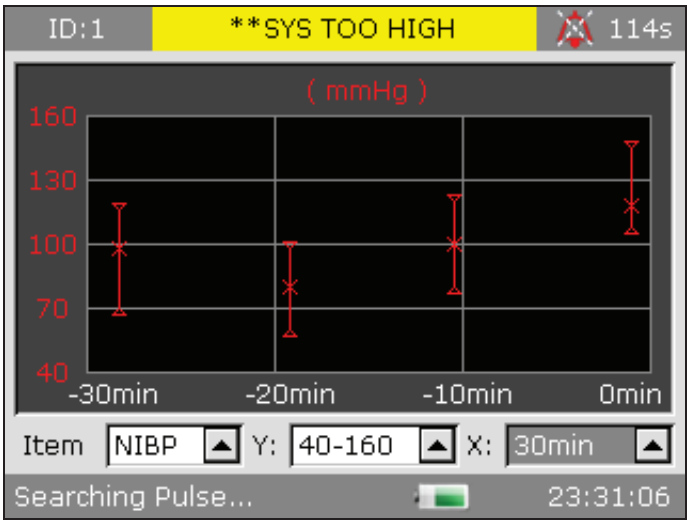


Figure 6-6 NIBP Trend Graph

You can set the items below the trend graph.

Item: you can set the display parameter to **NIBP, SpO_2** or **PR**.

Y: it stands for the ordinate which indicates the displayed data range.

X: it stands for the abscissa which indicates the displayed time range.

After selecting the **NIBP**, **SpO_2** or **PR,** the **Y** and **X** can be set as the following table shows:

Parameter	Y (data range)	X (time range)
SpO_2	0~100, 60~100, 80~100	30 min / 60 min / 120 min
NIBP	10~270, 20~180, 40~160	30 min / 60 min / 120 min
PR	30~300, 40~180, 40~120	30 min / 60 min / 120 min

Chapter 7 Recording

7.1 Recorder

A thermal dot matrix recorder is used for the monitor. It supports the printout of real time data, trend graph and trend table.

7.1.1 Performance of the Recorder

- Waveform record is printed at the rate of 25 mm/s
- 48mm wide printout papaer
- A real time waveform onscreen can be printed out

7.1.2 Operations

Requirement for the Recording Paper

Use only specified thermal paper. The use of any other paper can result in malfunction of the recorder, poor recorder performance or damage to the thermal printhead

Proper Operation

- When the recorder is working, the recording paper goes out steadily. Do not pull the paper outward with force; otherwise the recorder may be damaged.
- Do not operate the recorder without recording paper in the compartment.

Paper Out

When the alarm prompt **OUT OF PAPER** is displayed onscreen, the recorder can not start. Please load recording paper properly.

Replacing Paper Supply

1. Hold the upper arc part of the recorder door and pull it outwards to open the door.
2. Insert a new roll of paper into the compartment with the printable surface of the paper facing upwards.
3. Make sure that the paper is properly loaded with the edge of paper paralleling with the edge of the recorder door.
4. Ensure that a minimum of 2 cm of paper extends beyond the edge of the recorder door.
5. Close the recorder door.

NOTE:

1 Be careful not to insert paper with force, and avoid touching the printhead.

2 Do not leave the recorder door open unless when replacing paper or removing fault.

Removing Paper Jam

If the recorder works improperly or produces unusual sound, open the recorder door and check whether there is a paper jam. If yes, remove it following the procedure below:

1. Cut the paper from the feeding edge.
2. Open the recorder door.
3. Reload the paper and close the recorder door.

7.2 Outputing the Monitoring Data

By selecting the items on **Main Menu** > **Recorder** (Figure 7-1), you can output the real time data, trend graph and trend table.

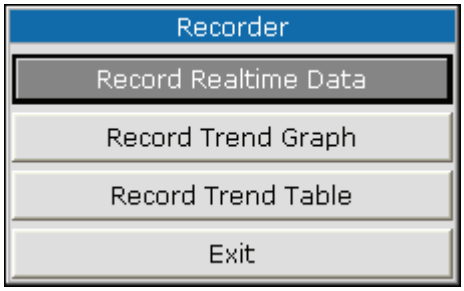


Figure 7-1

- **Record Realtime Data**: Select this item, and the recorder will output the real time data including measurements and SpO_2 waveforms.
- **Record Trend Graph**: Select this item, and the recorder will output the trend graph.
- **Record Trend Table**: Select this item, and the recorder will output the trend table.

Press the buttom **UP** or **DOWN** on the front panel to select an item among the above-mentioned items from the menu, and press  on the front panel to confirm it. Subsequently, the recorder will start outputting the monitoring data. Meanwhile, the selected item will be changed into **Stop Record** as shown below:

Figure 7-2

You can stop the current recording process by select **Stop Record** on the menu.

NOTE:

Do not use the recording function when a low battery alarm occurs, or automatic shutdown of the monitor may result.

Chapter 8 Maintenance and Cleaning

8.1 System Check

Before using the monitor, 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 monitor to make sure that the monitor is in good condition.

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

The overall check of the monitor, including the safety check, should be performed only by qualified personnel once every 24 months, and each time after fixing up.

All the checks that need you to open the monitor 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

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

2 Replace batteries according to the instruction of our service engineer.

3 The disposable accessories can not be reused.

NOTE:
To prolong the life of rechargeable battery, it is recommended to charge it at least once every month, and it must be done after the electric energy runs out.

8.2 General Cleaning

WARNING

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

CAUTION

Please pay special attention to the following items:

1 Most cleaning agents must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.

2 Do not use the grinding material, such as steel, wool etc.

3 Do not let the cleaning agent enter into the chassis of the system.

4 Do not leave the cleaning agents at any part of the equipment.

The monitor, cables and accessories 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 warm water (+40℃/+104℉ maximum) to clean the monitor shell. Do not use strong solvents such as acetone or trichloroethylene.

Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing. Do not permit any liquid to enter the monitor case and avoid pouring it on the monitor while cleaning. Do not allow water or cleaning solutions to enter the measurement connectors. Wipe around, except connector sockets.

Recommended cleaning agents are:

Tenside (dishwasher detergents)	Edisonite Schnellreiniger, Alconox
Ammonias	Dilution of Ammonia <3%, Window cleaner
Alcohol	Ethanol 70%, Isopropanol 70%, Window cleaner
Sodium Hypochlorite	1% ~ 10%

NOTE:

1 The diluted sodium hypochlorite from 500ppm (1:100 diluted bleaching agent) to 5000ppm (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.

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

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

4 Please disinfect timely to prevent the cross infection between patients.

8.3 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 blood pressure cuff are introduced in relative chapters respectively.

CAUTION

1 Follow the manufacturer's instruction to dilute the solution, or adopt the lowest effective concentration.

2 Do not let liquid enter the monitor.

3 No part of this monitor can be subjected to immersion in liquid.

4 Use a moistened cloth to wipe up any agent remaining on the monitor.

8.4 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.

You should use appropriate disinfectant. Recommended types of disinfectants are:

- Alcohol: Alcohol Ethanol up to 70%, 1- and 2- Propanol up to 70%
- Aldehyde: Glutaraldehyde up to 3.6%

WARNING

Please do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.

CAUTION

1 Follow the manufacturer's instruction to dilute the solution, or adopt the lowest effective concentration.

2 Do not let liquid enter the monitor.

3 No part of this monitor can be subjected to immersion in liquid.

4 Use a moistened cloth to wipe up any agent remained on the monitor.

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

8.5 Replacement of Fuse

Unscrew the fuse cap anticlockwise, replace the fuse (protector tube) and screw down the fuse cap clockwise. Fuse size: Φ5×20, Rated value: T 1.6 AL /250 V.

NOTE:
Switch off the power of the monitor before examining the fuse.

8.6 Cleaning Battery and Battery Compartment Cover

Use only non-caustic detergents such as soap and warm water (+40℃/+104℉ maximum) to clean the battery. Do not use strong solvent to clean battery, and do not dip the battery in liquid.

Chapter 9 SpO_2 Monitoring (Optional)

9.1 What is SpO_2 Monitoring

The monitor uses oximetry to measure functional oxygen saturation in the blood. SpO_2 Plethysmogram measurement is employed to determine the functional oxygen saturation of hemoglobin in the arterial blood. For example, if 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has an 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.
- The sensor contains LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 900 nm. The power of the sensor LED is less than 15 mW.

SpO_2/Pulse Monitoring

WARNING

1 ES (Electrosurgery) equipment wire and SpO_2 cable must not be tangled up.

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

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

NOTE:

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

2 The monitor should not be used under strong light, or the accuracy may not be satisfied.

9.2 Precautions During SpO_2/PR Monitoring

WARNING

1 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.

2 If the SpO_2 sensor can not work properly, please reconnect the sensor or change a new one.

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

4 Prolonged and continuous monitoring may increase the risk 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 neonates and patients 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.

5 Tissue damage may be caused by incorrect application or prolonged measurement duration using the sensor (more than 4 hours). Inspect the sensor periodically according to sensor user manual.

6 Neonate SpO_2 sensor can only be used as required, less than 20min at a time.

7 The sensor complies with the ISO 10993-1 for biocompatibility.

NOTE:

1 Make sure the nail covers the light window;

2 The wire should be on the backside of the hand;

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

4 SpO_2 waveform is not proportional to the pulse volume.

5 The accuracy of SpO_2 has been verified by clinical tests according to ISO9919. The monitor can only be used for SpO_2 measurement, not for accuracy assessment of other device.

6 A functional tester cannot be used to assess SpO_2 accuracy.

9.3 Monitoring Procedure

SpO_2 plethysmogram measurement

1. Connect the SpO_2 sensor and extension cable to the SpO_2 sensor port of monitor.
2. Switch on the monitor.
3. Enter **Patient Setup** menu to set **Patient Type** as required.
4. Attach the sensor to the appropriate site of the patient finger.
5. The measured SpO_2 is displayed on screen.

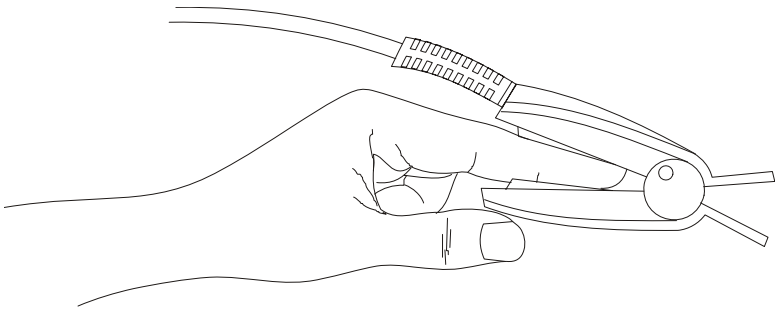


Figure 9-1 Mounting of the Sensor

9.4 Limitations of Measurement

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 monitor 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 good for test part
- The dissipation power is less than 50 μW, when the sensor temperature is higher than +41 ℃, you should shorten the measuring time.

9.5 SpO_2 Setup Menu

9.5.1 SpO_2 Setup

Click on **SpO_2 Setup** in **Main Menu** to open the following menu:

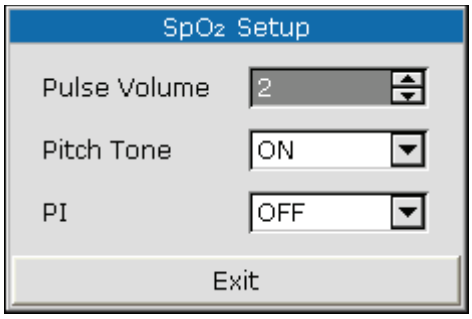


Figure 9-2 SpO_2 Setup

- **Pulse Volume**: Set it to level **0 ~ 5**.
- **Pitch Tone**: set it to **ON** or **OFF**.
- **PI**: If it is set to **ON**, the perfusion index will be presented on the main interface. If it is set to **OFF**, the perfusion index is unavailable onscreen.

9.5.2 Alarm Setup Menu

Enter **Main Menu** > **Alarm Setup**, In the menu, the alarm for SpO_2 or PR can be turned on or off**,** and the alarm limits can be adjusted. Select **ON** to enable alarm during SpO_2 monitoring; select **OFF** to disable the alarm function, and  will be displayed.

Set **High** for the higher alarm limit, and set **Low** for the lower alarm limit. If the measured value is higher than the higher alarm limit or lower than the lower alarm limit, the monitor will give an alarm.

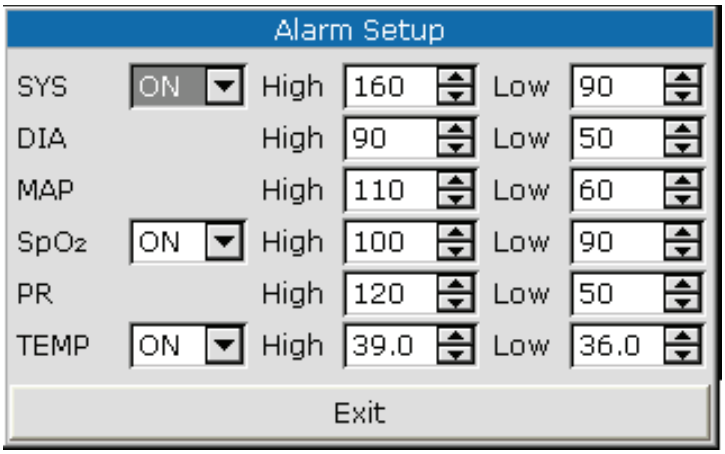


Figure 9-3 Alarm setup

WARNING

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

The range of SpO_2 alarm limit is: 0 ~ 100.

Default SpO_2 alarm limits:

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

The range of PR alarm limit is: 30 ~300.
Default PR alarm limits:

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

9.6 Alarm Description

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

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

Physiological alarm:

Message	Cause	Alarm Level
SpO_2 TOO HIGH	SpO_2 measuring value is above upper alarm limit.	Medium
SpO_2 TOO LOW	SpO_2 measuring value is below lower alarm limit.	Medium
PR TOO HIGH	PR measuring value is above upper alarm limit.	Medium
PR TOO LOW	PR measuring value is below lower alarm limit.	Medium

Message	Cause	Alarm Level
SpO_2 NO PULSE	Sphygmic signal from the measured position is too weak; the monitor does not detect any sphygmic signal.	High

Technical alarms:

Message	Cause	Alarm Level	What to do
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 SENSOR ERR	The sensor or connector has shortcut.	High	Change the sensor. If the problem persists, please notify biomedical engineer or manufacturer's service staff.
SpO_2 MODULE ERR	The parts of module have error.	High	Please notify biomedical engineer or manufacturer's service staff.
SpO_2 LOW PERFUSION	The measured signals coming from pulse are too weak.	Low	Reconnect the sensor well, or change the measuring site of body. If the problem persists, please notify biomedical engineer or manufacturer's service staff.
SpO_2 SENSOR OFF	SpO_2 sensor may be disconnected from the patient or the monitor.	High/ Low (Configured by the user)	Make sure that the monitor and the patient are in correct connection with the cables.
SpO_2 NO SENSOR	SpO_2 sensor was not connected well, or the connection is loose.	Low	Make sure the monitor and sensor is well connected, reconnect the sensor.
SpO_2 NOISY SIGNAL	There is interference with SpO_2 measurement signals and the waveform is abnormal.	Medium	Check the condition of patient and avoid patient movement; make sure the cable is well connected.

Prompt message:

Message	Cause
Searching pulse	SpO_2 sensor may be disconnected from the patient or the monitor.
SpO_2 ALARM OFF	The alarm of SpO_2 is turned off.

9.7 Maintenance and Cleaning

WARNING

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

2 Do not subject the sensor to autoclaving.

3 Do not immerse the sensor into any liquid.

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

5 The disposable accessories can not be reused.

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, 70% isopropanol, or other active reagents. However, connector of the sensor shall not be subjected to such solution.

For disinfecting:

Use a cotton ball or a soft mull moistened with disinfectant to wipe the surface of the sensor, and then dry it with a cloth. You should use appropriate disinfectant.

Recommended types of disinfectants are:

- Alcohol: Alcohol Ethanol up to 70%, 1- and 2- Propanol up to 70%.
- Aldehyde: Glutaraldehyde up to 3.6%.

Chapter 10 NIBP Monitoring (Optional)

10.1 Introduction

This monitor uses the oscillometric method for measuring NIBP. It can be used for adult, pediatric and neonatal patients.

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

In adult and pediatric mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10-1992) in relation to mean error and standard deviation, when compared to auscultatory measurements in a representative patient population. For the auscultatory reference, the fifth Korotkoff sound was used to determine the diastolic pressure.

In neonatal mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10-1992) in relation to mean error and standard deviation, when compared to intra-arterial measurements in a representative patient population.

WARNING

1 It is forbidden to perform NIBP measurements on the patient with sickle-cell disease or under any condition where the skin is damaged or expected to be damaged.

2 For a thrombasthenia 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 children to be subjected to overpressure.

4 Continuous use of the automatic measuring mode for short interval may lead to the discomfort of patient. If the deflated period is less than 30s, releases cuff pressure to below 15mmHg (adult patients), or below 5mmHg (neonatal patients).

NOTE:

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

2 The continuous measuring, automatic measuring and calibration can not be operated on neonatal or pediatric patients.

3 Please use the proper type of cuff as recommended in this manual, or the wrong type may lead to injury on the patient, especially when measuring neonatal patients.

4 It is suggested that the user should not start NIBP measuring when the low battery displays, or the monitor may be turned off automatically.

10.2 NIBP Monitoring

WARNING

1 Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, pediatric or neonatal.)

2 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.

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

Measuring procedure:

1. Plug in the sensor and switch on the system.
2. Check whether the patient type is appropriately selected. Enter **Main Menu > Patient Setup** menu and set **Patient Type** to required one.
3. Enter the **NIBP Setup** menu, set the **Unit** of NIBP and select a measurement mode. Select the **Interval** item for **Manual** or set the interval for auto measurement; or select the **Continual**.
4. Apply the blood pressure cuff to the patient's arm or leg following the instructions below.
   - 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 extremity.

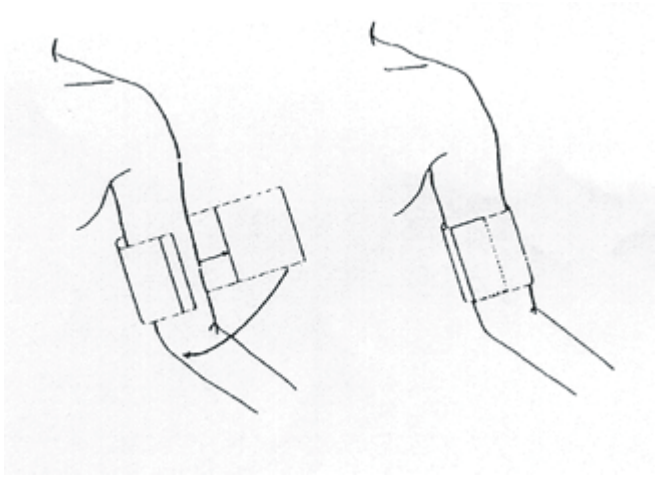


Figure 10-1 Applying Cuff

NOTE:

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

Size of reusable cuff for neonatal/pediatric/adult patients:

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

Size of disposable cuff for neonatal/pediatric/adult patients:

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

5. 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.

6. Press the **NIBP START/STOP** on the front panel to start a measurement. You can also stop this measurement by pressing this button.

WARNING

Prolonged NIBP measurements in automatic mode may be associated with purpuric, ischemic 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.

- To stop auto measuring:

  During auto measuring, press the **NIBP START/STOP** on the front panel at any time to stop auto measurement.

WARNING

If you repeatedly use **AUTO** measuring in a short term, it may lead to inaccurate readings or endanger patient's life.

- To start a manual measuring:
  - Access **NIBP Setup** menu and pick the **Interval** item. Select the **Manual** selection. Then press the **NIBP START/STOP** on the front panel to start a manual measurement.
  - During the idle period of auto measuring process, press the **NIBP START/STOP** on the front panel at any time to start a manual measurement. Then press the **NIBP START/STOP** on the front panel to stop manual measurement and the system continues to execute automatic measuring program according to selected time interval.
- To start a manual measuring during the automatic mode:

  Press the **NIBP START/STOP** on the front panel.
- To stop a manual measuring

  Repress the **NIBP START/STOP** on the front panel again.

WARNING

Prolonged NIBP 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.

- 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 min.
- To stop continuous measuring:

  During continuous measuring press the **NIBP START/STOP** on the front panel at any time to stop continuous measurement.

WARNING

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

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.

Initial Inflation Pressure

Patient Type	ADU	PED	NEO
Inflation Value	160mmHg	140mmHg	100mmHg

Measurement Limitations

For different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible.

- Patient Movement

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

- Cardiac Arrhythmia's

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

- Heart-lung Machine

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

- Pressure Changes

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

- Severe Shock

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

- Heart Rate Extremes

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

10.3 NIBP Setup Menu

10.3.1 NIBP Setup

In **Main Menu,** open the **NIBP Setup** menu shown as below:

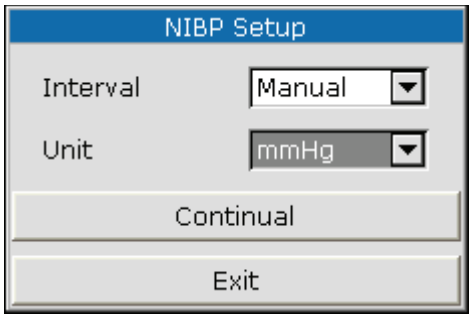


Figure 10-2 NIBP SETUP

- **Interval**: Set it to **Manual**, or **1/2/3/4/5/10/15/30/60/90/120/240/480 min**.
- **Unit**: Set the pressure unit to **mmHg** or **KPa**. The setting unit will display on the main interface.
- **Continual**: select it to do NIBP measuring continuously within 5min.

10.3.2 NIBP Alarm Setup

Enter **Main Menu** > **Alarm Setup**:

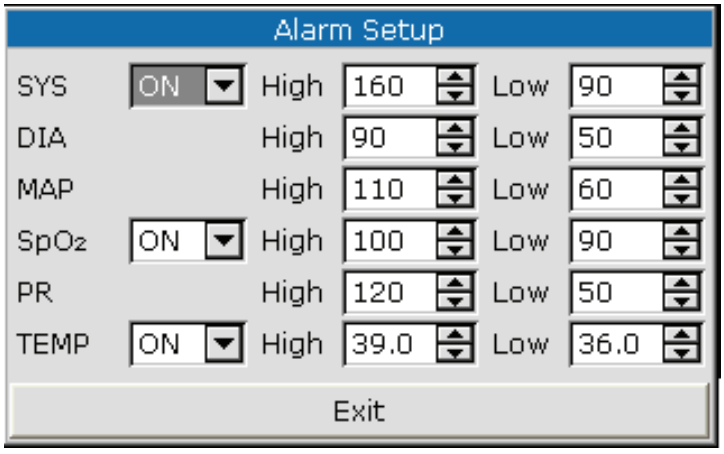


Figure 10-3 Alarm Setup

Set the **SYS, DIA, MAP** to turn on or off the alarm. Click **ON** to enable prompt message during the NIBP alarm; pick **OFF** to disable the alarm function, and there will be a  icon displayed.

WARNING

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

Set **High** for the higher alarm limit, and set **Low** for the lower alarm limit. If the measured value is higher than **High** or lower than **Low**, the monitor will give an alarm.

The adjusting range of NIBP alarm limits is: 0 mmHg ~ 300 mmHg.
Default NIBP alarm limits:

	ADU (mmHg)		**PED (mmHg)**		**NEO (mmHg)**	
	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 mmHg ~ 270 mmHg
DIA 10 mmHg ~ 215 mmHg
MAP 20 mmHg ~ 235 mmHg

Pediatric Mode

SYS 40 mmHg ~ 200 mmHg
DIA 10 mmHg ~ 150 mmHg
MAP 20 mmHg ~ 165 mmHg

Neonatal Mode

SYS 40 mmHg ~ 135 mmHg
DIA 10 mmHg ~ 100 mmHg
MAP 20 mmHg ~ 110 mmHg

When the monitor is configured to NIBP only measuring mode, the adjusting alarm limits of PR are displayed in the **ALARM SETUP** menu.

Default PR alarm limit:

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

The range of PR alarm limit:

	Max. Upper Limit (BPM)	Min. Lower Limit (BPM)	Step (BPM)
PR	300	0	1

10.4 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
SYS TOO HIGH	NIBP SYS measuring value is above upper alarm limit.	Medium
SYS TOO LOW	NIBP SYS measuring value is below lower alarm limit.	Medium
DIA TOO HIGH	NIBP DIA measuring value is above upper alarm limit.	Medium
DIA TOO LOW	NIBP DIA measuring value is below lower alarm limit.	Medium
MAP TOO HIGH	NIBP MAP measuring value is above upper alarm limit.	Medium
MAP TOO LOW	NIBP MAP measuring value is below lower alarm limit.	Medium

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

Message	Cause	Alarm Level	What to do
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 ILLEGAL RESET	The hardware pressure is too high	High	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP MODULE ERR	The NIBP module has failure.	High	
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.
AIR PREESURE ERR	The airway of NIBP has failure.	Low	
NIBP SIGNAL TOO WEAK	Cuff is too loose or patient pulse is too weak.	Low	Use other method to measure blood pressure.
NIBP NOISE SIGNAL	Because of 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.
NIBP SIGNAL SATURATED	Excessive motion.	Low	Stop the patient from moving.
CUFF TYPE ERR	Cuff type does not comply with the patient type.	Low	Select appropriate cuff type

Message	Cause	Alarm Level	What to do
MEASURE TIMEOUT	Measuring time has exceeded 120s (adult) or 90s (neonatal).	Low	Measure again or use other measuring methods.
INIT PRESSURE TOO HIGH	The initial pressure is too high during measuring	Low	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
PRESSURE RANGE EXCEED	The measured pressure exceeds the limit.	Low	Measure by other method.

Prompt message:

Message	Cause
Press NIBP START	You can start NIBP measuring of continual mode.
Manual measuring...	During manual measuring mode.
Automatic measuring...	During automatic measuring mode.
Continual measuring...	During continual measuring mode.
Measurement over	Measurement over
Calibrating...	During calibrating
Calibration over	Calibration over
Leakage testing...	During leakage test
Leakage test over	Leakage test over
NIBP Resetting...	NIBP module is resetting
NIBP Alarm Off	The alarm of NIBP is turned off.

10.5 Maintenance and Cleaning

WARNING

1 Do not squeeze the rubber tube on the cuff.

2 Do not allow liquid to enter the connector socket at the front of the monitor.

3 Do not wipe the inner part of the connector socket when cleaning the monitor.

4 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.

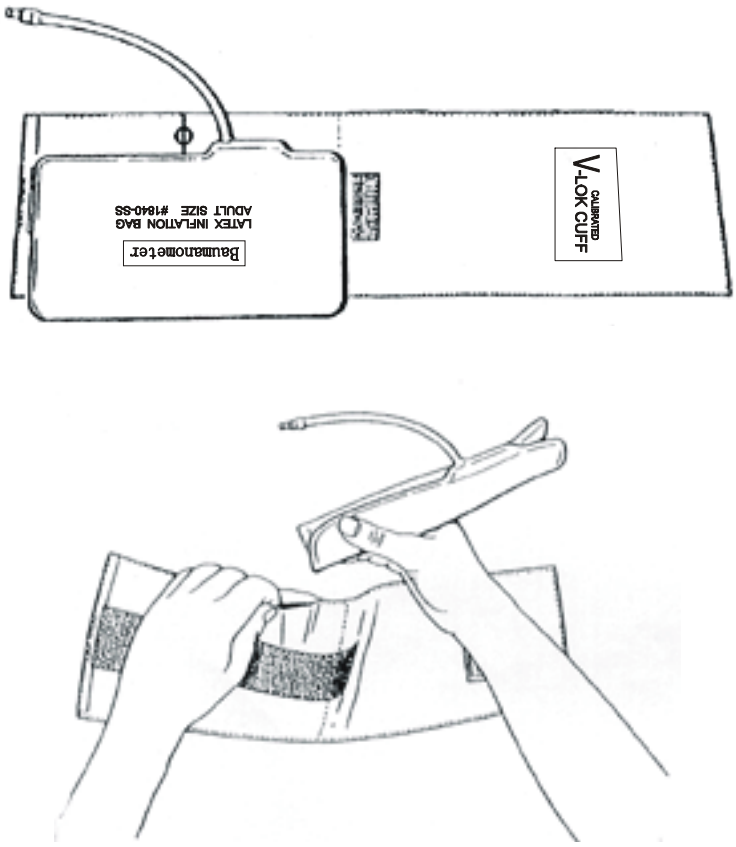


Figure 10-4 Replace Rubber Bag in Cuff

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.

Chapter 11 TEMP Monitoring (Optional)

11.1 TEMP Monitoring with T2 Module

11.1.1 Introduction

M3A with the T2 module takes a temperature in either Predict or Monitor Mode. In the Predict mode, the monitor measures oral/axillary/rectal TEMP in a short time, calculates and gets the measuring results. In Monitor mode, it can monitor patient for 10 min. The Oral/Axillary sensor and Rectal sensor are of standard configuration.

The monitor can only measure temperature of adult and pediatric patients. If the user measure temperature of neonate patient, the monitor will not display data.

Making a TEMP Measurement

- Select the correct sensor according to the measuring position and patient type.
- Apply the sensor to the patient. You are advised to use a protective rubber cover on sensor.
- Switch on the monitor and ensure the alarm settings (on or off, higher alarm or lower alarm limit) are appropriate for the patient and the type of temperature measurement.
- Select the correct measuring position in menu.

WARNING

1 To ensure optimal accuracy, always confirm that the correct mode and alarm limit are selected. Changing the measure position may lead to the change of alarm limit.

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

3 Take the TEMP probe and cable carefully. When they are not in 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.

4 The calibration of the temperature module is necessary every two years (or as frequently as dictated by your Hospital Procedures Policy). When you need to calibrate the temperature measurement, please contact the manufacturer.

5 Patient actions may interfere with accurate oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum or mints, brushing teeth, smoking or performing strenuous activity may affect temperature readings for up to 20min after ending activity.

6 Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.

WARNING

7 Biting the sensor tip while taking a temperature may result in damage to the sensor.

8 Use disposable TEMP sensor covers recommended by EDAN to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.

9 TEMP measurement isn't suitable for use during defibrillation.

11.1.2 Measuring Procedure

1 Ensure the sensor are well installed. There are icons indicating TEMP measuring position on the main interface. If changing measuring position or measuring mode is necessary, enter menu for setting.

2 Take out the sensor from the sensor bracket. After warm-up, it beeps and displays prompt for starting TEMP measuring in information area.

3 Load a sensor cover by inserting the sensor into a sensor cover and press the sensor handle firmly. The sensor handle will move slightly to engage the sensor cover.

4 Holding the sensor handle with your thumb and two fingers, insert it to the measuring position.

For measuring oral TEMP, place the sensor tip under the patient's tongue on either side of the mouth to reach the rear sublingual pocket. Have the patient close his lips around the sensor.

Figure 11-1 Measuring position in mouth

For measuring oral TEMP, do not take an axillary temperature through patient's clothing.

5 The monitor enters Predict measuring mode, — — — displays in the TEMP parameter area. After Predict measuring is over, the measuring result displays, and **MEASURE OVER** appears on the interface.

6 If the predict measuring is successfully finished, the monitor enters monitor mode after 30s; otherwise the monitor enter monitor mode immediately after the predict measuring. The

monitoring state lasts for 10 min, then the monitor enters waiting state. ——— displays in the TEMP parameter area on interface. Put the sensor back into the sensor bracket.

7 If necessary, repeat the measurement according to the procedure above.

NOTE:

1 After one measurement, the user should put the sensor back to the sensor bracket and then take it out for starting a new measurement.

2 The monitor's state can change from the **PREDICT** mode into the **MONITOR** mode, but it can not change from the **MONITOR** mode into the **PREDICT** mode.

11.1.3 TEMP Setup Menu

11.1.3.1 TEMP Setup

Click on the **TEMP Setup** in the **Main Menu** to display the following figure:

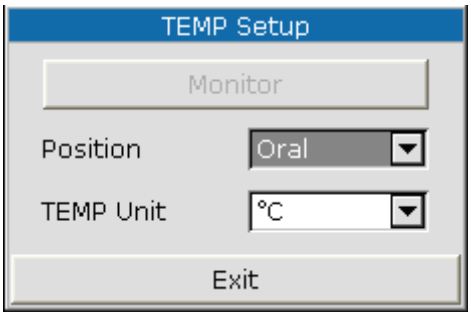


Figure11-2 TEMP Setup

- **Monitor**: when this item is selectable, select it to enter monitor mode.
- **Position**: you can set this item to **Oral, Auxillary** or **Recta.** The axillary sensor can be used for measuring oral/axillary temperature, while the rectal sensor for measuring rectal temperature.
- **TEMP Unit**: Set temperature unit to ℃ or ℉.

11.1.3.2 TEMP Alarm Setup

Click on **ALARM SETUP** in the **SYSTEM MENU**, and set the alarm higher limit or lower limit in the following figure:

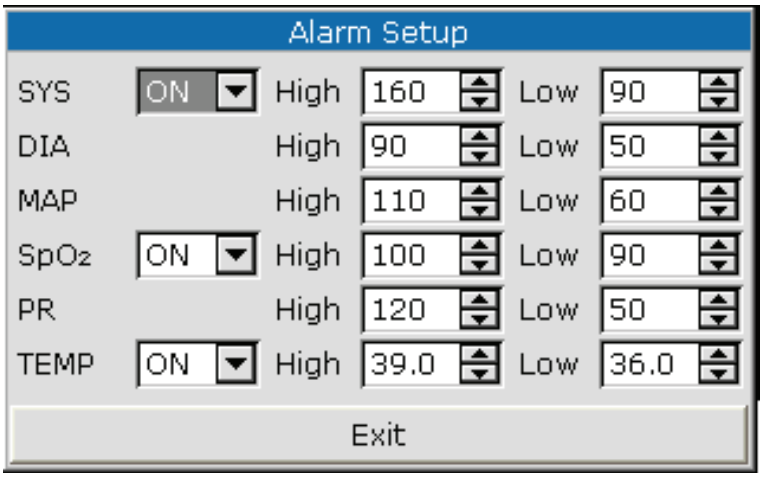


Figure 11-3 Alarm Setup Menu

- **TEMP**: set it to **ON** to enable prompt message during the TEMP alarm, while set to **OFF** to disable the alarm function, and display the  symbol besides TEMP numeric.

WARNING

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

Set **High** for the higher alarm limit, and set **Low** for the lower alarm limit.

The range for higher alarm limit and lower alarm limit is as follows:

Patient Type	Measure position	High	Low	Step
ADU	Oral/Axillary/Rectal	+42 ℃ (+107.6 ℉)	+35.5 ℃ (+95.9 ℉)	+ 0.1 ℃
PED	Oral/Axillary/Rectal	+42 ℃ (+107.6℉)	+35.5 ℃ (+95.9 ℉)	+ 0.1 ℃

11.1.4 Alarm Message

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

Physiological alarms:

Message	Cause	Alarm Level
TEMP TOO HIGH	Measuring value of TEMP is above upper alarm limit.	Medium
TEMP TOO LOW	Measuring value of TEMP is below lower alarm limit.	Medium

Technical alarms:

Message	Cause	Alarm Level	What to do
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.
TEMP EXCCED LIMIT	The TEMP value is beyond the range of +25℃ ~ +45℃.	Medium	Put the sensor into the sensor bracket, take it out and measure again.
TEMP NO SENSOR	TEMP sensor is not connected to the TEMP module.	Low	Connect the sensor and the monitor well, and measure again.
AMBIENT TEMP HIGH	The Sensor temperature is higher than +40℃	Low	Put the sensor into the sensor bracket, measure again after the ambient temperature reaches normal value.
AMBIENT TEMP LOW	The Sensor temperature is lower than +10℃		
TEMP SENSOR ERR	Offline: NTC resistance >R 0 ℃; Short:NTC resistance <R+100 ℃.	Medium	Put the sensor into the sensor bracket, take it out and measure again. If the problem persists, stop using measuring function of TEMP module, notify biomedical engineer or Manufacturer's service staff.
TEMP HEATER ERR	Single failure	Medium	Put the sensor into the sensor bracket, take it out and measure again. If the problem persists, stop using measuring function of TEMP module, notify biomedical engineer or Manufacturer's service staff.
TEMP SENSOR OFF	After the sensor temperature reaches Predict value, it descends to the value lower than Predict value.	Medium	Reconnect the sensor and make sure that the cable is properly connected.

Message	Cause	Alarm Level	What to do
TEMP MODULE ERR	TEMP module self check failure	High	Put the sensor into the sensor bracket, take it out and measure again. If the problem persists, stop using measuring function of TEMP module, notify biomedical engineer or Manufacturer's service staff.

Prompt:

Message	Cause	What to do
Ready to TEMP predict	The monitor prompts it after taking the sensor out of the bracket and warm-up is over.	Put the sensor to the measuring position and start measuring.
TEMP Predict complete	After the Predict measuring is over, the data and message display on the interface.	Enter monitoring state after the Predict state. After monitoring for 10 min, it returns to waiting state.

11.1.5 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 briefly exposed to temperatures between +80 ℃ ~ +100 ℃ (+176℉ ~ +212℉).

2 The probe must not be sterilized in steam.

3 Only detergents containing no alcohol can be used for disinfection.

4 All the sensors should be used with a protective rubber cover.

5 To clean the probe, hold the tip with one hand and rub the probe down from the connector with the other hand using a moist lint-free cloth.

NOTE:

1 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.

2 Do not disinfect the probe by means of boiled water.

3 The product has not been disinfected at the factory.

4 Any residue should be removed from the probe before being disinfected and sterilized, and avoid contacting corrosive solvent. Dipping 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.

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

6 Cavity temperature probe is suggested to be used only inside the recta. It is recommended to use the disposable cannula to prevent cross infection.

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

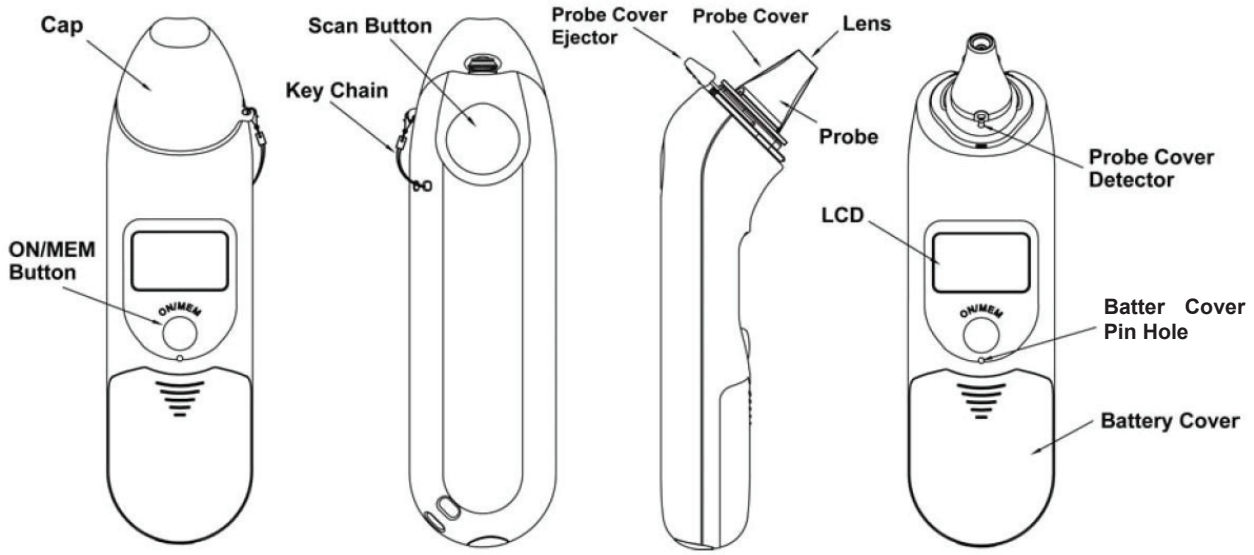
8 Do not force the cavity temperature probe against resistance when inserted into human body. Also it is not recommended to use it in bleeding part or cankerous part of human body.

11.2 TEMP Monitoring with TH Module

11.2.1 Introduction

M3A with the TH module (Intrared Ear Temperature Module) takes a temperature in the ear.

Diagram of the Intrared Ear Thermometer



WARNING

1 Keep the probe covers away from children.

2 Do not resue the disposable probe covers.

3 Only use the disposable probe covers supplied or recommended by EDAN. Use of other manufacturer's probe covers, reuse of disposable probe covers or absence of probe covers may produce temperature measurement errors and/or inaccuraies.

4 The intrared ear thermometer is not intended for neonatal patients.

CAUTION

1 Keep the probe window clean, dry, and undamaged at times to ensure accuate measurements. To protect the probe window, always keep the thermometer in the storage cover while transporting or when not in use.

2 Proper installation of the probe cover ensures accurate measurements.

3 Do not autoclave.

4 The thermometer is not waterproof. Do not immerse or drip fluids on it. Should this occur, dry the thermometer with warm air. Check for proper operation and accuracy.

CAUTION

5 Holding the thermometer too long may cause a higher ambient temperature reading of the probe, which could make the body temperature measurements lower than usual.

6 Check whether the thermometer is damaged once it drops. If you cannot make sure of it, send the complete device to your local dealer for recalibration.

7 Keep the unit dry and away from any liquids and direct sunlight.

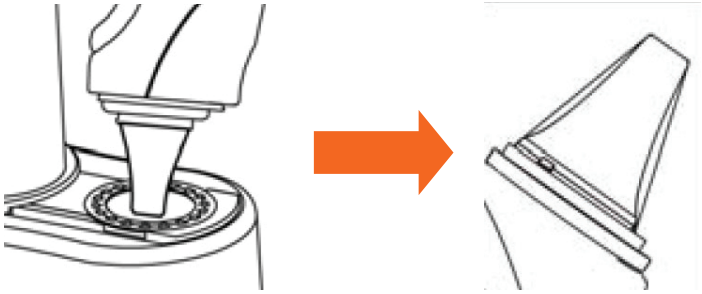
8 The probe should not be submerged into liquids.

9 For more details about using the infrared ear thermometer, refer to the accompanying operating instructions of the thermometer.

10 The monitor outfitted with the TH module must not be used together with other electrosurgery equipment, for example, ESU.

11.2.2 Measuring Procedure

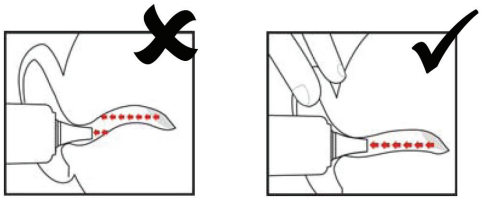
1. Align the center of the probe to the center of the probe cover. Make sure to place the adhensive side of probe cover upward.
2. Insert the probe into the probe cover on the probe cover loader until the probe cover clicks in place.



NOTE:

If the probe cover did not install well, the icon will flash on the LCD of the thermometer, and you cannot take the ear temperature (with four beep sounds heard and without reading on the LCD when measuring).

3. Press ON/MEM button of the thermometer. The icon will display on the LCD of the thermometer and you will hear two beep sounds.
4. Gently pull the ear back to straighten the ear cannal and snugly fit the probe into the ear canal, aiming towards the membrane of the eardrum to obtain an accurate reading.



NOTE:

For children over two-year old and adults: pull the ear straight up and back as shown below:

5. Press the "Scan" button for one second until you hear a long beep sound which signals the end of the measurement, and rusults will be shown on the display of the monitor.
6. Before starting another measurement, wait until all icons stop flashing and two beep sounds are heard.

WARNING

Replace the probe cover after each use to ensure an accurate reading and avoid cross contamination.

NOTE:

1 The thermometer will automatically shut down after one-minute pending to extend battery life.

2 The device must stay in stable ambient (room) temperature for 30 minutes before operation.

3 Before the measurement, please stay in a stable environmrnt for five minutes and avoid exercise or bath for 30 minutes.

4 It is recommended that you measure the same ear for three times. If the three measurements are different, select the highiest temperature.

5 Remember to compare the measurement result to the regular temperature of the patient.

6 There is no gender and age limitation for using infrared ear thermometer.

7 The data saved in the thermometer is the last measurement data before the thermometer is powered off.

8 Clinical repeatability: 0.12℃ (1~5 years old); 0.10℃ (>5 years old).

11.2.3 TEMP Setup Menu

Click on the **TEMP Setup** in the **Main Menu** to display the following figure:

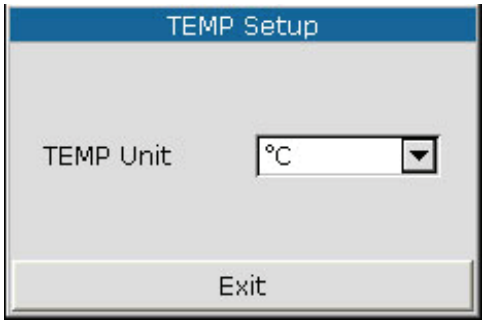


Figure11-2 TEMP Setup

■ **TEMP Unit**: Set temperature unit to ℃ or ℉.

For information about alarm setup, refer to section *11.1.3.2 TEMP Alarm Setup*.

11.2.4 Alarm Message

The alarm limits are as follows:

Patient Type	Measure position	ALM HI	ALM LO	Step
ADU/PED	Ear	+42 ℃ (+107.6 ℉)	+35.5 ℃ (+95.9 ℉)	+0.1 ℃

Physiological alarms:

Message	Cause	Alarm Level
TEMP HIGH	Measuring value of TEMP is above upper alarm limit.	Medium
TEMP LOW	Measuring value of TEMP is below lower alarm limit.	Medium

Technical alarms:

Message	Cause	Alarm Level	What to do
TEMP EXCEED LIMIT	The TEMP value is beyond the range of +34℃～+42.2℃.	Medium	Check the integrity of the probe cover, make sure it is clean, and take a new measurement.

The infrared ear thermometer will also give error messages on its screen. For details about the error messages, refer to the accompanying operating instructions of the thermometer.

NOTE:
If the infrared ear thermometer frequently signals ERR alarms, the insulated board inside the thermometer housing is malfunctioning or the ambient temperature changes, the monitor will delete the measurement values onscreen to avoid misoperation.

11.2.5 Replacing the Battery

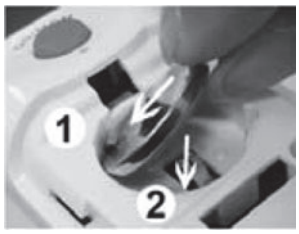
The device is supplied with one lithium cell CR2032x1.

To replacing the battery, follow the procedure:

1. Open the battery cover by inserting a pointed object into the battery cover pin hole; meanwhile, use thumb to push battery cover out.

2. Hold the thermometer and flip the battery out with a small screwdriver.

3. Insert the new battery under the metal hook on the left side ① and press the right side ② of the battery down until the it clicks in place.



WARNING

1 Keep the battery away from children.

2 Ensure the positive (+) side is up and the negative (-) side down.

11.2.6 Maintenance and Cleaning

Calibration Mode

To switch to calibration mode, follow the steps below:

a Press the ON/MEM button to turn the thermometer on. The display of the thermometer shows symbols and functions.

b Keep pressing the ON/MEM button for five seconds and you will see the “OFF” symbol on the display. Do not release the button until you see a dot onscreen.

c The thermometer is now in the Calibration Mode and the display is flashing and showing the “CAL” symbol.

NOTE:

It is suggested that a re-test is performed for the device on accuracy after three years. Please send the complete device to the dealers or nearest service address. However, if this device is used according to the operation instructions, periodic re-calibration is not required.

Cleaning

The probe is the most delicate part of the thermometer. Use it with care when cleaning the lens to avoid damage.

If the device is accidentally used without a probe cover, clean the probe as follows:

1. After the measurement, use the cotton swab moistened with alcohol (70% concentration) to clean the lens (on the inside of the probe).
2. Allow the probe to fully dry for at least one minute.

Chapter 12 Accessories and Ordering Information

WARNING

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

The following accessories are recommended when using this monitor.

Standard configuration including:

Part Number	Accessories
02.01.210119	EDAN SH1 adult reusable SpO_2 sensor (Only compatible with EDAN SpO_2 module).
01.57.040205-12	Adult NIBP cuff / (25cm ~ 35cm), CM1303
01.59.036118-11	NIBP cuff extension tube /3m, TPU.
01.13.36014	Power supply cable 220V (EUR Standard).
21.13.036384-10	Medical-grade power cable (USA standard)
21.21.064168	Rechargeable Lithium-Ion Battery/ TWSLB-009 (14.8V, 2.2 Ah)
11. 13.114214	Grounding line.

Optional Standard configuration including:

EDAN SpO_2	
02.01.210119	EDAN SH1 Adult Reusable SpO2 Sensor (Lemo) (Only compatible with EDAN SpO2 module), 2.5 m
12.01.109079	EDAN SH1 Adult Reusable SpO2 Sensor (DB9) (Only compatible with EDAN SpO2 module and EDAN SpO2 Extension cable), 1m
01.13.210001-11	EDAN SpO2 Extension cable (Only compatible with Disposable SpO2 Sensor, EDAN SpO2 Sensors and EDAN SpO2 module), 2m
01.13.210001	EDAN SpO_2 extension cable, DB9 to LEMO, TPU, 2M.
12.01.110492	EDAN SH3 neonatal SpO_2 sensor (Only compatible with EDAN SpO_2 module and extension cable).

12.01.110515	EDAN SH4 adult silicone soft-tip SpO_2 sensor (Only compatible with EDAN SpO_2 module and extension cable).
02.01.110531	EDAN SH4 adult silicone soft-tip SpO_2 sensor (Immersion disinfection).
02.01.210121	EDAN SH5 pediatric Silicone Soft-tip SpO2 Sensor (DB9) (Only compatible with EDAN SpO2 module and EDAN SpO2 Extension cable), 1m
01.57.040196	Adult disposable SpO_2 sensor/ SESI001B.
01.57.040197	Pediatry disposable SpO_2 sensor / SESJ001B.
01.57.040198	Infant disposable SpO_2 sensor / SELK001B.
01.57.040199	Neonate disposable SpO_2 sensor / SELL001B.
NIBP	
01.59.036118-11	NIBP cuff extension tube /3m, TPU
01.59.36036	NIBP Tube (3m) with connector
01.57.471021	Neonate disposable blood pressure cuff extension tube /3m.
01.57.040210	Adult blood pressure cuff (33cm~47cm), CM1304, with sensor 190.
01.57.040205-12	Adult blood pressure cuff (25 cm ~ 35cm), CM1303.
01.57.040211	Pediatry blood pressure cuff (18 cm ~ 26cm), CM1302, with sensor 190.
01.57.040212	Infant blood pressure cuff (10 cm ~ 19cm), CM1301, with sensor 190.
11.57.40020	Infant blood pressure cuff (10 cm ~ 19cm), CM1201, with sensor 190.
11.57.40018	Pediatry blood pressure cuff (18 cm ~ 26cm), CM1202, with sensor 190.
01.57.40029	Adult blood pressure cuff (25 cm ~ 35cm), CM1203, with sensor 190.
11.57.40074	Larger adult blood pressure cuff (33 cm ~ 47cm), CM1204, with sensor 190.
11.57.40097	Neonate disposable blood pressure cuff 5102 (6 cm ~ 9 cm).
11.57.40098	Neonate disposable blood pressure cuff 5104 (9 cm ~ 14cm).
01.57.471157	Neonatal #1 Disposable Blood Pressure Cuff (3-6cm) (Only compatible with Connecting Tube for Neonatal Cuff)

01.57.471158	Neonatal #2 Disposable Blood Pressure Cuff (4-8cm) (Only compatible with Connecting Tube for Neonatal Cuff)
01.57.471159	Neonatal #3 Disposable Blood Pressure Cuff (6-11cm) (Only compatible with Connecting Tube for Neonatal Cuff)
01.57.471160	Neonatal #4 Disposable Blood Pressure Cuff (7-13cm) (Only compatible with Connecting Tube for Neonatal Cuff)
01.57.471161	Neonatal #5 Disposable Blood Pressure Cuff (8-15cm) (Only compatible with Connecting Tube for Neonatal Cuff)
01.57.471021	Connecting Tube for Neonatal Cuff (Only compatible with Neonatal Disposable Cuff)
TEMP	
02.04.110140	Oral/Auxiliary Probe
02.04.110139	Rectal Probe
11.57.110159	TEMP disposable sensor cover (25 pcs) for T2 module
11.57.208058	Probe covers for TH module (200 pieces/ package)
11.57.208059	Probe cover loader for TH module (with 40 pieces probe cover)
01.13.036415-10	TH module communication wire
Others	
01.57.78035	Recording paper.
12.01.109480	Trolley.
02.01.109481	Wall mount bracket.
02.01.109592	Pole clamp/1 piece.
02.01.109636	Pole clamp/4 pieces.
01.13.36014	Power supply cable 220V (EUR Standard).
21.13.036384-10	Medical-grade power cable (USA standard)
21.21.064167	Rechargeable Lithium-Ion Battery/TWSLB-008 (14.8V, 4.4 Ah)
11.13.114214	Grounding line.

Chapter 13 Warranty and Service

13.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a) damage caused by mishandling during shipping.

b) subsequent damage caused by improper use or maintenance.

c) damage caused by alteration or repair by anyone not authorized by EDAN.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

13.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix Ⅰ Specifications

A1.1 Classification

Anti-electroshock type	Class Ⅰ equipment and internally powered equipment
EMC type	Group I Class A
Anti-electroshock degree	SpO_2, NIBP: BF Defibrillation type; TEMP: CF type (T2 module) BF type (TH module)
Ingress Protection	IPX1 (No protection against ingress of water if configured with TEMP module)
Working system	Continuous running equipment (no more than 7 days)
Compliant with Safety Standards	IEC 60601-1:1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN 60601-1-2:2001+A1, IEC 60601-1-8, ISO 9919, EN 1060-1, EN 1060-3, EN 1060-4, ANSI/AAMI SP10, IEC/EN 60601-2-30, IEC60601-2-49, EN 12470-4, EN 12470-5

A1.2 Specifications

A1.2.1 Size and Weight

Size	200.8 mm (L)×241 mm (H)×189 mm (D)
Weight	2.4 kg (without battery)

A1.2.2 Environment

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

Temperature	
Working	+5 °C ~ +40 °C
	With TEMP: +10 °C ~ +40 °C

Transport and Storage	-20 °C ~ +55 °C
	With TH module: -20 °C ~ +50 °C
Humidity	
Working	25% ~ 80% (non- condensing)
Transport and Storage	25% ~ 93% (non- condensing)
Altitude	
Working	860hPa ~ 1060hPa
Transport and Storage	700hPa ~ 1060hPa
Power Supply	Voltage: 100V–240V ~ Frequency: 50Hz/60Hz Input power: 70VA Battery: 14.8 V/4.4 Ah; 14.8 V/2.2 Ah.

A1.2.3 Display

Multicolor LCD	Resolution: 320×240, adjustable brightness 1 PLETH waveform
Seven-segment display	Display NIBP/SpO_2 measuring values and unit Patient type Pulse amplitude display
Messages	1 power supply indicator LED (Green) 1 power on indicator LED (Green) 1 alarm indicator LED (Cyan/Yellow/ Red) 1 alarm silence indicator LED (Yellow) 1 charge indicator LED (Yellow) 1 NIBP working status indicator LED (Backlight) 3 indicating modes correspond to alarm mode
NURSE CALL	
Drive mode	Relay

Electronic	≤1A, ≤125V ~, ≤110V DC
Isolated voltage	1500V ~ (line to ground)
Action	Normal open

A1.2.4 Battery

Quantity	1
Type	Li battery
Power-off delay	5 min ~ 15 min (After the low battery alarm)
Voltage	14.8 VDC
Capacitance	2.2 Ah 4.4 Ah (optional)
Working period	2.2 Ah: 8.5 hours 4.4 Ah: 17 hours (At +25℃, continuous SpO_2 measuring, automatic NIBP measuring per 15min)
Rechargeable period	2.2 Ah: 180 min 4.4 Ah: 360 min

A1.2.5 Recorder

Record width	48 mm
Paper speed	25 mm/s
Recording types	Current displayed parameter list recording
	Current displayed alarm list recording
	Real-time 8s waveform recording
	Recording of all the parameter of current patient ID

A1.2.6 Review

Trend List Review	100 hours, 30 seconds Resolution
Measurement Review	12, 000 groups measuring data

A1.2.7 NIBP (Optional)

Method	Oscillometric
Mode	Manual, Auto, Continuous
Measuring interval in AUTO mode	1/2/3/4/5/10/15/30/60/90/120/240/480 min
Continuous	5 min, interval is 5s
Measuring type	Systolic Pressure, Diastolic Pressure, Mean Pressure
Measuring range	
ADU mode	SYS 40 mmHg ~ 270 mmHg
	DIA 10 mmHg ~ 215 mmHg
	MAP 20 mmHg ~ 235 mmHg
PED mode	SYS 40 mmHg ~ 200 mmHg
	DIA 10 mmHg ~ 150 mmHg
	MAP 20 mmHg ~ 165 mmHg
NEO mode	SYS 40 mmHg ~ 135 mmHg
	DIA 10 mmHg ~ 100 mmHg
	MAP 20 mmHg ~ 110 mmHg
Alarm type	SYS, DIA, MAP
Cuff Pressure measuring range	0 mmHg ~ 300 mmHg
Pressure resolution	1 mmHg
Maximum mean error	±5 mmHg
Maximum standard deviation	8 mmHg
Maximum measuring time of single measurement	ADU/PED 120s NEO 90s
Typical measuring period	30s ~ 45s (depend on HR/motion disturbance)
Overpressure protection	Dual overpressure protection

ADU	(297±3) mmHg
PED	(240±3) mmHg
NEO	(147±3) mmHg
PR	
Measuring range	40 bpm ~ 240bpm
Accuracy	The maximum of ±3bpm or 3.5%

A1.2.8 SpO_2 (Optional)

Measuring Range	0% ~ 100 %
Alarm Range	0% ~ 100 %
Resolution	1 %
Accuracy	
ADU & PED	±2 %（70% ~ 100% SpO_2） Undefined（0% ~ 69% SpO_2）
NEO	±3 %（70% ~ 100% SpO_2） Undefined（0% ~ 69% SpO_2）
Pulse Rate	
Measuring Range	25 bpm ~ 300 bpm
Alarm Range	30 bpm ~ 300 bpm
Resolution	1 bpm
Accuracy	± 2 bpm
Data update period	1s
Wave length	
Red light	660±3 nm
Infrared light	905±5 nm
Emitted light energy	Less than 15 mW

A1.2.9 TEMP (Optional)

T2 Module:

Measuring range	25°C ~ 45°C
Working temperature	10°C ~ 40°C
Sensor type	Oral /axillary /rectal
Alarm range	35.5°C ~ 42°C
Resolution	0.1°C
Accuracy	±0.1°C (25°C ~ 45°C)
Response time	< 60s
Update time	1s ~ 2s

TH Module:

Measuring range	34°C ~ 42.2°C
Working temperature	10°C ~ 40°C
Alarm range	35.5°C ~ 42°C
Resolution	0.1°C
Accuracy	±0.2°C (35.5°C ~ 42°C) ±0.3°C (out of the limits)
Response time	1s

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 M3A is intended for use in the electromagnetic environment specified below, the customer or the user of the M3A should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The M3A uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The M3A is suitable for use in all establishments , other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

A2.2 Electromagnetic Immunity - For all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The M3A is intended for use in the electromagnetic environment specified below. The customer or the user of M3A 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; With TH module: ±2 kV contact ±4kV air.	±6 kV contact ±8 kV air With TH module: ±2 kV contact ±4kV 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	±2kV for power supply lines; With TH module: ±1 kV for power supply lines.	±2 kV for power supply lines; With TH module: ±1 kV for power supply lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the M3A requires continued operation during power mains interruptions, it is recommended that the M3A be powered from an uninterruptible power supply or a battery.
NOTE UT 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 manufacturer's declaration – electromagnetic immunity			
The M3A is intended for use in the electromagnetic environment specified below. The customer or the user of M3A should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the EUS T Ultrasound Scanner, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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 EUS TUltrasound Scanner is used exceeds the applicable RF compliance level above, the EUS T Ultrasound Scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EUS TUltrasound Scanner.

[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 M3A Vital Signs Monitor

The M3A is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the M3A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the M3A 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.7**	**3.7**	**7.3**
100	**12**	**12**	**23**

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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