

# M3

Vital Signs Monitor  
Version 2.3

## User Manual



# About this Manual

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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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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.

## 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.

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## Chapter 1 Intended Use and Safety Guidance

### 1.1 Intended Use/Indications for Use

The monitor is intended to be used by qualified physicians or personnel professionally trained and it is for monitoring adults, pediatrics and neonates in hospital environments.

This monitor is used to monitor vital signals for patients and is suitable for use in hospital environments including out-patient department, wards and NICU.

Monitored parameters include: NIBP, SpO<sub>2</sub>, pulse rate, Quick TEMP/Infrared TEMP.

### 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 0 °C ~+40 °C. 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 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.

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### **WARNING**

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

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## **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.

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### **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 concentrations of flammable anesthetics or other materials may occur.
  - 5 SHOCK HAZARD-To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.
  - 6 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.
  - 7 Use the battery only in this monitor. Do not connect battery directly to an electric outlet or cigarette lighter charger.
  - 8 Do not unplug the battery when monitoring.
  - 9 Always keep the battery away from fire.
  - 10 Do not solder the leading wire and the battery terminal directly.
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**WARNING**

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- 11 Make sure the monitor is used in the appointed range of voltage so that the effect of power supply can be ignored.
  - 12 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards. Furthermore all configurations shall comply with the valid version of the system standard IEC/EN60601-1. 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. If in doubt, consult our technical service department or your local distributor.
  - 13 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.
  - 14 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.
  - 15 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.
  - 16 Do not use a battery with serious scatch or deformation.
  - 17 Only patient cable and other accessories supplied by EDAN can be used. The performance and electric shock protection can not be guaranteed, and the patient may be injured otherwise.
  - 18 The user should check the monitor and accessories before use.
  - 19 Please set the alarm according to the individual status of patient to avoid delaying treatment. Ensure there will be alarm audio prompt when alarming.
  - 20 Devices connecting with monitor should be equipotential.
  - 21 The monitor is equipped with a wireless AP via network interface to receive RF electromagnetic energy. Therefore, any other equipment complies with CISPR radiation requirements may also interfere with the wireless communication and make it interrupted.
  - 22 Please disinfect timely to prevent cross infection between patients.
  - 23 When the monitor and electrosurgical device are used together, the user (physician or nurse) should guarantee the safety of patient.
  - 24 This monitor is not a device for treatment purposes.
  - 25 Do not touch the patient, bed or instrument during defibrillation.
  - 26 Do not service or maintain the monitor or any accessory which is in use with the patient.
  - 27 During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off. All last settings used will be recovered when the power is restored.
  - 28 If leakage or foul odor is detected, ensure that there's no fire around.
-

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**WARNING**

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- 29 Only NIBP and SpO<sub>2</sub> 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.
  - 30 The appliance coupler or mains plug is used as isolation means from supply mains. Position the monitor in a location where the operator can easily access the disconnection device.
  - 31 Wireless LAN equipment contains an intentional RF radiator that has the potential of interfering with other medical equipment, including patient implanted devices.
  - 32 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT. Use only EDAN-approved accessories.
  - 33 Without any external memory, all data measured (including trend data, review data, alarm events and so on) are cleared either when the monitor is turned off or when the monitor is powered down in the process of monitoring.
  - 34 Only items that have been specified as part of the system or specified as being compatible with the system can be connected to the system.
  - 35 SHOCK HAZARD - Don't connect electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.
  - 36 SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.
  - 37 Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously. Do not touch the signal input or output connector and the patient simultaneously.
  - 38 Connecting any accessory (such as external printer) or other device (such as the computer) to this patient monitor makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
    - a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and
    - b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety
  - 39 Additional multiple socket-outlet or extension cord can't be connected to the system.
  - 40 Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.
-

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**WARNING**

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- 41 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.
  - 42 Portable and mobile RF communications equipment can affect medical electrical equipment; refer to the recommended separation distances provided in Appendix A2 EMC Information.
  - 43 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.
  - 44 The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
  - 45 The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start monitoring patients.
  - 46 When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.
  - 47 To protect the monitor from damage during defibrillation, for accurate measurement information and to protect against noise and other interference, use only accessories specified by EDAN.
  - 48 No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
  - 49 Only use EDAN approved rechargeable batteries for the monitor.
  - 50 If several medical equipments are connected to a patient, the sum of the leakage currents shouldn't exceed the limits, otherwise it may cause shock hazard.
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**CAUTION**

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- 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, microwaves, 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.
-

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**CAUTION**














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- 5 Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.
  - 6 The device and reusable accessories may be sent back to the manufacturer for recycling or proper disposal after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.
  - 7 Avoid liquid splash and excessive temperature. The working temperature must be kept between 0 °C and +40 °C, and it is recommended to be kept between +10 °C and +40 °C when the monitor is equipped with TEMP module. The temperature should be kept between -20 °C and +55 °C during transportation and storage, and it is recommended to be kept between -20 °C and +50 °C when the monitor is equipped with TH module.
  - 8 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.
  - 9 Remove a battery whose life cycle has expired from the monitor immediately.
  - 10 Before using the device, the equipment, patient cable and electrodes etc. should be checked. Replacement shall be taken if there is any evident defect or signs of aging which may impair the safety or performance.
  - 11 A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area.
  - 12 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
  - 13 Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.
  - 14 A ventilated environment is required for monitor installation. Do not block up the ventilation grille at the back of the device.
- 

**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 This equipment is not intended for home usage.
- 4 If the device is discolored or damaged, then discontinue use of the device.
- 5 The pictures and interfaces in this manual are for reference only.
- 6 Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.
- 7 The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1: 2009.

## 1.2.7 Explanation of Symbols on the Monitor

1		TYPE CF APPLIED PART
2		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
3		TYPE BF APPLIED PART
4		Caution
5		Operating instructions
6		Refer to User Manual (Background: blue; Symbol: white)
7		Equipotential grounding
8		Power Supply switch
9		SERIAL NUMBER
10		CE marking
11		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
12		Date of manufacture
13		MANUFACTURER

14		Part Number
15		General symbol for recovery/recyclable
16		Disposal method
17	<b>Rx Only</b>	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
18	<b>IPX1</b>	Ingress Protection IPX1 (Protected against vertically falling water drops)
19		With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1, IEC 60601-2-30, IEC 60601-2-49
20		Warning (Background: yellow; Symbol and outline: black)

**NOTE:**

The user manual is printed in black and white.

## 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 following specification: 100 V–240 V ~, 50 Hz/60 Hz.
- ◆ Connect the power cord provided with the monitor. Connect the power cord to connector of the monitor. Connect the other end of the power cord to a grounded power outlet.

### NOTE:

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

- ◆ Connect to the ground line if necessary. Refer to *section1.2 Safety Guidance* for details.

### NOTE:

When the battery configuration is provided, after the monitor is transported or stored, the battery must be recharged. Switch 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 front panel to power on the monitor, LOGO information will be displayed on the screen.

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### **WARNING**

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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.

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#### **NOTE:**

- 1 Check all the functions of the monitor and make sure that the monitor is in good condition.
- 2 If rechargeable batteries are provided, recharge them after using the monitor every time to ensure the electric power is enough.
- 3 The interval between double presses of **ON/OFF** button should be more than 1 second.

## 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.

## 2.5 Checking the Recorder

If your monitor is equipped with a recorder, open the recorder door to check if paper is properly installed in the slot. If no paper is present, refer to *Chapter 6 Trend and Recording* for details.

## Chapter 3 Introduction

### 3.1 General Information

The monitor integrates the function of parameter measurement modules, display, recording and output to compose a compact, portable device. Its built-in replaceable battery provides convenience for patient movement. On the LCD display screen, SpO<sub>2</sub> waveform and all the monitoring parameters can be displayed clearly.

You may frequently use the following functions:

- ◆ ☐ SpO<sub>2</sub> monitoring (Refer to Chapter *Monitoring SpO<sub>2</sub>* for details)
- ◆ ☐ TEMP monitoring (Refer to Chapter *Monitoring TEMP* for details)
- ◆ ☐ NIBP monitoring (Refer to Chapter *Monitoring NIBP* for details)
- ◆ ☐ Alarm (Refer to Chapter *Alarms* for details)

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.



Figure 3-1 M3 Vital Signs Monitor

M3 Vital Signs Monitor can monitor:

- SpO<sub>2</sub>: Arterial Oxygen Saturation (SpO<sub>2</sub>);
- Pulse Rate (PR);
- SpO<sub>2</sub> PLETH (Plethysmogram);

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

TEMP: Temperature (TEMP)

## 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 is outfitted with the modules SpO<sub>2</sub>, NIBP and TEMP, the three parameters SpO<sub>2</sub>, NIBP and TEMP are onscreen in the general display mode. If the monitor is configured to the double-parameter measuring function as NIBP+SpO<sub>2</sub> or NIBP+TEMP, double parameters will be displayed onscreen. Also, the monitor can be configured to single parameter mode with SpO<sub>2</sub> measuring only or NIBP measuring only. In SpO<sub>2</sub> only or NIBP only measuring mode, the single parameter of SpO<sub>2</sub> or NIBP is displayed.

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

### 3.2.1 General Display Mode

The screen is divided into three areas:

- 1 Parameter area ①
- 2 Waveform/Trend list/Alarm list area ②
- 3 Information area ③ ④

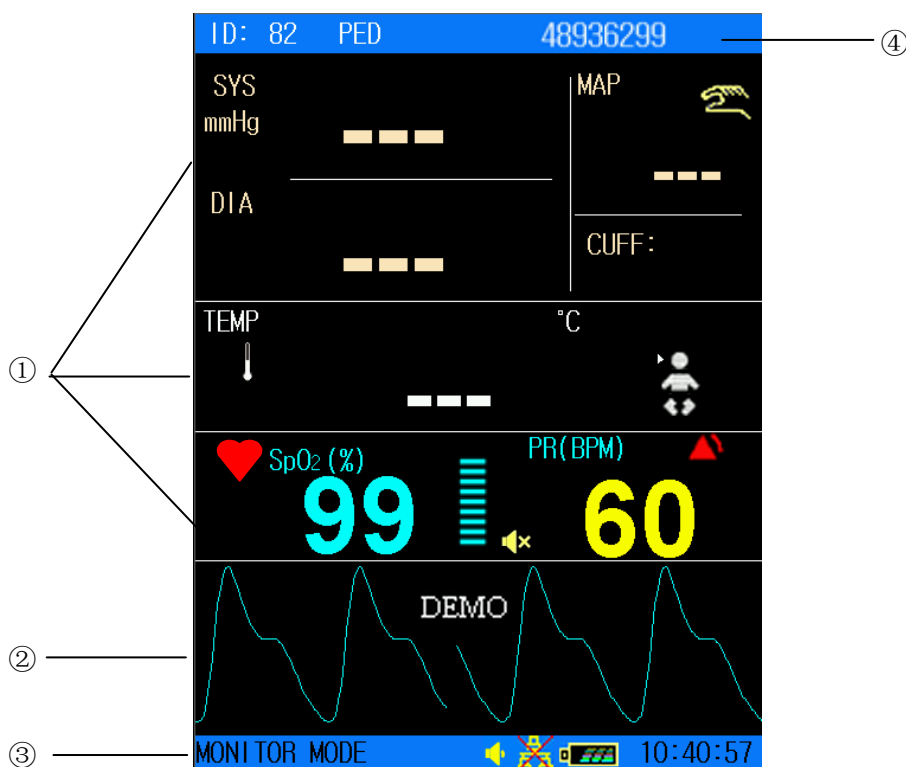


Figure 3-2 Main display with waveform

The Waveform area can display parameter trend list or alarm list. It displays as follows:

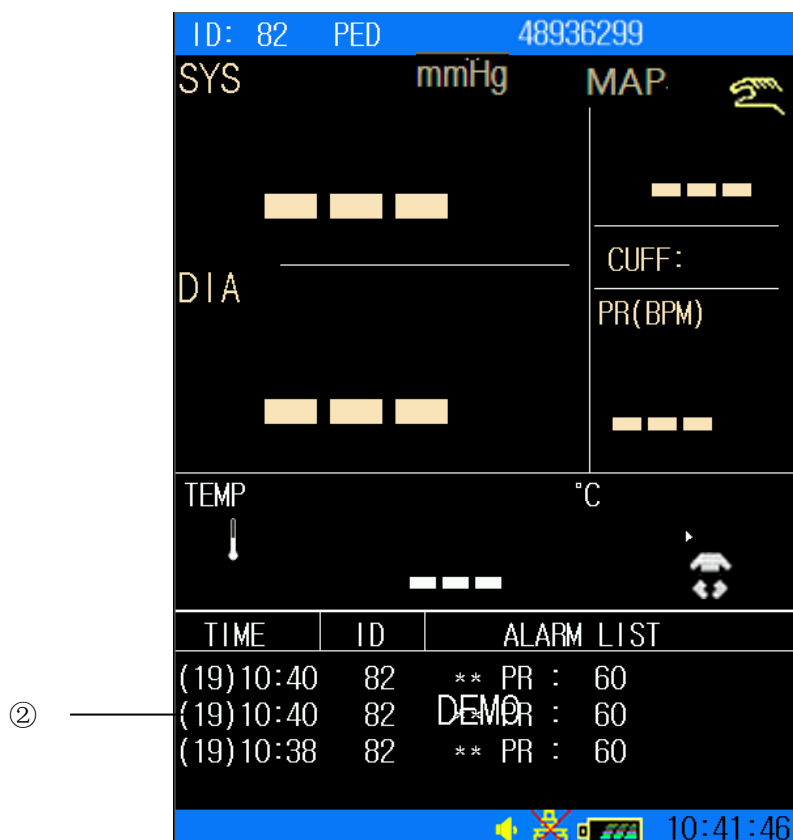


Figure 3-3 Main display with alarm list

The display on the screen can be changed to a trend graph as follows:

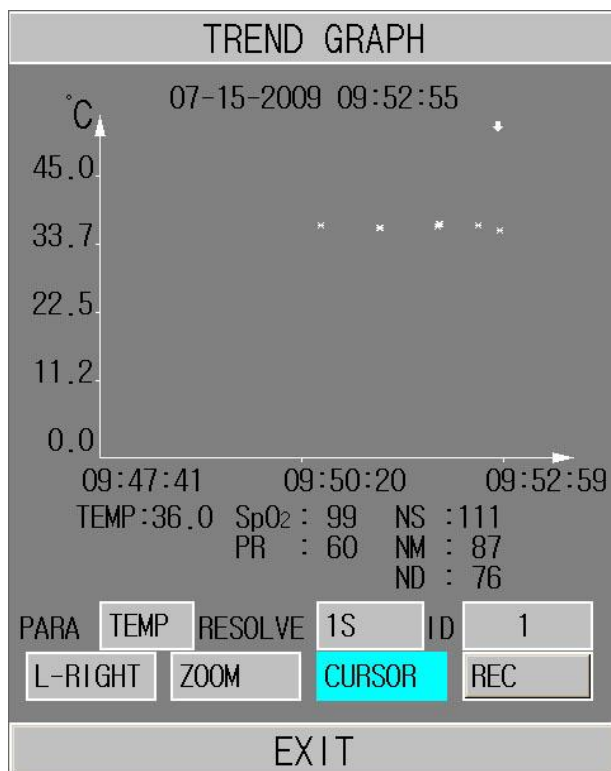
























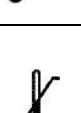
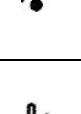




Figure 3-4 Display trend graph

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

	Battery status indicator
	Connected to mains power supply
	Barcode
	Volume indicator
	Network connection indicator
	Network connection off
	Medium/Low alarm
	High alarm icon
	Audio alarm off
	Audio alarm paused
	Parameter alarm off
	Patient type: ADU
	Patient type: PED
	Patient type: NEO
	NIBP manual mode
	NIBP interval mode

	NIBP continual mode	
	Heart beat	
	Measuring oral TEMP in ADU mode	For device with the T2 or F3000 TEMP module only.
	Measuring axillary TEMP in ADU mode	
	Measuring rectal TEMP in ADU mode	
	Measuring oral TEMP in PED mode	
	Measuring axillary TEMP in PED mode	
	Measuring rectal TEMP in PED mode	
	Measuring TEMP	
	Measuring value of TEMP is above the upper alarm limit. (Only for Predictive Mode)	
	Measuring value of TEMP is below the lower alarm limit. (Only for Predictive Mode)	
	Measuring ear TEMP	For device with the Infrared Ear Temperature module only.
ID	Current patient ID	
10:41:46	Current time	

**Parameter Area ( ①)**

Parameter area is on the right of Waveform area, and parameters are displayed:

SpO<sub>2</sub>:

- SpO<sub>2</sub> (Unit: %)
- PR (Pulse Rate, Unit: BPM).

NIBP:

- SYS, DIA, MAP (Unit: mmHg or kPa, 1 mmHg=0.133 kPa)
- Pulse Rate (Pulse Rate, Unit: bpm)
- NIBP measuring mode

TEMP: Temperature (Unit: °C or °F).

The PR signal from SpO<sub>2</sub> measuring takes priority to be displayed.

**Waveform/Trend List/Alarm List Area ( ②)**

It can display SpO<sub>2</sub> waveform, Trend tab or Alarm list. You can select it in the **SELECTION** of **SYSTEM MENU**.

**Information Area ( ③ ④)**

The information areas are to display operating status of the monitor and condition of the patient, including the following data:

- Patient type and ID;
- Signs indicating the net connection status;
- Signs indicating the battery or mains power supply status;
- Current time;
- Signs indicating the volume status;
- Alarms and prompts.

**Alarm Indicator and Alarm Status**

- In normal condition, 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 Double-Parameter Mode

#### NIBP+SpO<sub>2</sub> Interface

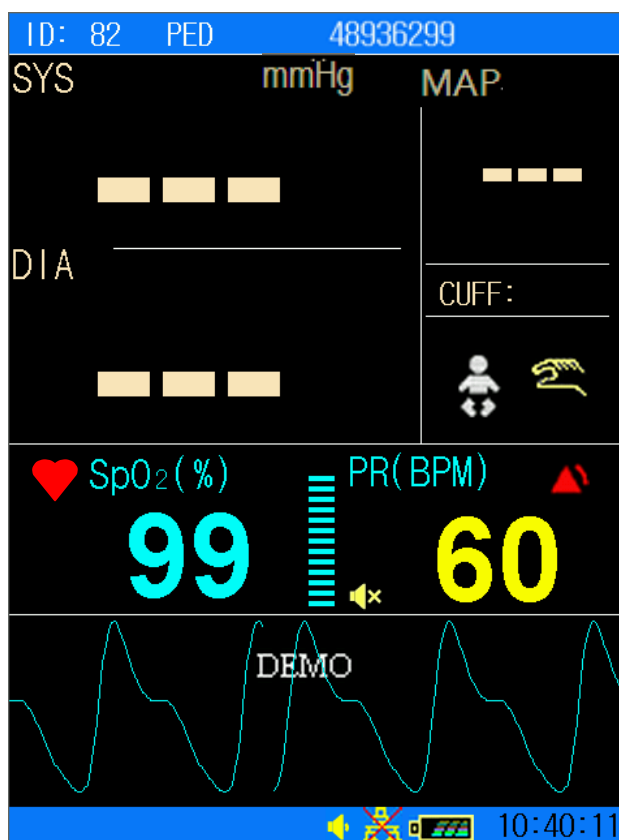


Figure 3-5 NIBP as the Main Parameter





Figure 3-6 SpO<sub>2</sub> as the Main Parameter**NIBP+TEMP Interface**

Figure 3-7 NIBP+TEMP Interface

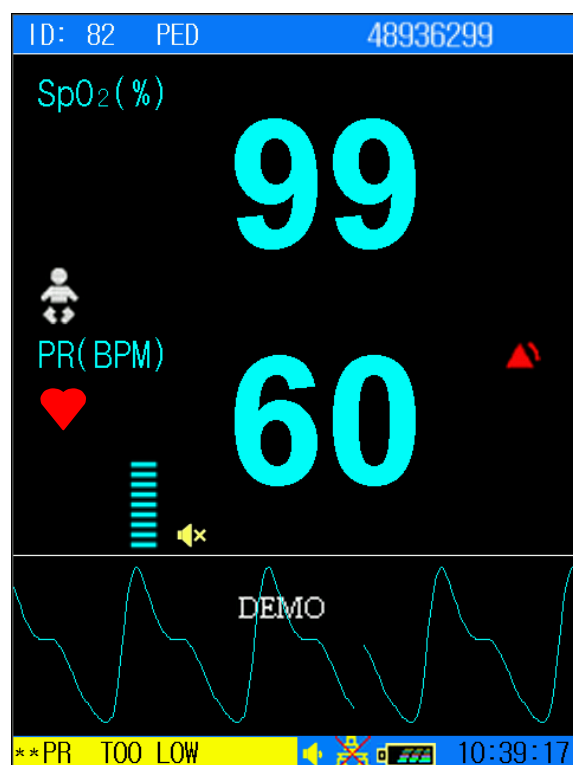
**3.2.3 Single Parameter Mode****SpO<sub>2</sub> only measuring mode**

Figure 3-8 Display in SpO<sub>2</sub> only mode

### NIBP only measuring mode

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

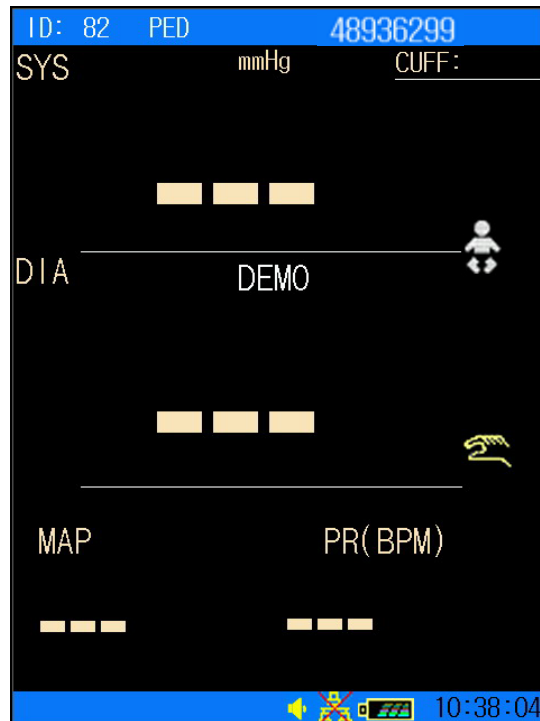


Figure 3-9 Display in NIBP only mode

## 3.3 Button Functions

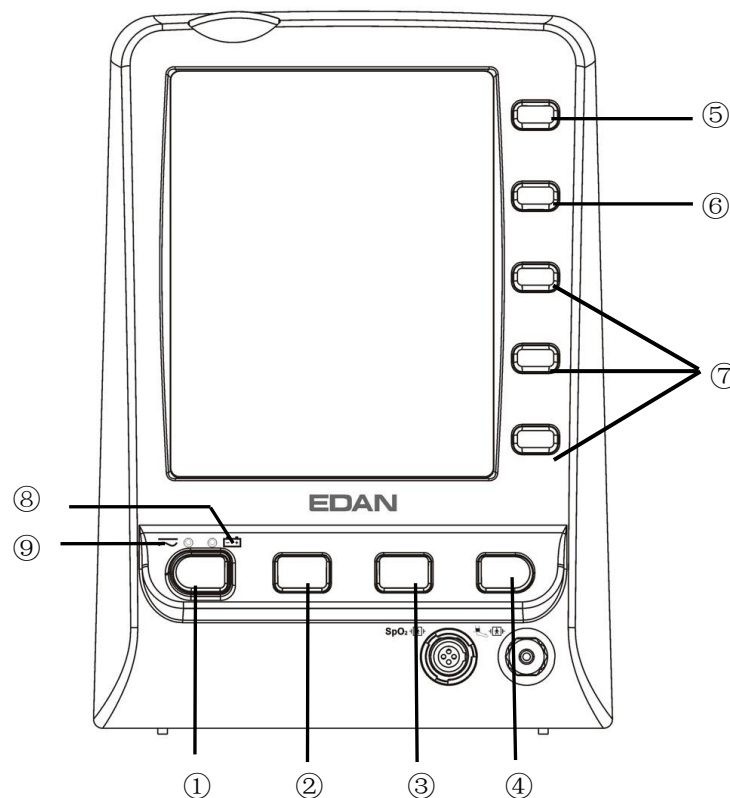














Figure 3-10 Buttons

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

①	<b>ON/OFF</b> 	When the monitor is off, press this button to switch on the monitor. When the monitor is on, press this button for less than 1 s, the monitor will enter the sleep mode (if STANDBY is set to ON). Press this button and hold it for $\geq 2$ s to switch off the monitor.
②	<b>AUDIO ALARM PAUSED/OFF</b> 	Press this button to pause or turn off the auditory alarm as needed.
③	<b>NIBP START/STOP</b> 	To inflate the cuff and start blood measuring. During the measuring process, press the button to stop measuring. (For the monitor with NIBP function).
	<b>ALARM LIMIT</b> 	For SpO <sub>2</sub> only monitor, the <b>NIBP START/STOP</b> button is changed to <b>ALARM LIMIT</b> button. Press this button to set the alarm limit of the parameters of SpO <sub>2</sub> .
④	<b>TREND/WAVEFORM</b> 	Press this button to switch between waveform display, trend graph and trend list display.
⑤	<b>HOT KEY (RECORD/SHORTCUT KEY FOR CHANGING PATIENT TYPE)</b> 	<p>In the monitoring mode, this hot key is configured as the record button by default. Press it, and you can print out the currently displayed waveforms, trend graph, trend lists or alarm lists. Pressing it while recording can stop recording.</p> <p>In the spot check mode, this hot key is configured as the shortcut key for changing the patient type. You can rapidly alter the patient type by pressing this button.</p>
⑥	<b>MENU</b> 	Press to open the <b>SYSTEM MENU</b> . Refer to <i>Chapter 4 System Menu</i> for details.

⑦	 <b>UP</b>  <b>OK</b>  <b>DOWN</b>	Select the items in menu, or decrease or increase the items. Confirm the selection by pressing <b>OK</b> .
---	---	--

The icons on the front panel:

⑧	 <b>CHARGE Indicator</b>	The LED besides this icon indicates the charging status. When the battery is being recharged, the LED is bright.
⑨	 <b>POWER Indicator</b>	The LED besides this icon indicates the power status. 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. There is a USB port on rear panel for Data storing function.

#### Left side of the monitor

At the left side of the monitor is the recorder (①).



Figure 3-11 Left Panel

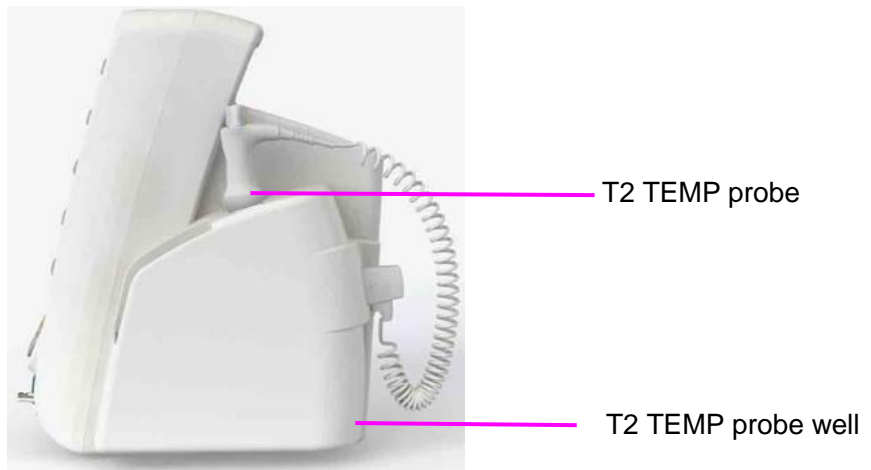
**Sensor port on the front panel**

Connectors for cables and sensors are as shown in Figure 3-11.

1. SpO<sub>2</sub> sensor connector ②
2. NIBP cuff connector ③

**Right side of the monitor**

If the monitor has TEMP function, there will be TEMP module and thermometer outfitted on the right side. Three optional TEMP measurement modules are available: T2 module, TH module (Infrared Ear Temperature module) and F3000 module. Refer to Figure 3-12.

**With T2 TEMP Module:****With Infrared Ear Temperature Module:**

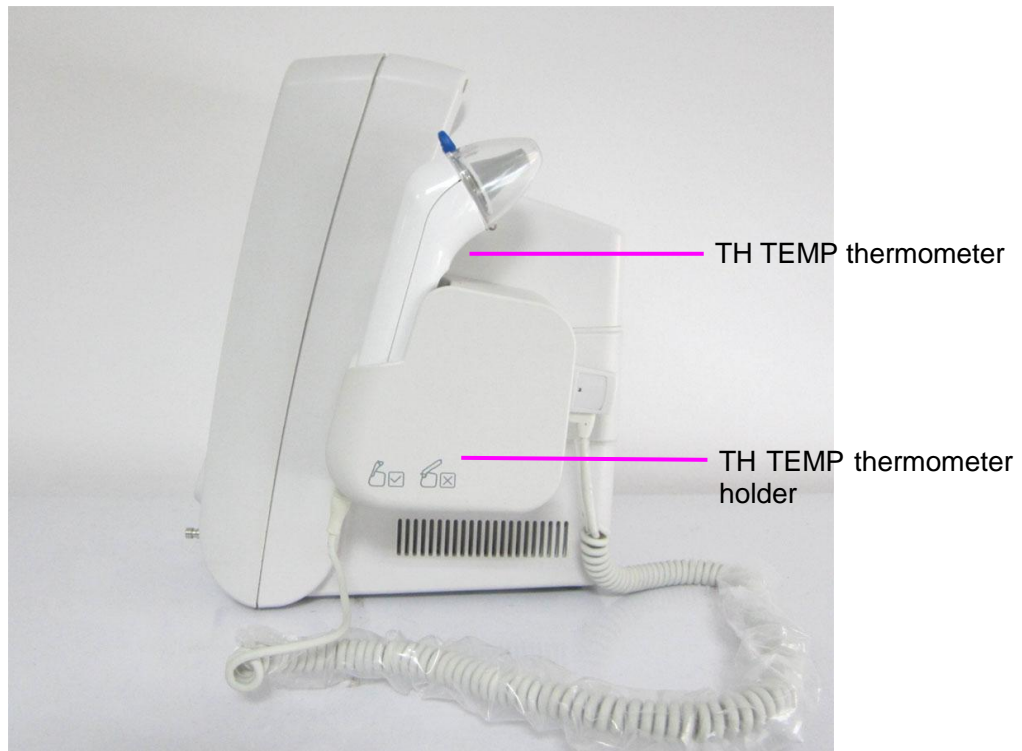
**With F3000 TEMP Module:**

Figure 3-12 Right Panel

**WARNING**

Only connect accessories supplied or recommended by EDAN to the device.

**Rear Panel**

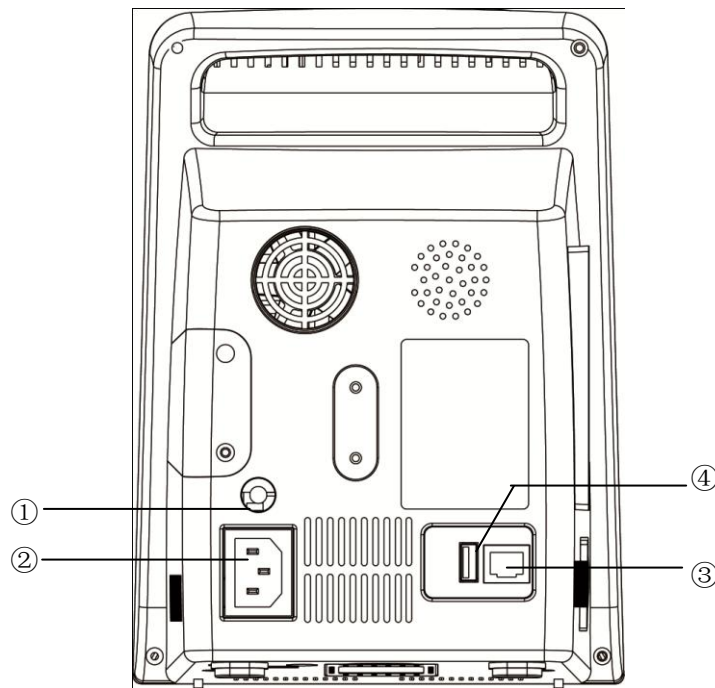


Figure 3-13 Rear Panel of M3

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

- ① Equipotential grounding terminal for connection with the hospital's grounding system.
- ② Power supply socket: 100 V–240 V ~, 50 Hz/60 Hz.
- ③ Network Interface: Standard RJ45 Socket, for connecting to MFM-CMS of EDAN.
- ④ USB connecting port for USB storage.

### Bottom panel

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

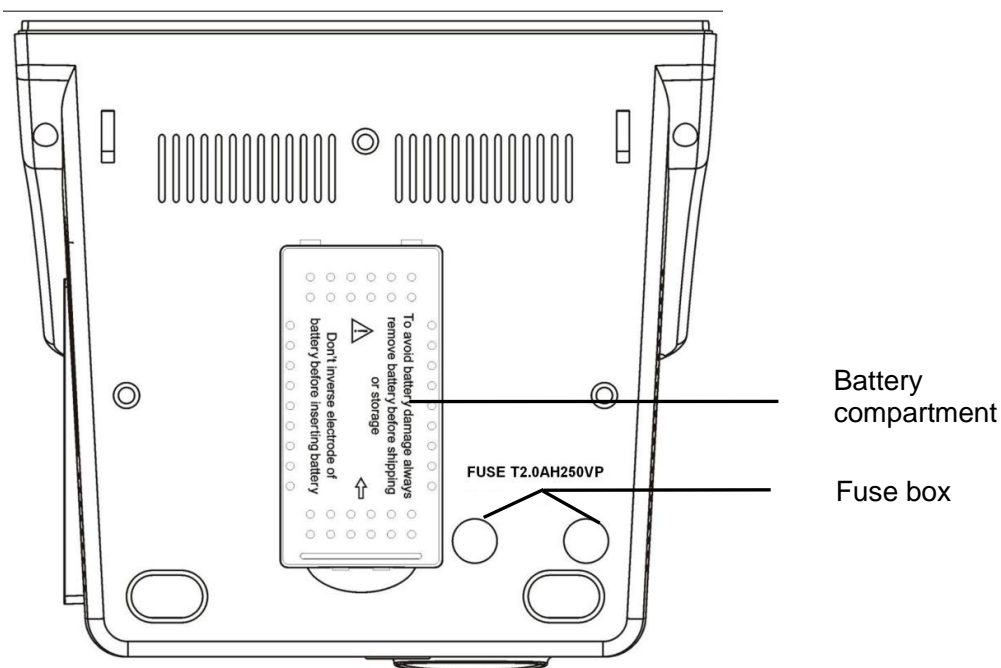


Figure 3-14 Bottom panel

## 3.5 Built-in Rechargeable Battery

### 3.5.1 Battery Safety Information

---

#### **WARNING**

- 1 Do not take off the battery when monitoring. The unexpected power supply off can not impact the monitor normal 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 that the effect of power supply can be not noticeable.
  - 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 circuit.
  - 7 Do not heat or throw battery into fire.
- 

---

#### **WARNING**

- 8 Do not use, leave battery close to fire or other places where temperature may be above +60 °C. 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.

---

### 3.5.2 Battery Status on the Main Screen

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. Battery status light is yellow when recharging, off when full.

Battery status symbols show the status of battery and the battery power remaining;



Remaining battery power: 100%.



Remaining battery power: 75%



Remaining battery power: 50%



Remaining battery power: 25%



Batteries are almost depleted and need to recharge immediately.

### 3.5.3 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery maintenance as recommended here can help to slow down this process.

1. Disconnect the patient from the monitor and stop all monitoring and measurement.
2. Switch the monitor power on and charge the battery for more than 6 hours continuously.
3. Disconnect monitor from mains power and let the monitor run until there is no battery power left and the monitor shuts off.
4. The running time of the battery reflects the battery performance.

If the running time is obviously less than the specified time in the specification, please change the battery or contact the service personnel.

### 3.5.4 Replacing the Battery

During monitoring state or communication state, when the battery is low or empty, the monitor will indicate a “BATTERY LOW” alarm.

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

### 3.5.5 Recycling the Battery

When the battery no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.

### 3.5.6 Maintaining the Battery

Batteries should be conditioned regularly to maintain their useful life.

Remove the batteries from the monitor if they are not used for a longer period of time. And recharge the batteries at a minimum of every 6 months when they are stored.

Discharge the battery completely once every month.

### 3.5.7 Battery Alarm Information

Technical Alarm:

Message	Cause	Alarm Level	What to do
Battery Low	Battery Low	High	Change the battery or charge the battery.

## 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 **MENU** on the front panel to open **SYSTEM MENU**. You can perform the following operations in this menu.

### 4.1 Patient Setup

Click on **PATIENT SETUP** in **SYSTEM MENU** to open the menu.

You can set the following patient information:

- ◆ **PAT ID**: Patient ID, 1~1000;
- ◆ **PAT TYPE**: Patient type; **ADU**, **PED**, or **NEO**.

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

- ◆ **BARCODE**: Display the patient barcode, maximum 20 bits

Pick **EXIT** to return to the previous menu.

### 4.2 Default Setup

#### NOTE:

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

- ◆ **FAC DEF CONFIG**: factory default configuration.
- ◆ **USER DEF CONFIG**: user-defined default configuration;
- ◆ **CONFIRM**: Confirm your choice, exit this submenu, and return to the previous menu.

### 4.3 System Setup

In this submenu, **SYSTEM SETUP** has a few items to set:

- ◆ **ALARM VOL**: Set alarm volume to **HIGH**, **MED** or **LOW**.
- ◆ **STANDBY**: Set it to **ON** or **OFF** to enable or disable the Sleep Mode function (Refer to *4.12 Sleep Mode*).
- ◆ **KEY VOL**: Set key volume to **HIGH**, **MED**, **LOW** or **OFF**.
- ◆ **BRIGHTNESS**: Set screen brightness to **HIGH**, **MED** or **LOW**.
- ◆ **SPHY VOL**: Set sphygmoc volume to **HIGH**, **MED**, **LOW** or **OFF**.
- ◆ **WORK MODE**: Set work mode to **MONI** (monitoring mode) or **SPOT** (spot check mode).

#### NOTE:

- 1 The work mode will be indicated in the information area.
- 2 In the spot check mode, audio and visual prompts for all medium and low technical alarms will be disabled; medium and low technical alarms will only be indicated by

turns in the information area. In the monitoring mode, audio and visual prompts for all alarms will be effective and alarms will be indicated by turns in the information area.

- 3 In the spot check mode, medium and low technical alarms cannot disable the settings of silencing the alarm. Only when a new physiological alarm or a high technical alarm occurs can the monitor automatically exit the alarm silenced status. In the monitoring mode, if a new alarm of any type occurs, the monitor will automatically exit the alarm silenced status.
- 4 In the spot check mode, no trend graph will be shown.

- ◆ **WAVE FORM:** Set displayed waveforms to **UNFILLED** or **FILLED**.
- ◆ **FACE SELECT:** Set **NIBP** or **SpO<sub>2</sub>** as the main displayed parameter onscreen (**FACE SELECT** is only available for the monitor with the configured modules NIBP+SpO<sub>2</sub>).
- ◆ **RECORDER SPEED:** Set recorder speed to **12.5 mm/s** or **25 mm/s**.
- ◆ **EXIT:** Return to the previous menu.

## 4.4 Selection


For the monitor outfitted with SpO<sub>2</sub>, NIBP and TEMP modules, you may select **SELECTION** in **SYSTEM MENU** to access this submenu, in which seven selections are available: **NIBP TREND TAB**, **SpO<sub>2</sub> TREND TAB**, **TEMP TREND TAB**, **ALL PARAMETERS**, **ALARM LIST**, **TREND GRAPH** and **TREND TABLE**. Only one item can be selected to display information on the interface.

- ◆ **NIBP TREND TAB:** to display NIBP trend table;
- ◆ **SpO<sub>2</sub> TREND TAB:** to display SpO<sub>2</sub> trend table;
- ◆ **TEMP TREND TAB:** to display TEMP trend table;
- ◆ **ALL PARAMETERS:** to display all parameters in the area;
- ◆ **ALARM LIST:** to display alarm list.
- ◆ **TREND GRAPH:** to display the trend graph.
- ◆ **TREND TABLE:** to display the trend table.

You can shift the data list to waveform display by pressing the **TREND/WAVEFORM** button on front panel.

For Single display mode, the **Selection** menus are different.

## 4.5 Deleting Data

If you press the button  when a trend list or an alarm list is displayed on the screen, it will display below selections:

**DELETE ID:** Entirely delete the trend and alarm data of the current monitored patient.

**DELETE ALL DATA:** Entirely delete the trend and alarm data of all the monitored patients.

Select **YES** to make the operation effective; select **NO** to cancel the operation.

## 4.6 Version

Select **VERSION** in **SYSTEM MENU** to check the version of the monitor and the configuration of the modules.

## 4.7 Time Setup

Select **TIME SETUP** in **SYSTEM MENU** to access the submenu of **TIME SETUP**. System time is in format of **Y-M-D**, **M-D-Y** or **D-M-Y**. Users can set the year, month, day, hour, minute and second. Pick the item you want to modify and confirm it by pressing **OK**. Select **EXIT** item to save the setup and return to the previous menu. If you want to exit the menu without saving it, press the **MENU** on front panel.

## 4.8 NIBP Setup

Refer to *9.4 NIBP Setup*.

## 4.9 TEMP Setup

Refer to *10.1.3 TEMP Setup for T2 Module* and *10.3.7 TEMP Setup for F3000 Module*.

## 4.10 Alarm Setup

Refer to *5.1.3 Alarm Setup*.

## 4.11 Maintain

Select **MAINTAIN** item in **SYSTEM MENU** to open **ENTER MAINTAIN PASSWORD** dialog box, in which you can enter password and then customize maintenance settings. Factory maintenance function is only available for the service engineers of EDAN or representative authorized by EDAN.

### User Maintain

Input the user password **9 9 8 1** in the **USER KEY** box and press **OK**, **USER MAINTAIN** menu will pop up, in which you can set following items.

**BED No.:** Set the bedside number to a value from 1 to 64.

**LANGUAGE:** Set the displayed language.

#### NOTE:

You should restart the monitor after changing the displayed language to make the operation effective.

**NURSE CALL:** Turn on or off the nurse call. When the parameter alarm occurs, the monitor gives 3s nurse call alarm prompt; if the audible 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.

**SERVER IP:** It can be changed by the user according to the IP of PC installed with MFM-CMS of EDAN.

**SERVER PORT:** Set server port.

**PRES UNIT:** Set the pressure unit to **mmHg** or **kPa**.

**TEMP UNIT:** Set the temperature unit to **°C** or **°F**.

**HOT KEY:** Set the hot key to **PATIENT** or **PRINT**.

**COLOR SELECT:** Set the color of displayed waveforms. 16 kinds of colors can be selected. Click on **DEFAULT** to return to the default configuration.

## **OTHER SETUP**

### ● **SpO<sub>2</sub> SETUP:**

#### ◆ **SpO<sub>2</sub> ALARM LEV**

You can configure the alarm level for **SpO<sub>2</sub> SENSOR OFF** to **HIGH** or **LOW**.

#### ◆ **SENSITIVITY**

The SpO<sub>2</sub> reading is the average of data collected within a specific time. You can set **Sensitivity** to **HIGH**, **MED** or **LOW** 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.

#### ◆ **PI**

PI is a numeric value indicating perfusion level. It reflects the perfusion level at the monitoring site. You can set it **ON** or **OFF**.

### ● **NIBP SETUP:**

◆ **AVG INTERVAL:** Set the average NIBP measurement interval to **1MIN**, **2MIN**, **3MIN**, **4MIN** or **5MIN**.

◆ **AVG TIMES:** Set the average NIBP measurement times to **3** or **5**.

◆ **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.

#### ◆ **LEAK TEST**

This item is used for an air leakage test. Select this item to start the air leakage test. Then the item will change into **STOP LEAK TEST**. Select it again, and the system will stop the air leakage test.

**WARNING**

This pneumatic 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 **LEAK TEST** by pressing **UP/DOWN**. It indicates **Leak testing...** in the information area.
- 5) The system will automatically inflate the pneumatic system to about 180 mmHg. After 20 seconds to 40 seconds, if system leakage has detected, the system will automatically open the deflating valve to stop the leak test and indicates NIBP Leak. If no system leakage is detected when the pneumatic system is inflated to 180 mmHg, the system will perform a deflation to an approximate value of 40 mmHg and subsequently perform the second phase leak test. After 20 seconds to 40 seconds, the system will automatically open the deflating valve and provide corresponding indication based on the test result.
- 6) If the alarm information of **AIR LEAK** appears, 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.

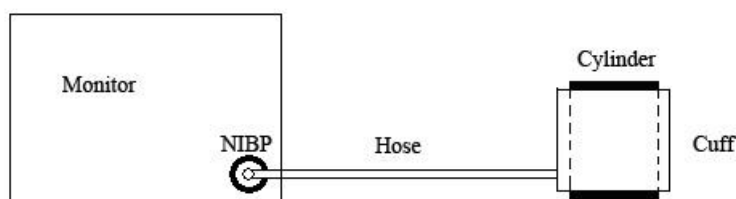




Figure 4-2 Diagram of NIBP Air Leakage Test

**◆ 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.

**● ALARM SETUP:****◆ AUDIO ALARM PAUSED**

To activate the auditory alarm function, you can set **AUDIO ALARM PAUSED** to any value:

**60s, 120s or 180s**, then press the button  on the front panel to pause audio alarm. The information area displays the remaining pause time in seconds with a yellow background. Key sounds and beat sounds keep their previous status. Auditory alarm will resume when you press the button  again or the pause time terminates.

#### ◆ **AUDIO ALARM OFF**

To activate the Audio Alarm Off function, you can set **AUDIO ALARM OFF** to **ON**, then press the button  on the front panel and hold it for more than three seconds to turn off auditory alarm. Key sounds and beat sounds keep their previous status. Press the button  again to resume auditory alarm. If you set **AUDIO ALARM OFF** to **OFF**, the function is inactivated.

### ● **BARCODE SETUP:**

#### ◆ **ID:**

Patient ID can maximally be a three-digit number. On this precondition, you can determine which digit in the barcode is the starting/ending digit for the patient ID via configuration of **START** and **END**. Take the following barcode for example. If you set **START** to **2** and **END** to **4**, the updated patient ID will begin with the second digit and end with the fourth digit in the barcode, namely 787.



9787121113260

#### ◆ **PAT TYPE:**

You can determine which digit in the barcode indicates the patient type. For example, if you set **PAT TYPE** to **1**, the first digit in the barcode will be identified as an indication of patient type.

#### ◆ **ON/OFF:**

If it is set to **ON**, the patient information is updated automatically by using a barcode scanner. If it is set to **OFF**, a message box indicating “**Confirm to update patient, yes?**” will pop up when scanning a barcode. Click on **YES** to automatically update patient information; click on **NO** to quit automatical update.

#### ◆ **ADU, PED, NEO:**

Select a digit from 0~9 to indicate the patient type. For example, if **ADU** is set to **9**, **PAT TYPE** is set to **1**, and the first digit in the barcode is 9, the patient type could be updated to ADU.

### **NOTE:**

- 1 The set value of **START/END** in **ID** as well as the set value of **PAT TYPE** must not exceed the length of the barcode.



- 2 If **START/END** is set to **0**, the patient ID will not be updated by using barcode scanner.
- 3 If **PAT TYPE** is set to **0**, the patient type will not be updated by using barcode scanner.
- 4 Barcodes containing characters other than digits or containing space will be considered invalid and cannot be identified. If any invalid character is detected, a message box indicating “**Special signs are in code bar!**” will pop up.
- 5 Connect the barcode scanner to the monitor and wait 10 seconds before starting the scanner.
- 6 Refer to the accompanying operator’s manual of the scanner for more information about its usage.

**EXIT:** Exit the menu.

- **SAVE CURRENT AS USER CONFIG:** Save the current setup as the user default configuration.

## Factory Maintain

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

### Calibrating NIBP

NIBP is not user-calibrated. NIBP pressure transducers must be verified at least once every two years by a qualified service professional, and calibrated, if necessary. See the Service Manual for details.

## 4.12 Data Store

The monitor can support the USB storage for the Data Store function. Enter the menu by **SYSTEM MENU > DATA STORE** to set the data storing function. You can set the storing interval, browse data, search data, and delete all the data or single item data.

- ◆ **ON/OFF:** set the Data Store function to **ON** or **OFF**.

Data stored in U disk consists of several folders, when the capacity of each ID folder exceeds 512KB, it will create a new folder and continue to store data. Data quantity depends on the capacity of U disk. When U disk is full, the monitor will prompt an alarm “Disk is not enough.” U disk can’t store waves.

---

### **WARNING**

---

- 1 If you want to stop the data storing function, you should set this item to **OFF** before unplugging the USB disk.
  - 2 Do not unplug the USB storage when storing data. If the data damaged by unplugging the USB storage during data storing can not be deleted on the monitor, the user can delete them on the PC.
- 

### **NOTE:**

If you set the item to **ON**, after restarting the monitor, this item will store data

automatically, otherwise you will have to manually store data.

◆ **INTERVAL**: set the storing interval by this item, it can be set to **1S**, **5S**, **10S**, **30S**, **1MIN** or **5MIN**.

◆ **MANAGEMENT**: select **BROWSE** to browse data stored before.

— **DELETE ALL**: select this item to delete all the data stored before. The dialog box displays: **All records will be deleted, OK?**

Select **YES** to delete all the data.

— **UP-DOWN**: select this item, then turn the page by pressing the UP or DOWN button to browse data.

— **SEARCH**: search data by patient ID, date and time.

— **RETURN**: select this item to return to the previous menu.

Select the single item data in **DATA BROWSER** menu; press **OK** to display the f menu.

The user can select to browse the **TREND TABLE**, **TREND GRAPH** or **ALARM LIST**.

The user can select **DELETE** to delete the single item data; or select the **RETURN** to return to the previous menu.

#### **NOTE:**

The data which is being stored can not be browsed in real time. Before searching data, you should turn off the **Data Store** function at first.

## **4.13 Sleep Mode**

### **Entering the Sleep Mode**

Select **SYSTEM MENU** > **SYSTEM SETUP** > **STANDBY** and configure the item to **ON**. Then you will see the dialogue after pressing the switch for less than 1s: **Enter sleep mode, yes?**

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

#### **NOTE:**

When the **SYSTEM SETUP** > **STANDBY** is **OFF**, or the monitor is in **DEMO** mode, or there is any inputting signal, pressing the **ON/OFF** button can not make the monitor enter the sleep mode.

### **Quitting the Sleep Mode**

In the sleep mode, if a new signal occurs or you press any button on the front panel, the monitor will enter the working mode.

#### **NOTE:**

- 1 If the following situation occurs, monitor will return to normal monitoring mode automatically: The monitor receives physiological signal of SpO<sub>2</sub>, and lasts for 5 s; 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 Sleep 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.

---

## 5.1 Alarm Modes

### 5.1.1 Alarm Level

Each alarm, either technical or physiological, has its own level. For alarm of higher level, when the alarm condition is active, the system will give a prompt in various ways. 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 problem in technical respect. It is the most serious alarm.

Medium-level alarm means serious warning.

Low-level alarm is a general warning.

The monitor provides two types of alarm: physiological alarms and technical alarms. Also, the monitor provides prompts. 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 certain monitoring process technically impossible or make monitoring result unbelievable. The monitor can give the character indication of monitoring process or other functions. And this character is called prompts.

The alarm levels for technical alarms and some physiological alarms are pre-set by the system and cannot be changed by the user in most of the cases. But you can alter the alarm level for **SpO<sub>2</sub> SENSOR OFF**. For more information, please refer to *SpO<sub>2</sub> SETUP* in 4.11 Maintain.

### 5.1.2 Alarm Modes

When 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 prompt is 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 monitor will give alarm prompt on the screen indicating the occurrence of alarm.

The description will display in Information area, such as “\*\*\*NS TOO HIGH”, and displays beside the parameter to indicate the low-medium level alarm.



Technical alarm will not prompt \* signal.

Alarm Level	Visual Prompt
High	1:  displays in Parameter area 2: *** displays in the information area (Physiological alarm only)
Medium	1:  displays in Parameter area 2: ** displays in the information area (Physiological alarm only)
Low	1:  displays in Parameter area 2: * displays in the information area (Physiological alarm only)

### Lamp light

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

Alarm Level	Visual Prompt
High	Alarm indicator flashes in red with the frequency of (1.4~2.8) Hz.
Medium	Alarm indicator flashes in yellow with the frequency of (0.4 ~0.8) Hz.
Low	Alarm indicator lights on in yellow.

### Alarm Sound

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

Alarm Level	Audio Prompt
High	Mode is “beep-beep-beep-----beep-beep, beep-beep-beep-----beep-beep”, which is triggered once every 5 s.
Medium	Mode is “beep-beep-beep”, which is triggered once every 25 s.
Low	Mode is “beep-”, which is triggered once every 30 s.

The sound pressure range for audible alarm signals is from 45 dB to 85 dB.

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

Select the **ALARM SETUP** in the **SYSTEM MENU** to open the submenu.

#### ◆ Alarm setup of each parameter

You can turn **ON** or **OFF** the alarm for each parameter, and set the upper and lower alarm limit for each parameter by **ALM HI** or **ALM LO**.

In the **ALARM SETUP** menu, set the alarm limit for each parameter.

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

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

Step 2: Select the **ALM HI** (higher alarm limit of **SYS**), **ALM LO** (lower alarm limit of **SYS**).

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

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

#### ◆ ALM REC and ALM REC TIME

By configuring **ALM REC**, 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 happens. If the item is **OFF**, the monitor will not automatically output the alarm information.

Additionally, if **ALM REC** is **ON**, you can also adjust the recording time of the alarm waveform to be outputted by setting **ALM REC TIME**. Available options are **8s**, **16s** and **32s**.

#### ◆ ALARM RESET

Selecting **ALARM RESET** in **ALARM SETUP**, the function of resetting alarm can be enabled.

After the alarm is reset, the monitor will stop auditory alarm including physiological alarm and technical alarm; the visual alarm indications are still displayed in information area; auditory alarm will prompt if a new alarm occurs.

## 5.2 Alarm Cause

Alarm occurs when:

1. Physiological alarm is evoked;
2. Technical alarm is evoked;

#### ◆ 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 Audio Alarm Paused

To activate the audio alarm paused function, you can select **SYSTEM MENU > MAINTAIN > USER MAINTAIN > OTHER SETUP > ALARM SETUP**, and set **AUDIO ALARM PAUSED** to **60S**, **120S** or **180S** (The default duration of auditory alarm pause is 120S), then press the button  on the front panel to pause audio alarm. During the audio alarm paused status:

- ◆ In the information area, the monitor displays audio alarm off icon  and **AUDIO PAUSED XXX S** with a yellow background.
- ◆ The button  on the front panel always flashes.
- ◆ The audio alarm is paused, and no alarms are sounding.
- ◆ The visual alarm indications are still displayed.
- ◆ Other audible signals are not affected, including beat volume, key volume.

Auditory alarm will resume when you press the button again or the paused time terminates.


When **AUDIO ALARM PAUSED** is set to **OFF**, this function is inactivated. The monitor has no response if you press the button .



**NOTE:**


If a new alarm occurs during the audio alarm paused status, the new alarm will not be sounding.


## 5.4 Audio Alarm Off

To activate the audio alarm off function, you can select **SYSTEM MENU > MAINTAIN > USER MAINTAIN > OTHER SETUP > ALARM SETUP**, and set **AUDIO ALARM OFF** to

**ON**, then press the button  on the front panel and hold it for more than three seconds to turn off audio alarm. During the audio alarm off status,

- ◆ In the information area, the monitor displays the audio alarm off icon  and **AUDIO ALARM OFF** with a red background.
- ◆ The button  on the front panel flashes in yellow, with frequency of (0.5~1) Hz.
- ◆ The audio alarm is turned off, and no alarms are sounding.
- ◆ The visual alarm indications are still displayed.
- ◆ Other audible signals are not affected, including beat volume, key volume.

Pressing the button  again can resume the audio alarm.

When **AUDIO ALARM OFF** is set to **OFF**, this function is inactivated. The monitor has no response if you press the button .

### NOTE:

If a new alarm occurs during the audio alarm off period, the new alarm will not be sounding.

## 5.5 Alarm Reset

To reset the alarm, you can select **SYSTEM MENU > ALARM SETUP > ALARM RESET**. After resetting the alarm,

- ◆ The audio alarm is turned off, and no alarms are sounding.
- ◆ The visual alarm indications are still displayed.
- ◆ It will not influence the configuration of physiological alarm off, audio alarm paused and audio alarm off status.

### NOTE:

If a new alarm occurs after the alarm is reset, the new alarm will be sounding.



## 5.6 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.

The setup for parameter alarms is in the menus. In the **SYSTEM 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 limit. The following actions take place:

1. Alarm message displays on the screen as described in alarm mode;
2. The monitor beeps in its corresponding alarm class and volume;
3. Alarm lamp flashes.

## 5.7 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 cause of alarm has been over, check that the alarm is working properly.

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

## 5.8 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 and Recording

In **SELECTION** submenu, the user can set the displayed contents to waveform, trend table or alarm list which can be printed out via **RECORD**.

### 6.1 General Information on Recording

A thermal dot matrices recorder with printout paper of 48mm wide is used for the monitor.

#### Performance of the Recorder:

Set the displayed content via **SYSTEM MENU > SELECTION**, trend table or alarm list. Then print it via **RECORD**.

Press the **RECORD** to print out the currently displayed content. Press the **UP/DOWN** button to page up or down the screen, then press **RECORD** to print it out.

The real-time waveform of 8s can be printed out.

#### NOTE:

- 1 You can press the **RECORD** on the control panel to stop the current recording process.
- 2 It is suggested that the user should not use the recorder when the low battery displays, or the monitor may be turned off automatically.

### 6.2 Recorder Operations

#### Record Paper Requirement

Only standard thermosensitive record paper can be used, otherwise the recorder may not function, the recording quality may be poor, and the thermosensitive printhead may be damaged.

#### Proper Operation

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

#### Paper Out

When **OUT OF PAPER** alarm is displayed, the recorder can not start. Please insert record paper properly.

#### Inserting Paper

- ◆ Pull outwards the upper arc part of the recorder casing to release the casing.
- ◆ Insert a new roll of paper into the paper cassette, printing side facing upwards.
- ◆ Ensure proper position and tidy margin.
- ◆ Pull about 2cm of the paper out, and then close the recorder casing.

**NOTE:**

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

**Removing Paper Jam**

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

- ◆ Cut the record paper from the feeding edge.
- ◆ Open the recorder casing.
- ◆ Re-insert the paper.

**6.3 Recorder Alarm Information**

Technical Alarm:

Message	Cause	Alarm Level	What to do
Recorder Out Of Paper	Recorder Out Of Paper	Low	Please install the paper.
Recorder setup needed	The user presses the <b>RECORD</b> button when the monitor is not installed with a recorder.	Low	Notify the manufacturer's service staff to install and set the recorder.

## Chapter 7 Maintenance/Cleaning

### **WARNING**

- 1 Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- 2 If you discover a problem with any of the equipment, contact your service personnel, or your authorized supplier.

### 7.1 Inspecting

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

The following items should be checked:

- If the environment condition and power supply meet requirement.
- If the power supply cord has damage and insulativity meets requirement.
- If the device and accessories have damage.
- Specified accessories.
- If the alarm system can work properly.
- If the recorder can work properly and the paper meets the requirement.
- Battery performance
- If all monitoring functions are in good conditions.
- If the grounding resistance and leakage current meet requirement.

If any damage or abnormality is found, please don't use the monitor and contact local Customer Service Center.

### 7.2 Maintenance Task and Test Schedule

Maintenance shall be carried out at least once every two years, or as specified by local regulations. The following tasks are for EDAN-qualified service professionals only. Contact an EDAN-qualified service provider if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance and Test Schedule	Frequency
Safety checks. Selected tests on the basis of IEC60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped.

Maintenance and Test Schedule	Frequency
Check all monitoring functions and measuring functions	At least once every two years, or as needed.

## 7.3 General Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

### 7.3.1 Cleaning the Monitor

#### **WARNING**

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

To surface-clean the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain..
3. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains..
4. Dry the monitor in a ventilated and cool place.

### 7.3.2 Cleaning the Reusable Accessories

#### 7.3.2.1 Cleaning the Blood Pressure Cuff

##### **Cleaning the Cuff:**

1. Take out the air bladder before cleaning.
2. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution. until no visible contaminants remain
3. Rinse the cuff and wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.

4. Wipe off with a dry cloth to remove residual moisture
5. Air dry the cuff thoroughly after cleaning.

**Replacing the Air Bladder:**

After cleaning, replace the air bladder into the cuff following the steps below:

1. Roll the bladder lengthwise and insert it into the cuff from the large opening at one end of the cuff.
2. Thread the hose from within the cuff and out through the small hole at the top of the cuff.
3. Adjust the bladder until it is in position.

**7.3.2.2 Cleaning the SpO<sub>2</sub> Sensor**

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution. until no visible contaminants remain
3. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
4. Wipe off with a dry cloth to remove residual moisture.
5. Leave the sensor to air dry.

**7.3.2.3 Cleaning the TEMP Sensor**

1. Wipe the patient contact area with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
3. Wipe off with a dry cloth to remove residual moisture.
4. Leave the sensor to air dry.

**7.4 Disinfection**

For devices or accessories that have been in contact mucosal surface, High Level disinfection must occur, for all other accessories, low level disinfection is appropriate. Clean the monitor and reusable accessories before they are disinfected. The validated disinfectants for cleaning the monitor and reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)
- Cidex OPA (High level disinfection of intracavitary temperature probe only)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

---

**WARNING**

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The monitor and reusable accessories shall be disinfected to avoid patient cross infection.

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## 7.4.1 Disinfecting the Monitor

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**WARNING**

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Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.

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To disinfect the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.
3. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
4. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
5. Dry the monitor for at least 30 minutes in a ventilated and cool place.

## 7.4.2 Disinfecting the Reusable Accessories

### 7.4.2.1 Disinfecting the Blood Pressure Cuff

#### **Disinfecting the Cuff:**

1. Take out the air bladder before disinfection.
2. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.
3. Leave the cuff and air bladder to air dry for at least 30 minutes.

#### **NOTE:**

Prolonged use of disinfectant may cause discoloration of the cuff.

#### **Replacing the Air Bladder:**

After disinfection, replace the air bladder into the cuff. Refer to Section 7.3.2.1 for more information.

### 7.4.2.2 Disinfecting the SpO<sub>2</sub> Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
3. Wipe off the disinfection solution with a dry cloth after disinfection.
4. Leave the sensor to air dry for at least 30 minutes.

### 7.4.2.3 Disinfecting the TEMP sensor

The intracavitary TEMP sensors should be reprocessed by high-level disinfection before and after use on each new patient. Cidex OPA is the validated agent for high level disinfection. Refer to the instructions of the disinfectant for the methods of disinfection. High level disinfection has been validated with a 12 minute soak. Rinse and dry according to the labeled instructions of Cidex OPA. Do not dampen the sensor connector.

For the skin TEMP sensors, disinfect them as follows using ethanol or isopropanol only:

1. Wipe the patient contact area with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the sensor to air dry.

## 7.5 Replacement of Fuse

Unscrew the fuse cap anticlockwise, replace the fuse (protector tube) and screw down the fuse cap clockwise. Fuse size:  $\Phi 5 \times 20$ , Rated value: T2.0 AH250 VP.

### NOTE:

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

## 7.6 Cleaning Battery and Battery Compartment Cover

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



## Chapter 8 SpO<sub>2</sub> Monitoring (Optional)

### 8.1 What is SpO<sub>2</sub> Monitoring

The monitor uses oximetry to measure functional oxygen saturation in the blood. SpO<sub>2</sub> 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 a SpO<sub>2</sub> oxygen saturation of 97%. The SpO<sub>2</sub> numeric on the monitor will read 97%. The SpO<sub>2</sub> numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO<sub>2</sub>/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

#### How the SpO<sub>2</sub>/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<sub>2</sub> 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 905 nm. The power of the sensor LED is less than 15 mW.

---

#### **WARNING**

Pulse oximetry can overestimate the SpO<sub>2</sub> value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.

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#### SpO<sub>2</sub>/Pulse Monitoring

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#### **WARNING**

- 1 ES (Electrosurgery) equipment wire and SpO<sub>2</sub> cable must not be tangled up.
  - 2 Do not put the sensor on extremities with arterial catheter or venous syringe.
- 

#### **NOTE:**

Do not perform SpO<sub>2</sub> 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<sub>2</sub> value.

## 8.2 Precautions during SpO<sub>2</sub>/Pulse Monitoring

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### **WARNING**

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- 1 Verify sensor cable fault detection before beginning of monitoring phase. Unplug the SpO<sub>2</sub> sensor cable from the socket, the screen will display the error message **SpO<sub>2</sub> SENSOR OFF** and the audible alarm is activated.
  - 2 If the SpO<sub>2</sub> sensor can not work properly, please reconnect the sensor or change a new one.
  - 3 Do not use the SpO<sub>2</sub> 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 neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. More frequent examinations may be required for different patients.
  - 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 The sensor complies with the EN ISO 10993-1: 2009 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<sub>2</sub> waveform is not proportional to the pulse volume.
- 5 Don't use the functional simulator to assess the SpO<sub>2</sub> accuracy
- 6 When the SpO<sub>2</sub> value is potentially incorrect, it will display "---".
- 7 The equipment is calibrated to display functional oxygen saturation.

## 8.3 Monitoring Procedure

### **SpO<sub>2</sub> plethysmogram measurement**

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient finger.
3. Plug the connector of the sensor extension cable into the SpO<sub>2</sub> socket on the SpO<sub>2</sub> module.

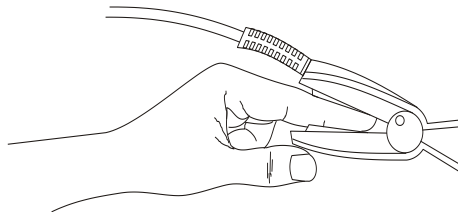


Figure 8-1 Mounting of the Sensor

## 8.4 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 carboxyhemoglobin and methemoglobin
- ◆ Low SpO<sub>2</sub>
- ◆ Circular perfusion is not good for test part
- ◆ It is recommended to use SpO<sub>2</sub> sensors described in *Chapter 12 Accessories*.

## 8.5 Assessing the Validity of a SpO<sub>2</sub> Reading

You can check the quality of the pleth wave and the stability of the SpO<sub>2</sub> values to assess whether the sensor functions properly and whether the SpO<sub>2</sub> readings are valid. Always use these two indications simultaneously to assess the validity of a SpO<sub>2</sub> reading.

Generally, the quality of the SpO<sub>2</sub> pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO<sub>2</sub> values also reflects the signal quality. Different from varying SpO<sub>2</sub> readings caused by physiological factors, unstable SpO<sub>2</sub> readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO<sub>2</sub> readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

**NOTE:**

- 1 The SpO<sub>2</sub> accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies composed of local healthy men and women from age 19 to 37(for EDAN SpO<sub>2</sub> module), from 18 to 50 (for Nellcor SpO<sub>2</sub> module), with various skin pigmentations.
- 2 The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).

## 8.6 SpO<sub>2</sub> Alarm Delays

There is a delay between a physiological event at the measurement site and the corresponding alarm at the monitor. This delay has two components:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.
2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system delay time.

## 8.7 PI\*

**\* Only applicable to the EDAN SpO<sub>2</sub> module.**

PI is a numeric value indicating perfusion level. It reflects the perfusion level at the monitoring site.

As the measurement of SpO<sub>2</sub> is based on the pulsation caused by the blood flow through the vessel, PI is in relation to the strength of the pulse. Also, you can use PI as a signal quality indicator for the measurement of SpO<sub>2</sub>.

PI is indicated by a value ranging from 0 to 10. The bigger the value is, the better the perfusion and the signal quality will be. The perfusion level and the signal quality are at their maximum when the value reaches 10. When PI is below 2, it indicates the low perfusion and the poor signal quality at the monitoring site; you need to reposition the sensor or find a better site.

The PI value will be displayed on the SpO<sub>2</sub> waveform area.

## 8.8 SatSeconds Alarm Management\*

**\* Only applicable to the Nellcor SpO<sub>2</sub> module.**

### 8.8.1 Describing SatSeconds

With traditional alarm management, upper and lower alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated by as little as one percentage

point, an alarm is immediately triggered. When the SpO<sub>2</sub> level fluctuates near an alarm limit, the alarm is triggered each time the limit is violated. Such frequent alarms can be distracting.

With the SatSeconds technique, upper and lower SpO<sub>2</sub> alarm limits are set in the same way as traditional alarm management. However, you can also set a SatSeconds limit that allows monitoring of SpO<sub>2</sub> below the selected lower alarm limit and above the selected upper alarm limit for a period of time before an alarm is triggered.

The method of calculation is as follows:

The number of percentage points that the SpO<sub>2</sub> falls outside the alarm limit is multiplied by the number of seconds that the SpO<sub>2</sub> level remains outside that limit. This can be stated as an equation:

$$\text{Points} \times \text{Seconds} = \text{SatSeconds}$$

Where:

Points = SpO<sub>2</sub> percentage points outside of the limit

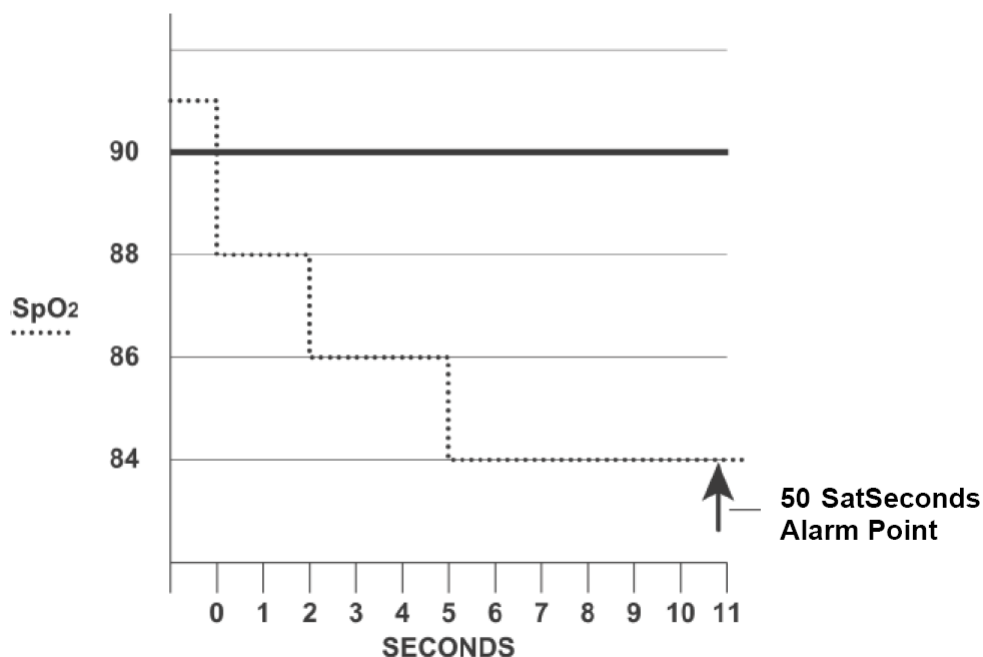
Seconds = number of seconds that SpO<sub>2</sub> remains at that point outside of the limit

The alarm response time, assuming a SatSeconds limit set at 50 and a lower alarm limit set at 90, is described and illustrated below.

In this example, the SpO<sub>2</sub> level drops to 88 (2 points below the limit) and remains there for a period of 2 seconds (2 points  $\times$  2 seconds = 4 SatSeconds). The SpO<sub>2</sub> then drops to 86 for 3 seconds and then to 84 for 6 seconds. The resulting SatSeconds values are shown below:

SpO <sub>2</sub>		Seconds		SatSeconds
2	$\times$	2	=	4
4	$\times$	3	=	12
6	$\times$	6	=	36
Total SatSeconds				= 52

After approximately 10.7 seconds, a SatSeconds alarm will be triggered, because the limit of 50 SatSeconds has been exceeded. See arrow (↑) in the following figure.



Alarm Response with SatSeconds

Saturation levels may fluctuate rather than remaining steady for a period of several seconds. Often, the patient SpO<sub>2</sub> may fluctuate above and below the alarm limit, re-entering the non-alarm range several times. During such fluctuation, the monitor integrates the number of SpO<sub>2</sub> points, both positive and negative, until either the SatSeconds limit is reached, or the patient SpO<sub>2</sub> returns within a normal range and remains there.

### 8.8.2 SatSeconds “Safety Net”

The SatSeconds “Safety Net” is for patients whose saturation makes frequent excursions below or above the SpO<sub>2</sub> limit but does not remain in violation long enough for the SatSeconds limit to be reached. If three or more SpO<sub>2</sub> alarm limit violations occur within a 60-second period, an alarm will be triggered even if the SatSeconds limit has not been reached.

### 8.8.3 Setting SatSeconds Duration

You can set **SatSeconds** to **Off** or to the duration among **10**, **25**, **50** and **100**. To configure the SatSeconds settings, enter the **SpO<sub>2</sub> Setup** menu and select the desired SatSeconds setting from the **SatSeconds** list.

## 8.9 Alarm

### 8.9.1 Adjustable Range of Alarm Limits

SpO<sub>2</sub>/ PR adjustable range of alarm limits:

Parameter	Max. Upper Limit	Min. Lower Limit	Step
SpO <sub>2</sub>	100	0	1
PR	300	30	1

Default SpO<sub>2</sub> alarm limits:

	<b>Max. Upper Limit</b>	<b>Min. Lower Limit</b>	<b>Step</b>
ADU	100	90	1
PED	100	90	1
NEO	95	88	1

Default PR alarm limits:

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

## 8.9.2 Alarm Information and Prompts

Physiological alarm:

<b>Message</b>	<b>Cause</b>	<b>Alarm Level</b>
SpO <sub>2</sub> HIGH	SpO <sub>2</sub> measuring value is above upper alarm limit.	Medium
SpO <sub>2</sub> LOW	SpO <sub>2</sub> measuring value is below lower alarm limit.	Medium
PR HIGH	PR measuring value is above upper alarm limit.	Medium
PR LOW	PR measuring value is below lower alarm limit.	Medium
NO PULSE	Sphygmie signal from the measured position is too weak; the monitor does not detect any sphygmie signal.	High

Technical alarms:

<b>Message</b>	<b>Cause</b>	<b>Alarm Level</b>	<b>What to do</b>
SpO <sub>2</sub> SENSOR OFF	The SpO <sub>2</sub> sensor may be disconnected from the patient.	Low	Make sure the sensor is attached to the patient's finger or another appropriate position.
SpO <sub>2</sub> COMM STOP	SpO <sub>2</sub> module failure or communication failure	High	Stop using measuring function of SpO <sub>2</sub> module; notify biomedical engineer or manufacturer's service staff.

Message	Cause	Alarm Level	What to do
SpO <sub>2</sub> LOW PERFUSION	The measured signals coming from pulse are too weak.or the pressure on measured site is too low.	Low	Reconnect the sensor, or choose another measured position. If the problem remains, please notify biomedical engineer or manufacturer's service staff.
NO SpO <sub>2</sub> SENSOR	SpO <sub>2</sub> sensor was not connected well or connected to the monitor, or the connection is loose.	Low	Reconnect the sensor with the monitor. Make sure the monitor is well connected with the cable.
SpO <sub>2</sub> NOISY SIGNAL	There is interference with SpO <sub>2</sub> measurement signals and the waveform is abnormal.	Low	Check the condition of patient and avoid patient movement; make sure the cable is well connected.

## Prompts:

Message	Cause
SEARCH PULSE	SpO <sub>2</sub> sensor may be disconnected from the patient or the monitor.



## Chapter 9 NIBP Monitoring (Optional)

### 9.1 Overview

This monitor uses the oscillometric method for measuring NIBP. It can be used for adult, pediatric and neonatal patients. It is also intended for use with pregnant, including pre-eclamptic 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.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI/ISO 81060-2:2013) in relation to mean error and standard deviation.

### 9.2 NIBP Safety Information

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#### **WARNING**

1. Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
  2. Do not measure NIBP on the arm of the same side with a mastectomy.
  3. Use clinical judgment to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
  4. Ensure that the correct setting is selected when performing measurements on children. It may be dangerous for the neonate to use an over pressure level. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.
  5. Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, pediatric or neonate.)
  6. Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
  7. Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.
  8. Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.
  9. NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.
  10. Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.
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-

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**WARNING**

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11. 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.
- 

**NOTE:**

- 1 The equipment is suitable for use in the presence of electrosurgery.
- 2 Verifying the calibration is only applicable for adults, and it can not be operated in automatic measuring interval. Continuous measuring can not be operated in automatic measuring interval either.
- 3 Please use the proper type of cuff as recommended in this manual, or the wrong type may lead to injury on patient, especially when measuring neonate.
- 4 Continuous use of the automatic measuring mode for short interval may lead to the discomfort of patient. Continuous measuring and automatic measuring in neonatal or pediatric mode may result in tissue damage or ischemia to the patient.
- 5 It is suggested that the user should not start NIBP measuring when the low battery displays, or the monitor may be turned off automatically.
- 6 If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.
- 7 NIBP measurement can be affected by extremes of temperature, humidity and altitude.
- 8 NIBP measurement value should be explained by qualified professionals.

### **9.3 NIBP Monitoring**

To obtain accurate measurements, the following operating steps need to be observed:

1. Ensure the patient position in normal use, including
  - ◆ Comfortably seated(or lie flat on back)
  - ◆ Legs uncrossed
  - ◆ Feet flat on the floor
  - ◆ Back and arm supported
  - ◆ Middle of the cuff at the level of the right atrium of the heart
2. Make sure the patient relaxes as much as possible and does not talk during the measurement.
3. Five minutes should elapse before the first reading is taken.

**NOTE:**

If a NIBP measurement is suspected, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.

To start the measurement:

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

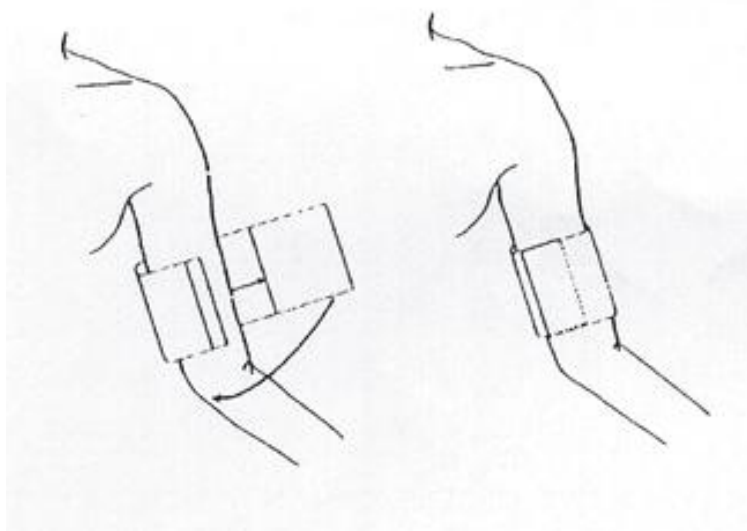


Figure 9-1 Applying Cuff

**NOTE:**

The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80%-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.

- ◆ Make sure that the cuff edge falls within the range of mark <—>. If it does not, use a larger or smaller cuff that fits better.
3. Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible you should apply the following corrections to the measured values:
    - ◆ If the cuff is placed higher than the heart level, add 0.75 mmHg (0.10 kPa) for each inch of difference.
    - ◆ If it is placed lower than the heart level, deduct 0.75 mmHg (0.10 kPa) for each inch of difference.
  4. Check whether the patient mode is appropriately selected. Access **PATIENT SETUP** menu from **SYSTEM MENU** and pick **PAT TYPE** item and select the required patient type.
  5. Select a measurement mode in the **NIBP SETUP** menu. Pick the **INTERVAL** item for **MANUAL** or set the interval for auto measurement; or select the **CONTINUAL** mode.

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

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### **WARNING**

Prolonged non-invasive blood pressure measurements in automatic mode may be associated with purpura, 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.

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## **Operation Prompts**

1. To start auto measurement:

Access **NIBP SETUP** menu and pick the **INTERVAL** item, in which the user may set up the time interval for auto measurement. After that, press the **NIBP START/STOP** on the front panel to start the auto measurement according to the selected time interval.

2. To stop auto measuring:

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

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### **WARNING**

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

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3. 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.

4. 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.

5. To stop measuring:

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

---

### **WARNING**

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

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**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	160 mmHg	140 mmHg	100 mmHg

**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 300 bpm.

## 9.4 NIBP Setup

Select **SYSTEM MENU >NIBP SETUP** and you will see the menu:

- ◆ **INTERVAL:** Set it to **MANUAL**, **AVG** or **1/2/3/4/5/10/15/30/60/90/120/240/480** min.  
When **Interval** is set to **AVG**, the monitor provides the result by averaging the values obtained from three or five times of NIBP measurement.

- ◆ **STAT**

Once this item is selected, the menu will automatically exit from the screen and the monitor will perform continuous measurement immediately.

## 9.5 Alarm

### 9.5.1 Adjustable Range of Alarm Limits

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 ~230 mmHg

DIA 10 mmHg ~180 mmHg

MAP 20 mmHg ~195 mmHg

Neonatal Mode

SYS 40 mmHg ~ 135 mmHg

DIA 10 mmHg ~ 100 mmHg

MAP 20 mmHg ~ 110 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

When the monitor is configured to NIBP only measuring mode, the PR is displayed in the **ALARM SETUP** menu.

The range of PR alarm limit:

	<b>Max. Upper Limit (bpm)</b>	<b>Min. Lower Limit (bpm)</b>	<b>Step (bpm)</b>
PR	240	40	1

Default PR alarm limit:

	<b>Max. Upper Limit (bpm)</b>	<b>Min. Lower Limit (bpm)</b>	<b>Step (bpm)</b>
ADU	120	50	1
PED	160	75	1
NEO	200	100	1

## 9.5.2 Alarm Information and Prompts

Physiological alarms:

<b>Message</b>	<b>Cause</b>	<b>Alarm Level</b>
NS HIGH	NIBP SYS measuring value is above upper alarm limit.	Medium
NS LOW	NIBP SYS measuring value is below lower alarm limit.	Medium
ND HIGH	NIBP DIA measuring value is above upper alarm limit.	Medium
ND LOW	NIBP DIA measuring value is below lower alarm limit.	Medium
NM HIGH	NIBP MAP measuring value is above upper alarm limit.	Medium
NM LOW	NIBP MAP measuring value is below lower alarm limit.	Medium

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

<b>Message</b>	<b>Cause</b>	<b>Alarm Level</b>	<b>What to do</b>
NIBP COMM ERR	NIBP module failure or communication failure.	High	Stop using measuring function of NIBP module; notify biomedical engineer or Manufacturer's service staff.
LOOSE CUFF	Cuff is no properly wrapped or no cuff exists.	Low	Properly wrap the cuff

Message	Cause	Alarm Level	What to do
AIR LEAK	During the leakage test, the leakage ratio exceeds 6 mmHg/min.	Low	Check and replace the leaking parts, if required, notify biomedical engineer or manufacturer's service staff.
NIBP PRESSURE ERROR	Decline of air pressure is less than 2 mmHg after 6 deflations.	Low	Check whether the airway is occluded or pressure sensor works properly in pressure meter mode. If the problem still exists, contact your service personnel.
WEAK SIGNAL	Cuff is too loose or patient pulse is too weak.	Low	Use other method to measure blood pressure.
NIBP Range Exceeded	Maybe the patient blood pressure value is beyond the measurement range.	High	Maybe the patient blood pressure value is beyond the measurement range.
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.
NIBP Self Test Error	When the monitor is powered on, NIBP module is detected to fail in calibration.	High	Contact your service personnel.
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.
NIBP System Failure	Start up measurement, manometer and leakage test, and NIBP fail in calibration.	Low	Contact your service personnel.
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 SECONDARY OVER PRESSURE	Secondary over pressure protection	High	Notify biomedical engineer or manufacturer's service staff.



<b>Message</b>	<b>Cause</b>	<b>Alarm Level</b>	<b>What to do</b>
CUFF TYPE ERR	Cuff type does not comply with the patient type.	Low	Select appropriate cuff type
NIBP TIME OUT	Measuring time has exceeded the specified time.	Low	Measure again or use other measuring method.

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

<b>Message</b>	<b>Cause</b>
Manual measuring...	During manual measuring mode.
Continual Measuring	In continuous measuring mode.
Auto measuring...	During automatic measuring mode.
Measurement over	Measurement over
Calibrating...	During calibrating
Calibration over	Calibration over
Leak testing...	During leakage test
Leak test over	Leakage test is over
Resetting...	NIBP module in resetting

## Chapter 10 TEMP Monitoring (Optional)

### 10.1 TEMP Monitoring with T2 Module

#### 10.1.1 Introduction

M3 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.
- ◆ 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.
- ◆ Switch on the monitor.
- ◆ It takes 5min for the body temperature to stabilize.

---

#### **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 Verification of the temperature module is necessary 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 activity has ended.
-

**WARNING**

- 6 Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.
- 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.
- 10 In monitoring mode, no physiological alarms are available.

**NOTE:**

The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1: 2009.

**10.1.2 Measuring Procedure**

Ensure the sensor is well installed. The icon indicating measuring position flashes in TEMP parameter area on the main interface. If necessary, change the **MEASURE MODE** and **MEASURE POS** (measure position) in menu.

Take out the sensor from the sensor bracket. After warm-up, it beeps and displays **WARM-UP OVER** in information area.

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.

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.

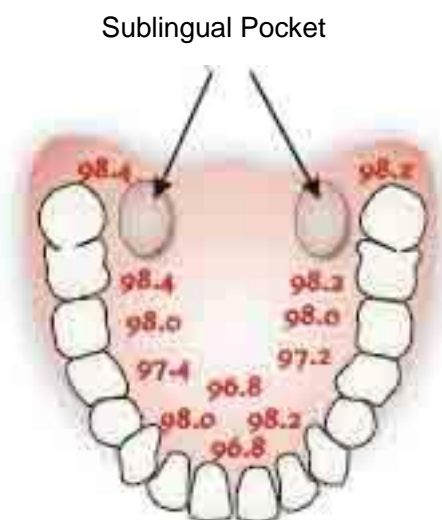


Figure 10-1 Measuring position in mouth

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

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.

If the predict measuring is successfully finished, the monitor enters **MONITOR** mode after 30s; otherwise the monitor enters **MONITOR** mode immediately after the predict measuring. The monitoring state lasts for 10 min, and then the monitor enters waiting state. — — — displays in the TEMP parameter area on interface. Put the sensor back into the sensor bracket.

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 reference body site temperature is the same as the temperature of the measuring site.

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.

### **10.1.3 TEMP Setup for T2 Module**

Click on the **TEMP SETUP** in the **SYSTEM MENU** to set the following items:

- ◆ **MEASURE MODE:** Set the measuring mode to **PREDICT** or **MONITOR**.
- ◆ **MEASURE POS:** Set the measuring position to **ORAL**, **AXILLARY** or **RECTA**. The axillary sensor can be used for measuring oral/axillary temperature, while the rectal sensor for measuring rectal temperature.

### **10.1.4 Alarm**

#### **10.1.4.1 Adjustable Range of Alarm Limits**

Patient Type	Measure position	ALM HI	ALM LO	Step
ADU	Oral/Axillary/Rectal	+42 °C (+107.6 °F)	+35.5 °C (+95.9 °F)	+0.1 °C
PED	Oral/Axillary/Rectal	+42 °C (+107.6 °F)	+35.5 °C (+95.9 °F)	+0.1 °C

#### **10.1.4.2 Alarm Information and Prompts**

##### **WARNING**

In monitoring mode, no physiological alarms are available.

## 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 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 exceed limit	The TEMP value is beyond the range of 35.5 °C ~ 42 °C	Medium	Put the sensor into the sensor bracket, take it out and measure again.
No TEMP SENSOR	TEMP sensor is not connected to the TEMP module.	Low	Connect the sensor and the monitor well, and measure again.
Ambient temp too high	The Sensor temperature is higher than +40 °C	Low	Put the sensor into the sensor bracket, measure again after the ambient temperature reaches normal value.
Ambient temp too low	The Sensor temperature is lower than +10 °C	Low	
PROBE ERROR	The probe cannot be identified.	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.
Warm-up error	Malfunction in the warm-up circuit	Medium	

Prompt:

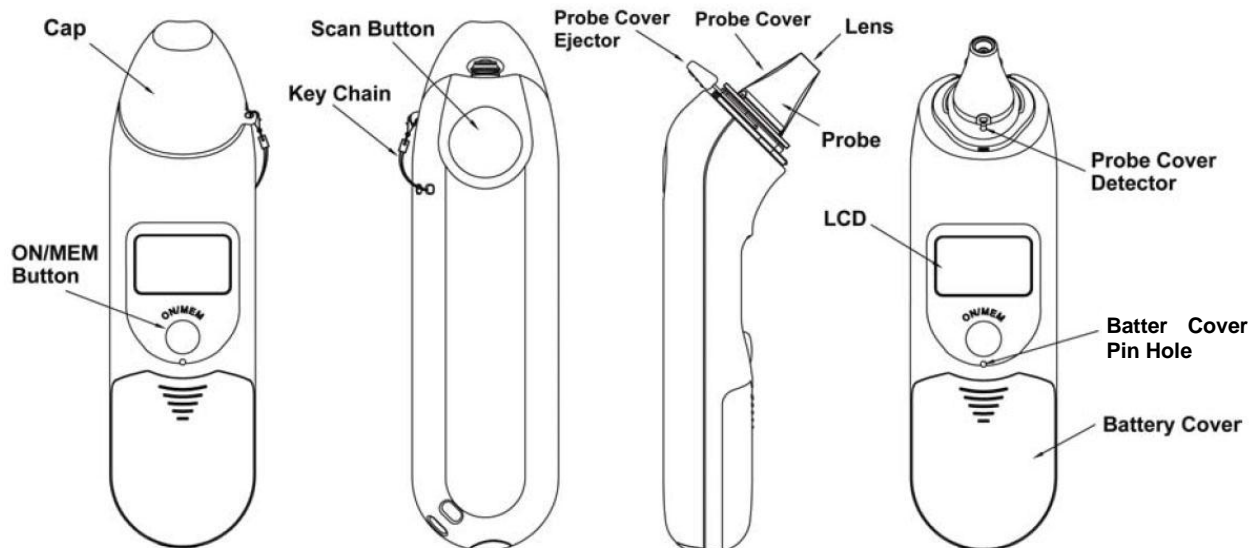
Message	Cause
Warm-up over	The monitor prompts it after taking the sensor out of the bracket and warm-up is over.
Measure over	After the Predict measuring is over, the data and message display on the interface.
Measure time out	No measuring result after the module entering Predict state for 30 s.
Probe temp too high	The original temperature of sensor $>+33\text{ }^{\circ}\text{C}$ and $\leq +40\text{ }^{\circ}\text{C}$ .
Temp SENSOR OFF	The probe is disconnected from the patient.

## 10.2 TEMP Monitoring with TH Module

### 10.2.1 Introduction

M3 with the TH module (Infrared Ear Temperature Module) takes a temperature in the ear.

#### Diagram of the Infrared Ear Thermometer



#### **WARNING**

- 1 The infrared ear thermometer is not intended for neonatal patients.
- 2 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 inaccuracies.

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**WARNING**

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- 3 Keep the probe covers away from children.
  - 4 Do not reuse the disposable probe covers.
- 

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**CAUTION**

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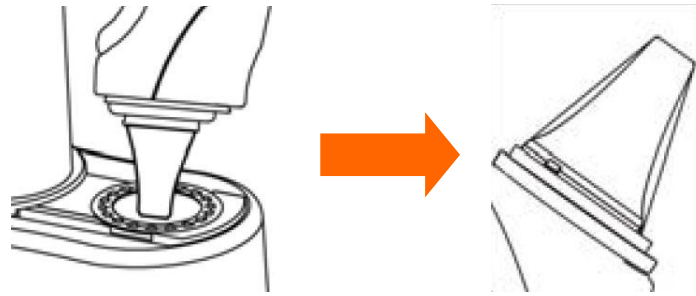
- 1 Keep the probe window clean, dry, and undamaged at times to ensure accurate measurements. To protect the probe window, always keep the thermometer in the storage cover while transporting or when not in use.
  - 2 Proper installation of the probe cover ensures accurate measurements.
  - 3 Do not autoclave.
  - 4 The probe should not be submerged into liquids.
  - 5 Keep the unit dry and away from any liquids and direct sunlight.
  - 6 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.
  - 7 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.
  - 8 For more details about using the infrared ear thermometer, refer to the accompanying operating instructions of the thermometer.
  - 9 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.
  - 10 The monitor outfitted with the TH module must not be used together with other electrosurgery equipment, for example, ESU.
  - 11 Verification of the temperature module is necessary as frequently as dictated by your Hospital Procedures Policy. When you need to calibrate the temperature measurement, please contact the manufacturer.
- 


**NOTE:**


The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1: 2009.

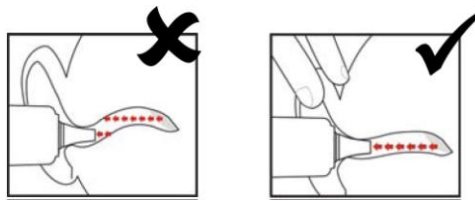
**10.2.2 Measuring Procedure**

1. Align the center of the probe to the center of the probe cover. Make sure to place the adhesive 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 canal 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 results 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 environment 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 highest 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 °C (1~5 years old); 0.10 °C (>5 years old).

## 10.2.3 Alarm

### 10.2.3.1 Adjustable Range of Alarm Limits

Patient Type	Measure position	ALM HI	ALM LO	Step
ADU/PED/NEO	Ear	+42 °C (+107.6°F)	+35.5 °C (+95.9 °F)	+0.1 °C

### 10.2.3.2 Alarm Information and Prompts

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 °C --42.2 °C.	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, and the monitor will delete the measurement values onscreen to avoid misoperation.

## 10.2.4 Replacing the Battery

The device is supplied with one lithium cell CR2032x1.

To replacing the battery, follow the procedure:

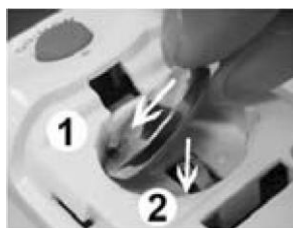
1. Open the battery cover by inserting a pointed object into the battery cover pin hole; meanwhile, use thumb to push battery cover out.



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**

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- 1 Keep the battery away from children.
  - 2 Ensure the positive (+) side is up and the negative (-) side down.
- 

## 10.3 TEMP Monitoring with F3000 Module

### 10.3.1 General Information

M3 with the F3000 module measures patient temperatures by oral, axillary or rectal means.

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.

The electromagnetic compatibility of this device has been verified by test according to the EN60601-1-2: 2007 requirements.

### 10.3.2 Safety Information

---

**WARNING**

- 1 Do not use this device near flammable anesthetics. Not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
  - 2 Do not use this thermometer without first installing a new probe cover.
  - 3 Use probe covers supplied by the manufacturer with this thermometer only. Use of any other probe cover will result in erroneous temperature readings.
  - 4 The thermometer and probe covers are Non-sterile. Do not use on abraded tissue.
  - 5 To limit cross contamination, use Blue devices for Oral and Axillary temperature taking only.
  - 6 Use RED devices only for RECTAL temperatures.
  - 7 Thoroughly dry all electrical contacts on both probe and thermometer after washing, or device may fail to function properly.
  - 8 For re-calibration, service or integrity checks, refer to a qualified Biomedical Technician or return to the manufacturer.
  - 9 Do not open the F3000 module. No user-serviceable parts inside. Opening of the module may affect calibration and voids warranty.
  - 10 Cleaning frequency and practices must be consistent with institutional policy for cleaning of non-sterile devices.
  - 11 The F3000 module is not intended for neonatal patients.
  - 12 Disposal of used probe covers must be performed in accordance with current medical practices or local regulations regarding disposal of infectious, biological medical waste.
  - 13 In monitoring mode, no physiological alarms are available.
- 

**NOTE:**

1. The materials with which the patient or any other person can come into contact conform with the standard of EN ISO 10993:2009
2. Even though this device has been designed to minimize the effects of electromagnetic interference, it does generate radio frequency energy. If not used in accordance with the instructions, the device could cause interference in other equipment operating within its vicinity. If the device is causing interference, the following actions may be taken in an attempt to correct the interference:
  - Re-orient or re-locate the receiving device.
  - Increase the separation between the devices.
  - Consult a customer service representative.

3. Verification of the temperature module is necessary as frequently as dictated by your Hospital Procedures Policy. When you need to calibrate the temperature measurement, please contact the manufacturer.
4. The reference body site temperature is the same as the temperature of the measuring site.

### 10.3.3 Probe Covers —Applying & Removing

1. Open probe cover box by lifting tab at top corner and pulling to remove top panel.
2. Insert box of probe covers into top of isolation chamber.

**NOTE:**

To aid infection control, never switch boxes between blue and red isolation chambers. Also, never switch probes between blue and red isolation chambers. Keep like colors together.

3. Remove probe from the probe well. This automatically turns on the thermometer.
4. To help remind the user to apply or remove a probe cover, a probe icon with flashing probe cover will be displayed when the probe is withdrawn from the probe well and following a completed temperature measurement.
5. Insert the probe end into a cover in the box. Push the handle firmly until you feel the cover “snap” into place.
6. Take appropriate temperature measurement (oral, axillary or rectal).
7. Eject the used cover into bio-waste container by pressing top button.
8. Remove, discard and replace box when empty.

### 10.3.4 Changing Isolation Chambers and Probes

**NOTE:**

1. For aiding in infection control, use only the Blue probe and Blue isolation chamber for Oral and Axillary temperature taking. The Red probe and Red isolation chamber must only be used for rectal temperature taking.
2. Do not attach a Red probe to a Blue isolation chamber or vice-versa.
1. To remove or replace any isolation chamber/probe assembly, grasp the isolation chamber from each side as shown.
2. Squeeze inward releasing the snaps and slide the isolation chamber up to pull off.
3. To replace, align probe well finger with opening in the top of the unit.
4. Slide the isolation chamber down until the side snaps “click” into place.
5. The probe is connected to the thermometer automatically.
6. To change probes, remove the isolation chamber as described previously.
7. Grasp the sides of the L-shaped connector piece with one hand and then using other hand

pull backward on the latch holding the end of the L-shaped connector.

8. Once free of the latch, slide the L-shaped connector out of isolation chamber.
9. To replace, properly align the top of the L-shaped connector to the slot on the back of the isolation chamber.
10. Then slide the connector up into the slot pressing firmly on the bottom of the connector until it “clicks” into place.

### 10.3.5 Measuring Mode

#### Predictive Mode

When **MEASURE MODE** is set to **PREDICT**, the monitor operates in Predictive Mode to provide fast and accurate temperature measurements.

#### Quick Predictive Mode

When **MEASURE MODE** is set to **QUICK PREDICT**, the monitor operates in Quick Predictive Mode which is an oral predictive measurement mode intended for situations where fast temperature measurements are desired.

Quick Predictive Mode allows clinicians to rapidly identify patients with “normal” body temperatures. If the patient temperature is outside of the “normal” range, the monitor will automatically switch into its standard predictive mode to provide a more accurate reading.

Quick Predictive Mode is not available when in Cold Mode.

#### Monitoring Mode

When **MEASURE MODE** is set to **MONITOR**, the monitor will perform continual temperature measurement for a maximum of 10 minutes.

Besides, in the following instances, the monitor will automatically switch to Monitoring Mode and perform temperature measurement for a maximum of 5 minutes until the temperature stabilizes:

1. When the monitor operates in Predictive Mode, no measurement site is detected or the temperature does not stabilize.
2. When the monitor operates in Predictive Mode or Quick Predictive Mode, the ambient temperature is greater than 35 °C (95 °F).

#### Cold Mode

Cold Mode is provided for use in applications where body temperatures may be lower than “normal”, such as for patients recently out of surgery.

The accuracy and measurement time of Cold Mode measurements are equivalent to standard prediction measurements at the respective body sites.

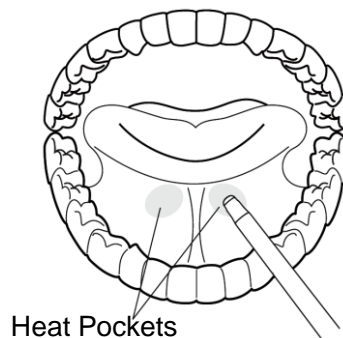
## 10.3.6 Measuring Procedure

### Oral and Axillary Temperature Taking

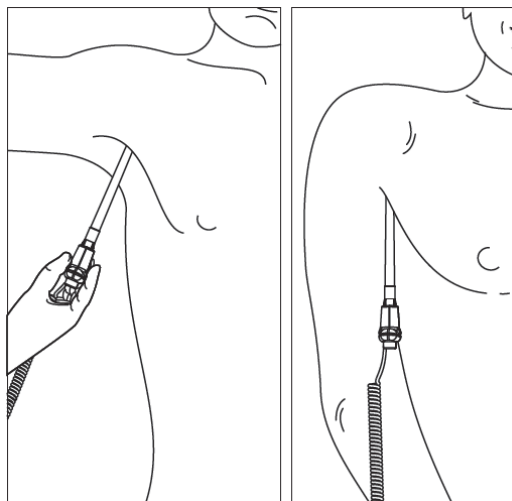
1. Make certain that the Blue isolation chamber /probe unit is attached.
2. Withdraw probe and apply a probe cover. The thermometer turns on automatically and a beep will be heard when the probe completes warm-up.
3. For Oral temperatures, insert the probe tip deep into the sublingual pocket next to the frenulum linguae, (vertical fold of tissue in middle of tongue), on one side or the other, toward the back of the mouth.

#### NOTE:

Accurate body temperature readings can only be obtained in one of these two “heat pocket” locations as shown. Temperatures taken in other mouth locations will result in inaccurate body temperature readings.



4. Patient's mouth must be CLOSED.
5. Securely hold the probe in place until the temperature is displayed.
6. For Axillary temperatures, have the patient raise the arm, then place the probe tip in the axilla. Press gently to assure good contact. For the most accurate temperature the probe tip should be placed directly against the patient's skin.
7. Have the patient then lower the arm and remain as still as possible. Hold the probe parallel to the arm as shown.



8. If three short beeps are heard, it means the unit switched to Monitoring Mode for this temperature only.
9. Two beeps are sounded when measurement is complete and the final temperature is displayed.
10. Eject the used cover into a bio-waste container by pushing top button.

### Rectal Temperature Taking

1. Make certain that the Red isolation chamber/probe unit is attached.
2. Withdraw the probe and apply a probe cover. Thermometer turns on automatically a beep will be heard when the probe completes warm-up.
3. Apply lubrication if desired.
4. Insert the probe into the patient's rectum. To ensure proper tissue contact, angle the probe slightly after insertion.\*
5. Depth of insertion is recommended at 1/2" to 3/4" (12 mm ~ 19 mm) for adults and 1/4" to 1/2" (6 mm ~ 13 mm) for children.
6. If three short beeps are heard, it means the unit switched to Monitoring Mode for this temperature only.
7. Two beeps are sounded when measurement is complete and the final temperature is displayed.
8. Eject the used cover into a bio-waste container by pushing top button.

#### NOTE:

- 1 Probe movement during a measurement can affect the thermometer's ability to measure the site temperature and may lengthen the time required to obtain a reading.
- 2 If a beep is not heard 10 seconds after withdrawing the probe from the probe well and starting temperature measurement in Predictive Mode or Quick Predictive Mode, check the physical connection of the F3000 module.

### 10.3.7 TEMP Setup for F3000 Module

Click **TEMP SETUP** in the **SYSTEM MENU**, and the following settings are available:

**MEASURE MODE:** Set the measuring mode to **PREDICT**, **QUICK PREDICT** or **MONITOR**.

**MEASURE POS:** Set the measuring position to **ORAL**, **AXILLARY** or **RECTA**.

**COLD MODE:** Activate /deactivate the cold mode by setting it to **ON** /**OFF**.

#### NOTE:

- 1 The **QUICK PREDICT** mode is for oral measurement only.
- 2 The **QUICK PREDICT** mode is unavailable when **COLD MODE** is set to **ON**.

- 3 Make sure all settings of TEMP Setup are properly set up every time before you withdraw the probe from the probe well. If you modify the settings immediately a measurement is completed, the new settings will be effective for the next measurement.

## 10.3.8 Alarm

### 10.3.8.1 Adjustable Range of Alarm Limits

Patient Type	Measure position	ALM HI	ALM LO	Step
ADU/PED	Oral/Axillary/Rectal	+43 °C (39 °C by default)	+33 °C (36 °C by default)	0.1 °C

### 10.3.8.2 Alarm Information and Prompts

#### **WARNING**

In monitoring mode, no physiological alarms are available.

Physiological alarms:

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

Technical alarms:

Message	Cause	Alarm Level	What to do
Temp Error E01	System error during synchronization.	Medium	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
Temp Error E02	System error during patient thermistor calibration.	Medium	
Temp Error E03	System error during heater thermistor calibration.	Medium	
Temp Error E04	System timing error.	Medium	
Heater error	Heater error.	Medium	



Message	Cause	Alarm Level	What to do
Temp Error P02	Direct Mode patient thermistor unstable or out of range.	Low	
Temp Error P03	Direct Mode heater thermistor unstable or out of range.	Low	
Temp Error P04	Predict Mode patient thermistor unstable or out of range.	Low	
Temp Error P05	Predict Mode heater thermistor unstable or out of range.	Low	
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 exceed limit	The TEMP value is out of the range of +30 °C ~ +43 °C.	Medium	Put the probe into the probe well; take it out and measure again.
No TEMP SENSOR	Probe configuration (or no probe connected) error.	Low	Well connect the probe and the monitor, and measure again.
Temp Error P06	Unable to pre-heat probe tip.	Low	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.  <b>NOTE:</b> Measure readings displayed on the screen are unreliable when the monitor indicates Temp Error P06.
Measure Site Error	The probe in use is not consistent with the measure position set on the monitor.	Medium	Correctly set the measure position on the monitor.

Message	Cause	Alarm Level	What to do
Measure Site Error	The probe in use is not consistent with the measure position set on the monitor.	Medium	Correctly set the measure position on the monitor.

## Prompts:

Message	Cause
Warm-up over	The monitor prompts it after the probe is taken out of the probe well and warm-up is over.
Measure over	Prediction measurement is completed.
Quick Predict Over	Quick prediction measurement is completed.
MONITORING	The mode is switching to Monitor Mode.

## Chapter 11 Other Functions

### 11.1 Nurse Call

The monitor provides dedicated nurse call port which is connected to nurse call system through the nurse call cable to perform the nurse call function.

**NOTE:**

Before using the function of nurse call, check if it is functioning normally.

### 11.2 Wireless Network

The monitor can constructs wireless network through AP (Access Point). Our company arranges the qualified engineers to install and set the wireless network for the user and test the corresponding performance. For details, please refer to *Patient Monitor Wireless Network Installation Guide*.

**NOTE:**

- 1 Be aware that some network-based functions may be limited for monitors on wireless networks in comparison with those on wired networks.
- 2 The obstacle may interfere with data transmission and even cause data loss.

### 11.3 Central Monitoring System

The monitor can be connected to the central monitoring system. Through the network:

1. The monitor sends patient information, real-time monitoring or measurement data to the central monitoring system.
2. The real-time monitoring information is displayed on the central monitoring system as the same to the monitor, and the central monitoring system can perform some bilateral control. For example: changing patient information, receiving patient, discharging patient and so on.
3. The alarm information of bed side monitor is displayed on the central monitoring system For example: audio alarm paused, audio alarm off and physiological alarm status and so on.

For detailed information, please refer to *MFM-CMS Central Monitoring System User Manual*.

**NOTE:**

- 1 Make sure the network connection between the monitor and the central monitoring system is in good condition when the time synchronization function on the monitor is active.
- 2 The time synchronization function might not be available to all software versions of MFM-CMS. Consult our technical service department or your local distributor for more information.
- 3 MFM-CMS can display max 12 bits barcode.
- 4 Make sure the **Free Online Mode** in CMS is turned on when the barcode is more than 12 bits, and then the monitor can display the real barcode.

## Chapter 12 Accessories

You can order accessories from EDAN supplies at [www.edan.com.cn](http://www.edan.com.cn) or consult your local Edan representative for details.

### **WARNING**

- 1 Never reuse disposable transducers, sensors, accessories and their casing that are intended for single use; or only use them on a single patient. Reuse may compromise device functionality and system performance and cause a potential hazard.
- 2 Use only EDAN-approved accessories. Using non-EDAN-approved accessories may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by EDAN with patient monitors by other manufacturers.
- 3 Do not use a sterilized accessory if its casing is damaged.

### **NOTE:**

Transducers and sensors have a limited shelf life. Refer to the package labeling.

The following cables may not all be available in all countries. Please check availability with your local EDAN supplier.

The following accessories are recommended when using this monitor.

<b>EDAN SpO<sub>2</sub></b>	
02.01.210119	SH1 Adult Reusable SpO <sub>2</sub> Sensor (Lemo)
02.01.210120	SH1 Adult Reusable SpO <sub>2</sub> Sensor (DB9)
02.01.110492	SpO <sub>2</sub> Warp Sensor, Neonate, 1m, reusable
02.01.210122	SH4 Adult Silicone Soft-tip SpO <sub>2</sub> Sensor
02.01.210121	SH5 pediatric Silicone Soft-tip SpO <sub>2</sub> Sensor
01.13.210001	SpO <sub>2</sub> adapter cable, standard (Lemo to DB9)
01.57.471238	SHD-N SpO <sub>2</sub> Sensor, Neonate, disposable
01.57.471237	SHD-I SpO <sub>2</sub> Sensor, Infant, disposable
01.57.471236	SHD-P SpO <sub>2</sub> Sensor, pediatric, disposable
01.57.471235	SHD-A SpO <sub>2</sub> Sensor, adult, disposable

<b>NELLCOR SpO<sub>2</sub></b>	
01.15.30043	Nellcor Reusable Adult SpO <sub>2</sub> Sensor (DS-100A OxiMax)
01.15.40096	Nellcor Reusable Adult/Neonate SpO <sub>2</sub> Sensor (OXI-A/N OxiMax)
01.13.30131	Nellcor SpO <sub>2</sub> Extension cable (Compatible with Nellcor OXI-Max SpO <sub>2</sub> module and Nellcor sensor)
<b>NIBP</b>	
01.57.471326	NIBP Cuff, E5, Infant,10-15cm, reusable
01.57.471327	NIBP Cuff, E6, Small child,13-17cm, reusable
01.57.471328	NIBP Cuff, E7, Child,16-21.5cm, reusable
01.57.471329	NIBP Cuff, E8, Small adult,20.5-28cm, reusable
01.57.471330	NIBP Cuff, E9, Adult,27-35cm, reusable
01.57.471331	NIBP Cuff, E10, Large adult,34-43cm, reusable
01.59.036118	NIBP Tube, 3m
01.57.471442	NIBP Cuff, E7,Child,reusable
01.57.471443	NIBP Cuff, E8,Small adult,reusable
01.57.471444	NIBP Cuff, E9,Adult,reusable
01.57.471005	NIBP Hose, Quick Connect to Quick Connect
01.57.471291	NIBP Tube, 3 m
01.57.471303	NIBP Tube, 3 m
01.57.471021	NIBP Tube for neonatal cuff, 3m

<b>TEMP (For T2 Module)</b>	
02.04.110140	Oral/Axillary Probe
02.04.110139	Rectal Probe
01.57.110159	Probe Covers, Welch Allyn REF #05031
<b>TEMP (For TH Module)</b>	
01.13.036415	Infrared Ear Thermometer Communication Cable
01.57.208057	Infrared Ear Thermometer
01.57.208058	Probe Cover
01.57.208059	Probe Cover Loader
<b>TEMP (For F3000 Module)</b>	
01.57.471312	Filac 3000 Oral Probe 4ft
01.57.471313	Filac 3000 Oral Probe 9ft
01.22.066159	Filac 3000 Oral Isolation Chamber
01.57.471314	Filac 3000 Rectal Probe 4ft
01.57.471315	Filac 3000 Rectal Probe 9ft
01.22.066160	Filac 3000 Rectal Isolation Chamber
01.57.471316	Filac 3000 Probe Covers
<b>Others</b>	
01.57.78035	Printing Paper
01.13.36014	Power Cable(IEC Standard) ,1.8 m
01.13.036106	Power cord(USA),1.8 m
01.21.064167	Rechargeable Lithium-Ion Battery/ TWSLB-008 (14.8 V, 4400 mAh)

01.21.064168	Rechargeable Lithium-Ion Battery/ TWSLB-009 (14.8 V, 2200 mAh)
01.21.064142	Rechargeable Lithium-Ion Battery/ TWSLB-002 (14.8 V, 2500 mAh)
01.21.064143	Rechargeable Lithium-Ion Battery/ TWSLB-003 (14.8 V, 5000 mAh)
01.13.036667	Power cord(3C),3 m
01.13.114114	Ground Cable
01.23.068003	USB barcode scanner (Cipher LAB 1000U, USB port, contact, CCD scan)
01.56.466104	M3 series portable bag
02.04.241690	Patient monitor mounting arm assembly kit
83.60.101950	MT-206 Trolley

**NOTE:**

The part name may vary depending on context, but the part number is constant.

## 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](mailto:support@edan.com.cn)



## Appendix I Specifications

### A1.1 Classification

Anti-electroshock type	Class I equipment and internal powered equipment
Anti-electroshock degree	SpO <sub>2</sub> , NIBP: BF TEMP: CF (T2 module) BF (TH module, F3000 module)
Ingress protection	IPX1 With T2, TH or F3000 TEMP module: Ordinary equipment (Sealed equipment without liquid proof)
Working system	Continuous operation equipment
Compliant with standards	IEC 60601-1: 2005+A1:2012; EN 60601-1: 2006+A1: 2013; IEC 60601-1-2:2007; EN 60601-1-2: 2007; IEC 80601-2-30: 2009; ISO 80601-2-61: 2011; ISO 80601-2-56: 2009; IEC 60601-2-49:2011

### A1.2 Specifications

#### NOTE:

The performance of the equipment with ☆ mark is determined to be essential performance.

#### A1.2.1 Size and Weight

Size	(174±2) mm (W)×(235±2) mm (H)×(189±2) mm(D)
Weight	≤3.5 kg (not including 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	0 °C ~ +40 °C (32 °F ~104 °F)
	With TEMP: +10 °C ~ +40 °C (50 °F ~104 °F)
Transport and storage	-20 °C ~ +55 °C (-4 °F ~131 °F)
	With TH module: -20 °C ~ +50 °C (-4 °F ~122 °F)
Humidity	
Working	15% RH ~ 95% RH (non-condensing)
Transport and storage	15% RH ~ 95% RH (non-condensing)
Altitude	
Working	86 kPa ~ 106 kPa
Transport and storage	70 kPa ~ 106 kPa
Power supply	Voltage: 100 V–240 V ~
	Frequency: 50 Hz/60 Hz
	Pmax: 70 VA, FUSE: T2.0 AH250 VP

### A1.2.3 Display

Device	5.6-inch color TFT. Resolution: 640×480
Messages	1 Power Supply Indicator LED (Green)
	1 Power On Indicator LED (Green)
	1 Alarm Indicator LED (Red/Yellow)
	1 Charge Indicator LED (Yellow)
	1 Alarm Mute Indicator LED (Backlight)
	1 NIBP Working Status Indicator LED (Backlight)
	3 indicating modes correspond to Alarm Mode

### A1.2.4 Battery

Quantity	1	
Type	Li-ion battery	
Capacitance	Standard: 2200 mAh/4400 mAh; Optional: 2500 mAh/5000 mAh	
Working period (With a new fully charged battery, at (25±2) °C, continuous SpO <sub>2</sub> measuring, NIBP automatic measuring mode with the operating interval of 15 minutes, automatic recording per 10 minutes)		
Typical Working Period	2200 mAh: 4 h; 4400 mAh: 8 h	2500 mAh: 7 h 5000 mAh: 14 h
Maximum Rechargeable Period	2200 mAh: 3.5 h 4400 mAh: 6 h	2500 mAh: 3.5 h 5000 mAh: 7 h
	(The monitor is on or in standby mode.)	

### A1.2.5 Recorder

Record width	48 mm
Paper speed	12.5 mm/s, 25 mm/s
Recording types	Parameter list recording
	Trend graph review recording
	Alarm list recording
	Real-time 8s waveform recording
	Recording of all the data of current patient ID
	Real-time alarm recording

### A1.2.6 Data Storage

Trend	72 h, at 1 min resolution
NIBP trend list	30, 000 groups
Alarm list	800 groups

**A1.2.7 NIBP (Optional)**

Mode	Manual, Auto, Continuous
Measuring interval in AUTO mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/240/480
Measure time in continuous measure mode	5 min, interval is 5 s
Measuring type	Systolic Pressure, Diastolic Pressure, Mean Pressure, Pulse Rate
☆Measuring range	
ADU mode	SYS 40 mmHg ~270 mmHg
	DIA 10 mmHg ~ 215 mmHg
	MAP 20 mmHg ~235 mmHg
PED mode	SYS 40 mmHg ~230 mmHg
	DIA 10 mmHg ~180 mmHg
	MAP 20 mmHg ~195 mmHg
NEO mode	SYS 40 mmHg ~ 135 mmHg
	DIA 10 mmHg ~100 mmHg
	MAP 20 mmHg ~110 mmHg
☆Alarm type	SYS, DIA, MAP, PR
☆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 120 s NEO 90 s
Typical measuring period	20 s ~ 35 s (depend on HR/motion disturbance)

Overpressure protection	
ADU	(297 ±3) mmHg
PED	(245 ±3) mmHg
NEO	(147 ±3) mmHg
PR	
☆Measuring range	40 bpm ~240 bpm
☆Accuracy	±3 bpm or 3.5%, whichever is greater

### A1.2.8 SpO<sub>2</sub> (Optional)

<b>EDAN module</b>	
☆Measuring Range	0% ~100%
☆Adjustable range of alarm limits	0% ~100%
Resolution	1%
☆Data update period	1 s
☆Accuracy	
Adult /Pediatric	±2% (70%~100% SpO <sub>2</sub> )
	Undefined (0~69% SpO <sub>2</sub> )
Neonate	±3% (70%~100% SpO <sub>2</sub> )
	Undefined (0~69% SpO <sub>2</sub> )
Pulse Rate	
☆Measuring Range	25 bpm~ 300 bpm
☆Adjustable range of alarm limits	30 bpm~ 300 bpm
Resolution	1 bpm
☆Accuracy	±2 bpm

PI		
Measuring Range		0-10. It displays 0 for invalid PI value.
Resolution		1
Sensor		
Red light		(660±3) nm
Infrared light		(905±10) nm
Emitted light energy		<15 mW
<b>Nellcor module (optional)</b>		
☆Measuring Range		1% ~100%
☆Adjustable range of alarm limits		0% ~100%
Resolution		1%
☆Data update period		1s
☆Accuracy	DS-100A, OXI-A/N(Adult):	±3% (70% ~100% SpO <sub>2</sub> )
	OXI-A/N(Neonate):	±4% (70% ~100% SpO <sub>2</sub> )
Pulse Rate		
☆Measuring Range		20 bpm ~ 300 bpm
☆Adjustable range of alarm limits		30 bpm ~ 300 bpm
Resolution		1 bpm
☆Accuracy		±3 bpm (20 bpm ~250 bpm)
Sensor		Wave length: approximately 660 nm and 900 nm
		Emitted light energy: <15 mW

**NOTE:**

The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

## A1.2.9 TEMP (Optional)

### T2 Module:

☆Measuring range	Monitor mode: 25 °C~45 °C Predict mode: 35.5 °C~42 °C
Working temperature	10 °C ~40 °C
Sensor type	Oral /axillary /rectal
☆Adjustable range of alarm limits	35.5 °C ~42 °C
Resolution	0.1 °C
☆Accuracy	Monitor mode: $\pm 0.1$ °C (25 °C~ 45 °C)
Response time	< 60 s
Update time	1 s~ 2 s
Warm-up time	<10 s
Time for predicting	<30 s
Calibration	Self-test interval: $\leq 5$ min
Measuring Mode	Direct Mode/ Adjusted Mode
Transient Response Time	$\leq 30$ s
Clinical Bias	(-0.2 to -0.4 )°C
Limits of Agreement	0.49
Stability	0.14 °C

### NOTE:

The direct mode refers to monitor mode, while adjusted mode refers to predict mode.

### TH Module:

☆Measuring range	34 °C~ 42.2 °C
Working temperature	10 °C~ 40 °C
☆Adjustable range of alarm limits	35.5 °C~ 42 °C

Resolution	0.1 °C
Response time	1 s
Measuring Mode	Adjusted Mode
Clinical Accuracy	±0.2 °C (0.4 ° F) (35.5 °C ~42 °C) (95 ° F ~107.6° F) ±0.3 °C (0.5° F) (out of the range mentioned above)
Laboratory Accuracy	±0.2 °C

**F3000 Module:**

☆Measuring range	30 °C~43 °C
Prediction measurement range	35 °C~43 °C
Cold mode prediction measurement range	33 °C~43 °C
Working temperature	10 °C ~ 40 °C
Sensor type	Oral /axillary /rectal
☆Adjustable range of alarm limits	33 °C~43 °C
Resolution	0.1 °C
☆Accuracy	Monitoring Mode and Predictive Mode: ±0.1 °C Quick Predictive Mode: ±0.3 °C
Typical measurement time (after insertion into measurement site)	Oral (Quick Predictive Mode): (3~5) s (non-fever temps); (8~10) s (fever temps)
	Oral (Predictive Mode): (6~10) s
	Axillary: (8~12) s
	Rectal: (10~14) s
	Monitoring Mode (all sites): (60~120) s
Measuring Mode	Direct Mode /Adjusted Mode
Transient Response Time	≤30 s



Clinical Bias	(-0.2 to -0.4 )°C
Limits of Agreement	0.49
Stability	0.14 °C

**NOTE:**

The direct mode refers to monitor mode, while adjusted mode refers to predictive mode and quick predictive mode.

**A1.2.10 Wireless Network**

Compliant with Standard and Directive	IEEE802.11b/g, R&TTE Directive (99/5/EEC)
Frequency Range	2.412 GHz ~2.462 GHz (America) 2.412 GHz ~2.484 GHz (Japan) 2.412 GHz ~2.472 GHz (ETSI)
Working frequency segment	Ch1 ~ 11 (America) Ch1 ~ 14 (Japan) Ch1 ~ 13 (ETSI)

## Appendix II EMC Information - Guidance and Manufacture's Declaration

### A2.1 Electromagnetic Emissions

Guidance and manufacture's declaration-electromagnetic emission		
The M3 is intended for use in the electromagnetic environment specified below; The customer or the user of the M3 should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The M3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC/EN 61000-3-3	Complies	The M3 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.

### A2.2 Electromagnetic Immunity


Guidance and manufacture's declaration – electromagnetic immunity			
The M3 is intended for use in the electromagnetic environment specified below. The customer or the user of M3 should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 kV contact ±8 kV air;	±6 kV contact ±8 kV air With TH module: ±2 kV contact ±4kV air. With F3000 module: ±4 kV contact	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

		$\pm 6$ kV air.	
Electrical fast transient/burst IEC/EN 61000-4-4	$\pm 2$ kV for power supply lines; With TH module: $\pm 0.5$ kV for power supply lines.	$\pm 2$ kV for power supply lines; With TH module: $\pm 0.5$ kV for power supply lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	$\pm 1$ kV line to line $\pm 2$ kV line to ground	$\pm 1$ kV line to line $\pm 2$ kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 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 the M3 requires continued operation during power mains interruptions, it is recommended that the Vital signs monitor be powered from an uninterruptible power supply or a battery.
<b>NOTE</b> UT is the a.c. mains voltage prior to application of the test level.			

**NOTE:**

Technological limitations don't allow higher immunity levels.

## A2.3 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The M3 is intended for use in the electromagnetic environment specified below. The customer or the user of M3 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the M3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = 1.2\sqrt{P} \quad 150 \text{ kHz to } 80 \text{ MHz}$
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p><b>NOTE 1</b> At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p><b>NOTE 2</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a</sup> 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</p>			

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 vital signs monitor is used exceeds the applicable RF compliance level above, the vital signs monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the vital signs monitor.

<sup>b</sup> 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 M3			
The M3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the M3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the M3 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
<b>NOTE 1:</b> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
<b>NOTE 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

## Appendix III Abbreviation

Abbr	English Full Name/Description
AC	Alternating current
Adu	Adult
Art	Arterial
aVF	Left foot augmented lead
aVL	Left arm augmented lead
aVR	Right arm augmented lead
BC	Burst count
BP	Blood pressure
BTPS	Body temperature and pressure, saturated
CCU	Cardiac care unit
CISPR	International Special Committee on Radio Interference
CMS	Central monitoring system
COHb	Carboxyhemoglobin
CVP	Central venous pressure
DC	Direct current
Des	Desflurane
Dia	Diastolic
ECG	Electrocardiogram
EEC	European Economic Community
EEG	Electroencephalogram
EMC	Electromagnetic compatibility
EMG	Electromyogram
EMI	Electromagnetic interference
Enf	Enflurane
ER	Emergency room
ESU	Electrosurgical unit
EtN <sub>2</sub> O	End-tidal nitrous oxide
Eto	Ethylene oxide
EtO <sub>2</sub>	End-tidal oxygen

<b>Abbr</b>	<b>English Full Name/Description</b>
FCC	Federal Communication Commission
FDA	Food and Drug Administration
Fi	Fraction of inspired
FiCO <sub>2</sub>	Fraction of inspired carbon dioxide
FiN <sub>2</sub> O	Fraction of inspired nitrous oxide
FiO <sub>2</sub>	Fraction of inspired oxygen
Hal	Halothane
Hb	Hemoglobin
Hb-CO	Carbon mono-xide hemoglobin
HR	Heart rate
ICP	Intracranial pressure
ICU	Intensive care unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
Iso	Isoflurane
LA	Left arm
LAP	Left atrial pressure
LCD	Liquid crystal display
LED	Light emitting diode
LL	Left leg
MAP	Mean arterial pressure
MDD	Medical Device Directive
MethHb	Methemoglobin
MRI	Magnetic resonance imaging
N/A	Not applicable
N <sub>2</sub>	Nitrogen
N <sub>2</sub> O	Nitrous oxide
Neo	Neonate
NICU	Neonatal intensive care unit
NIBP	Non-invasive blood pressure

<b>Abbr</b>	<b>English Full Name/Description</b>
O <sub>2</sub>	Oxygen
OR	Operating room
oxyCRG	Oxygen cardio-respirogram
PA	Pulmonary artery
PACU	Post-anaesthesia care unit
PAWP	Pulmonary artery wedge pressure
Ped	Pediatric
Pleth	Plethysmogram
PR	Pulse rate
PVC	Premature ventricular complex
R	Right
RA	Right arm
RAP	Right atrial pressure
Resp	Respiration
RHb	Reduced hemoglobin
RL	Right leg
RM	Respiration mechanics
RR	Respiration Rate
SEF	Spectral edge frequency
Sev	Sevoflurane
SpO <sub>2</sub>	Oxygen saturation of arterial blood
SQI	Signal quality indicator
SR	Suppression ratio
SYS	Systolic pressure
TB	Blood Temperature
TD	Temperature difference
TEMP	Temperature
TP	Total power
USB	Universal serial bus



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