M3A

Vital Signs Monitor
Version 2.4

User Manual

CE 0123

EDAN

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 holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

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

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

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

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

Terms Used in this Manual

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

WARNING

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

CAUTION

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

NOTE

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

Table of Contents

Chapter 1 Intended Use and Safety Guidance

1.1 Intended Use/Indications for Use

This monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for SpO_2 (oxygen saturation of arterial blood), NIBP (non-invasive blood pressure) and TEMP (quick temperature or infrared ear temperature) of 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 paramenters include: NIBP, SpO_2, 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 ℃ and +40 ℃. Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5 cm) 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.

WARNING

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

1.2.5 Condensation

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

1.2.6 Safety Precautions

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

WARNING

1 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.

2 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.

3 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.

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

5 The device must be connected to the ground to avoid signal interference.

WARNING

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

7 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.

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

9 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.

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

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

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

13 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.

14 Always keep the battery away from fire.

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 scratch or deformation.

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

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

19 Devices connecting with the monitor should be equipotential.

20 This monitor is not a device for treatment purposes.

21 The monitor is suitable for use in the presence of electrosurgery. When the monitor is used with HF surgical equipment, user (doctor or nurse) should be cautious about patient safety.

WARNING

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

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

24 Do not touch the patient, table or instrument during defibrillation.

25 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.

26 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT. Use only EDAN-approved accessories.

27 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.

28 Do not service or maintain the monitor or any accessory which is in use with the patient.

29 Additional multiple socket-outlet or extension cord can’t be connected to the system.

30 Measured data (including trend data, review data and so on) are saved in dataflash either when the monitor is turned off or when the monitor is powered down in the process of monitoring.

31 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.

32 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.

33 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.

34 All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.

35 Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

WARNING

36 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.

37 If device conflict occurs when monitor is connected to gateway, please modify the IP address of the conflicted monitor.

38 Do not touch accessible parts of medical or non-medical electrical equipment in the patient environment and the patient simultaneously, such as USB connector, VGA connector or other signal input/output connectors.

39 Please disinfect timely to prevent cross infection between patients.

40 Connecting any accessory (such as external printer) or other device (such as the computer) to this 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 standards.

41 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.

42 Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment, please refer to the recommended separation distances provided in Appendix A2 EMC Information.

43 Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.

44 The monitors are intended for use by trained healthcare professionals in hospital environments.

45 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.

46 SHOCK HAZARD-To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.

47 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.

48 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.

WARNING

49 If several items of medical equipment are interconnected, pay attention to the sum of the leakage currents, otherwise it may cause shock hazard. Consult your service personnel.

50 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.

51 Route all cables carefully to avoid possible entanglement, apnea, or electrical interference.

52 For the device mounted over the patient, sufficient precautionary measures should be taken to prevent it from falling on the patient.

53 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION

1 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.

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

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

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

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

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

7 Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

CAUTION

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 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.

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

11 A potential hazard may 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 Poor connection might be caused by frequently plugging and unplugging the power cord. Check the power cord regularly and replace it in time.

NOTE:

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

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

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: 2013.

8 When there's measurement beyond range, invalid measurement or no measurement value, it will display “---”.

9 To protect eyes from damage, don't look directly at supplementary light for long time.

10 Make sure networking function is used in a secure network environment.

11 In normal use, the operator shall stand in front of the monitor.

1.2.7 Protecting Personal Information

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. EDAN recommends health care organizations or medical institutions to implement a comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement security practices or measures that include:

1. Physical safeguards - physical safety measures to ensure that unauthorized personnel do not have access to the monitor.
2. Operational safeguards - safety measures during operation.
3. Administrative safeguards - safety measures in management.
4. Technical safeguards - safety measures in technical field.

CAUTION

1 The access/operation of the monitor is restricted to authorized personnel only. Assign only staff with a specific role the right to use the monitor.

2 Ensure that all device components maintaining personal information (other than removable media) are physically secure.

3 Ensure that the data are deleted after the patient is discharged. (Refer to Section 4.6 *Data Management*).

4 Ensure that the monitor is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported monitors within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.

5 Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the **Factory Maintain** settings.

6 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.

7 When the monitor is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the monitor. (Refer to Section 4.6 *Data Management*).

8 Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the monitor.

9 Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against Dos and DDos attacks, and keep it up to date.

10 Dos and DDos protection of the router or switch must be turned on for defensing against attacks.

NOTE:

Log files generated by the monitor are used for system troubleshooting and do not contain protected medical data.

1.2.8 Explanation of Symbols on the Monitor

1		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
2		TYPE BF APPLIED PART
3		TYPE CF APPLIED PART
4		Warning (Background: yellow; Symbol and outline: black)
5		Operating instructions
6		Refer to User Manual (Background: blue; Symbol: white)
7	P/N	Part Number
8		Equipotential grounding
9		Power Supply switch
10		Write and read data into and from store
11	SN	SERIAL NUMBER
12	CE 0123	CE marking
13	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

14		Date of manufacture
15		MANUFACTURER
16		General symbol for recovery/recyclable
17		Disposal method
18	Rx Only	Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.
19	IPX1	Ingress Protection IPX1 (Protected against vertically falling water drops)
20		Caution
21		This way up
22		Fragile
23		Keep away from rain
24		Stacking limit by number
25		Handle with care
26		Do not step on
27	ETL CLASSIFIED C ETL US LISTED Intertek 4005997	Conforms to UL Std. 60601-1, IEC Std. 60601-2-30, IEC Std. 60601-2-49 Certified to CSA Std. C22.2 No 601.1, CSA Std. C22.2 No 60601-2-30, CSA Std. C22.2 No 60601-2-49

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 the 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 section *1.2 Safety Guidance* for details.

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

2.3 Powering on the Monitor

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

WARNING

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

NOTE:

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

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

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

4 After long-time continuous running, please restart the monitor to ensure the monitor's steady performance and long lifespan.

5 If the system is not used for a longer period of time, its system time may be inaccurate. In this case, reset the system time after powering on.

6 If the system time cannot be saved and resumes the default value after restart, contact the service department of EDAN to replace the button cell in main board.

2.4 Connecting Sensor to Patient

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

NOTE:

For information on correct connection, refer to related chapters.

Chapter 3 Introduction

3.1 General Information

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

You may frequently use the following functions:

- SpO_2 monitoring (Refer to Chapter *Monitoring SpO_2* 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.

M3A with the T2 TEMP Module

M3A with the TH TEMP Module

M3A with the F3000 TEMP Module

Figure 3-1 M3A Vital Signs Monitor

M3A Vital Signs Monitor can monitor:

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

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

TEMP: Temperature.

3.2 Screen Display

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

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

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

3.2.1 All Parameters Display

The screen is divided into three areas:

1 Parameter area ①

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

3 Information area ③ ④

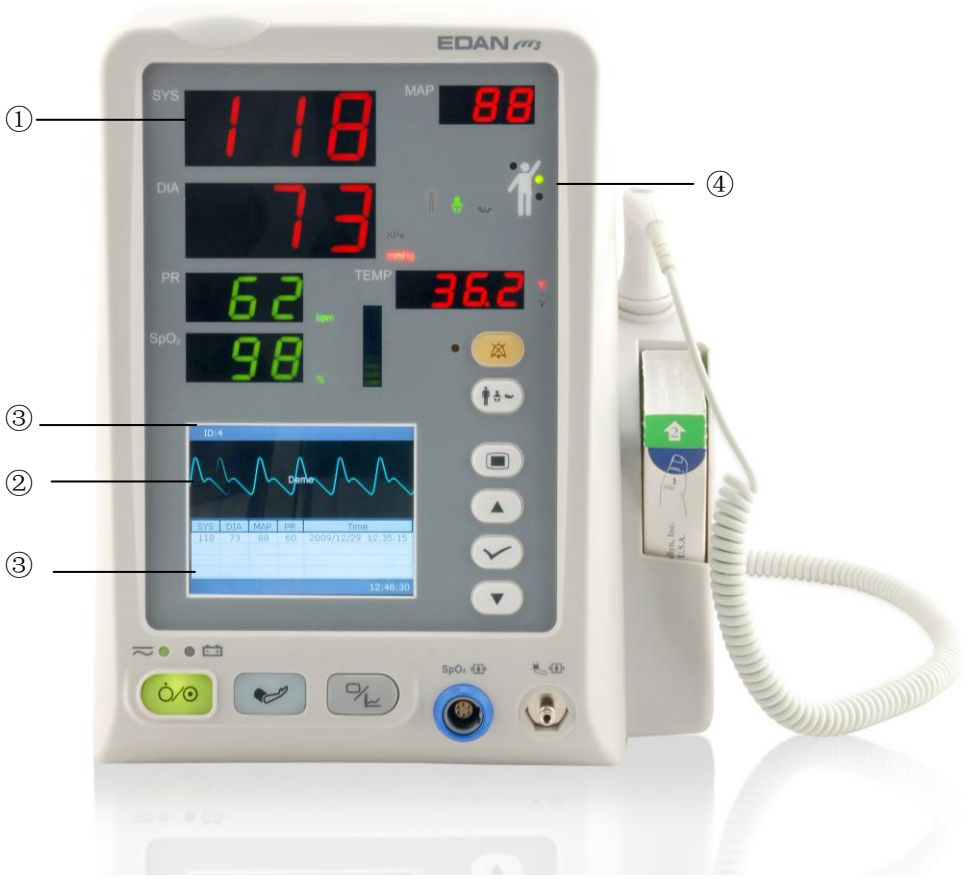


Figure 3-2 Main Display

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

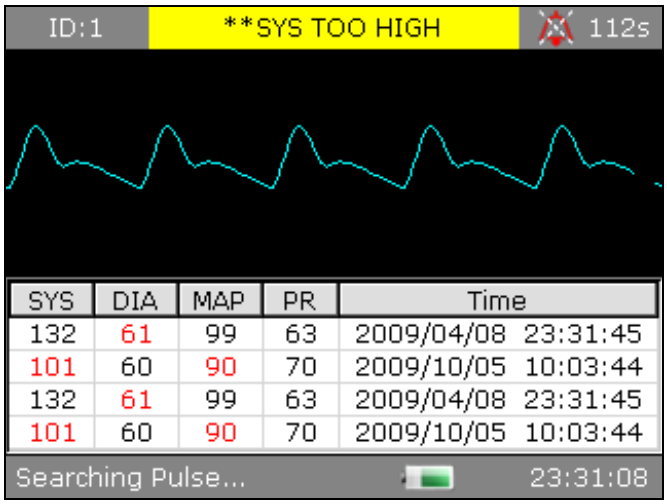


Figure 3-3 NIBP Multi-group Review

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

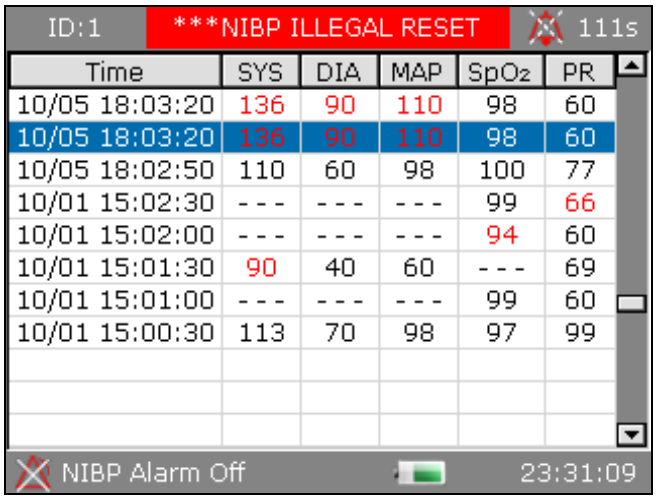


Figure 3-4 Display Trend List

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

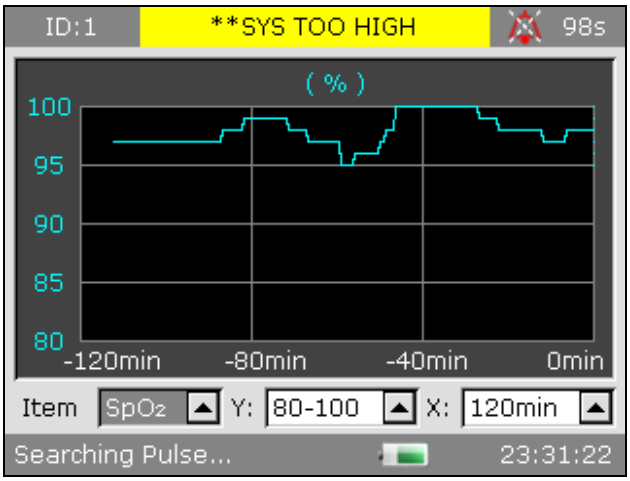


Figure 3-5 Display SpO_2 Trend Graph

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

	Battery status indicator	
	Connected to mains power supply	
	Audio alarm off	
	Audio alarm paused	
	Parameter alarm off	
	Indicates an error occurs	
	Note	
	Warning	
	Password protection	
	Patient type: ADU (adult)	
	Patient type: PED (pediatric)	
	Patient type: NEO (neonatal)	
	Measuring oral TEMP	For device with the T2 TEMP module and F3000 module only.
	Measuring axillary TEMP	
	Measuring rectal TEMP	
	Measuring ear TEMP	For device with the Infrared Ear Temperature module (TH module) only.
ID	Current patient ID	
23:31:08	Current time	

Parameter Area (①)

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

SpO_2:

- SpO_2 (Unit: %)
- PR (Pulse Rate, Unit: BPM).
- SpO_2 alarm limit

NIBP:

- SYS, DIA, MAP (Unit: mmHg or kPa; 1 mmHg=0.133 kPa).
- Pulse Rate (Pulse Rate, Unit: BPM)

TEMP:

- Temperature (Unit: ℃ or ℉).

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

Waveform/Trend List (②)

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

Information Area (③ ④)

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

The information area contains the following data:

- Patient type and ID;
- NIBP measuring mode;
- Signs indicating the battery or mains power supply status;
- Current time;
- Alarms and prompts.

Alarm Indicator and Alarm Status

- In normal conditions, the alarm indicator does not light.
- When an alarm is generated, the alarm indicator lights or flashes. The color of light represents the alarm level. Refer to *Chapter 5 Alarm* for details.
- Refer to relevant content of parameters for Alarm information and prompt.

Charging Indicator and Charging Status

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

3.2.2 Optional Displays

SpO_2 - only measuring mode

Figure 3-6 Display in SpO_2 - only Mode

NIBP- only measuring mode

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

Figure 3-7 Display in NIBP - only Mode

3.3 Button Functions

Figure 3-8 Buttons

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

①	**ON/OFF** 	When the monitor is off, press this button to turn it on. When the monitor is on, press this button and hold for >3s to turn off the monitor; press this button, the menu for entering Standby Mode is displayed.
②	**NIBP START/STOP** 	To inflate the cuff and start blood measuring. During the measuring process, press the button to stop measuring. (For the monitor with NIBP function).
	ALARM LIMIT 	For SpO_2 only monitor, the **NIBP START/STOP** button is changed to **ALARM LIMIT** button. Press this button to set the alarm limits of the parameters of SpO_2.

③	**TREND/WAVEFORM** 	Press this button to switch among waveform display, trend list and trend graph display.
④	**AUDIO ALARM PAUSED/OFF** 	Press this button to pause or turn off the auditory alarm as needed.
⑤	**PATIENT TYPE** 	Press this button to change the patient type which is displayed on the front panel.
⑥	**MENU** 	Press to open the **Main Menu**. Refer to *Chapter 4 System Menu* for details.
⑦	**UP**  **OK**  **DOWN** 	Press **UP** or **DOWN** to select an item or to increase/ decrease a number. Confirm the selection by pressing **OK**.

The icons on the front panel:

⑧	 **CHARGE Indicator**	The LED beside this icon indicates the charging status. When the battery is being recharged, the LED is bright.
⑨	 **POWER Indicator**	The LED beside this icon indicates the power condition. When the monitor connects to the mains power supply, the LED is bright.

3.4 Interfaces

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

Sensor port on the front panel

Figure 3-9 Sensor Connectors

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

1. SpO_2 sensor connector ①

2. NIBP cuff connector ②

WARNING

Only connect the device to EDAN supplied or recommended accessories.

Rear Panel

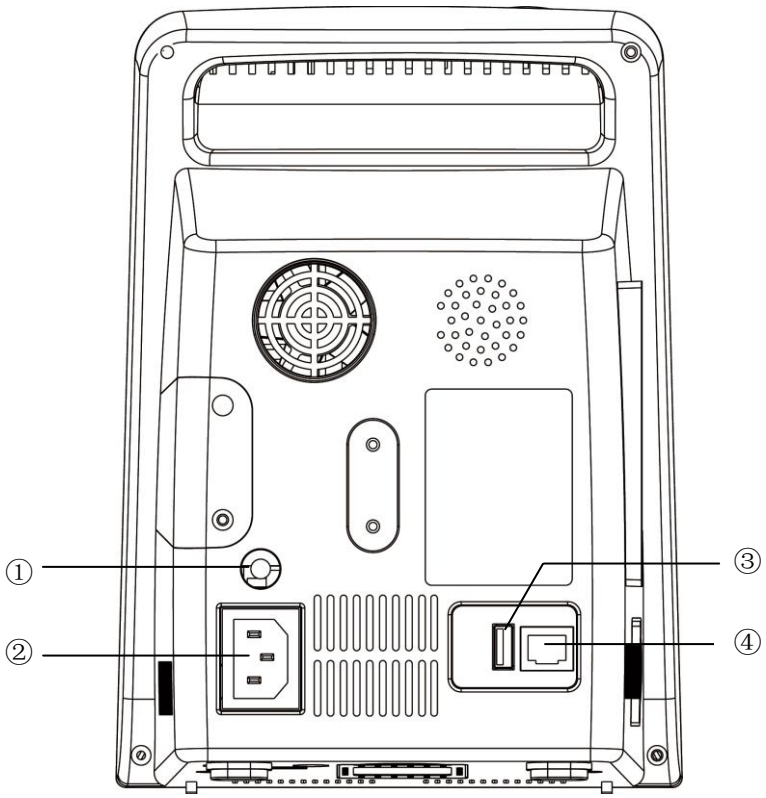


Figure 3-10 Rear Panel

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

① Equipotential grounding terminal for connection with the hospital's grounding system.

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

③ USB connecting port for USB storage.

④ Network Interface: Standard RJ45 Socket, for connecting to MFM-CMS of EDAN.

Bottom panel

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

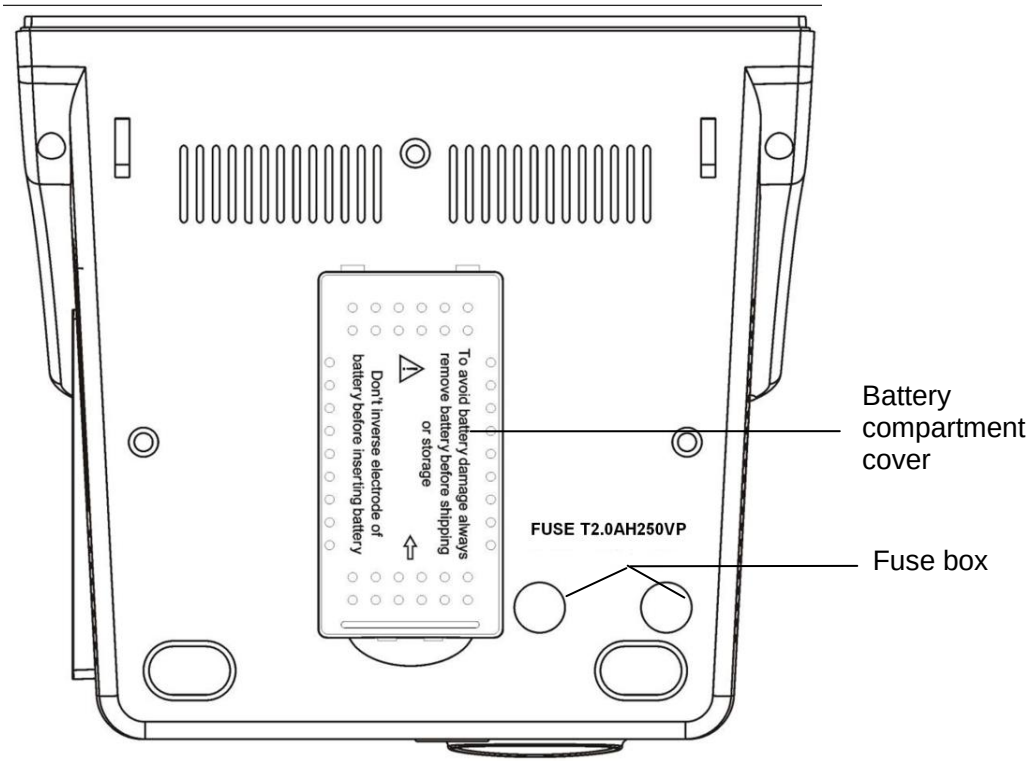


Figure 3-11 Bottom Panel

3.5 Built-in Rechargeable Battery

3.5.1 Battery Safety Information

WARNING

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

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

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

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

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

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

7 Do not heat or throw battery into fire.

8 Only use EDAN approved rechargeable batteries for the monitor.

WARNING

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

10 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.

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

12 The service life of the battery depends on the service frequency and time. The service life of the battery is about three years if the battery is well maintained and stored. The service life of the battery may shorten if it is used inappropriately. If the battery life is exhausted and not replaced in time, it may cause damage or heat to the device.

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. The battery status indicator is light in yellow when being recharged, and off when full.

Battery status symbols show the status of battery and 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

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

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

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.

NOTE:

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

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

4.1 Patient Setup

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

You can set the following patient information:

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

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

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

4.2 NIBP Setup

Please refer to *9.3 NIBP Setup* for more information.

4.3 SpO_2 Setup

Please refer to *8.8 SpO_2 Setup* for more information.

4.4 TEMP Setup

Please refer to *10.1.3* or *10.2.3 TEMP Setup* for more information.

4.5 Alarm Setup

Refer to *5.1.3 Alarm Setup*.

4.6 Data Management

Select **Data Management** in **Main Menu** to open the menu.

- **Start Data Transmission**: select this item to start transmitting data from monitor to data management software.
- **Clear Trend List-Clear Current ID**: Select this item to clear current ID.
- **Clear Trend List-Clear All ID**: select this item to clear all ID.

NOTE:

1 If data storage reaches the maximum, the monitor can't store data; the user needs to manually delete some data to continue.

2 It is recommended to format the USB flash drive to the FAT file type via PC prior to use.

Please refer to *Chapter 6.1 Trend List* for details.

4.7 Recorder

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

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

Please refer to *Chapter 6 Recording* for more information.

4.8 System Setup

There are a few items to be set in this submenu: **General Setup**, **General Alarm Setup**, **Time&Date Setup**, and **Default Configuration**.

4.8.1 General Setup

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

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

4.8.2 General Alarm Setup

Select General Setup in System Setup to open submenu.

- **Alarm Volume**: set alarm volume to level **1** ~ **3**.

4.8.3 Time & Date Setup

Select **Time & Date Setup** in **System Setup** to access the submenu. System time is in format of **yy-mm-dd**, **mm-dd-yy** or **dd-mm-yy**. Users can set the year, month, day, hour, minute and second. Select the item you want to modify and confirm it by pressing **Confirm**. Select **Cancel**

item to save the setup and return to the previous menu. If you want to exit the menu without saving it, press the **MENU** button on front panel.

4.8.4 Default Configuration

NOTE:
Select any item in this submenu to cancel the current setup and use the selected default setup. The one labeled with ■ is current configuration.

- **Factory Default Config**: select the factory default configuration.
- **User Default Config**: select the user-defined default configuration.
- **Restore Selected Config**: select this item to restore the selected configuration.

4.9 Maintenance

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

User Maintenance

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

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

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

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

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

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

- **NIBP Setup**

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.

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**.

NIBP Reset: select it to reset the NIBP module.

Restore measurement status.

Pick this item to restore initial settings of the pressure pump.

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

Leak Test

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

WARNING

This leakage test other than being specified in the ISO 81060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

Procedure of the Air Leakage Test:

1) Connect the cuff securely with the socket for NIBP air hole.
2) Wrap the cuff around the cylinder of an appropriate size.
3) Access the **NIBP Setup** menu.
4) Select the **Leakage Test** item by pressing the **UP/DOWN** button. It displays indicates **Leakage Test** on the bottom of the parameter area.
5) The system will automatically inflate the pneumatic system to about 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 AIR 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 no prompt appears on the bottom of the NIBP parameter area, it indicates that the airway is in good status and no air leaks exist. However if the prompt AIR LEAK appears in the place, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the pneumatic test. If the failure prompt still appears, please contact the manufacturer for repair.

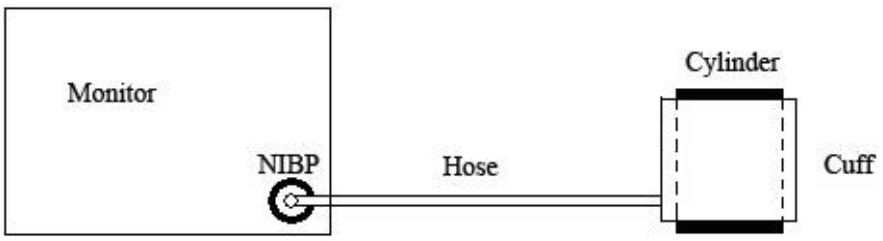


Figure 4-1 Diagram of NIBP Air Leakage Test

- **SpO_2 Setup**

Sensitivity

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

Sensor Off

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

- **Alarm Setup**

  Audio Alarm Paused

  To activate the auditory alarm function, you can set **Audio Alarm Paused** to any value: **60 s**, **120 s** or **180 s**, then press the button  on the front panel to pause audio alarm. The information area displays the remaining pause time in seconds. 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.

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

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

- **Other Setup**

- **Net Setup**

Access **Net Setup** and you can see the menu:
Bed No.: Set the bedside monitor number to a value from 1~64.

Server IP

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

Server Port: Set the server port.

- **Barcode Setup**

ID Start/ID End:

You can determine which digit in the barcode is the starting/ending digit for the patient ID via configuration of **ID Start** and **ID End**.

Patient Type:

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

Auto:

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.

Adult/ **Pediatry**/ **Neonate**:

Select a digit from 0~9 to indicate the patient type.

NOTE:

1 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 in barcode!**" will appear.

2 Make sure the patient ID number obtained from the barcode is within the range of patient ID stored in the monitor, or a message box indicating "**Invalid patient ID!**" will appear.

3 Connect the barcode scanner to the monitor and wait 10 seconds before starting the scanner.

4 Refer to the accompanying operator's manual of the scanner for more information about its usage.

- **Save as User Default Config**: save the current setup as the user default configuration;
- **Exit**: Exit the menu.

Factory Maintenance

Factory maintenance function is only available for the service personnel 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.

Version

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

4.10 Standby Mode

Entering Standby Mode

When the monitor is on, and **Main Menu > System Setup > General Setup** > **Standby Mode** is set to **ON**, press the **ON/OFF** button, the dialog box displays: **Sure to enter standby mode? (Press any key to return)**. Select **YES** to enter the standby 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 for more than 2 seconds can not make the monitor enter the sleep mode.

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

1. If the monitor is measuring, press the **ON/OFF** button for less than 2 seconds, the dialog box displays: **Cannot enter standby mode while measurement going…**
2. If the battery is low, press the **ON/OFF** button for less than 2 seconds, the dialog box displays: **Cannot enter standby mode due to BATTERY LOW alarm!**

Quitting Standby Mode

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

NOTE:
1 In the following situations, the monitor will return to normal monitoring mode automatically: The monitor receives physiological signal of SpO_2, and lasts for 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 standby mode.

Chapter 5 Alarm

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

WARNING

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

5.1 Alarm Modes

5.1.1 Alarm Level

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

High-level alarm indicates the patient's life is in danger or the monitor has serious technical problems. It is a most serious alarm.

Medium-level alarm means serious warning.

Low-level alarm is a general warning.

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 alarms refer to system failure which can make a 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.

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

5.1.2 Alarm Modes

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

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

NOTE:

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

Screen display

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

Technical alarm will not prompt * signal.

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

Lamp light

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

Alarm Level	Visual Prompt
High	Alarm indicator flashes in red with 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 cyan.

Alarm sound

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

Alarm Level	Audio Prompt
High	Mode is "beep-beep-beep------beep-beep, beep-beep-beep------beep-beep", which is triggered once every 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 of auditory alarm is in the range of 45 dB ~ 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

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

- **Alarm setup of each parameter**

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

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

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

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

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

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

WARNING

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

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

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 **Main Menu** > **Maintenance > User Maintenance > Alarm Setup**, and set **Audio Alarm Paused** to **60 s**, **120 s** or **180 s** (The default duration of auditory alarm pause is 120 s):

Then press the button  for less than 2 s to pause audio alarm.

During the audio alarm paused status:

- In the information area, the monitor displays audio alarm off icon  and audio alarm paused **XXXs**.
- The audio alarm (including technical alarm and physiological alarm) is paused, and no alarms are sounding, the visual alarm indications are still displayed.
- The audio alarm paused/off indicator on the front panel flashes in yellow, with interval of 1s.
- 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 **Main Menu** > **Maintenance > User Maintenance > Alarm Setup**, and set **Audio Alarm Off** to **ON**,

Then press the button  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 
- The audio alarm paused/off indicator on the front panel always flashes.
- The audio alarm (including technical alarm and physiological 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 **Main Menu** > **Alarm Setup** > **Alarm Reset**. After resetting the alarm,

- The audio alarm (including technical alarm and physiological 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.

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

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

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

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

5.7 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 the cause of the alarm is cleared, check that the alarm is working properly.

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

5.8 Testing Alarms

When you switch the monitor on, a self test is started with a "Di" tone. 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

6.1 Trend List

The NIBP Multi-Group list is displayed as follows:

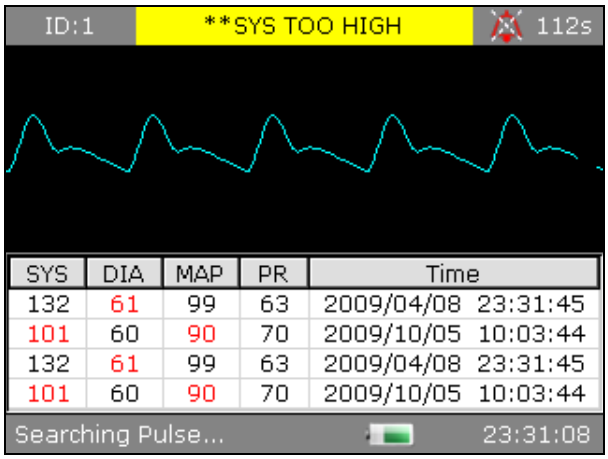


Figure 6-1 NIBP Multi-Group Review

Press **TREND/WAVEFORM** button to change the waveform to trend list.
Select **Main Menu** > **Data Management**, display: **Start Data Transmission**, **Clear Trend List-Clear Current ID**, and **Clear Trend List-Clear All ID**.
Select **Clear Trend List-Clear Current ID**, display the dialog box: **Clear Current ID**?

Select **Clear Trend List-Clear All ID**, display the dialog box: **Clear All ID**?

When deleting all data, the process bar is diaplayed: **Clearing data** 50%...

6.2 Trend Graph

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

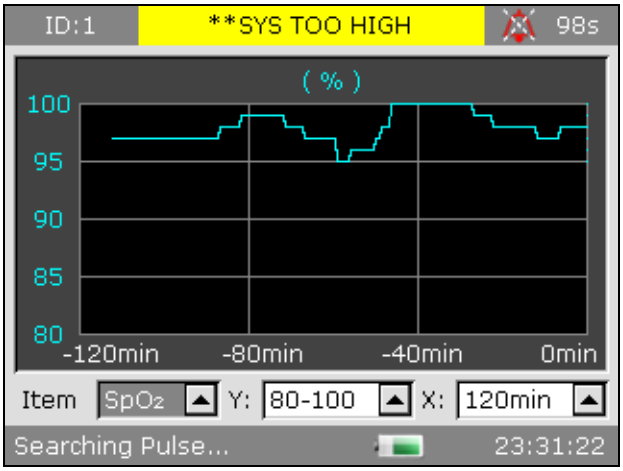


Figure 6-2 SpO_2 Trend Graph

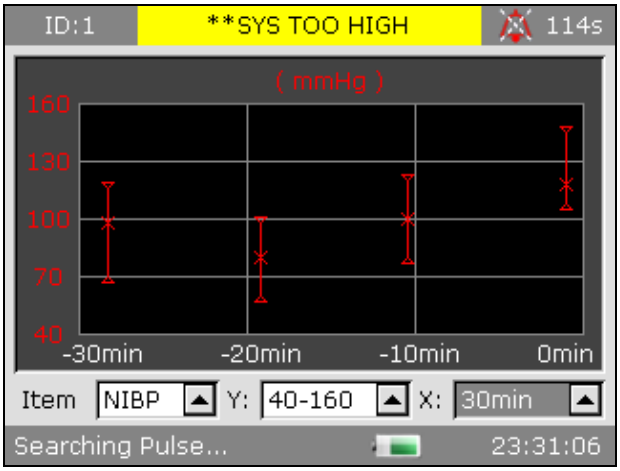


Figure 6-3 NIBP Trend Graph

You can set the items below the trend graph.

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

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

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

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

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

6.3 Recording

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

6.3.1 Recorder Operations

Requirement for the Recording Paper

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

Proper Operation

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

Paper Out

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

Replacing Paper Supply

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

NOTE:

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

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

Removing Paper Jam

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

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

6.3.2 Outputing the Monitoring Data

By selecting the items on **Main Menu** > **Recorder**, you can output the real time data, trend graph current trend table and history trend table.

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

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

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

NOTE:

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

6.3.3 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.
No Recorder	The user presses the **RECORD** button when Recorder is not configured.	Low	Notify the manufacturer's service staff to install and set the recorder.

Chapter 7 Maintenance and 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.

3 The maintenance operations like software upgrade of the device can only be completed by EDAN's qualified service professionals.

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. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water 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_2 Sensor

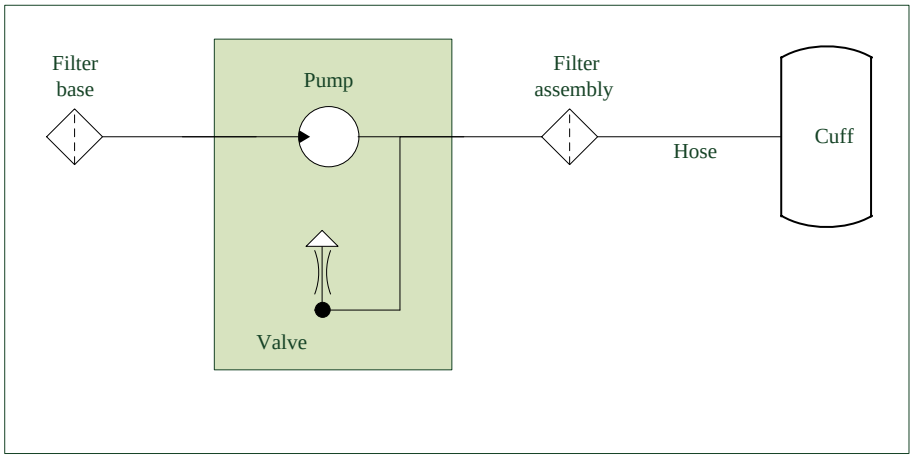
1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution. until no visible contaminants remain
3. After cleaning, wipe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

7.3.3 Cleaning the Dust-proof Filter Assembly

The dust-proof filter system is shown as below figure. Through filtering the dust in air and the abnormal objects during deflation, the dust proof filter system can extend the pump’s lifetime and reduce the effect of dust on measurement accuracy.



The recommended cleaning frequency is once every month, if the environment is dusty, the frequency may be twice every month, if the sound during inflation is noisier than usual, user needs to clean the dust-proof filter assembly according to the real condition.

To clean the filter base, follow these steps:

1. Switch off the monitor and disconnect it from the power line, open the battery door and take out battery;
2. Put one A6 size paper under the assembly, use a clean and dry cotton swab to clean the filter base, until it is clean;
3. Recycle the paper with dust.

NOTE:

1 Don't use wet cotton bud to clean the filter base.

2 Disassembling the filter base is prohibited.

3 If you need to replace the filter base, please contact EDAN's service personnel.

To clean the filter assembly, follow these steps:

1. Turn on the monitor, and set patient type as Adult;
2. Disconnect the extend cable and NIBP cuff ;
3. Press the  button on front panel to inflate, the abnormal objects in the dust proof filter assembly will be blown out, if there is still abnormal object, press  button again to repeat.

NOTE:

1 The dust proof filter assembly is designed in the device, users can't disassemble the device to clean.

2 If you need to replace the dust proof filter assembly, please contact EDAN's service personnel.

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

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

CAUTION

1 Do not use any disinfectant containing additional active ingredients other than those listed, such as disinfectant didecyl dimethyl ammonium bromide which contains quanternary ammonium salt.

2 Although the monitor chemically resistant to most common hospital cleaners, disinfectants and non-caustic detergents, different cleaners or disinfectants are not recommended and may stain the monitor, such as disinfectant didecyl dimethyl ammonium bromide which contains quanternary ammonium salt.

7.4.1 Disinfecting the Monitor

WARNING

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

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_2 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: Φ5×20, Rated value: T 2.0 AH /250 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 ℉ maximum) to clean the battery. Do not use strong solvent to clean battery, and do not dip the battery in liquid.

Chapter 8 SpO_2 Monitoring (Optional)

SpO_2 is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO_2 measuring unit. SpO_2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. The SpO_2 parameter can also provide a pulse rate (PR) and a plethysmogram wave (Pleth).

8.1 Safety Information

WARNING

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

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

3 Correct and proper sensor application: if the sensor is too loose, it might compromise the optical alignment, and even cause the sensor to fall off. If the sensor is too tight, (such as the application site is too large or becomes too large due to edema), excessive pressure and local tissue ischemia, hypoxia and lack of nutrition may occur on the application site. Prolonged and continuous monitoring may increase the risk of Skin irritations or lacerations. To avoid these damages, users should periodically check surrounding skin of application site according to the patient's condition and pressure sensor, inspect the if there is sign of stress-related damage in surrounding tissue, and regularly change the application site. For the patients whose fluid is easy to transfer and/or the patients with systemic or localized edema, users should inspect the skin and change application site more frequently.

4 Use only EDAN permitted sensors and extension cables with the monitor. Other sensors or extension cables may cause improper monitor performance and/or minor personal injury.

5 High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the high limit alarm off.

6 When serious arrhythmia is present, the SpO_2 pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO_2) value.

NOTE:

1 Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line.

2 When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient’s condition.

3 SpO_2 waveform is not directly proportional to the pulse volume.

4 The device is calibrated to display functional oxygen saturation.

5 A Functional tester or simulator cannot be used to assess the SpO_2 accuracy. However, it can be used to demonstrate that a particular monitor reproduces a calibration curve that has been independently demonstrated to meet a particular accuracy.

6 If the surrounding temperature increases, the operator should pay attention to the site of poor perfusion, and increase the frequency of checking the skin and changing the measurement site to prevent burns. If the initial skin temperature is less than 35 °C, the temperature of all the listed sensors on the skin will not exceed 41 °C during working.

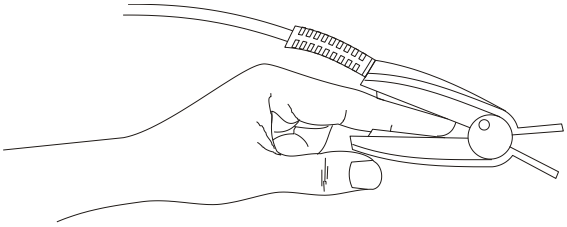
7 The cumulative use time for the SpO_2 sensor in a single patient should be less than 30 days.

8.2 Measuring SpO_2

1. Select the correct patient category setting (adult/pediatric and neonatal), as this is used to optimize the calculation of the SpO_2 and pulse numerics.
2. During measurement, ensure that the application site:
   – has a pulsatile flow, ideally with a good circulation perfusion.
   – has not changed in its thickness, causing an improper fit of the sensor.

Measurement Procedure

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



Mounting of the Sensor

WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours. For neonate, change the measuring site every 20 minutes.

NOTE:

1 Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

2 Inspect the sensor to ensure that the light emitter and receiver are aligned with each other and there is no gap between the sensor and the finger. All the light emitted by the light emitter must pass through the patient's tissue. The sensor cable should be placed on the back of the hand.

3 Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

8.3 Measurement Limitations

Certain patient conditions can affect the measurements or cause the loss of the pulse signal.

Inaccurate measurements can be caused but not limited by:

- incorrect sensor application
- high levels of ambient light sources, such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight
- failure to cover the sensor with opaque material in high levels of ambient light conditions
- dysfunctional hemoglobins
- low peripheral perfusion
- excessive or violent patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents (nail polish, dye, pigmented cream)
- defibrillation
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- electromagnetic interference

Loss of pulse signal can occur for the following reasons:

- the sensor is applied too tightly
- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor
- low peripheral perfusion

NOTE:

1 To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

2 Adjacent SpO_2 sensors may interfere with each other (eg, multiple SpO_2 measurements in the same patient). Be sure to cover the sensor with opaque material to reduce cross-interference.

3 Move the sensor to a less active site, and keep the patient still, if possible.

8.4 Assessing the Validity of a SpO_2 Reading

You can check the quality of the pleth wave and the stability of the SpO_2 values to assess whether the sensor functions properly and whether the SpO_2 readings are valid. Always use these two indications simultaneously to assess the validity of a SpO_2 reading.

Generally, the quality of the SpO_2 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_2 values also reflects the signal quality. Different from varying SpO_2 readings caused by physiological factors, unstable SpO_2 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_2 readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

1 The SpO_2 accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. SpO_2 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 healthy men and women from age 19 to 37, with various skin pigmentations. Note that the study population was healthy adults and not in the actual intended use population.

2 The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).

3 During monitoring, if the monitor's reading differs significantly from the patient's physiological condition, it indicates that the signal may be disturbed, resulting in an inaccurate reading. In this case, the artifact can disguise as a similar reading, causing the monitor to fail to send an alarm. In order to ensure reliable monitoring, it is necessary to regularly check whether the sensor is wearing properly and the signal quality is good.

8.5 SpO_2 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.

8.6 PI (Perfusion Index)*

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

As the measurement of SpO_2 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_2.

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_2 waveform area.

8.7 SpO_2 Setup

Click on **SpO_2 Setup** in **Main Menu** to enter into **SpO_2 Setup** menu:

- **Pulse Volume**: Set it to level **0 ~ 5**.
- **Pitch Tone**: Set it to **ON** or **OFF**. Pulse frequency has positive correlation with measurement value.
- **PI**: If it is set to **ON**, the perfusion index will be presented on the main interface. If it is set to **OFF**, the perfusion index is unavailable on screen.

8.8 Alarm

8.8.1 Adjustable Range of Alarm Limits

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

Default SpO_2 alarm limits:

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

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

Default PR alarm limits:

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

	Max. Upper Limit	Min. Lower Limit	Step
NEO	200	100	1

8.8.2 Alarm Information and Prompts

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

Physiological alarms:

Message	Cause	Alarm Level
SpO_2 HIGH	SpO_2 measuring value is above upper alarm limit.	Medium
SpO_2 LOW	SpO_2 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
SpO_2 NO PULSE	The signal of the measurement site is too weak due to insufficient blood supply and environmental factors, so the monitor can't detect the pulse signal.	High

Technical alarms:

Message	Cause	Alarm Level	What to do
SpO_2 COMM STOP	SpO_2 module failure or communication failure	High	Stop using measuring function of SpO_2 module; notify biomedical engineer or manufacturer's service staff.
SpO_2 SENSOR OFF	SpO_2 sensor may be disconnected from the patient or the monitor.	Low	Make sure the sensor is well connected to the patient's finger or other parts. Make sure the monitor and cables are well connected.
SpO_2 LOW PERFUSION	The pulse signal is too weak or the perfusion of the measurement site is too low. The SpO_2 value and PR value might be inaccurate then.	Low	Reconnect the sensor well, or change the measuring site of body. If the problem persists, please notify biomedical engineer or manufacturer's service staff.

Message	Cause	Alarm Level	What to do
SpO_2 NO SENSOR	SpO_2 sensor was not connected well, or the connection is loose.	Low	Make sure the monitor and sensor is well connected, reconnect the sensor.
SpO_2 NOISY SIGNAL	There is interference with SpO_2 measurement signals due to patient movement, ambient light, electrical interference or else.	Medium	Check the condition of patient and avoid patient movement; make sure the cable is well connected.
SpO_2 Interference	Ambient light around the sensor is too strong.	Medium	Reduce interference of the ambient light and avoid sensor's exposure to strong light.
SpO_2 Sensor ERR	Malfunction in the SpO_2 sensor or in the extension cable.	High	Replace the SpO_2 sensor or the extension cable.

Prompt message:

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

Chapter 9 NIBP Monitoring (Optional)

9.1 Introduction

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 (ISO 81060-2:2013) in relation to mean error and standard deviation. In clinical investigation method with a reference sphygmomanometer, the fifth Korotkoff sound was used to determine adult diastolic pressure, and the fourth Korotkoff sound was used to determine pediatric diastolic pressure.

9.2 NIBP Safety Information

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 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.

5 Do not attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to patient.

6 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.

7 Ensure that the correct patient type is selected before performing measurements. Do not apply the higher adult inflation, overpressure limits and measurement duration for neonatal patients. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.

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

9 Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.

WARNING

10 NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.

11 Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.

12 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.

NOTE:

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

2 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.

3 Continuous use of the automatic measuring mode for short intervals 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.

4 NIBP measurement can be affected by extremes of temperature, humidity and altitude.

5 NIBP measurement value should be explained by qualified professionals.

6 The pulse rate based on the NIBP measurement may differ from the heart rate based on the ECG waveform. NIBP measures the number of peripheral pulse pulsations, and the heart rate is measured by the electrical signal of the heart. When the electrical signals of the heart occasionally fail to cause the peripheral blood vessels to pulse or the patient's peripheral perfusion is poor, the difference happens.

7 The cumulative use time for the NIBP cuff in a single patient should be less than 30 days.

9.3 Measurement Limitations

Measurements are impossible with pulse rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible in the following situations:

- A regular arterial pressure pulse is hard to detect.
- Patients with cardiac arrhythmias.
- Patients with excessive and continuous movement such as shivering or convulsions.
- Patients with rapid blood pressure changes.
- Patients with severe shock or hypothermia that reduces blood flow to the peripheries.

- Patients with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.
- Patients on an edematous extremity.

9.4 NIBP Monitoring

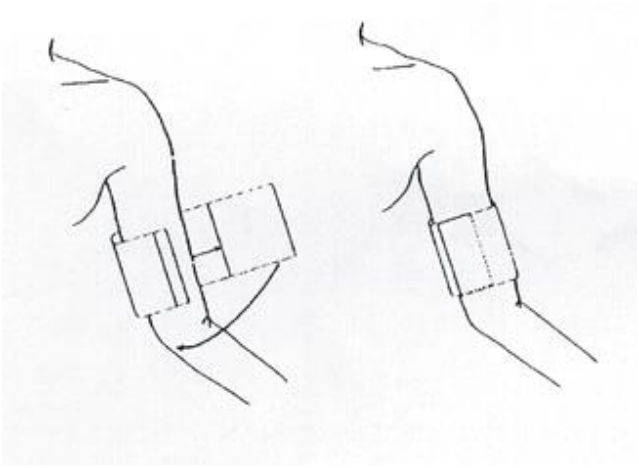
To obtain accurate measurements, the following operating steps need to be observed:

1. Ensure the patient position in normal use, including:

- Comfortably seated or lie flat, 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;
- During the measurement, relax as much as possible, neither talking nor applying external pressure against the cuff.

2. Connect the air hose to the connector on the socket and switch on the monitor.

   Apply the blood pressure cuff to the patient's arm or leg and follow the instructions below.



Cuff Usage

-Ensure that the cuff is completely deflated.

-Apply the appropriate size cuff to the patient (About the cuff size selection, please refer to Section *NIBP Accessories*), and make sure that the symbol "Φ" is over the artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.

4 Check whether the patient type is appropriately selected. **Main Menu** > **Patient Setup** menu and set **Patient Type** to required one.

5 Enter the **NIBP Setup** menu, set the **Unit** of NIBP and select a measurement mode. Select the **Interval** item for **Manual** or set the interval for auto measurement; or select the **Continual**.

3. Press the  button on the front panel to start a measurement.

4. Wait until the first reading is taken.

NOTE:

1 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.

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

3 Please make sure the cuff is well connected. A leak of air may cause measurement error.

4 Please select the cuff with the suitable size. An unsuitable cuff may cause incorrect measurements.

5 Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.

9.4.1 Operation Prompts

- 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.

- To stop auto measuring:

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

WARNING

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

- To start a manual measuring:
  - Access **NIBP Setup** menu and pick the **Interval** item. Select the **Manual** selection. Then press the **NIBP START/STOP** on the front panel to start a manual measurement.

WARNING

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

- To start a continuous measuring:

  Access the **NIBP Setup** menu and pick the **Continual** item to start a continuous measurement. The continuous measurement will last 5 min.

- To stop 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 it may enter the conduit or inside the monitor, contact local Customer Service Center.

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

9.4.2 Correcting the Measurement if Limb is not at Heart Level

To correct the measurement if the limb is not at heart level to the displayed value:

Add 0.75 mmHg (0.10 kPa) for each centimeter higher or	Deduct 0.75 mmHg (0.10 kPa) for each centimeter lower or
Add 1.9 mmHg (0.25 kPa) for each inch higher	Deduct 1.9 mmHg (0.25 kPa) for each inch lower

9.5 NIBP Setup

In **Main Menu**, open the **NIBP Setup** 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.
- **Unit**: Set the pressure unit to **mmHg** or **KPa**. The setting unit will display on the main interface.
- **Continual**: select it to do NIBP measuring continuously within 5min.

9.6 Alarm

9.6.1 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

PR adjustable range of alarm limits:

	Adjustable range	Step (bpm)
PR	40~240	1

Default PR alarm limits:

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

9.6.2 Alarm Information and Prompts

Physiological alarms:

Message	Cause	Alarm Level
SYS HIGH	NIBP SYS measuring value is above upper alarm limit.	Medium
SYS LOW	NIBP SYS measuring value is below lower alarm limit.	Medium
DIA HIGH	NIBP DIA measuring value is above upper alarm limit.	Medium
DIA LOW	NIBP DIA measuring value is below lower alarm limit.	Medium
MAP HIGH	NIBP MAP measuring value is above upper alarm limit.	Medium
MAP LOW	NIBP MAP measuring value is below lower alarm limit.	Medium

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

Message	Cause	Alarm Level	What to do
NIBP COMM STOP	NIBP module failure or communication failure.	High	Stop using measuring function of NIBP module; notify biomedical engineer or manufacturer's service staff.
NIBP INVALID RESET	The hardware pressure is too high	High	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP MODULE ERR	The NIBP module has failure.	High	
LOOSE CUFF	Cuff is no properly wrapped or no cuff exists.	Low	Properly wrap the cuff.
AIR LEAK	NIBP pump, valve, cuff or tube has a leakage.	Low	Check and replace the leaking parts, if required, notify biomedical engineer or manufacturer's service staff.
AIR PREESURE ERR	The airway of NIBP has failure.	Low	
NIBP SIGNAL TOO WEAK	Cuff is too loose or patient pulse is too weak.	Low	Use other method to measure blood pressure.
NIBP NOISY SIGNAL	Because of arm motion, signal noise is too large or pulse rate is not regular.	Low	Make sure that the patient under monitoring is motionless.
OVER PRESSURE	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP SELFTEST ERR	When the monitor is powered on, NIBP module is detected to fail in calibration.	High	Contact your service personnel.
CUFF TYPE ERR	Cuff type does not comply with the patient type.	Low	Select appropriate cuff type

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

Prompt message:

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

Chapter 10 TEMP Monitoring (Optional)

10.1 TEMP Monitoring with T2 Module

10.1.1 Introduction

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

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

Making a TEMP Measurement

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

WARNING

1 To ensure optimal accuracy, always confirm that the correct mode and alarm limit are selected. Changing the measure position may lead to the change of alarm limit.
2 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable from the socket, and then the screen will display the error message **TEMP SENSOR OFF** and the audible alarm is activated.
3 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.
4 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 20 min after ending activity.
6 Biting the sensor tip while taking a temperature may result in damage to the sensor.
7 TEMP measurement isn't suitable for use during defibrillation.
8 Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.

WARNING

9 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.
10 Make sure you have set the correct measuring position before you start a measurement, or the result will be inaccurate.
11 Do not move the probe during measurement.
12 In monitoring mode, no physiological alarms are available.

NOTE:

The cumulative use time for the oral or rectal temperature probe in a single patient should be less than 24 hours.

10.1.2 Measuring Procedure

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

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

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

4 Holding the sensor handle with your thumb and two fingers, and 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.

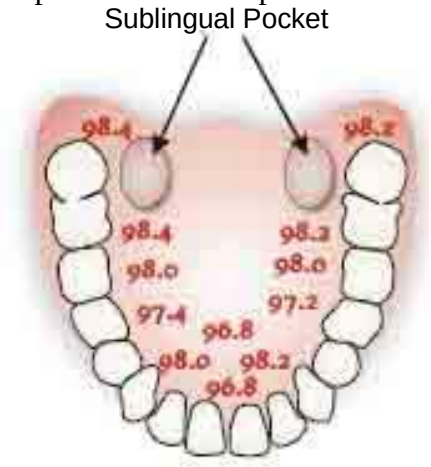


Figure 10-1 Measuring Position in Mouth

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

5 The monitor enters Predict measuring mode, — — — displays in the TEMP parameter area.

After Predict measuring is over, the measuring result displays, and **MEASURE OVER** appears on the interface.

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

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

NOTE:

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

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

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

10.1.3 TEMP Setup

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

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

10.1.4 Alarm

10.1.4.1 Adjustable Range of Alarm Limits

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

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

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 EXCCED LIMIT	The TEMP value is beyond the range of +25 °C ~ +45 °C.	Medium	Put the sensor into the sensor bracket, take it out and measure again.
TEMP NO SENSOR	TEMP sensor is not connected to the TEMP module.	Low	Connect the sensor and the monitor well, and measure again.
AMBIENT TEMP HIGH	The Sensor temperature is higher than +40 °C.	Low	Put the sensor into the sensor bracket, measure again after the ambient temperature reaches normal value.
AMBIENT TEMP LOW	The Sensor temperature is lower than +10 °C.		
TEMP SENSOR ERR	The TEMP sensor cannot work properly.	Medium	Put the sensor into the sensor bracket, take it out and measure again. If the problem persists, stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
TEMP HEATER ERR	Malfunction in the warm-up circuit.	Medium	

Message	Cause	Alarm Level	What to do
TEMP SENSOR OFF	After the sensor temperature reaches Predict value, it descends to the value lower than Predict value.	Medium	Reconnect the sensor and make sure that the cable is properly connected.

Prompt:

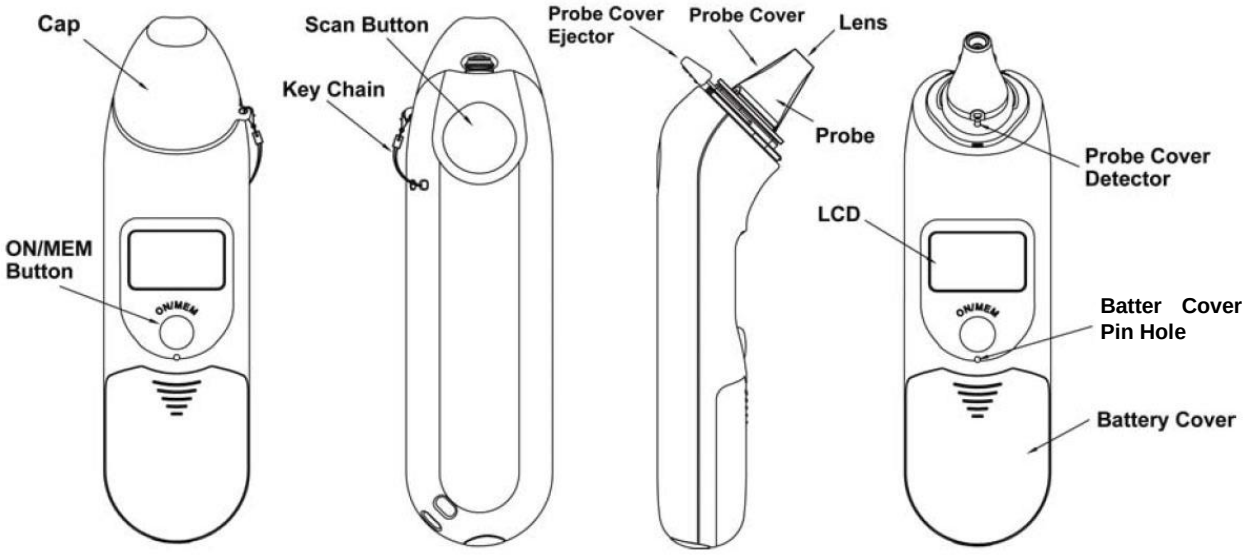
Message	Cause
Ready to TEMP predict	The monitor prompts it after taking the sensor out of the bracket and warm-up is over.
TEMP Predict complete	After the Predict measuring is over, the data and message display on the interface.
TEMP alarm off	The alarm of TEMP is turned off.

10.2 TEMP Monitoring with TH Module

10.2.1 Introduction

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

Diagram of the Infrared Ear Thermometer



WARNING

1 Keep the probe covers away from children.

2 Do not reuse the disposable probe covers.

WARNING

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

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

5 This thermometer converts the ear temperature to display its 'oral equivalent' (according to the result of the clinical evaluation to get the offset value). The thermometer is adjusted to display an oral temperature equivalent. Oral Mode = Ear Mode + 0.30 °C.

CAUTION

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

2 Proper installation of the probe cover ensures accurate measurements.

3 Do not autoclave.

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

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

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

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

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

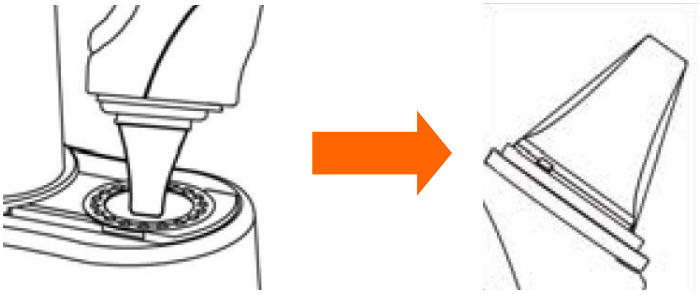
9 The monitor outfitted with the TH module must not be used together with other electrosurgery equipment, for example, ESU.

10 The probe should not be submerged into liquids.

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.

10.2.2 Measuring Procedure

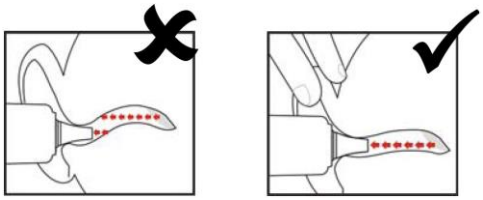
1. Align the center of the probe to the center of the probe cover. Make sure to place the adhensive side of probe cover upward.
2. Insert the probe into the probe cover on the probe cover loader until the probe cover clicks in place.



NOTE:

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

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



NOTE:

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

5. Press the "Scan" button for one second until you hear a long beep sound which signals the end of the measurement, and 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 highiest temperature.

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

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

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

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

10.2.3 TEMP Setup

Click on the **TEMP Setup** in the **Main Menu**:

- **TEMP Unit**: Set temperature unit to **°C** or ℉.

10.2.4 Alarm

10.2.4.1 Adjustable Range of Alarm Limits

The alarm limits are as follows:

Patient Type	Measure position	Alarm Limits	Step
ADU/PED	Ear	+35.5 °C (+95.9 ℉)~+42 °C (+107.6 ℉)	+0.1 °C

10.2.4.2 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 ℃ --42.2 ℃.	Medium	Check the integrity of the probe cover, make sure it is clean, and take a new measurement.

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

NOTE:

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

10.2.5 Replacing the Battery

The device is supplied with one lithium cell CR2032x1.

To replacing the battery, follow the procedure:

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

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

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

WARNING

1 Keep the battery away from children.

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

10.3 TEMP Monitoring with F3000 Module

10.3.1 General Information

M3A with the F3000 module measures patient temperatures by oral, axillary or rectal means.

The electromagnetic compatibility of this device has been verified by test according to the EN60601-1-2: 2015 requirements.

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.

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 Use probe covers supplied by the manufacturer with this thermometer only. Use of any other probe cover will result in erroneous temperature readings.

3 Do not use this thermometer without first installing a new probe cover.

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 Disposal of used probe covers must be performed in accordance with current medical practices or local regulations regarding disposal of infectious, biological medical waste.

11 Cleaning frequency and practices must be consistent with institutional policy for cleaning of non-sterile devices.

12 The F3000 module is not intended for neonatal patients.

13 In monitoring mode, no physiological alarms are available.

NOTE:

1 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.

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

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 cumulative use time for the oral or rectal temperature probe in a single patient should be less than 24 hours.

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 **Mode** is set to **Predict**, the monitor operates in Predictive Mode to provide fast and accurate temperature measurements.

Quick Predictive Mode

When **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 **Mode** is set to **Monitor**, the monitor will perform continual temperature measurement for a maximum of 5 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 ℃ (95 ℉).

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.

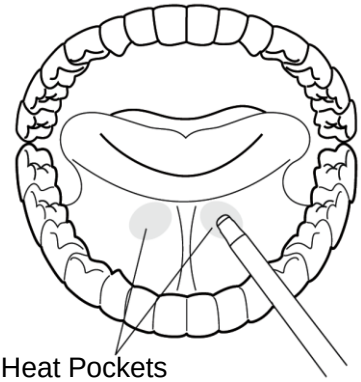
10.3.6 Measuring Procedure

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 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:

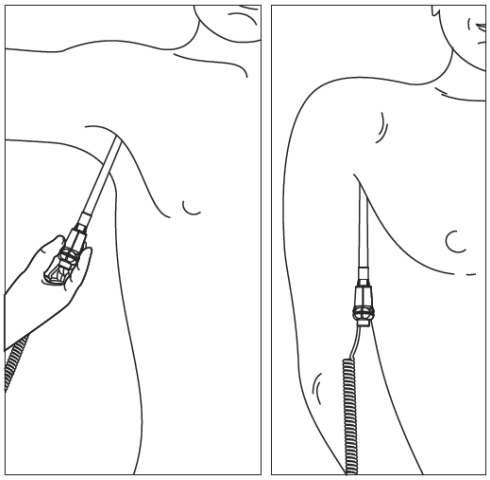
Accurate body temperature readings can only be obtained in one of these two "heat pocket" locations as shown. Temperatures taken in other mouth locations will result in inaccurate body temperature readings.



Heat Pockets

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 **Main Menu**, and the following settings are available:

Mode: Set the measuring mode to **Predict**, **Quick Predict** or **Monitor**.

Position: Set the measuring position to **Oral**, **Axillary** or **Rectal**.

Cold Mode: Activate /deactivate the cold mode by setting it to **ON** /**OFF**.

TEMP Unit: Set temperature unit to ℃ or ℉.

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 LIMITS	Step
ADU/PED	Oral/Axillary/Rectal	+33 °C (36 °C by default) ~ +43 °C (39 °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 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 SENSOR ERR	Incorrect sensor type or incorrect measure sites	Medium	Use the correct type of sensor; choose the correct measesure site.
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. **NOTE:** Measure readings displayed on the screen are unreliable when the monitor indicates Temp Error P06.
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	
Temp Error P02	Monitor Mode patient thermistor unstable or	Low	

Message	Cause	Alarm Level	What to do
Temp Error P04	out of range.	Low	
Temp Error P03	Predict Mode heater thermistor unstable or out of range.	Low	
Temp Error P05		Low	

Prompts:

Message	Cause
Ready to TEMP predict	The monitor prompts it after the probe is taken out of the probe well and preheating is completed.
Prediction complete	Prediction measurement is completed.
TEMP Monitor	The monitor operates in 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 Network

The monitor can be connected with PC through network port. Our company arranges the qualified engineers to install and set the wired network for the user and test the corresponding performance.

NOTE:

If signal is unstable, the signal transmission may be degraded.

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 forth.
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:

When deploying the network of the monitor and MFM-CMS, it is recommended to isolate the network and the Intranet system of the hospital by using VLAN so as to ensure the network security.

Chapter 12 Accessories

You can order accessories from EDAN supplies at 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.

12.1 SpO_2 Accessories

Part Number	Accessories
02.01.210119	SH1 Adult Reusable SpO_2 Sensor (Lemo)
02.01.210120	SH1 Adult Reusable SpO_2 Sensor (DB9)
02.01.110492	SpO_2 Warp Sensor, Neonate, 1 m, resuable
02.01.210122	SH4 Adult Silicone Soft-tip SpO_2 Sensor
02.01.210121	SH5 pediatric Silicone Soft-tip SpO_2 Sensor
01.13.210001	SpO_2 adapter cable, standard (Lemo to DB9)
01.57.471238	SHD-N SpO_2 Sensor, Neonate, disposable
01.57.471237	SHD-I SpO_2 Sensor, Infant, disposable
01.57.471236	SHD-P SpO_2 Sensor, pediatric, disposable

Part Number	Accessories
01.57.471235	SHD-A SpO_2 Sensor, adult, disposable
01.13.036336	SpO_2 adapter cable, extended (Lemo to DB9)
02.01.210673	SH3 Neonate Wrap SpO_2 Sensor

12.2 NIBP Accessories

Part Number	Accessories
01.57.471326	NIBP Cuff, E5, Infant, 10-15 cm, reusable
01.57.471327	NIBP Cuff, E6, Small child, 13-17 cm, reusable
01.57.471328	NIBP Cuff, E7, Child,16-21.5 cm, reusable
01.57.471329	NIBP Cuff, E8, Small adult,20.5-28 cm, reusable
01.57.471330	NIBP Cuff, E9, Adult, 27-35 cm, reusable
01.57.471331	NIBP Cuff, E10, Large adult, 34-43 cm, reusable
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, 3 m
01.57.471005	NIBP Hose, Quick Connect to Quick Connect

12.3 TEMP Accessories

Part Number	Accessories
T2 Module	
02.01.110130	Temperture Probe, Rectal, FT20
02.01.110131	Temperture Probe, Oral/Axillary, FT10
01.57.110159	Probe Covers, WelchAllyn REF #05031
TH Module	
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
F3000 Module	
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

12.4 Other Accessories

Part Number	Accessories
01.57.78035	Printing Paper
01.13.36014	Power Cable (IEC Standard) ,1.8 m
01.13.036106	Power cord (USA), 1.8 m
01.21.064142	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)
01.13.01950	Power cord (3C), 3 m
01.13.114214	Ground Cable
01.23.068003	USB barcode scanner (Cipher LAB 1000U, USB port, conntact, CCD scan)
01.18.052267	Planar barcode sanner (Z-3152SR(U), DC 5 V, 280 mA, USB port)
01.56.466104	M3 series portable bag
02.04.241690	Patient monitor mounting arm assembly kit
83.60.101950	MT-206 Trolley
83.60.261648	MT-206 (S) Trolley
02.01.214392	Dust proof filter assembly
01.51.411705	Filter base

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.

Appendix I Specifications

A1.1 Classification

Anti-electroshock type	Class I equipment and internally powered equipment
Anti-electroshock degree	SpO_2, 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 Safety Standards	IEC 60601-1: 2005+A1:2012; EN 60601-1: 2006+A1: 2013; IEC 60601-1-2:2014; EN 60601-1-2: 2015; 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 kg (without battery)

A1.2.2 Function Configuration

Model	Standard Function	Optional Function
M3A	SpO_2, NIBP	TEMP

A1.2.3 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 ℉~104 ℉)
	With TEMP: +10 °C ~ +40 °C (50℉~104℉)
Transport and Storage	-20 °C ~ +55 °C (-4 ℉~131 ℉)
	With TH module: -20 °C ~ +50 °C (-4 ℉~122 ℉)
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 AH/250 VP

A1.2.4 Display

Multicolor LCD	Resolution: 320×240, adjustable brightness
Messages	1 power supply indicator LED (Green) 1 power on indicator LED (Green) 1 alarm indicator LED (Cyan/Yellow/ Red) 1 alarm silence indicator LED (Yellow) 1 charge indicator LED (Yellow) 1 NIBP working status indicator LED (Backlight) 3 indicating modes correspond to alarm mode

A1.2.5 Battery

Quantity	1
Type	Li battery
Capacitance	Standard: 2500 mAh; Optional: 5000 mAh
Typical Working Period	2500 mAh: 9 h; 5000 mAh: 18 h (With a new fully charged battery, at 20 °C~30 °C, continuous SpO_2 measuring, NIBP automatic measuring mode with the operating interval of 4 hours)
Maximum Rechargeable Period	2500 mAh: 4 h 5000 mAh: 6 h (Monitor is on or in standby mode.)

A1.2.6 Recorder

Record width	48 mm
Paper speed	25 mm/s
Recording types	Real-time data recording
	Trend graph review recording
	Trend table review recording
	Alarm list recording

A1.2.7 Data Storage

Trend data storage	12, 000 groups data

A1.2.8 NIBP

Complies with IEC 80601-2-30: 2009+A1: 2013.

Mode	Manual, Auto, Continuous
Measuring interval in AUTO mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/240/480
Continuous	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
	DIA10 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
Pre-inflation Pressure	
Adult Mode	Default: 160 mmHg Range: 80/100/120/140/150/160/180/200/220/240 mmHg
Pediatric Mode	Default: 140 mmHg Range: 80/100/120/140/150/160/180/200 mmHg

Neonatal Mode	Default: 100 mmHg Range: 60/70/80/100/120 mmHg

A1.2.9 SpO_2

Complies with ISO 80601-2-61: 2011.

☆Measuring Range	0% ~100%
☆Adjustable Range of Alarm Limits	0% ~100%
Resolution	1%
Data update period	1s
☆Accuracy	
ADU & PED	±2% (70% - 100% SpO_2) Undefined (0% - 69% SpO_2)
NEO	±3% (70% - 100% SpO_2) Undefined (0% - 69% SpO_2)
Perfusion Index	
Measuring Range	0-10. It displays 0 for invalid PI value.
Resolution	1 bpm
Sensor	
Red light	(660±3) nm
Infrared light	(905±10) 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).

A1.2.10 PR

	Measuring range	Accuracy	Resolution
PR (SpO_2)	25 bpm to 300 bpm	±2 bpm	1 bpm
PR (NIBP)	40 bpm to 240 bpm	±3 bpm or 3.5%, whichever is greater	1 bpm

A1.2.11 TEMP

Complies with ISO 80601-2-56: 2009.

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: ± 0.1 °C (25 °C ~ 45 °C) (not including transducer)
Response time	< 60 s
Update time	1 s ~ 2 s
Warm-up time	< 10 s
Time for predicting	< 30 s
Calibration	Self-test interval: ≤ 5 minutes
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 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
☆Laboratory Accuracy	± 0.2 °C

Response time	1 s
☆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)
Measuring Mode	Adjusted Mode

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
Measuring Mode	Direct Mode /Adjusted Mode
Clinical Bias	(-0.2 to -0.4) °C
Limits of Agreement	0.49
Stability	0.14 °C
Transient Response Time	≤ 30 s
☆Accuracy	Monitoring Mode and Preditive Mode: ±0.1 °C Quick Predictive Mode: ± 0.3 °C
Typical measurement time (after insertion into measurement site)	Oral (Quick Predictive Mode): (3~5) seconds (non-fever temps); (8~10) seconds (fever temps)
	Oral (Predictive Mode): (6~10) seconds
	Axillary: (8~12) seconds
	Rectal: (10~14) seconds
	Monitoring Mode (all sites): (60~120) seconds

NOTE:

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

Appendix Ⅱ EMC Information - Guidance and Manufacture's Declaration

A2.1 Electromagnetic Emissions

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

NOTE:

The EMISSIONS characteristics of M3A make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) M3A might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

A2.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity
M3A is intended for use in the electromagnetic environment specified below. The customer or the user of M3A should assure that it is used in such an environment.

Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV for line to line ±2 kV for line to ground	±1 kV for line to line ±2 kV for 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	30 A/m	30 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	0 % UT; 0.5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 ° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles) Single phase: at 0 ° 0 % UT; 250/300 cycle	0 % U_T; 0.5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °and 315 ° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0 ° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of M3A requires continued operation during power mains interruptions, it is recommended that M3A be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

A2.3 Electromagnetic Immunity

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">M3A is intended for use in the electromagnetic environment specified below. The customer or the user of M3A should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC/EN 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC/EN 61000-4-6</td><td>3 V_{rms}
150 kHz to 80 MHz
6Vrms[c] in ISM bands between 0.15 MHz and 80 MHz</td><td>3 V_{rms}
150 kHz to 80 MHz
6Vrms[c] in ISM bands between 0.15 MHz and 80 MHz</td><td>Portable and mobile RF communications equipment should be used no closer to any part of M3A, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2\sqrt{P}$ 150KHz to 80MHz
$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz</td></tr>
<tr><td>Radiated RF
IEC/EN 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz
See table 1</td><td>3 V/m
80 MHz to 2.7 GHz
Comply with table 1</td><td>$d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the M3A, including cables specified by the manufacturer).
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 meters (m).
Field strengths from fixed RF transmitters, as determined by an</td></tr>
</table>

			electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which M3A is used exceeds the applicable RF compliance level above, M3A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating M3A.

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

c The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

A2.4 Recommended Separation Distances

Recommended separation distances between

portable and mobile RF communications equipment and M3A

M3A is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of M3A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and M3A as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter(m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 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.

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

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

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	Electromyelogram
EMI	Electromagnetic interference
Enf	Enflurane
ER	Emergency room
ESU	Electrosurgical unit
EtN_2O	End-tidal nitrous oxide
Eto	Ethylene oxide

Abbr	English Full Name/Description
EtO_2	End-tidal oxygen
FCC	Federal Communication Commission
FDA	Food and Drug Administration
Fi	Fraction of inspired
$FiCO_2$	Fraction of inspired carbon dioxide
FiN_2O	Fraction of inspired nitrous oxide
FiO_2	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
MetHb	Methemoglobin
MRI	Magnetic resonance imaging
N/A	Not applicable
N_2	Nitrogen
N_2O	Nitrous oxide
Neo	Neonate
NICU	Neonatal intensive care unit

Abbr	English Full Name/Description
NIBP	Non-invasive blood pressure
O_2	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_2	Pulse Oxygen Saturation
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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