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# iM3

Vital Signs Monitor

Version 1.1

## User Manual

CE<sub>0123</sub>

  
**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) cannot be held liable.

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## Responsibility of the Manufacturer

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

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

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

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

## Terms Used in this Manual

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

### **WARNING**

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

### **CAUTION**

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

### **NOTE**

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

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# Chapter 1 Intended Use and Safety Guidance

## 1.1 Intended Use/Indications for Use

The monitor is intended to be used for monitoring, storing, recording, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitor is intended for use by trained healthcare professionals in hospital environments.

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

The monitor is not intended for MRI environments. TEMP module is not intended for neonates.

## 1.2 Safety Guidance

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

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### **WARNING**

- 1 Before using the device, the equipment, patient cable and sensors etc. should be checked. Replacement should be taken if there is any evident defect or signs of aging which may impair the safety or performance.
  - 2 Medical technical equipment such as these monitor/monitoring systems must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.
  - 3 EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
  - 4 SHOCK HAZARD-To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.
  - 5 Do not come into contact with the patient, table, or the monitor during defibrillation.
  - 6 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.
  - 7 Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.
  - 8 Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
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**WARNING**

- 9 Route all cables carefully to avoid possible entanglement, apnea, or electrical interference. For the device mounted over the patient, sufficient precautionary measures should be taken to prevent it from falling on the patient.
  - 10 Devices connecting with monitor should be equipotential.
  - 11 Do not rely exclusively on the auditory alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
  - 12 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.
  - 13 Only patient cable and other accessories supplied by EDAN can be used. The performance and electric shock protection cannot be guaranteed, and the patient may be injured otherwise. Prior to use, check if the casing of a disposable accessory is intact. Do not use it if its casing is damaged.
  - 14 When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.
  - 15 If several medical equipments are connected to a patient, the sum of the leakage currents shouldn't exceed the limits, otherwise it may cause shock hazard.
  - 16 In monitor mode, when monitoring is in process, if the power supply is off and there is no battery for standby, the monitor will be off. The settings configured by the user can be stored, and settings not configured by user keep no change. That is, the last settings used will be recovered when the power is restored. In round or spot-checking mode, the patient type will be restored to adult by default, and the monitor is in status with no patients, and other settings processing after power off are the same with that in monitor mode.
  - 17 If leakage or foul odor is detected, ensure that there's no fire around.
  - 18 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be 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.
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**WARNING**

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- 19 The packaging is to be disposed of according to local or hospital's regulations; otherwise, it may cause environmental contamination. Place the packaging at the place which is inaccessible to children.
  - 20 This equipment is not intended for home usage.
  - 21 Do not service or maintain the monitor or any accessory which is in use with the patient.
  - 22 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.
  - 23 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
  - 24 The monitors are MR Unsafe. The monitors are not intended for use in an MRI environment.
  - 25 Only recommended batteries can be used for the monitor.
  - 26 In monitor mode, without use of data store function, all data measured (including trend data, review data, alarm events and so on) are cleared either when the monitor is turned off or when the monitor is powered down in the process of monitoring.
  - 27 Additional multiple socket-outlets or extension cords can't be connected to the system.
  - 28 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.
  - 29 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.
  - 30 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.
  - 31 Portable and mobile RF communications equipment can affect medical electrical equipment; refer to the recommended separation distances provided in this user manual.
  - 32 Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.
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**WARNING**

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- 33 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.
  - 34 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.
  - 35 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.
  - 36 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.
  - 37 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.
  - 38 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT. The equipment can protect against the effects of the discharge of a defibrillator. Use only EDAN-approved accessories.
  - 39 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.
  - 40 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.
  - 41 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.
  - 42 Clinical decision making based on the output of the device is left to the discretion of the provider.
  - 43 The monitor is equipped with Wi-Fi to receive RF electromagnetic energy. Therefore, any other equipment complying with CISPR radiation requirements may also interfere with the wireless communication and make it interrupted.
  - 44 If the earth protection system is not stable, use the batteries for power supply.
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**WARNING**

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- 45 Wireless LAN equipment contains an intentional RF radiator that has the potential of interfering with other medical equipment, including patient implanted devices. Be sure to perform the electromagnetic compatibility test, as described in the Wireless LAN System Installation, before installation and any time new medical equipment is added to the Wireless LAN coverage area.
  - 46 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.
  - 47 When the monitor is used with HF surgical equipment, user (doctor or nurse) should be cautious about patient safety.
  - 48 If device conflict occurs when monitor is connected to gateway, please modify the IP address of the conflicted monitor.
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**CAUTION**

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- 1 Electromagnetic Interference - Ensure that the environment in which the patient monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, microwaves, etc.
  - 2 Keep the environment clean. Avoid vibration. Keep it far away from corrosive medicine, dust area, high temperature and humid environment.
  - 3 Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.
  - 4 Do not use autoclave or gas to sterilize the monitor, recorder or any accessories.
  - 5 The device and reusable accessories may be sent back to the manufacturer for recycling or proper disposal after their useful lives.
  - 6 Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.
  - 7 Remove a battery whose life cycle has expired from the monitor immediately.
  - 8 To ensure patient safety, use only parts and accessories manufactured or recommended by EDAN.
  - 9 Before connecting the monitor to the AC power, make sure the voltage and the power frequency are consistent with the requirements indicated on the device label or in this user manual.
  - 10 Protect the device against mechanical damage resulting from falls, impacts, and vibration.
- 
-






### **CAUTION**

- 11 Do not touch the touch screen with a sharp object.
- 12 A ventilated environment is required for monitor installation. Do not block up the ventilation grille at the back of the device.
- 13 The device must be connected to the ground to avoid signal interference.
- 14 To protect eyes from damage, don't look directly at supplementary LED for long time.
- 15 Poor connection might be caused by frequently plugging and unplugging the power cord. Check the power cord regularly and replace it in time.







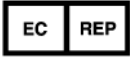






### **NOTE:**





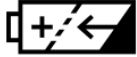

- 1 Position the device in a location where the operator can easily see the screen and access the operating controls.
- 2 The monitor can only be used on one patient at a time.
- 3 If the monitor gets damp or liquid pours on the monitor, please contact the service personnel of EDAN.
- 4 This monitor is not a device for treatment purposes.
- 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 monitor may not be compatible with all models of USB flash drives. Use the USB flash drives that are recommended by EDAN.

### 1.3 Explanation of Symbols on the Monitor

1		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
2		TYPE BF APPLIED PART
3		Caution
4		MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
5		Equipotential grounding



6		Alternating Current
7		Power Supply switch
8		SERIAL NUMBER
9		Network port
10		USB (Universal Serial Bus) Connection
11		CE marking
12		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
13		Date of manufacture
14		MANUFACTURER
15	P/N	Part Number
16		General symbol for recovery/recyclable
17		Disposal method
18		Operating instructions
19		Refer to User Manual (Background: Blue; Symbol: White)

20		Warning (Background: Yellow; Symbol & outline: black)
21	<b>IPX1</b>	Ingress Protection IPX1 (Protected against vertically falling water drops)
22		With respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1, IEC 60601-2-30, IEC 60601-2-49
23	<b>Rx Only</b>	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
24		Non-ionizing electromagnetic radiation
25		Output/ Nurse call
26		Chargeable battery
27		Battery check

**NOTE:**

The user manual is printed in black and white.

## Chapter 2 Installation

### NOTE:

- 1 The monitor installations and settings must be configured by the authorized hospital personnel.
- 2 To ensure that the monitor works properly, please read the user manual and follow the steps before using the monitor.

### 2.1 Initial Inspection

Before unpacking, check the packaging and ensure that there are no signs of mishandling or damage. If the shipping cartons are damaged, contact the carrier for compensation and package them again.

Open the package carefully and remove the monitor and accessories. Check that the contents are complete and that the correct options and accessories have been delivered.

If you have any question, please contact your local supplier.

### 2.2 Mounting the Monitor

If all situations are normal, please place the monitor on a flat, level surface, on a trolley or mount on a wall. About how to install the trolley or wall mount for the monitor, please refer to *Trolley Installation Guide* or *Wall Mounting Bracket Assembly Instruction*.

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#### **WARNING**

- 1 The wall mounting bracket can be fixed only on a concrete wall.
  - 2 The safe loads of the wall mounting bracket and the trolley are 7.5 kg and 11 kg respectively. Exceeding the safe load may cause bracket to fail and the device to fall.
- 
- 

### 2.3 Connecting the Power Cable

Connection procedure of the AC power line is listed below:

- 1 Make sure the AC power supply complies with the following specifications: 100 V-240 V~, 50 Hz/60 Hz.
- 2 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:

- 1 Connect the power cable to the socket specialized for hospital use.
- 2 Only use the power cable supplied by EDAN.

### 2.4 Checking the Monitor

Make sure there is no damage on the measurement accessories and cables. Then turn on the monitor, check whether the monitor can start normally. Make sure all alarm lamps light up and the alarm sound is heard when turning on the monitor. Please refer to chapter *Testing Alarms*.

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**WARNING**

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If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact customer service center immediately.

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**NOTE:**

- 1 Check all the functions of the monitor and make sure that the monitor is in good status.
- 2 If rechargeable batteries are provided, charge them after using the device every time, to ensure the electric power is enough.
- 3 After long-time continuous running, please restart the monitor to ensure the monitor's steady performance and long lifespan.

## 2.5 Connecting Sensor to Patient

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

**NOTE:**

For information on correct connection, refer to related chapters.

## 2.6 Checking the Recorder

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

## 2.7 Setting Date and Time

To set the date and time:

1. Select **Menu > System Setup > Date/Time**.
2. Adjust the date display format based on the user's habit.
3. Set the correct time of year, month, day, hour, min and sec.

## 2.8 Handing Over the Monitor

If you are handing over the monitor to the end-users directly after configuration, make sure that it is in normal working status and let user know the status.

The users must be adequately trained to use the monitor before monitoring a patient. To achieve this, they should have access to, and read, the following documentation delivered with the monitor:

- User Manual (this book) - for full operating instructions.
- Quick Reference Card - for quick reminders during use.

## Chapter 3 Basic Operation

This user manual describes all features and options. Your monitor may not have all of them; they are not all available in all geographies. Your monitor is highly configurable. What you see on the screen, how the menus appear and so forth, depend on the way it has been tailored for your hospital and may not be exactly as shown here.

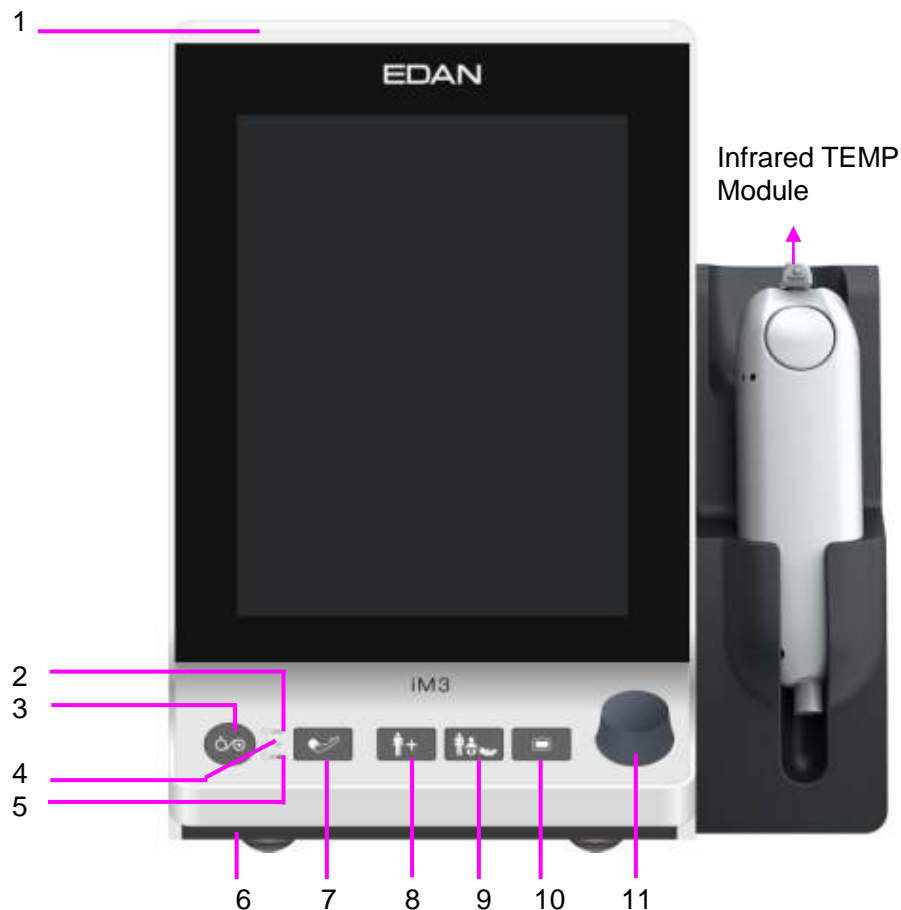
You may frequently use the follow functions:

- ◆ SpO<sub>2</sub> monitoring (Refer to *Monitoring SpO<sub>2</sub>* for more information.)
- ◆ PR monitoring (Refer to *Monitoring PR* for more information.)
- ◆ NIBP monitoring (Refer to *Monitoring NIBP* for more information.)
- ◆ TEMP monitoring (Refer to *Monitoring TEMP* for more information.)
- ◆ Alarm (Refer to *Alarms* for more information.)

### 3.1 Overview

#### 3.1.1 Front View

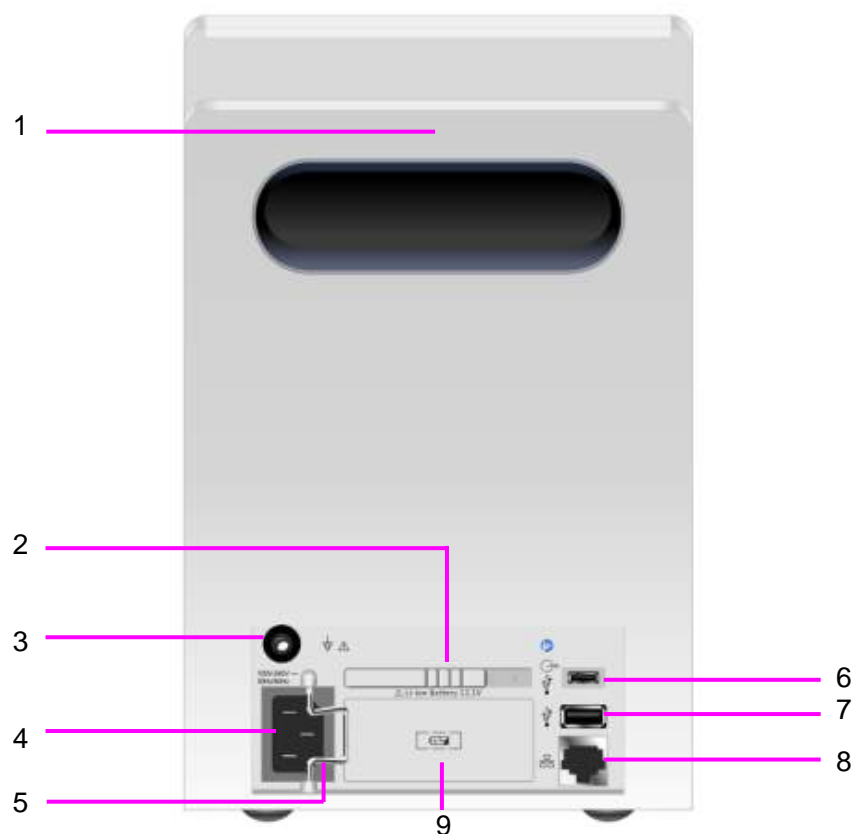




1	Alarm indicator/Standby indicator	When an alarm occurs, the alarm indicator will light or flash. The color of light represents the alarm level; Light indicator will light and flash to represent the standby status.
2	On/Off indicator	When monitor is turned on, the indicator is in green.
3	Power supply switch	When the monitor is connected to the AC power supply, press the key to turn the monitor on. When the monitor is turned on, press the key over 3 seconds to turn the monitor off.
4	AC power indicator	When the monitor is connected to AC power, the indicator is in green.
5	Battery indicator	Refer to the section <i>Battery Power Indicator</i> for details.
6	Speaker	For alarm tones, pulse tones and so forth.
7	Start/stop NIBP measurement	Press this button to inflate the cuff and start blood pressure measurement. During the measurement, press the button to stop the measurement.
8	Admit/Create new patient	<ul style="list-style-type: none"> <li>• In monitor mode, press the button to admit a new patient.</li> <li>• In round mode, press the button to create a new patient.</li> </ul>

		<ul style="list-style-type: none"> <li>In spot-checking mode, press the button to admit a new patient. The parameters data displayed in interface will be cleared. Series No. will be automatically added by one and other setting items are empty by default.</li> </ul>
9	Switch patient type	<p>It is used to switch patient type, and relevant configuration will be updated.</p> <ul style="list-style-type: none"> <li>In monitor mode, press the button to switch patient type. A confirmation window will be displayed.</li> <li>In round and spot-checking mode, press and hold the button to switch patient type. There is no window to be displayed.</li> </ul>
10	Menu	<p>Press the button to open main menu.</p> <p>When the main menu is open, press this button to return to the main interface</p>
11	Rotary Knob (hereinafter called knob)	<p>The user can rotate the knob clockwise or anticlockwise. This operation can make the highlighted item shift up, down, left or right to choose the desired item. Remember, when using the knob, rotate this button to highlight, and press it to select the item.</p>

### 3.1.2 Rear View



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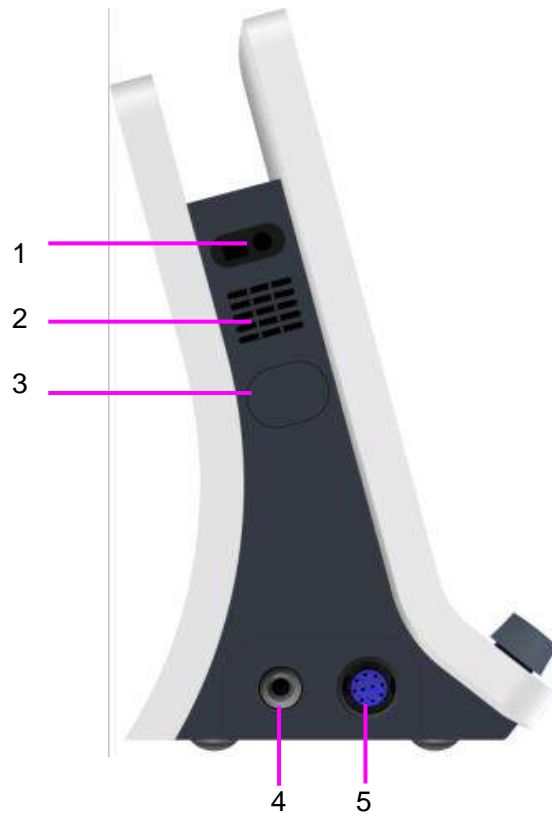
1	Portable handle/Accessory collecting
2	Battery compartment latch
3	Equipotential grounding terminal. If the monitor is used together with other devices, connect this terminal to eliminate potential ground differences between devices.
4	AC power input
5	Power cable safety latch. Used to prevent the power supply cord from falling.
6	OTG interface/nurse call port. <ul style="list-style-type: none"><li>• OTG interface: it connects the monitor to computer via data-line. The data in monitor can be transformed into CSV file and exported to computer.</li><li>• Nurse call port: it connects the monitor to the hospital's nurse call system. Alarms indications are alerted through the nurse call system if configured to do so.</li></ul>
7	USB interface. They are used to connect the USB device.
8	Network interface. It connects the monitor to the central monitoring system (also named as MFM-CMS) via standard network cable.
9	Battery

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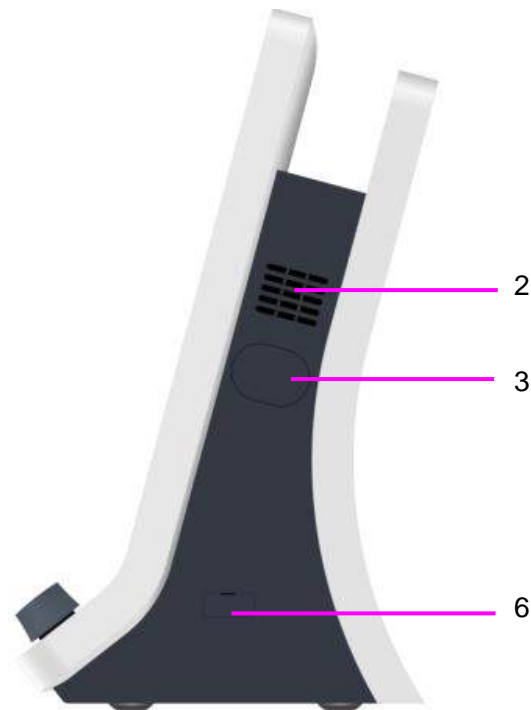


### 3.1.3 Side View

Left side



Right side



1	Built-in barcode scanner window
2	Heat sink
3	Built-in interface (there is Vent & dust-free baffle inside for NIBP on the left side.)
4	NIBP interface
5	SpO <sub>2</sub> interface
6	TEMP communication interface

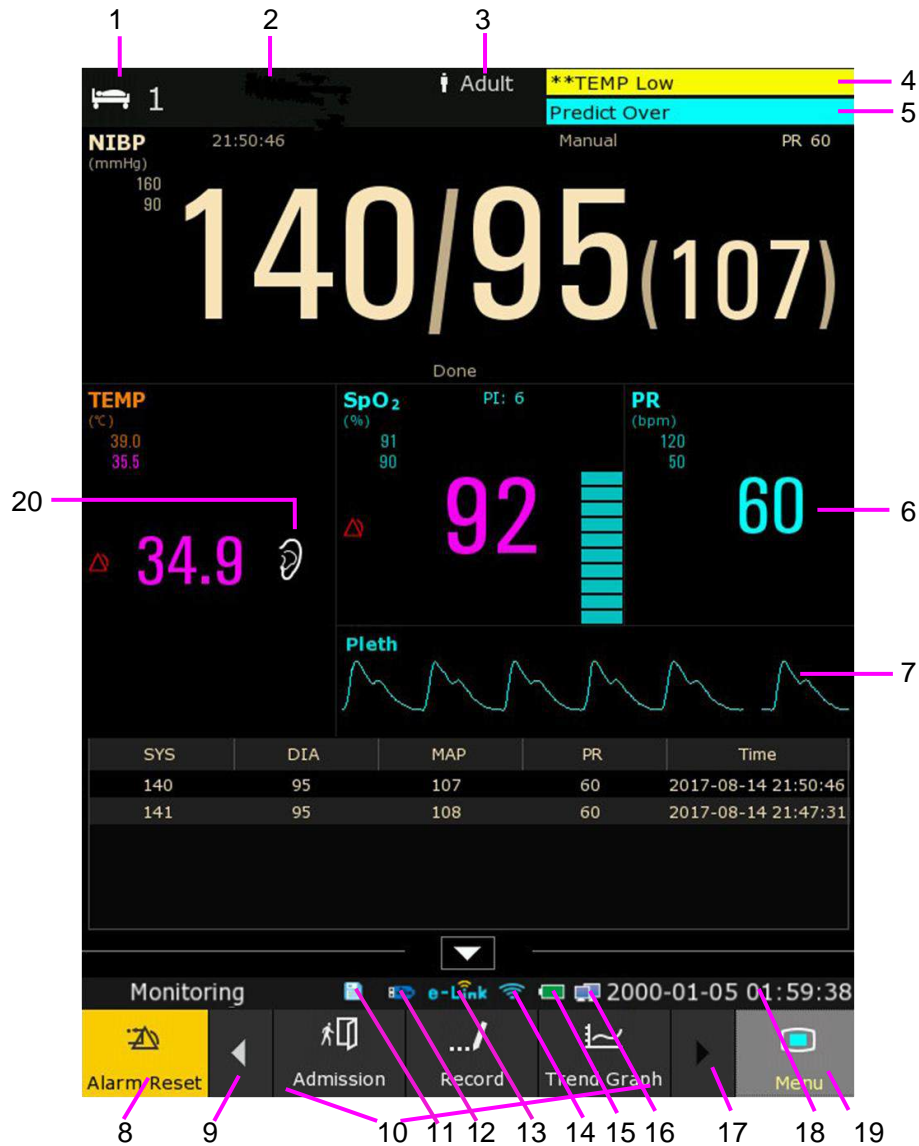
**NOTE:**

To avoid blocking and affecting NIBP measurement, user can open the built-in interface coverplate and clean vent & dust-free baffle routinely. If NIBP measurement is still affected after cleaning, please contact the service personnel of EDAN.

## 3.2 Operating and Navigating

Everything you need to operate the monitor is contained on its screen. Almost every element on the screen is interactive. Screen elements include measurement data, waveforms, screen keys, information fields, alarms fields and menus. The configurability of the monitor means that often you can access the same element in different ways. For example, you might be able to access an item through its on-screen setup menu, via a hard key, or via a shortcut key. The User Manual always describes how to access items via an on-screen menu. You may use whichever way you find most convenient.

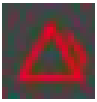
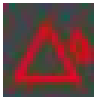
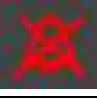
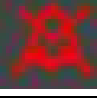
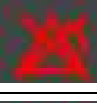






Patient information area	Physiological alarms area
	Technical alarms area
Parameters data area	
<b>General information area</b> (Left is function info.; Right is symbol area, from right to left, including data storage status, e-link, Wi-Fi network, USB flash disk, AC power, battery status, wired network, date & time)	
Permanent key & Shortcut key area	










1	Bed number
2	Patient name and MRN
3	Patient type
4	Physiological alarms area
5	Technical alarms area
6	Measurement value
7	Parameter waveform
8	Alarm reset key
9	Scroll left to display more shortcut keys
10	Shortcut key area
11	Storage device is in the process of storing
12	Removable storage status symbol of U flash disk

13	e-link symbol
14	Wi-Fi network symbol
15	Battery status symbol
16	Wired network symbol
17	Scroll right to display more shortcut keys
18	Date and time
19	Menu
20	RESP measuring position symbol

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

	In monitor mode: Medium/Low alarm
	In monitor mode: High alarm icon
	In monitor mode: Audio alarm off
	In monitor mode: Audio alarm paused
	In monitor mode: Parameter alarm off In spot-checking or round mode: Parameter Alert off
	NIBP SYS alarm off/Alert off
	NIBP MAP alarm off/Alert off
	NIBP DIA alarm off/Alert off
	Patient type: ADU
	Patient type: PED
	Patient type: NEO

	Measuring oral TEMP in ADU mode	For device with the T2A or F3000 TEMP module only.
	Measuring axillary TEMP in ADU mode	
	Measuring rectal TEMP in ADU mode	
	Measuring oral TEMP in PED mode	
	Measuring axillary TEMP in PED mode	
	Measuring rectal TEMP in PED mode	
	Measuring ear TEMP	For device with the TH Infrared TEMP

### 3.2.1 Using Keys

The monitor has four different types of keys. If the key sound is enabled, the monitor gives a normal key sound when the operation is valid.

#### 3.2.1.1 Permanent Keys

A permanent key is a graphical key that remains on the screen all the time to give you fast access to functions.



To display the main setup menu



To reset the alarm for monitor mode only



To create new patient for spot-checking mode only



To select patient for round mode only



















### 3.2.1.2 Shortcut Keys

A shortcut key is a configurable graphical key, located at the bottom of the main screen. It gives you fast access to functions. The selection of shortcut keys available on your monitor depends on your monitor configuration and on the options purchased. Enter into **Menu > User Maintain > Shortcut** to choose and configure.

In monitor mode, the displayed keys are: Alarm Mute, Admission, Trend graph, Trend table, Alarm review, NIBP review, NIBP measurement, General, Standby mode, Record, Barcode scanning and Score.

In round mode, the displayed keys are: New patient, Review, NIBP AVG, NIBP measurement, General, Record, Standby, Barcode scanning, Night mode and Score.

In spot-checking mode, the displayed keys are: Record, Review, NIBP AVG, NIBP measurement, General, Standby mode, Barcode scanning, Night mode and Score.

	Audio alarm paused/off		Quickly admit a patient
	Enter interface		NIBP measurement
	Review the trend graph		Review the trend table
	Review the alarm event		Enter NIBP review
	General setup		Standby mode
	Record output		NIBP average measurement
	Enter review interface		Night mode
	Barcode scanning		Enter round record interface
	Select this item by the trim knob to enable the touch screen operation		Create new patient

### 3.2.1.3 Hardkeys

A hardkey is a physical key on a monitoring device, such as the main menu key on the front panel. Refer to the illustration in *Front View* for more information.

### 3.2.1.4 Pop-up Keys

Pop-up keys are task-related graphical keys that appear automatically on the screen when required. For example, the confirmation pop-up key appears only when you need to confirm a change.

## 3.3 Operating Mode

### 3.3.1 Demo Mode

To change the operating mode into the demo mode, please refer to the following procedure:

Select **Menu > Common Function**, then choose **Demo Mode** from the popup interface and input password **3045**.

To exit **Demo Mode**, select **Menu > Common Function > Demo Mode**.

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#### **WARNING**

Demo Mode is for demonstration purposes only. You must not change into Demo Mode during monitoring. In Demo Mode, all stored trend information is deleted from the monitor's memory.

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### 3.3.2 Standby Mode

■ The following ways can be used to enter into standby mode.

1. Manual standby: press the shortcut key  on the screen directly or select **Menu > Common Function > Standby**.

2. Automatic standby: In spot-checking or round mode, if there is no measurement, alarm and operation in process, the monitor can enter standby mode automatically without any operations in specified time. Please enter **Menu > System Setup > General > Auto Standby** to choose time from **1 min, 2 min, 5 min, 10 min, 30 min, 1 hour** or **close**. **30 min** is default setting. In monitor mode, permanent setting is **Off**.

■ In standby mode:

1. Light indicator will light and flash. The monitor stops monitoring patients and stores previous monitoring data.
2. The monitor won't respond to all alarms and prompts, except Battery Low alarm.
3. Audio alarm paused status discontinues. Audio alarm off, alarm off, alarm reset and alarm latch status are not influenced.
4. Continuous real-time recording will be stopped immediately, and other recording task will be stopped after current recording finished.
5. MFM-CMS won't update monitoring data, and will display monitor's standby mode. If network is disconnected, monitor will make request for connection.

■ The monitor exits standby mode in any of the conditions:

1. The user clicks anywhere on the screen or presses any key.
2. Battery Low alarm occurs.
3. MFM-CMS or gateway sends exit order to monitor.

After exiting standby mode, the monitor resumes monitoring, including parameter monitoring, storage and alarm; users need to press Recorder key to restart recording.

**NOTE:**

The monitor is unable to enter into standby mode when exporting data.

### 3.3.3 Night Mode

To switch to night mode, you may:

- Select the shortcut key  on the main screen, or
- Select **Menu > Common Function > Night Mode**.

**NOTE:**

In night mode, the sound of key and pulse is muted; the alarm volume and screen brightness are down to their minimum; the settings including key volume, PR volume, alarm volume and screen brightness are unavailable.

### 3.3.4 Other Modes

Select **Menu > System Setup > Mode** to choose **Monitoring Mode** (also called Monitor mode in this text), **Spot Mode** (also called Spot-checking mode in this text) or **Round Mode**. Then, the selected working mode will be displayed in left part of general information area. Details of these 3 modes refer to Chapter *Managing Patients*.

**NOTE:**

1. After the mode switch, the history data can be checked in the previous working mode.
2. In these 3 modes, each setting item is respectively independent. For instance, in monitor mode, NIBP parameter is selected in parameters setup, but this setting is not affected and still keeps unchanged when the monitor enters spot-checking mode or round mode.

## 3.4 Changing Monitor Settings

### 3.4.1 Adjusting Screen Brightness

To change the screen brightness, select **Menu > System Setup > General**, and select the appropriate setting for the screen brightness. **10** is the brightest, **1** is the least bright.



## 3.4.2 Adjusting Volume

### 3.4.2.1 Adjusting Key Volume

The key volume is the volume you hear when you select any field on the monitor screen or when you turn the knob.

To adjust the key volume, select **Menu > System Setup > General**, then select the appropriate setting for the key volume: six levels represent volume and level five represents the maximum, and level zero represents volume off.

### 3.4.2.2 Adjusting Alarm Volume

To change the alarm volume, select **Menu > System Setup > General** and select the desired setting for the **AlarmVolume** item: five levels represent volume and level five represents the maximum, and level one represents minimum. Alarm volume cannot be off.

### 3.4.2.3 Adjusting Alert Volume

In monitoring or spot mode, to change the alert volume, select **Menu > System Setup > General** and select the desired setting for the **Alert Volume** item: six levels represent volume and level five represents the maximum, and level zero represents volume off.

## 3.5 Checking Your Monitor Information

To check the monitor information, please select **Menu > Common Function > Device Information**. Monitor information includes **Device, Config, About, Network**.

**Device** includes: Device Name, Department, Serial Number.

**Config** includes: the configuration monitor supported (such as Wi-Fi, Wired, USB, Barcode, etc.), Factory model of the parts supported and Protocol Version. The currently used configurations are marked with √.

**About** includes: software version, parameters version and so on.

**Network** includes: Network method, the monitor IP, server IP (such as MFM-CMS) and so on.

## 3.6 Networked Monitoring

Your monitor can be connected to the wired network and the wireless network. If the monitor is networked, a network symbol is displayed on the screen.

### NOTE:

- 1 Be aware that some network-based functions may be limited for monitors on wireless networks in comparison to those on wired networks.
- 2 When selecting dynamic IP mode, please check the IP address from MFM-CMS.

### 3.7 Common Settings

Select **Menu > User Maintain**, then type the correct password **ABC** into the displayed interface.

**Common** settings include: Department, Language, Nurse call, Internal Scanner Mode, Scanner Management, Scanner Setup, Format internal storage device and so on.




#### **WARNING**

Change to date and time will influence the storage of trend data.

#### **NOTE:**

To make the language change validate, please restart the monitor.

### 3.8 Disabling the Touch Screen

The user can disable touch screen operation by selecting and holding the permanent key  for three seconds. A message of **Screen Locked** and the symbol  will be displayed at the bottom of screen. To enable the touch screen operation, select and hold the menu key  for three seconds again.

### 3.9 Using the Barcode Scanner

To enter the barcode setup menu, please select **Menu > User Maintain**. After entering the required password **ABC**, select **Common > Scanner Setup**. Then the user can set MRN, last Name, first Name and so on.

If internal scanner is configured and it has also been set to on in **Factory Maintain**, user can choose **Manual** or **Auto** for **Internal Scanner Mode** in **User Maintain** to scan the barcode.

User can also check relevant barcode device information in **Scanner Management**.

In monitor mode, after barcode scanning, a message will be displayed to ask user to confirm the update. User can choose based on requirements. In round mode, after barcode scanning, a dialog box to confirm information will be displayed. New creation will be finished after user's confirmation. In spot-checking mode, scanning barcode can create new patient directly.

If the barcode scanner is connected for the first time, a message will be displayed to ask user to confirm the connection. User can choose based on requirements. Please refer to chapter *Accessories* for the recommended scanner 01.23.068023.

#### **NOTE:**

The start and end code should be set before using scanner to update patient, otherwise the barcode can't be recognized normally. After setting start and end code, user should also set male code and female code to distinguish the gender.

### 3.10 Using Keyboard and Mouse

The monitor can connect keyboard and mouse via USB interface. Mouse is used for controlling cursor and keyboard for inputting.

## Chapter 4 Alarms

The alarm information here applies to all measurements. Measurement-specific alarm information is discussed in the sections of individual measurements.

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### **WARNING**

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

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### 4.1 Alarm Category

In monitor mode, the monitor provides two types of alarms: physiological alarms and technical alarms. Also, the monitor provides prompts.

In round or spot-checking mode, the monitor provides alert information (please refer to chapter *Alert Setup* for details) instead of physiological alarms, and technical alarms. **Battery Low** will be displayed in a special audio and visual way. The mode is “DO-DO-DO”, which is triggered once every 25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz ~ 0.8 Hz.

#### 4.1.1 Physiological Alarms

If one or several physiological parameters of the currently monitored patient exceed the predefined alarm limit, the monitor will give an alarm, and this type of alarm is called physiological alarms. About the detailed alarm information, please refer to the Section *Physiological Alarm Information*.

#### 4.1.2 Technical Alarms

If one or several technical status of the device is in abnormal status, the monitor will give an alarm. And this type of alarm is called technical alarms. Technical alarms can't be disabled. About the detailed alarm information, please refer to Section *Technical Alarm Information*.

#### 4.1.3 Prompts

The monitor can give the character indication of monitoring process or other functions. And this character is called prompts. About the detailed alarm information, please refer to Section *Prompts*.

### 4.2 Selecting Alarm Tone Type

The user can select the alarm tone type as desired.

1. Select **Menu > User Maintain**, and enter the required password **ABC**.
2. Select **Alarm**, and set **Alarm Tone** to **Standard** or **Mode 1**.
  - ◆ **Standard**: Standard alarm sound according to IEC 60601-1-8.
  - ◆ **Mode 1**: User customized alarm sound according to clinical applications.

## 4.3 Alarm Levels

In terms of severity, the device's alarm levels can be classified into three categories: high level alarms, medium level alarms and low level alarms.

### 1. High level alarms

A high level alarm intensively warns the operator of a high priority alarm condition which requires immediate operator response. Failure to respond to the cause of the alarm condition is likely to result in death or irreversible injury of the patient.

### 2. Medium level alarms

A medium level alarm warns the operator of a medium priority alarm condition which requires prompt operator response. Failure to respond to the cause of the alarm condition is likely to result in reversible injury of the patient.

### 3. Low level alarms

A low level alarm reminds the operator of a low priority alarm condition which requires response. And the response time for a low priority alarm condition can be greater than that for a medium priority alarm condition. Failure to respond to the cause of the alarm condition is likely to result in discomfort or reversible minor injury of the patient.

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

#### Standard

Alarm level	Prompt
High	Mode is “DO-DO-DO-----DO-DO, DO-DO-DO-----DO-DO”, which is triggered once every 8-10 seconds. The alarm indicator flashes in red, with frequency of 1.4 Hz~2.8 Hz. The alarm message flashes with red background, and the symbol *** is displayed at the alarm area.
Medium	Mode is “DO-DO-DO”, which is triggered once every 23-25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz~0.8 Hz. The alarm message flashes with yellow background, and the symbol ** is displayed at the alarm area.
Low	Mode is “DO-”, which is triggered once every 28-30 seconds. When physiological alarm is triggered, the alarm indicator is constantly yellow. While for technical alarm, the alarm indicator is constantly blue. The alarm message flashes with yellow background, and the symbol * is displayed at the alarm area.

#### Mode 1

Alarm level	Prompt
High	Mode is “Di-Di-Di-Di-Di-Di”, which is triggered once every 10 seconds. The alarm indicator flashes in red, with frequency of 1.4 Hz~2.8 Hz. The alarm message flashes with red background, and the symbol *** is

	displayed at the alarm area.
Medium	Mode is “Di-Di-Di”, which is triggered once every 25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz~0.8 Hz. The alarm message flashes with yellow background, and the symbol ** is displayed at the alarm area.
Low	Mode is “Di-”, which is triggered once every 30 seconds. When physiological alarm is triggered, the alarm indicator is constantly yellow. While for technical alarm, the alarm indicator is constantly blue. The alarm message flashes with yellow background, and the symbol * is displayed at the alarm area.

The sound pressure range for standard audible alarm signals is from 45 dB to 85 dB, and for Mode 1 is from 30 dB to 85 dB.

When different level alarms occur at the same time, alarm sound and alarm indicator prompt the highest level alarm, alarm messages display in turn.

The parameter area has two flash methods to prompt alarms: background flash and text flash. User can click respective parameter area to enter parameter setup menu > **Alarm** > **Visual Effect**:

1. **Text Flash**: text flashes with frequency of 1 Hz.
2. **Background Flash**: background flashes with frequency of 1 Hz.


### **WARNING**

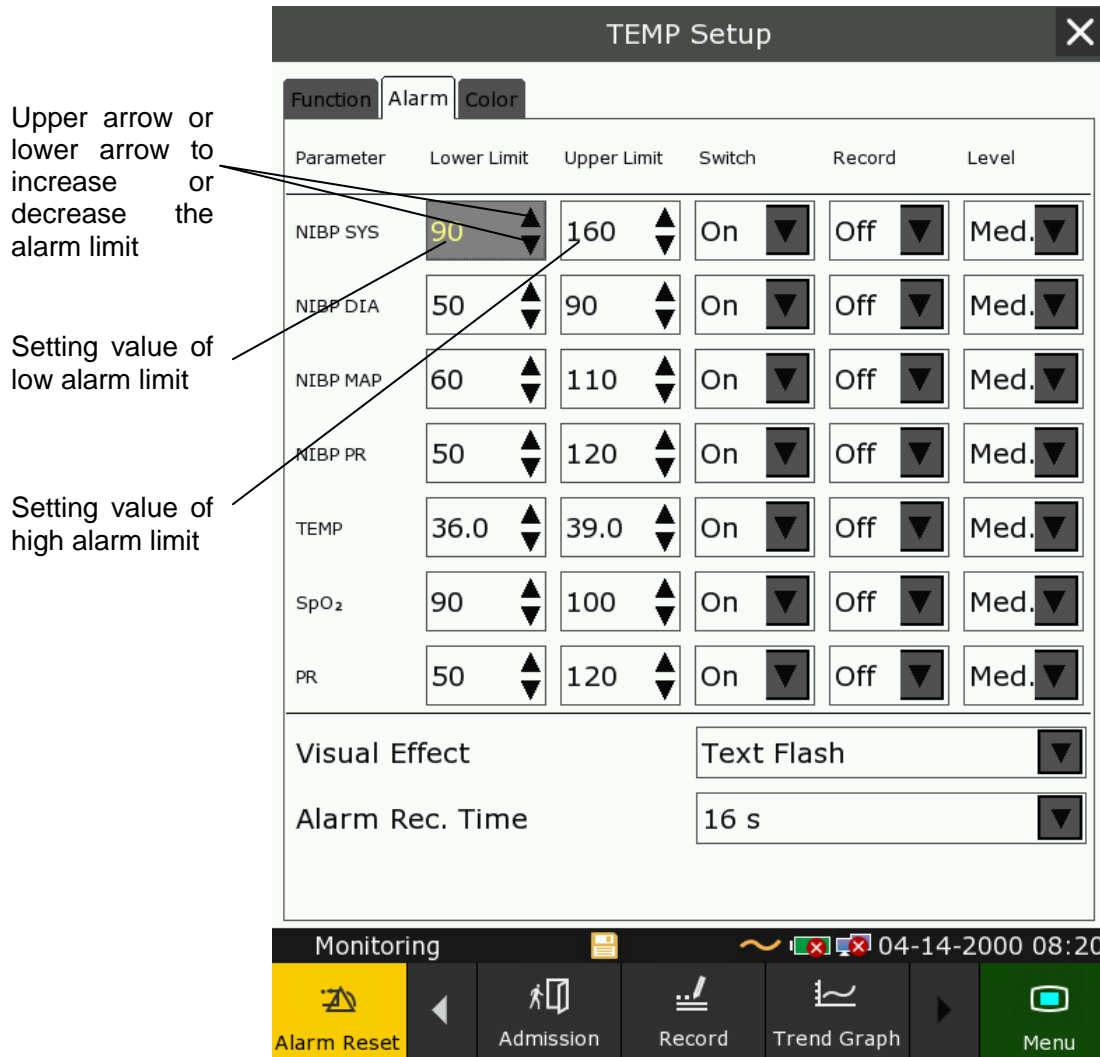
- 1 Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
- 2 Ensure the volume is properly set up. When the sound pressure of audible alarm is below or equivalent to the ambient noise, it may be difficult for the operator to distinguish the audio alarm.

## 4.4 Controlling Alarm

### 4.4.1 Setting Parameter Alarm

In monitor mode, parameter alarm settings including alarm switch, alarm record, alarm level and alarm limit are available on the respective alarm setup menu for each parameter. Click respective parameter area to enter parameter setup menu > **Alarm** to open the menu shown below for alarm settings of each parameter. Also, click **Alarm Rec. Time** to set the waveform length of alarm record. 8 s, 16 s and 32 s are optional.






















When alarm switch is off, the parameter alarm off icon  will be displayed in the corresponding parameter displaying area.





Upper arrow or lower arrow to increase or decrease the alarm limit

Setting value of low alarm limit

Setting value of high alarm limit

Parameter	Lower Limit	Upper Limit	Switch	Record	Level
NIBP SYS	90	160	On 	Off 	Med. 
NIBP DIA	50	90	On 	Off 	Med. 
NIBP MAP	60	110	On 	Off 	Med. 
NIBP PR	50	120	On 	Off 	Med. 
TEMP	36.0	39.0	On 	Off 	Med. 
SpO <sub>2</sub>	90	100	On 	Off 	Med. 
PR	50	120	On 	Off 	Med. 

Visual Effect: Text Flash 

Alarm Rec. Time: 16 s 


Monitoring 04-14-2000 08:20

Alarm Reset Admission Record Trend Graph Menu

**WARNING**

- 1 When the alarm is set to **Off**, the monitor won't give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.
- 2 Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.
- 3 Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.


4.4.2 Audio Alarm Paused

You can temporarily prevent alarms from sounding by pressing shortcut key .

You can set the alarm pause time as desired. The default alarm pause time is 120 s.

1. Select **Menu > User Maintain**, and enter the required password **ABC**.
2. Select **Alarm**, and set **Pause Time** to **60 s**, **120 s**, or **180 s**.

When alarms are paused,

- ◆ The audio alarm is turned off, and no alarms are sounding.
- ◆ The visual alarm indications are still displayed.
- ◆ The monitor displays the audio alarm paused icon .
- ◆ The monitor displays the remaining pause time in seconds with red background.

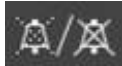
When the alarm pause time expires, the audio alarm paused status is automatically terminated and alarm is sounding. You can also terminate the alarm paused status by pressing shortcut key



#### NOTE:


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

### 4.4.3 Audio Alarm off

Set **Pause Time** to **Permanent**, press shortcut key , the monitor displays information: **please confirm whether to activate audio alarm off function?** Click **Yes**, the monitor will enter into audio alarm off status. Click **No**, the monitor will keep current status.

- The audio alarm is turned off, and no alarms are sounding.
- The visual alarm indications are still displayed.


**Remind signal:** Audio alarm off symbol  and **Audio Alarm off** on a red colored background are displayed with an interval of 2 s during the audio alarm off status.

Pressing shortcut key  again can resume the audio alarm.

#### NOTE:

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

### 4.4.4 Alarm Reset

Select the shortcut key  on the screen directly or select **Menu > Alarm Setup > Alarm Reset**. When the alarm is reset,

- ◆ No alarms are sounding until a new alarm occurs.
- ◆ As for the active alarms, the visual alarm indications are still displayed.

- ◆ All latching alarms are cleared. If the alarm condition is no longer present, all alarm indications stop and the alarm is reset.
- ◆ It will not influence the configuration of physiological alarm off, audio paused, and audio off status.


**NOTE:**

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

## 4.5 Latching Alarms

To configure the alarm latching setting, select **Menu > Maintenance > User Maintain > Alarm** and choose **Alarm Latch** which can be set to **On** or **Off**. When it is set to **Off**, alarm indications end when the alarm condition ends. When it is set to **On**, the visual and audible alarm indications are still displayed after the alarm condition ends; meanwhile, the alarm time is also displayed for the latched alarm for your reference. The indication lasts until you acknowledge the alarm.



You can use the permanent key  on the screen to acknowledge the latched alarm.

## 4.6 Alarm of SpO<sub>2</sub> Sensor Off

In monitor mode, user can enter **Menu > User Maintain > Alarm** to adjust the alarm level of **SpO<sub>2</sub> Sensor Off** to **High, Med.** or **Low**. It is set to **Low** by default.

In monitor mode, it is processed and displayed as prompt without adjustable level.

## 4.7 Network Disconnected Alarms

To configure the network disconnected alarms, select **Menu > User Maintain > Network** and choose **Disconnect Alarm** which can be set to **On** or **Off**. The alarm is off by default.

**NOTE:**

1. When the monitor is connected with the central monitoring system, you must set **Disconnect Alarm** to **On**.
2. If **Disconnect Alarm** occurs during audio alarm paused or audio alarm off status, the monitor will prompt a sounding alarm with information of **NetWork Disconnect**. During the network disconnected status, activating audio alarm paused or audio alarm off function can disable the audio alarm signal of **Disconnect Alarm**.

## 4.8 Delete All Alarm Events

Select **Menu > User Maintain > Alarm > Clear Alarm Log** to delete.

---

**WARNING**

The deleted alarm events are beyond retrieve. Please use this function cautiously.

---



## 4.9 Testing Alarms

When you switch the monitor on, a self test is started with two “Di” tone. You must check that the alarm indicator lights (it lights in red, yellow and blue in turn during starting up) and that you hear a single tone (that is same with low level alarm sound). This indicates that the visible and auditory 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.

**NOTE:**

The monitor will reboot in 3 seconds due to self-test failure.

## Chapter 5 Alarm Information

### 5.1 Physiological Alarm Information

#### **WARNING**

During monitoring, the physiological alarms SpO<sub>2</sub> No Pulse and SpO<sub>2</sub> Desat Limit are preset to be on and cannot be turned off.

Message	Cause	Alarm level
<b>SpO<sub>2</sub></b>		
SpO <sub>2</sub> High	SpO <sub>2</sub> measuring value is above upper alarm limit.	User-selectable
SpO <sub>2</sub> Low	SpO <sub>2</sub> measuring value is below lower alarm limit.	User-selectable
SpO <sub>2</sub> 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
SpO <sub>2</sub> Desat	SpO <sub>2</sub> measuring value is below the SpO <sub>2</sub> Desat Limit.	High
<b>PR</b>		
PR High	PR measuring value is above upper alarm limit.	User-selectable
PR Low	PR measuring value is below lower alarm limit.	User-selectable
<b>NIBP</b>		
SYS High	SYS measuring value is above upper alarm limit.	User-selectable
SYS Low	SYS measuring value is below lower alarm limit.	User-selectable
DIA High	DIA measuring value is above upper alarm limit.	User-selectable
DIA Low	DIA measuring value is below lower alarm limit.	User-selectable
MAP High	MAP measuring value is above upper alarm limit.	User-selectable
MAP Low	MAP measuring value is below lower alarm limit.	User-selectable
<b>TEMP</b>		
TEMP HIGH	Measuring value of TEMP is above upper alarm limit.	User-selectable
TEMP LOW	Measuring value of TEMP is below lower alarm limit.	User-selectable

## 5.2 Technical Alarm Information

Message	Cause	Alarm Level	Action Taken
<b>SpO<sub>2</sub></b>			
SpO <sub>2</sub> Sensor Off	SpO <sub>2</sub> sensor may be disconnected from the patient measuring site.	User-selectable	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 <sub>2</sub> Sensor Err	Malfunction in the SpO <sub>2</sub> sensor or in the extension cable.	Low	Replace the SpO <sub>2</sub> sensor or the extension cable.
SpO <sub>2</sub> No Sensor	SpO <sub>2</sub> sensor was not connected well or connected to the monitor, or the connection is loose.	Low	Make sure the monitor and sensor are well connected, reconnect the sensor.
SpO <sub>2</sub> Comm Fail	SpO <sub>2</sub> module failure or communication failure	High	Stop using measuring function of SpO <sub>2</sub> module, and notify biomedical engineer or manufacturer's service staff.
SpO <sub>2</sub> Low Perfusion	The pulse signal is too weak or the perfusion of the measurement site is too low. (EDAN SpO <sub>2</sub> )	Low	Reconnect the SpO <sub>2</sub> sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.
SpO <sub>2</sub> Noisy Signal	There is interference with SpO <sub>2</sub> measurement signals due to patient movement, ambient light, electrical interference or else. (EDAN SpO <sub>2</sub> )	Low	Check the condition of patient and avoid patient movement; make sure the cable is well connected.

Message	Cause	Alarm Level	Action Taken
SpO <sub>2</sub> Interference Light	Ambient light around the sensor is too strong. (EDAN SpO <sub>2</sub> )	Low	Reduce interference of the ambient light and avoid sensor's exposure to strong light.
<b>NIBP</b>			
NIBP Comm Fail	NIBP module failure or communication failure	High	Stop using measuring function of NIBP module, and notify biomedical engineer or manufacturer's service staff.
NIBP Leak	NIBP pump, valve, cuff or tube has a leakage. (EDAN NIBP)	Low	Check the connections and the wrapped cuff to see whether they are all prepared well. If failure persists, please notify biomedical engineer or manufacturer's service staff.
NIBP Excessive Pressure	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP Init Pressure High	The initial pressure is too high during measuring	Low	
NIBP Aux Excessive Pressure	Pressure has exceeded the second safety limit as specified.	High	Notify biomedical engineer or manufacturer's service staff.

<b>Message</b>	<b>Cause</b>	<b>Alarm Level</b>	<b>Action Taken</b>
NIBP Time Out	Measuring time has exceeded the specified time.	Low	Measure again or use other measuring method.
NIBP Self Test Error	Sensor or other hardware errors.	Low	If failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP Cuff Type Error	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.
NIBP System Pressure Abnormality	Atmospheric pressure or system pressure is abnormal. The valve is occluded so that deflation is failed.	Low	Check whether the airway is occluded or pressure sensor works properly. If the problem still exists, contact your service personnel.
NIBP System Failure	NIBP is not calibrated.	High	Contact your service personnel.
NIBP Weak Signal	Cuff is too loose or patient pulse is too weak.	Low	Use other methods to measure blood pressure.
NIBP Range Exceeded	Maybe the patient blood pressure value is beyond the measurement range.	High	Use other methods to measure blood pressure.
NIBP Loose Cuff	Cuff is not properly wrapped or no cuff is connected.	Low	Properly wrap the cuff.

Message	Cause	Alarm Level	Action Taken
NIBP Interference	Signal noise is too large or pulse rate is not regular due to the patient movement.	Low	Make sure that the patient under monitoring is motionless.
NIBP Leak Test Error	Fail to deflate normally during the leak test, so NIBP leak test cannot be finished.	Low	Test again. If the problem still exists, contact your service personnel.
<b>T2A TEMP</b>			
Temp COMM STOP	TEMP module failure or communication failure.	High	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
Temp exceed limit	The TEMP value is beyond the range of 35.5 °C ~ 42 °C	Medium	Put the sensor into the sensor bracket, take it out and measure again.
No TEMP SENSOR	TEMP sensor is not connected to the TEMP module.	Low	Connect the sensor and the monitor well, and measure again.
Ambient temp too high	The Sensor temperature is higher than +40 °C	Low	Put the sensor into the sensor bracket, measure again after the ambient temperature reaches normal value.
Ambient temp too low	The Sensor temperature is lower than +10 °C	Low	
Warm-up error	Malfunction in the warm-up circuit	Medium	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.

Message	Cause	Alarm Level	Action Taken
Measure Site Error	The probe in use is not consistent with the measure position set on the monitor.	Medium	Correctly set the measure position on the monitor.
<b>TH TEMP</b>			
Temp exceed limit	The TEMP value is beyond the range of 34 °C ~ 42.2 °C	Medium	Check the integrity of the probe cover, make sure it is clean, and take a new measurement.
<b>F3000 TEMP</b>			
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	Direct Mode patient thermistor unstable or out of range.	Low	
Temp Error P03	Direct Mode heater thermistor unstable or out of range.	Low	

Message	Cause	Alarm Level	Action Taken
Temp Error P04	Predict Mode patient thermistor unstable or out of range.	Low	
Temp Error P05	Predict Mode heater thermistor unstable or out of range.	Low	
Temp Error P06	Unable to pre-heat probe tip.	Low	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.  <b>NOTE:</b> Measure readings displayed on the screen are unreliable when the monitor indicates Temp Error P06.
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.



Message	Cause	Alarm Level	Action Taken
Measure Site Error	The probe in use is not consistent with the measure position set on the monitor.	Medium	Correctly set the measure position on the monitor.
<b>Others</b>			
Battery Low	Battery Low	High	Please change the battery or charging.
Recorder Out Of Paper	Recorder Out Of Paper	Low	Please install the paper
Recorder Not Installed	The user presses the <b>RECORD</b> button when the monitor is not installed with a recorder.	Low	Notify the manufacturer's service staff to install and set the recorder.
Removable device is full	Less than 10M space is left in the removable device.	Low	Delete some data in the removable device or use another removable device.
Removable dev read-only	The removable device is read-only.	Low	Repair the removable device or replace it with a new one.
Network Disconnect	In distributed alarm system, the monitor's network is disconnected.	Low	<ol style="list-style-type: none"> <li>1) Check if the network cable is well connected.</li> <li>2) Check if the CMS is turned on.</li> <li>3) Check if the IP of bedside monitor and CMS are on the same network segment.</li> </ol>

### 5.3 Prompts

Message	Cause
SpO <sub>2</sub> Search Pulse	SpO <sub>2</sub> module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.
SpO <sub>2</sub> Noisy Signal	There is interference with SpO <sub>2</sub> measurement signals due to patient movement, ambient light, electrical interference or else. (Nellcor SpO <sub>2</sub> )
Manual Measuring	In manual measuring mode
Continual Measuring	In continuous measuring mode
Auto Measuring	In automatic measuring mode
AVG Measuring	In average measuring mode
Measurem. Canceled	Press the “Start/stop NIBP measurement” button to stop the measurement.
Calibrating	During calibrating
Calibrat. Canceled	Calibration is over.
Leak. Test Running	The leakage test is in process.
Leak.Test Canceled	Pneumatic test over
Resetting	NIBP module in resetting
Please Start	NIBP module is in idle status.
Done	NIBP measurement is completed.
Measure time out	No measuring result after the module entering Predict state for 30 s.
Probe temp too high	The original temperature of sensor $>+33\text{ }^{\circ}\text{C}$ and $\leq+40\text{ }^{\circ}\text{C}$ .
Warm-up over	The monitor displays this message after taking the sensor out of the bracket and warm-up is over.
Predict over	After the Predict measuring is over, the data and message display on the interface.
Incomplete parameter input, unable to score	In MEWS interface, parameters are not completely input.
No WIFI module detected	No Wi-Fi module is detected.
Temp SENSOR OFF	The probe is disconnected from the patient.

Message	Cause
Quick Predict Over	Quick prediction measurement is completed.
MONITORING	The mode is switching to Monitor Mode.

## 5.4 Adjustable Range of Alarm Limits

SpO<sub>2</sub> alarm limits are listed as follows (unit %):

	ALM HI	ALM LO
SpO <sub>2</sub>	100	20

SpO<sub>2</sub> Desat Limit are listed as follows (unit %):

SpO <sub>2</sub> Desat Limit	Default value: 80%, Adjustable range: 20% ~ 99%, adjustment step 1%
	Path: <b>User Maintain &gt; Alarm &gt; SpO<sub>2</sub> Desat Limit</b>

PR alarm limits is listed as follows: unit (bpm)

	ALM HI	ALM LO
PR	300	30

NIBP alarm limits are listed as follows: unit (mmHg, kPa, 1 mmHg=0.133 kPa)

EDAN module:

Patient Type		ALM HI	ALM LO
ADU	SYS	270	40
	DIA	215	10
	MAP	235	20
	PR (NIBP)	240	40
PED	SYS	230	40
	DIA	180	10
	MAP	195	20
	PR (NIBP)	240	40
NEO	SYS	135	40
	DIA	100	10
	MAP	110	20
	PR (NIBP)	240	40

SunTech module:

Patient Type		ALM HI	ALM LO
ADU	SYS	260	40
	DIA	200	20
	MAP	220	26
	PR (NIBP)	220	30
PED	SYS	230	40
	DIA	160	20
	MAP	183	26
	PR (NIBP)	220	30
NEO	SYS	130	40
	DIA	100	20
	MAP	110	26
	PR (NIBP)	220	30

TEMP alarm limits are listed as follows:

Patient Type	ALM HI	ALM LO	Step
ADU/PED	+42 °C (+107.6 °F)	+35.5 °C (+95.9 °F)	+0.1 °C (32.2 °F)

## Chapter 6 Managing Patients

### 6.1 Monitor Mode

Monitor mode is used for single patient's monitoring and management.

#### 6.1.1 Admitting a Patient

The monitor displays physiological data and stores it in the trends as soon as a patient is connected. This allows you to monitor a patient who is not yet admitted. It is however important to admit patients properly so that you can identify your patient on recordings, reports, and networked devices.

During admission you enter data that the monitor needs for safe and accurate operation. For example, the patient category setting determines the algorithm the monitor uses to process and calculate some measurements, the safety limits that are applied for some measurements, and the alarm limit ranges.

To admit a patient, please:

1. Select **Menu > Patient Management > New Patient**, or press the Admit/Create new patient hardkey on the front panel, or scan patient barcode by using barcode scanning shortcut, then a message is displayed to ask the user to confirm to update patient.
2. Click on **No** to cancel this operation; click on **Yes**, the **Patient Info** window is displayed.
3. Enter the patient information:
  - **MRN**: Enter the patient's medical record number.
  - **Last Name**: Enter the patient's last name (family name).
  - **First Name**: Enter the patient's first name.
  - **Bed No.:** Select a bed No. from 1 to 254.
  - **Doctor**: Enter the attending doctor for the patient.
  - **Gender**: **Male**, **Female** and **N/A**.
  - **Type**: Choose the patient type, either **Adult**, **Pediat**, or **Neonat**.
  - **BloodType**: **N/A**, **A**, **B**, **AB** and **O**.
  - **Pace**: Choose **On** or **Off** (You must select **On** if your patient has a pacemaker).
  - **Date of Birth**: Enter the patient's date of birth.
  - **Date of Admission**: Enter the patient's date of admission.
  - **Height**: Enter the patient's height.
  - **Weight**: Enter the patient's weight.
  - **Height unit**: **cm** or **inch**.
  - **Weight unit**: **kg** or **lb**.

**NOTE:**

Creating new patient and updating patient will clear the history data in the monitor associated with the patient.

### 6.1.1.1 Patient Category

The patient category setting determines the algorithm which the monitor uses to process and calculate some measurements, the safety limits that are applied for some measurements, and the alarm limit ranges.

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**WARNING**

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Changing the patient category may change the relevant configuration (such as alarm limits). Always check alarm limits to make sure that they are appropriate for your patient.

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### 6.1.2 Quick Admit

If you do not have the time or information to fully admit a patient, you can use Quick Admit to quickly admit a patient and complete the rest of the patient information later. To quickly admit a patient, please:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu > Patient Management > Quick Admit**, then a message is displayed to ask the user to confirm to update patient.
3. Click on **No** to cancel this operation; click on **Yes** to continue and the **Quick Admit** window is displayed.
4. Configure **Type** and **Pace** to the correct setting and click **Yes** to finish the quick patient admission operation. If you want to quit the operation, click **No**.

### 6.1.3 Editing Patient Information

To edit the patient information after a patient has been admitted, select **Menu > Patient Management > Patient Info.**, and make the required changes on the popup interface.

## 6.2 Round Mode

Round mode is used for parameter measurement and for multiple patients' round data management (maximum 1000 patients at the same time).


### 6.2.1 Patient Management

Select **Menu > Patient Management** to enter Patient Management window where patients information are listed, including bed No., name, patient type and patient ID. If monitor is power off, this information list will be stored.

Also, user can create, import and delete patients in this window, or click one patient line to edit patient information.

### 6.2.1.1 Create New Patient

To create new patient, you may:

1. Select **Menu > Patient Management > New Patient**, or
2. Select the shortcut key  on the main screen, or
3. Press Admit/Create new patient hardkey on the front panel, or
4. Use **Select Patient** permanent key, and then click icon + in popup window , or
5. Scan patient barcode by using barcode scanning shortcut key.

In patient creation window, user can input patient information. When patients' number exceeds the upper limit 1000, monitor will display a prompt.

### 6.2.1.2 Import Patient

Select **Patient Management > Import** to enter import patient window and choose **Source** which includes: **USB flash disk** or **Network**.

If USB flash disk is select, before importing, please set the imported data file to CSV format, and file name should be fixed as: ImportPatientList.csv

When you need to edit the patient information in the file, the following ways are optional:

- ◆ Use Excel to edit: patient information format should be 'bed No. + first name + last name + patient type + MRN'. Patient type can only be English, such as: 23 Wang Xiaoming adult 123456.
- ◆ Use OneNote to edit: patient information format should be 'bed No., first name, last name, patient type, MRN'. Patient type can only be English and the comma in English should also be kept, such as: 23, Wang, Xiaoming, adult, 123456.

#### **NOTE:**

- 1 In the patient list of CSV data file, first name, last name and MRN cannot be more than 63 bits for each, and bed No. cannot be more than 5 bits and must also be the numbers from 1 to 99999.
- 2 In importing process, the monitor will import the patient information that meets the requirements, and the wrong patient information will be prompted. The wrong patient information needs to be revised and re-imported.

All patients to be imported will be listed in a new window. Choose patients you want and click **Import**.

During importing, if the total patients in the monitor exceed upper limit (1000 patients), a confirmation box will be popped up. Choose **OK** to enter patient management window and delete part of existing patients, then return to import patient window to import again. Choose **NO** to return to import patient window and delete part of patients who need to be imported, then import again.

If patient bed NO. has conflict, a confirmation box will be popped up '**Bed NO.XXX has conflict. Update now?**'. Choose **OK** to replace the current patient information which has bed No. conflict. Choose **all** to replace information of all patients who have bed No. conflicts. Choose **NO** to prevent the current replacing and continue importing. Choose **ALL NOT** to prevent replacing of all patients who have bed No. conflicts.

### 6.2.1.3 Delete Patient

Select **Patient Management** > **Delete** > choose patients who need to be deleted > **Delete Selected**, or directly select **Delete Page** or **Delete All**.

This operation can only delete the patient information in patient management window but cannot delete patient history data.

### 6.2.2 Choose Patient for Measurement

Choose the patient for measurement and the patient information will be displayed in the main interface. Also, this patient information keeps the same with that in patient management window.



Click **Select Patient** shortcut key to enter select patient window:

- All patients' bed No. and name are displayed in window. The circle near bed No. shows measurement status by colour. Green means a measured patient has normal measurement value; Red means a measured patient has abnormal measurement value; white means a measured patient has invalid measurement value or patient was not measured.
- To choose patient for current measurement, Click one patient and the patient information will be displayed in the main interface.
- Click icon + to create new patient who will be displayed in the place where the icon + is, and whose information will be synchronized to patient management window.
- **Refresh**: when new round is needed, press this key to refresh all patients' measurement status and enter into pending status.

### 6.2.3 Round Record

#### 6.2.3.1 Original Data Table

The Original data table of single patient is displayed at the bottom of the main interface, is stable and cannot be hidden. If the displayed data exceed maximum 20 groups, the earliest data will be replaced by the latest one. The corresponding original data for round record cannot be deleted.

In the table, SpO<sub>2</sub> data will be updated by following ways:

- By time interval: Click SpO<sub>2</sub> parameter area to enter SpO<sub>2</sub> parameter setup menu > **SpO<sub>2</sub> Storage Inteval**, choose from **30 S**, **1 min**, **2 mins** and **5 mins**. **30 S** is default setting;
- By spot-checking data: when TEMP value is got and when NIBP starts to be measured.



### 6.2.3.2 Round Record Confirmation

- Choose round record

Choose manually: in original data table, click the grey reversed triangle and choose data as the parameter's round record. Or in the original data table area, choose parameter value as round record.

Choose automatically: the round record is subject to the latest valid measurement by default.

- Generate round record

Generate manually: by clicking round record generation key in round record area.

Generate automatically: by switching patient, power off or standby operation, the valid measurement data will automatically generate the round record.

Round record time is subject to the time when round record generates from original data.

## 6.3 Spot-checking Mode

Spot-checking mode is used for spot-checking measurement and for management of multiple patients' spot-checking data.

### 6.3.1 Admit Patient

There are following ways to admit patient. If monitor is connected to network server, the patient information can be synchronized to the network server after admission.

1. Select **Menu > Patient Management**, click **New Patient** to enter new patient window.
2. Select permanent key of create new patient, or press Admit/create new patient hardkey, or scan patient barcode by using barcode scanning shortcut key, and the monitor will automatically finish admitting new patient (that is, series No. will be automatically added by one and other setting items are empty by default, or the monitor updates the information to main interface according to barcode scanning).

### 6.3.2 Modify Patient Information

Select **Patient Management > Patient Info**, or directly click patient information area in main interface to check and modify (serial No. is not editable).

If the monitor is shut down and restarted, the patient information will be restored by default, that is, the patient type is adult and the other information is blank.

## 6.4 Inquire for Patient Information via Network

In monitor, round or spot-checking mode, if the monitor is connected to network server and **ADT Query** (in **User Maintain**) is also set to on, patient information can be checked by MRN.

Select **Menu > Patient Management > New Patient > input MRN** and click **Search** to get patient information and the patient information will be updated to the monitor.

## 6.5 Central Monitoring System

The monitor can be connected to the central monitoring system only in monitor mode. 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.

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

And the monitor supports HL 7 protocol.

### NOTE:

- 1 Use wired instead of wireless networking when connecting the monitor to central monitoring system in the operating room because the ESU will interfere with a wireless network, which may cause networking failure.
- 2 Make sure the network connection between the monitor and the central monitoring system is in good condition when the time synchronization function on the monitor is active (default setting is off. Setting path: **System Setup > Date/Time > Sync Time**). If the setting is on, the monitor will accept time synchronization from MFM-CMS.
- 3 The time synchronization function might not be available to all software versions of MFM-CMS. Consult our technical service department or your local distributor for more information.

## Chapter 7 User Interface

Changing some settings may have the risk, so only the authorized person can change them. After changing the settings, please notify the operator.

### 7.1 Setting Interface Style

The user can set the interface based on the requirement, such as: Parameters needing to be monitored.

### 7.2 Selecting Display Parameters

The user can select the display parameters based on the monitoring and measurement requirements.

Click **Menu > Module Setup** to select the required parameters from the popup interface.

Exit the menu and the screen will adjust the parameters automatically.

### 7.3 Changing Parameter and Waveform Colors

The user can set the display colors of parameter and waveform as desire. Click respective parameter area to enter parameter setup menu > **Color Setup** to make color changes on parameter and waveform.

### 7.4 User Configuration

Users can save the current monitor's configuration, delete the saved user configuration and rename it. Three pieces of user configuration can be saved in the monitor. User can select as desire. The one labeled with ● is current configuration.

To save the user configuration:

1. Select **Menu > Default Setup > User Configure**.
2. Click on **Save**, enter a file name for the configuration and confirm it. A message will display after the operation.

To delete the user configuration:

1. Select **Menu > Default Setup > User Configure**.
2. Select the configuration file needed to delete from the list, click on **Delete** and confirm the operation. A message will display after the operation.

To rename the user configuration:

1. Select **Menu > Default Setup > User Configure**.
2. Select a configuration file needed to rename from the list and click on **Rename**.
3. Enter a name for the configuration file and confirm it.

## 7.5 Default Configuration

To set default configuration, select **Menu > Default Setup**. On the **Default** menu, users can choose a factory configuration (adult, pediatric or neonate) based on the patient category. Also, users can choose a user configuration saved in the monitor if it is available. For more information about user configuration, refer to *User Configuration*.

To check the configuration currently used, select **Menu > Default Setup**. The one labeled with ● is current configuration. If there's no labeled configuration, it means the currently used configuration is not one of them.

## Chapter 8 Monitoring SpO<sub>2</sub>

### 8.1 Overview

SpO<sub>2</sub> is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO<sub>2</sub> measuring unit. SpO<sub>2</sub> Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% of the hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO<sub>2</sub> oxygen saturation of 97%. The SpO<sub>2</sub> numeric on the monitor will read 97%. The SpO<sub>2</sub> numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO<sub>2</sub>/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

### 8.2 SpO<sub>2</sub> Safety Information

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**WARNING**

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- 1 If the SpO<sub>2</sub> sensor cannot work properly, please reconnect the sensor or change a new one.
  - 2 Do not use the SpO<sub>2</sub> sensors if the packaging or the sensor is damaged and return them to the vendor.
  - 3 Prolonged and continuous monitoring may increase the risk of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. More frequent examinations may be required for different patients.
  - 4 Tissue damage may be caused by incorrect application or prolonged measurement duration using the sensor (more than 4 hours). Inspect the sensor periodically according to the sensor user manual.
  - 5 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.
  - 6 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 alarm off.
  - 7 When serious arrhythmia is present, the SpO<sub>2</sub> pulse rate may differ from ECG heart rate but this does not indicate an inaccurate SpO<sub>2</sub> value.
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**NOTE:**

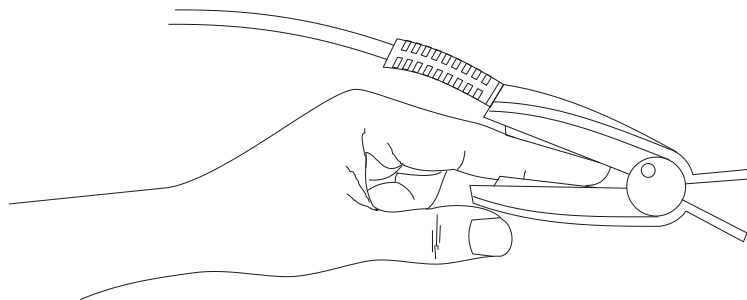
- 1 Make sure the nail covers the light window. The wire should be on the backside of the hand.
- 2 SpO<sub>2</sub> waveform is not proportional to the pulse volume.
- 3 Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line.
- 4 Don't use the functional simulator to assess the SpO<sub>2</sub> accuracy.
- 5 The device is calibrated to display functional oxygen saturation.
- 6 The materials with which the patient or any other person can come into contact conform with the standard of EN ISO 10993-1: 2009.
- 7 When the SpO<sub>2</sub> value is potentially incorrect, it will display “-?-”.

## 8.3 Measuring SpO<sub>2</sub>

1. Select the correct patient category setting (adult/pediatric and neonatal), as this is used to optimize the calculation of the SpO<sub>2</sub> 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<sub>2</sub> socket.



Mounting of the Sensor

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**WARNING**

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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.

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**NOTE:**

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

## 8.4 Measurement Limitations

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

Inaccurate measurements can be caused 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
- poor peripheral perfusion
- excessive 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
- low perfusion

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
- poor peripheral perfusion

**NOTE:**

- 1 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.
- 2 To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.
- 3 Move the sensor to a less active site, and keep the patient still, if possible.

- 4 For Nellcor SpO<sub>2</sub> module, the algorithm automatically extends the amount of data required for measuring SpO<sub>2</sub> and PR depending on the measurement conditions. During normal measurement conditions the averaging time is 6 to 7 seconds. During conditions such as those caused by low perfusion, interference (e.g., external interference such as ambient light or patient movement), or a combination of these, the algorithm automatically extends the amount of data required beyond 7 seconds. If the resulting dynamic averaging time exceeds 20 seconds, the screen will display prompt message “SpO<sub>2</sub> Search Pulse” and SpO<sub>2</sub> and PR will continue to be updated every second. As these conditions extend, the amount of data required continues to increase. If the dynamic averaging time reaches 40 seconds, the screen will display high-level alarm message “SpO<sub>2</sub> No Pulse” indicating a loss-of-pulse condition.

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

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

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

### **NOTE:**

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

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

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 setting. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.

2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system delay time.

## 8.7 Perfusion Index (PI)\*

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

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

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

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

The PI value will be displayed in the SpO<sub>2</sub> parameter area.

## 8.8 Setting Pitch Tone

If tone modulation is on, the PR sound lowers when the SpO<sub>2</sub> level drops. In the **SpO<sub>2</sub> Setup** menu, select pitch tone to toggle between **On** and **Off**.

## 8.9 Setting Sensitivity

The different sensitivity indicates different refresh frequency. **High** indicates the refresh frequency of SpO<sub>2</sub> value is the most frequent. To change the sensitivity, please follow the steps:

- 1 Select the **SpO<sub>2</sub> Setup** menu;
- 2 Select **Sensitivity** on the interface and select the desired sensitivity from the popup list.

## 8.10 NIBP/SpO<sub>2</sub> Simul Measurement Setting

Enter **SpO<sub>2</sub> Setup** > **NIBP Simul** to choose **ON** or **OFF**. t1~t2 is the beginning and ending time. T1 and t2 respectively means beginning and ending (cuff deflation over) NIBP measurement.

When NIBP/SpO<sub>2</sub> Simul measurement is set to on:

- General information area displays **NIBP Simul**;
- During t1~t2, there are no SpO<sub>2</sub> and PR physiological alarms
- Before t1 and after t2, there are normal SpO<sub>2</sub> and PR physiological alarms

- It will not influence other functions of the monitor.

## 8.11 SatSeconds Alarm Management\*

\* Only applicable to the Nellcor SpO<sub>2</sub> module. \* Not applicable to MFM-CMS.

### 8.11.1 Describing SatSeconds

With traditional alarm management, upper and lower alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated by as little as one percentage point, an alarm is immediately triggered. When the SpO<sub>2</sub> level fluctuates near an alarm limit, the alarm is triggered each time the limit is violated. Such frequent alarms can be distracting.

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

The method of calculation is as follows:

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

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

Where:

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

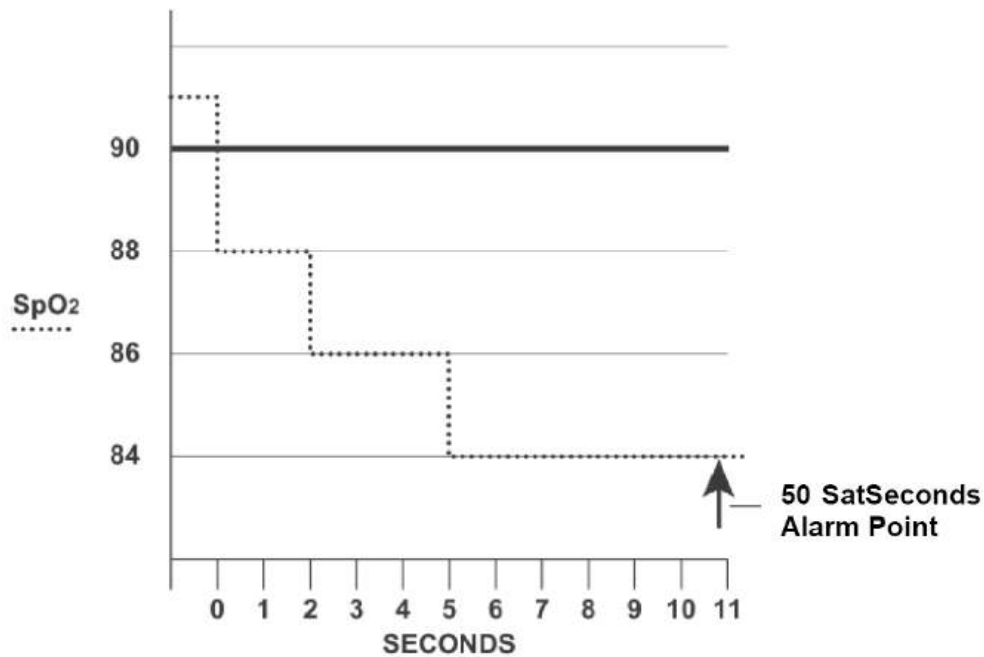
Seconds = number of seconds that SpO<sub>2</sub> remains at that point outside of the limit

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

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

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

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



Alarm Response with SatSeconds

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

### 8.11.2 SatSeconds “Safety Net”

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

### 8.11.3 Setting SatSeconds Duration

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

## Chapter 9 Monitoring PR

### 9.1 Overview

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm). You can display a pulse from any measured SpO<sub>2</sub> signal or NIBP measurement.

### 9.2 PR Source

PR source can be from SpO<sub>2</sub> or NIBP, and is not selectable. SpO<sub>2</sub> is preferred source if PR from SpO<sub>2</sub> is valid. If PR is on, and SpO<sub>2</sub> & NIBP both are off, PR parameter area will display **No source**.

### 9.3 Setting PR Volume

Select **Function** in PR Setup menu, then select the appropriate setting for the PR volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the PR volume will be off. Beat frequency has positive correlation with measurement value.

## Chapter 10 Monitoring NIBP

### 10.1 Overview

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

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

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

### 10.2 NIBP Safety Information

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#### **WARNING**

- 1 Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
  - 2 Do not measure NIBP on the arm of the same side with a mastectomy.
  - 3 Use clinical judgement to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
  - 4 Ensure that the correct setting is selected when performing measurements. It may be dangerous for the neonate to use an over pressure level. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.
  - 5 The equipment is suitable for use in the presence of electrosurgery.
  - 6 Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, child or neonate.)
  - 7 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.
  - 8 Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
  - 9 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.
  - 10 Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.
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**WARNING**

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- 11 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.
  - 12 NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.
  - 13 Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.
  - 14 Verifying the calibration is only applicable for adults, and it cannot be operated in automatic measuring interval. Continuous measuring cannot be operated in automatic measuring interval either.
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**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.

### 10.3 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.

## 10.4 Measurement Methods

There are four methods of measuring NIBP:

- Manual - measurement on demand. Manual is the default setting in round and spot-checking mode.
- Auto - continually repeated measurements (between 1 and 480 minute adjustable interval). Auto is used in monitor mode only.
- Continual- the measurement will run consecutively in five minutes with intervals of 5 seconds, then the monitor enters manual mode or auto mode.
- Average – between 1 and 5 minute adjustable AVG interval, measurement will run as specified AVG times (3 or 5 times are optional), then gets average value. Average is used in round or spot-checking mode only. After finishing average measurement, the monitor enters manual mode.

To change **Measure Mode**, **Interval**, **AVG Interval** and **AVG Times**, please select **NIBP Setup > Function Setup**.

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### **WARNING**

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

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## 10.5 Measurement Procedures

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

1. Ensure the patient position in normal use, including
  - ◆ Comfortably seated (or lie flat on back)
  - ◆ Legs uncrossed
  - ◆ Feet flat on the floor
  - ◆ Back and arm supported
  - ◆ Middle of the cuff at the level of the right atrium of the heart
2. Relax as much as possible and do not talk during the measurement.
3. Wait for five minutes until the first reading is taken.

### **NOTE:**

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.

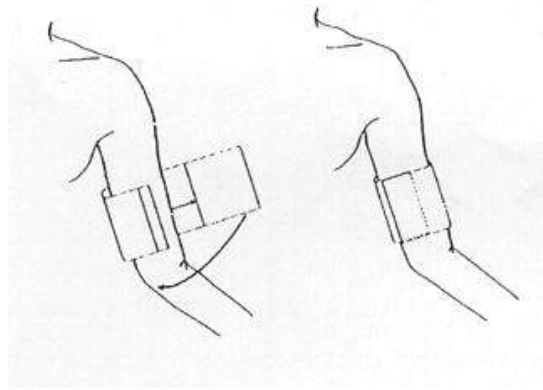
To start the measurement:

1. Connect the air hose and switch on the monitor.
2. Apply the blood pressure cuff to the patient's arm and follow the instructions below. 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.

**NOTE:**

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



Cuff Usage

3. Connect the cuff to the air tubing.
4. Check whether the patient type is appropriately selected. Clicking patient information area or pressing Switch Patient Type hardkey can change patient **Type**.
5. Select a measurement mode in the **NIBP Setup** menu. Refer to section *Operation Prompts* for details.
6. Press the  button on the front panel to start a measurement.

**NOTE:**

- 1 Please make sure the cuff is well connected. A leak of air may cause measurement error.
- 2 Please select the cuff with the suitable size. An unsuitable cuff may cause incorrect measurements.
- 3 Do not disinfect the cuff with radiation or gas, or the cuff will be deteriorated.
- 4 Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.




- 5 NIBP parameter area can display real-time cuff pressure value till displaying SYS value.
- 6 NIBP parameter area keeps measured value for 30 mins. If there is no measurement to continue, the area will display invalid value after 30 mins.

### 10.5.1 Operation Prompts


#### 1. Manual Measuring

Access the **NIBP Setup > Function** menu and set the **Measure Mode** item to **Manual**. Then

press the  button on the front panel to start a manual measurement. During measurement, pressing this button at any time can stop measurement.

#### 2. Automatical Measurement

Access the **NIBP Setup > Function** menu and set the **Measure Mode** item to **Auto**, then press the

 button on the front panel to start the automatical measurement according to the selected time interval. During measurement:


- If measurement is failed or monitor receives the command for suspending, measurement will be stopped. The next measurement will be continued after interval. If alarms of NIBP Excessive Pressure or NIBP Aux Excessive Pressure are present, the whole measurement will be stopped. Manually operation is necessary for a new auto measurement.
- During interval, if interval is changed, after ending of new interval countdown, monitor will start measurement automatically.
- During interval, if user manually starts the measurement, the next auto measurement will start after the ending of countdown which starts from the latest manual measurement; During interval, if user makes a continuous measurement, the whole measurement will be over on the basis of continuous measurement.

#### 3. Continuous measurement

Access the **NIBP Setup** menu; click **Continual** to start a continuous measurement. The continuous measurement will last 5 minutes.

#### 4. AVG measurement

Access **NIBP Setup > Function** menu, set **AVG interval** and **AVG times**, and click **NIBP AVG**; or

click AVG shortcut key  directly to start measurement. During measurement:

- The parameter interface will display **AVG-n** for the Nth measurement;
- Invalid value will not be used for counting average. Invalid value every measurement will result in invalid average;
- There will have sounding of DU... after entire measurement is finished. At that time, a final average value can be displayed. The bottom part of the interface displays **done**, and meanwhile, alert information and technical alarms of the last measurement will be cleared, and alert



information can work normally. The value for each measurement and final average value will be stored in round records/spot-checking trend table which uses icon \* to mark the average value;

- In specified interval, if interval and times have been changed again, the whole average measurement will be ended and measurement times will be zero;
- Other operations, such as changing patient type, entering DEMO or standby mode and so on, can stop the measurement. Meanwhile, parameter interface will be updated;
- At the end of the last measurement, if user presses NIBP measurement key before monitor gets average value with DU... sounding, a new round of average measurement will be started with prompt **AVG-1 (n)** and NIBP average value of the last round will not be displayed. N in **AVG-1 (n)** means the specified AVG times.

#### 5. Stopping measurement

During measurement, press the  button on the front panel at any time to stop measurement.

#### NOTE:

- 1 In auto or average mode, when measurement is in process, pressing the  button can only stop the current measurement, and cannot end the entire measurement mode. At the end of countdown, monitor continues to finish the NIBP measurement; when measurement is in interval, pressing the  button can start measurement in advance.
- 2 To end the whole AVG measurement, please click AVG measurement shortcut key, or click **Stop** in NIBP setup menu.

### 10.5.2 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

### 10.6 NIBP Multi-Review Window

In monitor mode, clicking the triangle icon at the bottom of main interface can display/hide NIBP multi-review window.

### 10.7 Resetting NIBP

Available for EDAN module only.

When the pressure does not work properly and the system fails to give a message for the problem, pick **Reset** in the **User Maintain > NIBP** menu to activate self-test procedure, and thus restore the system from abnormal performance.

## 10.8 Calibrating NIBP

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

## 10.9 Leakage Test

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### **WARNING**

This leakage test other than being specified in the EN 1060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

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### Procedure of 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. Make sure the patient type has been set to **Adult**.
4. Access **Menu > User Maintain**.
5. Select **Leakage Test** in **NIBP**. Then the prompt **Leak. Test Running** will appear indicating that the system has started the leakage test.

For EDAN module:

The system will automatically inflate the pneumatic system to about 180 mmHg. After 20 seconds to 40 seconds, if system leakage has detected, the system will automatically open the deflating valve to stop the leak test and indicates **NIBP Leak**. If no system leakage is detected when the pneumatic system is inflated to 180 mmHg, the system will perform a deflation to an approximate value of 40 mmHg and subsequently perform the second phase leak test. After 20 seconds to 40 seconds, the system will automatically open the deflating valve and provide corresponding indication based on the test result.

For SunTech module:

#### **NOTE:**

When applying high pressures; take special care to increase the pressure at a rate that will not cause unwanted overpressure errors (300 mmHg).

Manually inflate the pneumatic system to approximately 250 mmHg. Start the timer and wait 60 seconds for the pneumatic system to reach its pressure equilibrium point. After the waiting period, record the pneumatic pressure level (P1) and wait another 60 seconds and record the pneumatic

pressure level again (P2). Safety circuitry on the module only allows the pressure in the pneumatic system to remain above 10mmHg for 180 seconds. When this safety time limit is exceeded, the valves will open releasing the pressure. Subtract P2 from P1 and this is the leak rate per minute.

- If the alarm information **NIBP Leak** appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the leakage test. If the failure prompt still appears, please contact the manufacturer for repair.

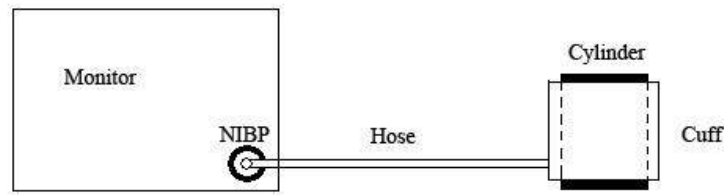


Diagram of NIBP Air Leakage Test

## 10.10 Setting Inflation Value

To change the inflation value:

- Select **NIBP Setup > Function Setup > Inflation value**;
- Choose **AUTO** or other inflation values from the pull-down list.
  - ◆ If other inflation values are chosen, the preset value by users will be adopted as the inflation value when measuring blood pressure.
  - ◆ If **AUTO** is chosen, the default value will be adopted as the inflation value when measuring blood pressure.

## 10.11 Measuring PR

Access **NIBP Setup > Function Setup**, and set **PR** to **ON** or **OFF**.

- The NIBP parameter area displays PR value from NIBP;
- Monitor will not record PR value from NIBP;
- NIBP review table will display PR, and other review tables won't.

## 10.12 NIBP Auto Recording

In monitor mode, the monitor supports NIBP recording for each valid measurement. Access **Menu > System Setup > Recorder > NIBP Trigger Recording** to choose ON. Default setting is Off.

## Chapter 11 Monitoring TEMP

### 11.1 Quick TEMP with T2A Module

#### 11.1.1 Introduction

iM3 with the T2A module takes a temperature in either Predict or Monitor Mode. In the Predict mode, the monitor measures oral/axillary/rectal TEMP in a short time, calculates and gets the measuring results. In Monitor mode, it can monitor patient for 10 min. The Oral/Axillary sensor and Rectal sensor are of standard configuration.

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

#### Making a TEMP Measurement

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

It takes 5min for the body temperature to stabilize.

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#### **WARNING**

- 1 To ensure optimal accuracy, always confirm that the correct mode and alarm limit are selected. Changing the measure position may lead to the change of alarm limit.
  - 2 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable from the socket, and then the screen will display the error message **TEMP SENSOR OFF** and the audible alarm is activated.
  - 3 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.
  - 4 Verification of the temperature module is necessary as frequently as dictated by your Hospital Procedures Policy. When you need to calibrate the temperature measurement, please contact the manufacturer.
  - 5 Patient actions may interfere with accurate oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum or mints, brushing teeth, smoking or performing strenuous activity may affect temperature readings for up to 20min after activity has ended.
-

**WARNING**

- 6 Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.
- 7 Biting the sensor tip while taking a temperature may result in damage to the sensor.
- 8 Use disposable TEMP sensor covers recommended by EDAN to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.
- 9 Temp measurement isn't suitable for use during defibrillation.
- 10 In monitoring mode, no physiological alarms are available.

**NOTE:**

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

### 11.1.2 Measuring Procedure

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

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

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

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

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

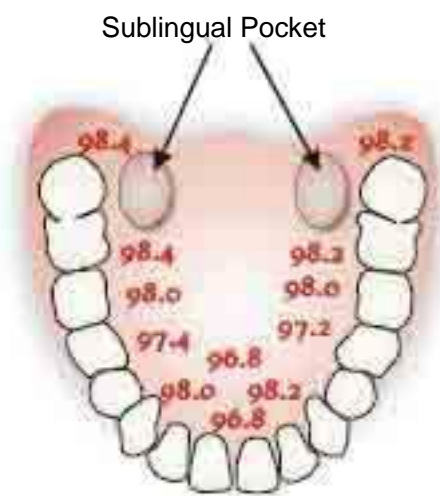


Figure 11-1 Measuring position in mouth

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

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

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

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

**NOTE:**

1. After one measurement, the user should put the sensor back to the sensor bracket and then take it out for starting a new measurement.
2. The reference body site temperature is the same as the temperature of the measuring site.

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

### 11.1.3 TEMP Setup for T2A Module

Enter **TEMP SETUP** to set the following items:

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

Make sure **MEASURE POS** is properly set up every time before you withdraw the probe from the probe well. After withdrawing the probe from the probe well, make sure **MEASURE MODE** is properly set up.

## 11.2 Quick TEMP with F3000 Module

### 11.2.1 Introduction

iM3 with the F3000 module measures patient temperatures by oral, axillary or rectal means.

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

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

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**WARNING**

- 1 Do not use this device near flammable anesthetics. Not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- 2 Do not use this thermometer without first installing a new probe cover.
- 3 Do not reuse the disposable probe covers.
- 4 Use probe covers supplied by the manufacturer with this thermometer only. Use of any other probe cover will result in erroneous temperature readings.
- 5 The thermometer and probe covers are Non-sterile. Do not use on abraded tissue.
- 6 To limit cross contamination, use Blue devices for Oral and Axillary temperature taking only.
- 7 Use RED devices only for RECTAL temperatures.
- 8 Thoroughly dry all electrical contacts on both probe and thermometer after washing, or device may fail to function properly.
- 9 For re-calibration, service or integrity checks, refer to a qualified Biomedical Technician or return to the manufacturer.
- 10 Do not open the F3000 module. No user-serviceable parts inside. Opening of the module may affect calibration and voids warranty.
- 11 Disposal of used probe covers must be performed in accordance with current medical practices or local regulations regarding disposal of infectious, biological medical waste.
- 12 Cleaning frequency and practices must be consistent with institutional policy for cleaning of non-sterile devices.
- 13 The F3000 module is not intended for neonatal patients.
- 14 In monitoring mode of TEMP module, no physiological alarms are available.
- 15 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.

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**NOTE:**

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



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

### 11.2.2 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.

### 11.2.3 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.

## 11.2.4 Measuring Mode

### **Predictive Mode**

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

### **Quick Predictive Mode**

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

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

Quick Predictive Mode is not available when in Cold Mode.

### **Monitoring Mode**

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

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

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

### **Cold Mode**

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

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

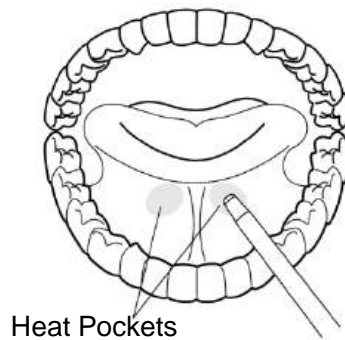
## 11.2.5 Measuring Procedure

### Oral and Axillary Temperature Taking

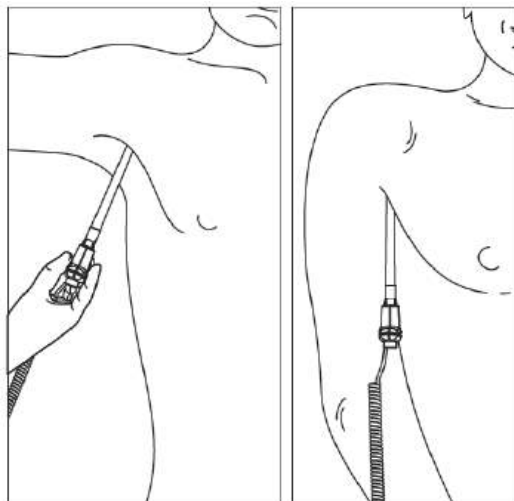
1. Make certain that the Blue isolation chamber /probe unit is attached.
2. Withdraw probe and apply a probe cover. The thermometer turns on automatically and a beep will be heard when the probe completes warm-up.
3. For Oral temperatures, insert the probe tip deep into the sublingual pocket next to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

#### NOTE:

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



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



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

### **Rectal Temperature Taking**

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

#### **NOTE:**

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

### **11.2.6 TEMP Setup for F3000 Module**

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

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

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

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

**NOTE:**

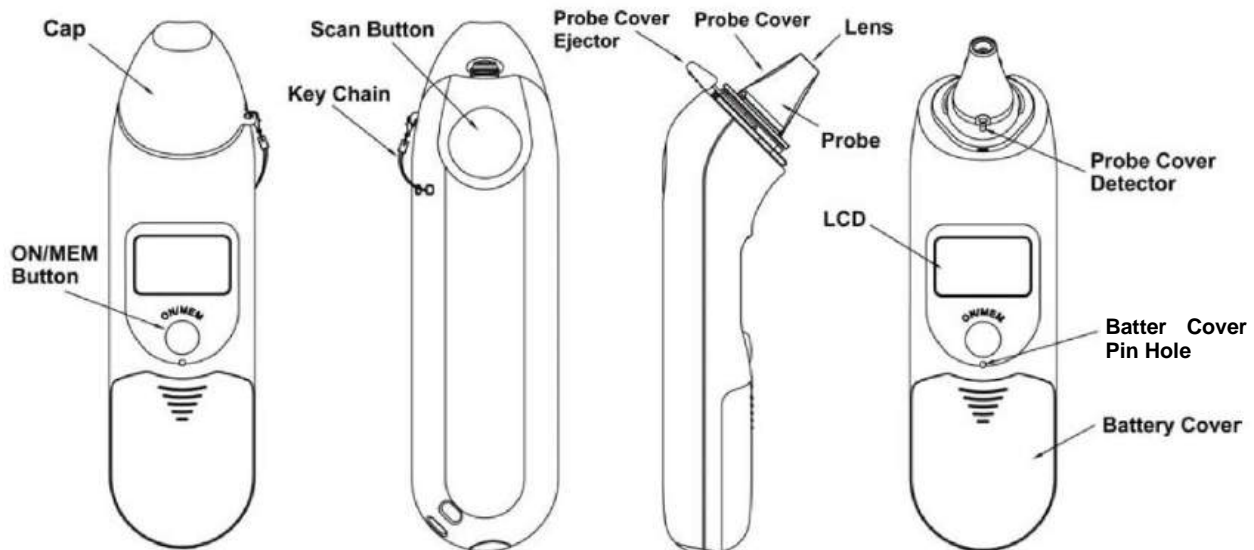
- 1 The **QUICK PREDICT** mode is for oral measurement only.
- 2 The **QUICK PREDICT** mode is unavailable when **COLD MODE** is set to **ON**.
- 3 Make sure all settings of TEMP Setup are properly set up every time before you withdraw the probe from the probe well. If you modify the settings immediately a measurement is completed, the new settings will be effective for the next measurement.

## 11.3 Infrared TEMP with TH Module

### 11.3.1 Introduction

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

Diagram of the Infrared Ear Thermometer:



### **WARNING**

- 1 The infrared ear thermometer is not intended for neonatal patients.
- 2 Only use the disposable probe covers supplied or recommended by EDAN. Use of other manufacturer's probe covers, reuse of disposable probe covers or absence of probe covers may produce temperature measurement errors and/or inaccuracies.
- 3 Keep the probe covers away from children.
- 4 Do not reuse the disposable probe covers.
- 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**

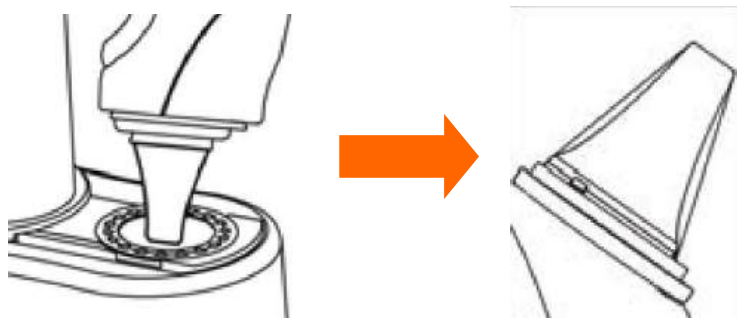
- 1 Keep the probe window clean, dry, and undamaged at times to ensure accurate measurements. To protect the probe window, always keep the thermometer in the storage cover while transporting or when not in use.
- 2 Proper installation of the probe cover ensures accurate measurements.
- 3 Do not autoclave.
- 4 The probe should not be submerged into liquids.
- 5 Keep the unit dry and away from any liquids and direct sunlight.
- 6 The thermometer is not waterproof. Do not immerse or drip fluids on it. Should this occur, dry the thermometer with warm air. Check for proper operation and accuracy.
- 7 Holding the thermometer too long may cause a higher ambient temperature reading of the probe, which could make the body temperature measurements lower than usual.
- 8 For more details about using the infrared ear thermometer, refer to the accompanying operating instructions of the thermometer.
- 9 Check whether the thermometer is damaged once it drops. If you cannot make sure of it, send the complete device to your local dealer for recalibration.
- 10 The monitor outfitted with the TH module must not be used together with other electrosurgery equipment, for example, ESU.
- 11 Verification of the temperature module is necessary as frequently as dictated by your Hospital Procedures Policy. When you need to calibrate the temperature measurement, please contact the manufacturer.

**NOTE:**


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


### 11.3.2 Measuring Procedure

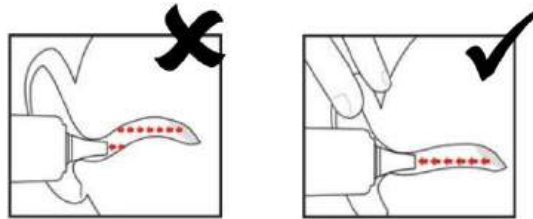
1. Align the center of the probe to the center of the probe cover. Make sure to place the adhesive side of probe cover upward.
2. Insert the probe into the probe cover on the probe cover loader until the probe cover clicks in place.



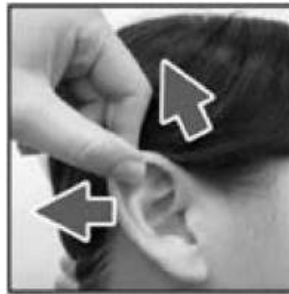
**NOTE:**

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

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

**NOTE:**

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



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

**WARNING**

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

**NOTE:**

- 1 The thermometer will automatically shut down after one-minute pending to extend battery life.
- 2 The device must stay in stable ambient (room) temperature for 30 minutes before operation.
- 3 Before the measurement, please stay in a stable environment for five minutes and avoid exercise or bath for 30 minutes.

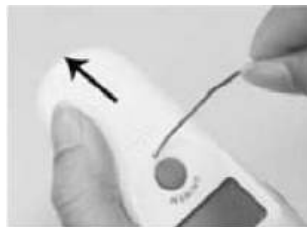
- 4 It is recommended that you measure the same ear for three times. If the three measurements are different, select the highest temperature.
- 5 Remember to compare the measurement result to the regular temperature of the patient.
- 6 There is no gender and age limitation for using infrared ear thermometer.
- 7 The data saved in the thermometer is the last measurement data before the thermometer is powered off.
- 8 Clinical repeatability: 0.12 °C (1~5 years old); 0.10 °C (>5 years old).
- 9 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.
- 10 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.

### 11.3.3 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.





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**WARNING**

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- 1 Keep the battery away from children.
  - 2 Ensure the positive (+) side is up and the negative (-) side down.
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## Chapter 12 Review (in Monitor Mode)

In monitor mode, the monitor provides 120-hour trend data of all parameters, storage of 1200 NIBP measurement results, 200 alarm events and so on. This chapter gives detailed instruction for review of all data.

### 12.1 Trend Graph Review

- The latest 1-hour trend is displayed every 1 or 5 seconds.
- The latest 120-hour trend is displayed every 1, 5 or 10 minutes.

To review Trend Graph, please press the **Trend Graph** shortcut key on the screen or select **Menu > Review > Trend Graph**, then the trend graph interface is displayed.

In the trend graph, the y-axis stands for the measurement value and x-axis stands for the time.

#### 12.1.1 Selecting Trend Graph of Specific Parameter

The monitor can review trend graph of different parameters. To change the existing trend graph, please select **Menu > Review > Trend Graph** and select a required parameter name from the popup list.

#### 12.1.2 Adjusting Trend Scale

You can use **Zoom** on the trend graph review interface to adjust the trend scale. Once you adjust the trend scale on the trend graph review interface, you also change the trend scale of the related parameters for the screen trend displayed on the main screen.



#### 12.1.3 Setting Interval

The monitor can support five kinds of interval. To set an appropriate interval, please select **Menu > Review > Trend Graph** and an interface is displayed. Choose **Interval** on the interface to open the list and select an appropriate interval among **1 s**, **5 s**, **1 min**, **5 min** and **10 min**.

#### **NOTE:**

Please select 1 sec interval if completed NIBP data is expected to display on the screen.

#### 12.1.4 Scrolling Left and Right the Screen

All trend graphs can't be displayed on the current screen due to the screen limitation. The user can scroll left and right the screen manually to see measurement trends that do not fit in the current view by selecting and pressing the symbol  and  displayed on the trend graph.



### 12.2 Trend Table Review

To review the trend table, please press the **Trend Table** key on the screen or select **Menu > Review > Trend Table**, then the trend table is displayed.

## 12.2.1 Setting Interval

The monitor can support eleven kinds of interval. To set an appropriate interval, please select **Menu > Review > Trend Table** and an interface is displayed. Choose **Interval** on the interface to open the list and select an appropriate interval among **1 s, 5 s, 30 s, 1 min, 3 min, 5 min, 10 min, 15 min, 30 min, 60 min** and **NIBP**.



## 12.2.2 Scrolling the Screen

All trend tables can't be displayed on the current screen due to the screen limitation. The user can scroll left, right, up and down the screen manually to see measurement trend tables that do not fit in the current view by selecting and pressing the symbol  and  displayed on the trend graph.

## 12.3 NIBP Review

To review the NIBP measurement data, select the **NIBP Review** shortcut key on the screen or select **Menu > Review > NIBP** or click NIBP Multi-Review Window at the bottom of main interface, then the **NIBP Review** window is displayed.

### 12.3.1 Scrolling the Screen

All measurement data can't be displayed on the current screen due to the screen limitation. The user can scroll up and down the screen manually to see measurement data that doesn't fit in the current view by selecting and pressing the symbol  and  displayed on the **NIBP Review** interface.



## 12.4 Alarm Review

To review the alarm event, select the **Alarm Review** shortcut key on the screen or select **Menu > Review > Alarm**, then the **Alarm Review** Window is displayed.

### NOTE:

The monitor can store a maximum of 200 alarm events. As soon as the alarm event storage is full, the earliest alarm event will be replaced by the latest one.

### 12.4.1 Scrolling the Screen

All alarm events can't be displayed on the current screen due to the screen limitation. The user can scroll up and down the screen manually to see alarm events that don't fit in the current view by selecting and pressing the symbol  and  displayed on the **Alarm Review** interface.

## 12.4.2 Selecting Alarm Event of Specific Parameter

The monitor can review alarm event of the specific parameters. To view the alarm event of the specific parameter, please select **Menu > Review > Alarm Review** and choose **Event Type** to select the required parameter name from the popup list.

## 12.4.3 Setting Time Index

The user can set end time of alarm review by selecting the **Time Index** option displayed on the alarm review interface.

If the user selects **Current Time** on the popup interface, the alarm events occurring before the current time are displayed on the alarm event review interface.

If the user selects **User Define**, he can define the review time by setting time box displayed on the interface. The alarm events occurring before the **User Define** option are displayed on the alarm event review interface.

## 12.5 Technical Alarm Checking

Click technical alarm area to check the current technical alarms. Technical alarms which have happened earlier and do not presently exist cannot be checked.


## 12.6 Event Marking

Event mark is used to note the classified events which are related with patient or may have influence on parameters monitoring, such as take or inject medicine, or kinds of treatments. There are four kinds of event marking at most: event A, event B, event C and event D.

Access **Menu > Common Function > Event Setup** to check event mark. Besides, these areas can also display event mark: trend graph window, trend table window and alarm review window.

## Chapter 13 Review (in Round or Spot-checking Mode)


### 13.1 Round Record Management

Select **Menu** > **Review**, or click review shortcut key  directly to enter round record management window.

- Click **Time Span** to display round record in specified period. The valid round records in 12 hours before the latest valid round record will be displayed by default.
- Click **All** to display all round records in specified period. Abnormal value is displayed in red. Choose **Alert** to display abnormal value in specified period. **All** is the default setting which will be recovered if user exit and enter this window again.
- The round record is in **order** by **Bed No.** or **Time**. Time order is the default setting which will be recovered if user exit and enter this window again.
- **Upload, Record, Export** or **Delete** is used for uploading, record outputting, exporting or deleting the round records user chose (not including its original data). The round record can be printed automatically once each record is generated. Enter **Menu** > **System Setup** > **Recorder** > **Auto Recording** to choose On/Off. Default setting is on.
- Clicking one round record can display its original data (20 groups at most), including patient information, parameters value and this round record. Clicking **Confirm** can output the original data in this window.

If monitor is powered off, the parameters data and original data in main interface will be cleared and round record will be stored. Each 1GB space can store 100 thousand groups of round records at least, including patient information and 20 original records.

### 13.2 Review Spot-checking Data

Select **Menu** > **Review**, or directly select review shortcut key  to enter review window.

- Click double triangle to turn page.
- Set the time to display spot-checking data in specified period. The valid spot-checking data in 12 hours before the latest valid spot-checking data will be displayed by default.
- Click **All** to display all spot-checking data in specified period. Abnormal value is displayed in red. Choose **Alert** to display abnormal value in specified period. **All** is the default setting which will be recovered if user exit and enter this window again.
- **Upload, Record, Export** or **Delete** is used for uploading, record outputting, exporting or deleting all spot-checking data in specified period. Monitor will upload all patient information & data which haven't been uploaded by default. User can also choose and upload all patient data manually, including the data which have been uploaded. Also, the spot-checking data can be printed automatically once each spot-checking data is generated.

Enter **Menu > System Setup > Recorder > Auto Recording** to choose On/Off. Default setting is on.

Spot-checking data can be sent by HL7 gateway and uploaded to network server. Also, it can be uploaded in real time once each valid spot-checking is finished, if the monitor is in networking and is also connected with network server.

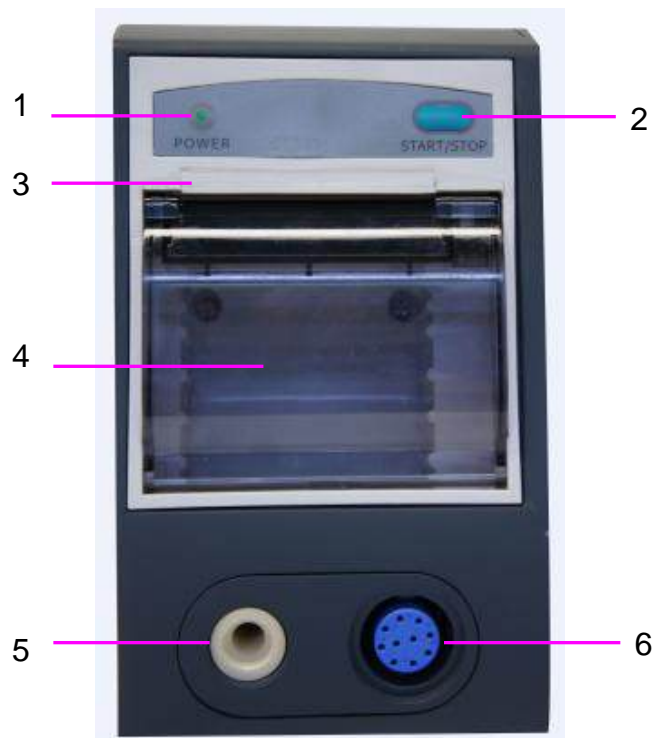
### 13.3 Spot-checking Data Trend Table

Spot-checking Data Trend Table locates the bottom of main interface. First line is the latest data. Click triangle at the bottom to show/hide trend table.

If monitor is powered off, parameters data and trend data in main interface will be cleared. User can check history data in review menu.

## Chapter 14 Recording

A thermal dot matrix recorder is used for the monitor and can support many recording types and output patient information, measurement data, review data waveform and so forth.



1	Recording indicator
2	Paper feeding key: press this key to start or stop feeding recording paper without outputting anything on the paper
3	Paper outlet
4	Recorder door
5	NIBP interface
6	SpO <sub>2</sub> interface

### 14.1 Performance of the Recorder

- Waveform record is printed at the rate of 12.5 mm/s, 25 mm/s or 50 mm/s; default setting is 25 mm/s.
- 49 mm ~ 50 mm wide printout paper.
- Record one SpO<sub>2</sub> waveform; default setting is off.
- User-selectable real-time recording time and waveform.
- Auto recording interval is set by the user, and the waveform is in accordance with the real time recording.

**NOTE:**

It is suggested that the user should not use the recorder when the low battery displays, or the monitor may be turned off automatically.

## 14.2 Starting and Stopping Recording

The monitor provides several types of stripe recording. You can start recording following the procedure below:

Recording Type	Description/ Procedure
Continual real-time recording	In monitor mode, enter <b>Menu &gt; System Setup &gt; Recorder</b> , select <b>Continual</b> in <b>R-T Rec Time</b> , and press record shortcut key to start or stop recording. 8 s is default setting.
8-second real-time recording	In monitor mode, select <b>8 s</b> in <b>R-T Rec Time</b> , set <b>Record Interval</b> as needed, and press record shortcut key to start recording. Press the key again to stop recording or when R-T Rec time ends, the monitor stops recording automatically. The runtime for each wave is 8 seconds. The record Interval can be set as: <b>Off, 10 min, 20 min, 30 min, 40 min, 50 min, 1 h, 2 h, 3 h, 4 h.</b>
Recording manually	In spot-checking or round mode, press record shortcut key to start the recording of the current patient's data. Press the key again to stop recording.
Trend graph recording	Select <b>Menu &gt; Review &gt; Trend Graph</b> , click <b>Record</b> in trend graph window to start recording. Press record shortcut key to stop the recording.
Trend table recording	Select <b>Menu &gt; Review &gt; Trend Table</b> , click <b>Record</b> in trend table window to start recording. Press record shortcut key to stop the recording.
NIBP review recording	Select <b>Menu &gt; Review &gt; NIBP Review</b> , click <b>Record</b> in NIBP review window to start recording. Press record shortcut key to stop the recording.
Alarm review recording	Select <b>Menu &gt; Review &gt; Alarm Review</b> , select one alarm and click <b>Record</b> in alarm review window to start recording. Press record shortcut key to stop the recording.
Recording automatically	Support auto recording for round record and spot-checking data. Please refer to chapter <i>Round Record Management</i> and <i>Review Spot-checking Data</i> for details. Default setting is off.



Recording Type	Description/ Procedure
NIBP auto triggered recording	Support NIBP auto triggered recording. Please refer to <i>NIBP Auto Recording</i> for details. Default setting is off.

To manually stop recording, click **Record** again in the related windows.

The recorder will stop recording in the following situations:

- The recording task is finished.
- No paper in the recorder.
- Malfunction stops the recorder from running properly.

**NOTE:**

You can also use the record shortcut key to manually start or stop recording.

## 14.3 Recorder Operations and Status Messages

### 14.3.1 Record Paper Requirement

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

### 14.3.2 Proper Operation

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

### 14.3.3 Paper Out

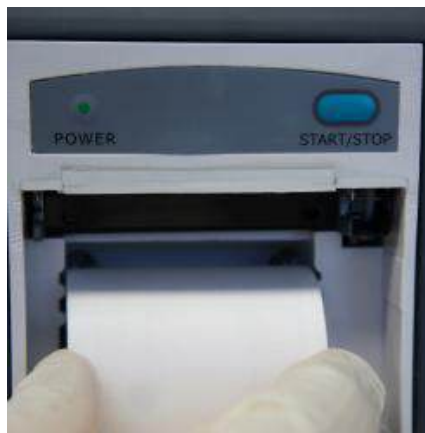
When the **Recorder Out OF Paper** alarm is displayed, the recorder cannot start. Please insert record paper properly.

### 14.3.4 Replacing Paper

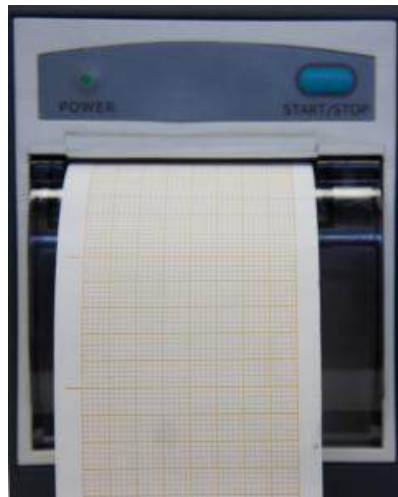
1. Pull outwards the upper arc part of the recorder casing to release the casing, shown in the following figure.



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



3. Ensure proper position and tidy margin.



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

**NOTE:**

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

### 14.3.5 Removing Paper Jam

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

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

**NOTE:**

1. If the monitor is not installed with a recorder, it will indicate **RECORDER SETUP NEEDED** after pressing the **Record** button.
2. Do not touch the thermo-sensitive print head when performing continuous recording.

## Chapter 15 Other Functions

### 15.1 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. Enter **Menu > User Maintain > Common > Nurse Call** to choose ON or OFF (default).

Nurse call and OTG are mutual excluded. That means, when nurse call is set to Off, the OTC function is On.

**NOTE:**

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

### 15.2 Wi-Fi

Wi-Fi modules are optional to be configured in the monitors. And you should configure the settings on the monitor following the steps below before connecting the monitor to a wireless network:

1. Select **Menu > User Maintain**, and input the password **ABC**.
2. In the **User Maintain** menu, select **Network**.
3. In the **Network** menu, select **Wi-Fi** from the **Network Type** list. And click **Config** to open the **Wi-Fi Setup** window. The available networks will be listed in this window.
4. Choose a network from the window. You will be prompted to enter the password of that network if a password is required.

If the monitor is successfully connected to the selected network, it will be indicated by the message **Connected**, and the local IP address of the monitor will be displayed in the **Wi-Fi Setup** window. Also, a symbol indicating the networking state will be displayed on the lower portion of the main screen. The meanings of the networking state symbols are explained below:



Wi-Fi signal intensity: Level 4



Wi-Fi signal intensity: Level 3



Wi-Fi signal intensity: Level 2



Wi-Fi signal intensity: Level 1

**NOTE:**

- 1 Be aware that some network-based functions may be limited for monitors on wireless networks in comparison with those on wired networks.
- 2 The obstacle may interfere with data transmission and even cause data loss.
- 3 To make the change of the Bed No. effective when the monitor has been connected to a wireless network, you need to disconnect the wireless connection and then connect

it again or reboot the monitor.

- 4 If the monitor fails to connect to any wireless network or no available wireless network is in the Wireless Setup window, switch the Network Type from Wireless to Wired and then to Wireless again. Then retry to connect to a wireless network.
- 5 Use the wireless device recommended by EDAN, otherwise some exceptional situations such as frequent network disconnection may occur on the monitor.
- 6 The wireless driver is compatible with channels 1-11 only.
- 7 When signal intensity is level 2 or less, signal may be unstable and signal transmission may be influenced.

## 15.3 E-link Function

The monitor can transmit data through e-link if it is configured with e-link module.

To activate/disable the function, select **User Maintain** > input password **ABC** > select **Network** > set **e-link** to on/off. Default setting is OFF. When monitor is normally connected to communication device, e-link symbol for connection will be displayed in general information area. Otherwise, the e-link symbol for disconnection will be displayed.

### ■ e-link Name setup

When e-link switch is turned on, the **e-link Name** of monitor can be set. E-link name setup for monitors of same model has fixed rules. 20 characters are supported at most. For example: iM3 default e-link name “VS\_3\_XXXX”.

### ■ the pairing code setup

Connection permission (e.g. pairing code) is needed for the first connection. Enter **User Maintain** > **Network** > **e-link Key** to set the pairing code which only includes 10 numerics at most. Default pairing code is 1234. If connection is successful, e-link symbol for connection will be displayed in general information area, and then the data can be transmitted to communication device.

### ■ Data transmission. The supported data includes: patient information, parameter measurement data.

1. The monitor automatically transmits real-time data to communication device when every measurement finishes. The data to be transmitted include:

Continual measurement data: SpO<sub>2</sub> data, transmission time;

Spot-checking measurement data: NIBP, SpO<sub>2</sub>, TEMP (prediction data of Quick TEMP and infrared TEMP data), and transmission time.

2. The monitor responds to the communication device's request to transmit data. The data to be transmitted include:

The data displayed in current interface: NIBP, SpO<sub>2</sub>, TEMP (prediction data of Quick TEMP and infrared TEMP data), transmission time.

3. Batch data transmission. The data to be transmitted include:

Round records stored in the monitor: NIBP, SpO<sub>2</sub>, TEMP (prediction data of Quick TEMP and infrared TEMP data), manual confirmation mark, and transmission time. All round records which haven't been transmitted in the round record interface will be transmitted by default. User can also select the data as needed.

Spot-checking trend data: the Spot-checking trend data and transmission time.

After batch transmission, user can separately enter "all records" interface to check the transmission result of round records, and enter "review" interface to check the transmission result of spot-checking trend data. All data which have been transmitted successfully will be marked.

**NOTE:**

- 1 The supported e-link version is BLE4.0, which is applicable in 3 system environments: iOS, Android and Windows.
- 2 When the monitor is powered off or enters standby mode, e-link is automatically disconnected and needs to be reconnected next time.

## 15.4 Uploading Data to Network Server

The data of round records and spot-checking records can be uploaded to network server.

Upload manually: Click **Menu** > **Review** > **Upload** or click review shortcut key directly, user can choose as needed and upload the round/spot records. The upload results will be prompted by pop-up window.

Upload automatically: in **User Maintain** > **Network** > **Real-time Upload**, if the setting is **ON**, when monitor is in networking and is also connected with network server, after each round/spot record is stored in **Review** window, monitor will upload this round/spot record to network server in real time. The upload results can be identified in **Review** > **Upload** window. The data which have been uploaded successfully will be displayed in grey font.

## 15.5 Storing Data in the Storage Device

### 15.5.1 Data Stored in the Storage Device

In monitor mode, a single piece of patient data maximally contains the following information:	
Patient information	MRN, name, date of birth, date of admission, gender, type, height, weight, blood type, doctor, bed No., department
Trend graph and trend table	240 hours
NIBP measurement review	1200 sets
Alarm review	200 sets

**NOTE:**

When store time for single patient data reaches 240 hours, the monitor will create a new folder for continuous data store.

In round mode, storage data maximally contains the following information:		
Round record	MRN, name, type, bed No., round record and original record	Up to 800 thousand sets
SpO <sub>2</sub>	Storage starting time, SpO <sub>2</sub> value, PR value	Up to 20 sets for a single patient
NIBP	SYS, DIA, MAP, PR, measurement time	Up to 20 sets for a single patient
TEMP	TEMP value, measurement time	Up to 20 sets for a single patient

In spot-checking mode, storage data maximally contains the following information:
16 million sets of spot-checking data for multiple patients.

When data reach the maximum, you can choose to **Keep storing** (default) or **Stop storing** by selecting **Menu > System Setup > Storage > if storage space is full**.

If you choose **Keep storing**, as soon as the data is full, the earliest data will be replaced by the latest one.

If you choose **Stop storing**, the monitor will stop data storing and the latest data cannot be stored when the data reach the maximum.



## 15.5.2 Selecting a Storage Device

To configure the storage device, select **Menu > System Setup > Storage > Storage Device**, and choose the storage medium from the pop-up list as desired.

In round or spot-checking mode, Storage Device is fixed as **Internal Storage Device**.

In monitor mode, **Internal Storage Device** (default) and **Removable Device** can be selected.

When you choose **Internal Storage Device** as the storage medium, if configured, the storage device name will automatically become **Internal Storage Device**. If not configured, **Null** will be displayed in the storage device name. You may plug several removable devices into the monitor at the same time, but only one is operative. You can select a removable device as a working one among the plugging devices by selecting **Menu > System Setup > Storage > Storage Device** and choosing the device name from the list.–

After you configure the appropriate storage device, click exit. If the storage device is successfully starting data storing, the monitor will be indicated by the symbol . If there is no enough space in storage device, or the storage device is read-only/damaged, the symbol  will be displayed.

The monitor will stop storing data in the storage device under the following circumstances:

- There is no enough space in the storage device for storing data.
- The removable device is read-only.
- The monitor is switched off.

- The power supply is off.

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### **CAUTION**

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- 1 Not all the removable devices are compatible with the monitor, Use the removable devices recommended by EDAN.
  - 2 Do not set the read-only switch on the removable device to on when the removable device is inserted in the monitor.
  - 3 It is recommended to format the USB flash drive to the FAT file type via PC prior to use.
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## 15.5.3 Reviewing Data Stored in the Storage Device

In monitor mode:

To review data stored in the storage device, select **Menu > Review > History Patient**. You can choose to review the storage device as desired from the pop-up list. Choose a patient from the list to review the data including patient information, trend graph, trend table, NIBP measurements, arrhythmia event, alarm event and waveform.

If **Internal Storage Device** is selected, clicking **Export all data** can export all patients' data. Choosing one patient's data in history patient list, and clicking **Export Current Data** can export this patient's data.

In round or spot-checking mode:

Please refer to chapter *Round Record Management* or *Review Spot-checking Data* for review data.

## 15.5.4 Deleting Data Stored in the Storage Device

In monitor mode:

To delete data of one patient, choose the patient from the list after selecting **Menu > Review > History Patient**, and then click **Delete data** on the **Review** menu. Further confirmation of deletion is required.

To delete data of all patients, select **Menu > Review > History Patient** and click **Delete all data** on the **History Patient Review** menu. Further confirmation is required.

In round or spot-checking mode:

Please refer to chapter *Round Record Management* or *Review Spot-checking Data* for review data.

## 15.5.5 Exporting Data Stored in the Internal Storage Device

- In monitor mode, to export data of one patient from the internal storage device to the removable device:

Choose the patient from the list after selecting **Menu > Review > History Patient**, and then click



**Export Current Data** on the **Review** menu.

To export data of all patients, select **Menu > Review > History Patient** and click **Export all**.

You can also use the OTG interface to connect the monitor to the PC, and user can view and copy the data which stored in internal storage device through the PC.

- In round or spot-checking mode, to export round records/spot-checking records in the specified time to the removable device , and also to the internal storage device:

Choose **Menu > Review > Export**, and confirm the operation as needed.

If no removable device is connected, the data will be exported to the internal storage device directly. User can view the data through OTG interface.

In round and spot-checking mode, the formats of exported CSV data file names are ‘XXX-Round-Records’ and ‘XXX-Spot-Review.csv’ respectively, in which the XXX means export time.

### 15.5.6 Ejecting a Removable Device

Before unplugging a removable device from the monitor, you need to select **Menu > System Setup > Storage > Removable Device** and click **Eject** to uninstall the removable device. In this menu, you can also check the remaining capacity of the storage device.

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#### **CAUTION**

Do not remove the removable device without ejecting it during data storing, or the removable device might be damaged.

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### 15.5.7 Recording Data by Recorder

In monitor mode:

To recording the review data, please enter **Menu > Review > History Patient >** choose one patient data in history patient window **> Review >** choose your desired data to review **> Record**.

The data to be recorded include: trend graph, trend table, NIBP review and alarm review.

In round or spot-checking mode:

Please refer to chapter *Round Record Management* or *Review Spot-checking Data* for review data.

### 15.5.8 Formatting the Internal Storage Device

To format the internal storage device, select **Menu > User Maintain > Common > Format internal storage device**. Further confirmation is required.

#### **NOTE:**

- 1 As soon as the internal storage device is formatted, all the data will be cleared.
- 2 You have no need to restart the monitor after formatting is successful. The internal

storage device can be identified and loaded automatically.

- 3 If formatting is failed, try again. Restart the monitor and retry the formatting, or contact the service personnel of the manufacturer if formatting is failed repeatedly.

## 15.6 Warning-Score System

User can use warning-score system to get score and sum up based on measurement value or input value of each vital sign. Depending on the score calculated, an action list with appropriate recommendations is displayed. Warning-score system includes EWS, NEWS and MEWS system, which are mutual excluded. That is, only one system can be used at the same time.

### 15.6.1 Warning-Score Interface

The interface includes EWS, NEWS and MEWS sub-interface.

To enter the interface: 1. By shortcut key. Click **User Maintain > Shortcut** to select **Score**. Then click Warning Score shortcut key to enter; 2. By menu. Click **Menu > Score** to enter.

To exit the interface: 1. By shortcut key. Click Score shortcut key to exit; 2. By menu. Click X button on the top right of the interface.

Before exiting interface, if selected **Method** is score calculator, the monitor can exit not only this interface, but also this function; if selected **Method** is auto score, the monitor can only exit this interface instead of this function.

The above rule is also applicable to the switchover between sub-interface. (e.g., if selected **Method** is auto score, sub-interface is switched over from EWS to NEWS, however, EWS function is still in working.)

#### **NOTE:**

Operations, including power-off, updating patient and entering standby or Demo mode, will stop current warning-score, and also monitor will exit this function.

### 15.6.2 Warning-Score Method

Warning-Score method includes score calculator (default) and auto score. If score calculator is selected, user needs to input information manually, such as **HR/PR, TMEP, Consciousness** and so on, and then click **Start to Score**. The monitor will calculate and display score result.

#### **NOTE:**

If any of above information is not completely input, the monitor will prompt information: **Incomplete parameter input, unable to score.**

### 15.6.3 Warning-Score Criteria

In EWS interface, select **Criteria** to check score criteria as following:

Value							
	3	2	1	0	1	2	3
HR (bpm)		≤40	41~50	51~100	101~110	111~129	≥130
SYS (mmhg)	≤70	71~80	81~100	101~199		≥200	
RESP (rpm)		≤8		9~20	21~24	25~29	≥30
TEMP (°C)		≤35	35.1~36.0	36.1~37.9	38~38.9	≥39	
SpO <sub>2</sub> (%)	<86	86~91	92~93	≥94			
Consciousness			NC	A	V	P	U

In NEWS interface, select **Criteria** to check score criteria as following:

Value							
	3	2	1	0	1	2	3
RESP (rpm)	≤8		9~11	12~20		21~24	≥25
SpO <sub>2</sub> (%)	≤91	92~93	94~95	≥96			
TEMP (°C)	≤35.0		35.1~36.0	36.1~38.0	38.1~39.0	≥39.1	
SYS (mmHg)	≤90	91~100	101~110	111~219			≥220
HR (bpm)	≤40		41~50	51~90	91~110	111~130	≥131
Consciousness				A			V/P/U
Oxygen		Yes		No			

In MEWS interface, select **Criteria** to check score criteria as following:

Value							
	3	2	1	0	1	2	3
HR (bpm)		≤40	41~50	51~100	101~110	111~129	≥130
SYS (mmhg)	≤70	71~80	81~100	101~109		≥200	
RESP (rpm)		<9		9~14	15~20	21~29	≥30
TEMP (°C)		<35.0		35.0~38.4		≥38.5	
Consciousness				A	V	P	U
Age				<50	50~70		>70

The relationship between consciousness level and its display result is as below:

Consciousness	Displayed Result
Sober	A
Responsive to Voice	V
Responsive to Pain	P
Unresponsive	U

### 15.6.4 Warning-Score Result

Warning-Score results include parameter value, score value, time and severity level. The relation for value and severity level is as following:

EWS	Severity Level	Color	Warning-score Reminders
EWS=0~2	/	Off-white	Please keep close to the condition of patient's life signs.
EWS=3	Low	Green	Please inform medical personnel that observing and checking should be taken every 1 hr. Or call the doctor to give appropriate actions if necessary.
EWS=4~5	Medium	Amber	Please inform medical personnel that observing and checking should be taken every 20 mins~1 hr. Or call the doctor to give appropriate actions if necessary.
EWS $\geq$ 6	High	Red	Please inform medical personnel and emergency team that consultation should be taken every 10 mins, keep close to blood gas condition, and start emergency plan.

NEWS	Severity Level	Color	Warning-score Reminders
NEWS=0	/	Off-white	Observing and checking should be taken every 12 hrs at least, and keep close to the condition of patient's life signs.
NEWS=1~4	Low	Green	Observing and checking should be taken every 4 hrs~6 hrs at least. Or please increase monitoring frequency or nurse-care level, if necessary.
NEWS=5~6	Medium	Amber	Observing and checking should be taken every 1 hr at least. Or call the doctor to give appropriate actions if necessary.
One single parameter's score value=3 points			
NEWS≥7	High	Off-white	Please inform medical personnel that urgent checking should be taken. Or monitoring in ICU is consideration, if urgent and necessary.

MEWS	Severity Level	Color	Warning-score Reminders
MEWS<5	Non-urgent	Off-white	For stable life signs and no life danger, normal handling is recommended.
MEWS=5	Observing	Green	Keep close to the condition of patient's life signs, and appropriate treatment can be taken.
5<MEWS≤9	Warning	Amber	The condition is urgent and may be worse. Keep close observing and give treatment timely.
MEWS>9	Critical	Red	The condition is bad. Urgent rescue and treatment are recommended.

### 15.6.5 Warning-Score Trend Table

Trend table provides the monitored patient's scores during a period of time; it includes score time, score parameters and value, MEWS score. To check the trend table, click **Trend Table** button in Warning-Score interface. EWS, NEWS and MEWS can respectively support 1200 groups of trend review at least.

### 15.7 Alert Setup

In round mode or spot-checking mode, if physiological parameters of the currently monitored patient exceed the predefined limit, the monitor will give alert information instead of

physiological alarms.

Enter the respective parameter setup menu to set alert limit and alert switch.

Alert can be indicated by the system in following different ways:

- ◆ Parameter area has two flash methods to prompt: background flash and text flash. User can select one method from **Visual Effect**.
- ◆ A sound of DU is used to indicate alert.
- ◆ Parameters storage table (including the table in main interface and the table in data management window) and has red mark to indicate the alert value.
- ◆ Alert information area displays prompts with blue background. (alert information area is the physiological alarm area in monitor mode.)

**NOTE:**

- 1 For TEMP module, TEMP alert can only be used in predictive mode of quick TEMP and in infrared TEMP.
- 2 Generally, monitor displays SYS alert value. When multiple values are abnormal, alert value will be displayed in order of SYS, DIA and MAP.
- 3 When alert is set to Off, the monitor won't give a prompt even if an alert occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.
- 4 Prior to monitoring, make sure that the limit settings are appropriate for your patient.
- 5 Setting limits to extreme values may cause the alert system to become ineffective. It is recommended to use the default settings.

## Chapter 16 Using Battery

This monitor can run on battery power, which ensures its uninterrupted operation even when AC power supply is interrupted. The battery recharges whenever the monitor is connected to the AC power source. During monitoring, if the AC power is interrupted, the monitor will take power from the internal battery. If the monitor is powered by battery, the monitor will switch off automatically before the battery is completely depleted.

### 16.1 Battery Safety Information

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#### **WARNING**

- 1 Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.
  - 2 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.
  - 3 Periodic checks on the battery performance are required. Change the battery if necessary.
  - 4 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.
  - 5 Do not unplug the battery when working is in process.
  - 6 Do not heat or throw the battery into a fire.
  - 7 Do not use, leave the battery close to fire or other places where temperature may be above 60 °C.
  - 8 Do not immerse, throw, or wet the battery in water/seawater.
  - 9 Do not destroy the battery: do not pierce the battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the battery.
  - 10 Use the battery only in the monitor. Do not solder the leading wire and the battery terminal directly.
  - 11 If liquid leaking from the battery gets into your eyes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately. If liquid leaks of the battery splash onto your skin or clothes, wash well with fresh water immediately.
  - 12 Keep away from fire immediately when leakage or foul odor is detected.
  - 13 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.
  - 14 Do not use a battery with serious scratch or deformation.
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**WARNING**

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- 15 When the monitor is running on battery power, do not replace the battery during monitoring patients; or the monitor will be powered off, which may result in patient injury.
  - 16 Do not place battery in the monitor with the (+) and (-) in the wrong way.
  - 17 Due to high ambient temperature, the monitor gives out **Battery Error** alarm. To protect the battery from damage, please take battery out for cooling and then charge.
- 
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## 16.2 Battery Power Indicator

The indicator labeled Battery on the front panel of the monitor illuminates in green when the monitor is battery powered and illuminates in yellow when battery is being charged. The indicator is not illuminated when the monitor is not powered or when AC power is applied.

## 16.3 Battery Status on the Main Screen

Battery status symbols show the status of each battery detected and the combined 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.



No battery is installed.

## 16.4 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.

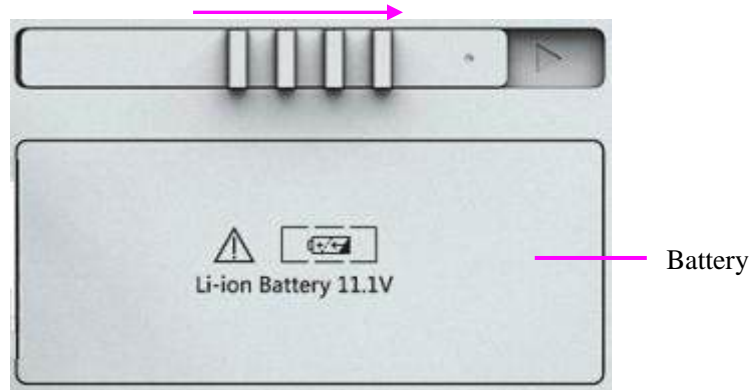


4. The running time of the battery reflects the battery performance.

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

## 16.5 Replacing the Battery

To install or replace the battery, please follow the procedure:



1. Push the battery latch to the right according to indication.
2. Take battery out.
3. Insert the new battery into the battery compartment.
4. Close battery latch.

## 16.6 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.

### **WARNING**

Do not disassemble batteries, put them into fire or cause them to short circuit. They may ignite, explode or leak, causing personal injury.

## 16.7 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.

## Chapter 17 Care and Cleaning

Use only the EDAN-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

EDAN Instruments has validated the cleaning and disinfection instructions included in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

### 17.1 General Points

Keep your monitor, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the monitor and reusable accessories after they are cleaned and disinfected.

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#### **CAUTION**

If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or EDAN service engineer.

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### 17.2 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.

## 17.2.1 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.

## 17.2.2 Cleaning the Reusable Accessories

### 17.2.2.1 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 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. 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.

### 17.2.2.2 Cleaning the SpO<sub>2</sub> Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.

2. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution. until no visible contaminants remain
3. 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.

### 17.2.2.3 Cleaning the TEMP Sensor/Quick TEMP Probe

1. Wipe the sensor/probe with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the sensor/probe to air dry.

## 17.3 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%)

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

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### **WARNING**

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

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### 17.3.1 Disinfecting the Monitor

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### **WARNING**

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

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To disinfect the monitor, follow these steps:

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

## 17.3.2 Disinfecting the Reusable Accessories

### 17.3.2.1 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.

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

After disinfection, replace the air bladder into the cuff. Refer to Section *16.2.2.1* for more information.

#### **NOTE:**

Prolonged use of disinfectant may cause discoloration of the cuff.

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

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

### 17.3.2.3 Disinfecting the TEMP sensor

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

1. Wipe the sensor 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.

## 17.4 Cleaning and Disinfecting Other Accessories

For cleaning and disinfecting other accessories, refer to the instructions delivered with the accessories. If the accessories are not accompanied by instructions, refer to this manual for the methods of cleaning and disinfecting the monitor.

## Chapter 18 Maintenance

### **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.

### 18.1 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 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.

### 18.2 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.
Check all monitoring functions and measuring functions	At least once every two years, or as needed.

## Chapter 19 Warranty and Service

### 19.1 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.

### 19.2 Contact Information

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

Alternatively, you can send an email to EDAN service department at: [support@edan.com.cn](mailto:support@edan.com.cn).



## Chapter 20 Accessories

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

### **WARNING**

- 1 Never reuse disposable transducers, sensors, accessories and so forth that are intended for single use, or single patient use only. 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.

### **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.

### 20.1 SpO<sub>2</sub> Accessories

Part Number	Accessories
<b>For EDAN Module</b>	
02.01.210120	SH1 Adult Reusable SpO <sub>2</sub> Sensor (DB9)
02.01.210673	SH3 Neonate Warp SpO <sub>2</sub> Sensor
02.01.210122	SH4 Adult Silicone Soft-tip SpO <sub>2</sub> Sensor
02.01.210121	SH5 pediatric Silicone Soft-tip SpO <sub>2</sub> Sensor
02.57.225000	SH6 SpO <sub>2</sub> Sensor, Ear Clip, Adult/Pediatric, 1m, reusable
01.57.471068	7 pin, SpO <sub>2</sub> Extension cable
01.57.471235	SHD-A SpO <sub>2</sub> Sensor, adult, disposable
01.57.471236	SHD-P SpO <sub>2</sub> Sensor, pediatric, disposable
01.57.471237	SHD-I SpO <sub>2</sub> Sensor, Infant, disposable
01.57.471238	SHD-N SpO <sub>2</sub> Sensor, Neonate, disposable
01.57.471746	SHD-A SpO <sub>2</sub> Sensor, adult, disposable, EDAN 2

<b>Part Number</b>	<b>Accessories</b>
01.57.471747	SHD-P SpO <sub>2</sub> Sensor, pediatric, disposable, EDAN 2
01.57.471748	SHD-I SpO <sub>2</sub> Sensor, Infant, disposable, EDAN 2
01.57.471749	SHD-N SpO <sub>2</sub> Sensor, Neonate, disposable, EDAN 2
<b>For Nellcor Module</b>	
01.15.30043	Nellcor Reusable Adult SpO <sub>2</sub> Sensor (DS-100A OxiMax)
01.15.40096	Nellcor Reusable Adult/Neonate SpO <sub>2</sub> Sensor (OXI-A/N OxiMax)
01.57.471069	Nellcor SpO <sub>2</sub> Extension cable (Compatible with Nellcor OXI-Max SpO <sub>2</sub> module and Nellcor sensor)
01.57.040436	Nellcor forehead sensor, Adult/Pediatric, >10 kg, MAX-FAST
01.57.040437	Nellcor strip winding sensor, Pediatric/Infant, 3 kg-40 kg, hand/foot, OXI-P/I
01.57.040438	Nellcor multisite sensor, >1 kg, hand, D-YS
01.57.040440	Nellcor sticking sensor, Adult, >30 kg, hand, MAX-A/MAX-AL
01.57.040441	Nellcor sticking sensor, Neonatal/Adult < 3kg or >40 kg, foot, MAX-N
01.57.040442	Nellcor sticking sensor, Infant, 3 kg-20 kg, foot, MAX-I
01.57.040445	Nellcor sticking sensor, Pediatric, 10 kg-50 kg, hand, MAX-P

## 20.2 NIBP Accessories

<b>Part Number</b>	<b>Accessories</b>
<b>For EDAN Module</b>	
01.57.471326	NIBP Cuff, E5, Infant, 10-15cm, reusable
01.57.471327	NIBP Cuff, E6, Small child, 13-17cm, reusable
01.57.471328	NIBP Cuff, E7, Child, 16-21.5cm, reusable
01.57.471329	NIBP Cuff, E8, Small adult, 20.5-28cm, reusable
01.57.471330	NIBP Cuff, E9, Adult, 27-35cm, reusable
01.57.471331	NIBP Cuff, E10, Large adult, 34-43cm, reusable
01.59.473007	NIBP Hose, 3.0 m, $\Phi$ 7.2 mm* $\Phi$ 3.6 mm, TPU 85A
01.57.471323	NIBP Cuff, Neonate, 10cm-15cm, reusable

<b>Part Number</b>	<b>Accessories</b>
01.57.471324	NIBP Cuff, Neonate, 6cm-11cm, reusable
01.57.471157	NIBP Cuff, neonatal #1, 3-6cm,disposable
01.57.471158	NIBP Cuff, neonatal #2, 4-8cm,disposable
01.57.471159	NIBP Cuff, neonatal #3, 6-11cm,disposable
01.57.471160	NIBP Cuff, neonatal #4, 7-13cm,disposable
01.57.471161	NIBP Cuff, neonatal #5, 8-15cm,disposable
<b>For SunTech Module</b>	
01.57.471157	NIBP Cuff, neonatal #1, 3 cm -6 cm, disposable
01.57.471158	NIBP Cuff, neonatal #2, 4 cm -8 cm, disposable
01.57.471159	NIBP Cuff, neonatal #3, 6 cm -11cm,disposable
01.57.471160	NIBP Cuff, neonatal #4, 7 cm -13cm,disposable
01.57.471161	NIBP Cuff, neonatal #5, 8 cm -15cm,disposable
01.57.471494	APC Cuff, Child (Green), Range: 12 cm– 19 cm
01.57.471495	APC Cuff, Small Adult (Royal Blue), Range: 17 cm – 25 cm
01.57.471496	APC Cuff, Adult (Navy Blue), Range: 23 cm – 33 cm
01.57.471497	APC Cuff, Large Adult (Burgundy), Range: 31 cm – 40 cm
01.57.000974	OPC Cuff, Child, rang: 12 cm -19cm
01.57.000976	OPC Cuff, Small Adult, rang: 17 cm -25cm
01.57.000977	OPC Cuff, Adult, rang: 23 cm -33cm
01.57.000978	OPC Cuff, Large Adult, rang: 31 cm -40cm

### 20.3 TEMP Accessories

<b>Part Number</b>	<b>Accessories</b>
<b>TEMP (For T2A Module)</b>	
02.01.110131	Oral/Axillary Probe

02.01.110130	Rectal Probe
01.57.471871	Disposable Probe Covers
<b>TEMP (For TH Module)</b>	
01.13.036415	Infrared Ear Thermometer Communication Cable
01.57.208057	Infrared Ear Thermometer
01.57.208058	Probe Cover
01.57.208059	Probe Cover Loader
<b>TEMP (For F3000 Module)</b>	
01.57.471312	Filac 3000 Oral Probe 4ft
01.57.471313	Filac 3000 Oral Probe 9ft
01.22.066159	Filac 3000 Oral Isolation Chamber
01.57.471314	Filac 3000 Rectal Probe 4ft
01.57.471315	Filac 3000 Rectal Probe 9ft
01.22.066160	Filac 3000 Rectal Isolation Chamber
01.57.471316	Filac 3000 Probe Covers

## 20.4 Other Accessories

<b>Part Number</b>	<b>Accessories</b>
02.21.064365	Rechargeable Lithium-Ion Battery /TWSLB-012
01.57.78035	Recorder paper
01.18.052245	Netac USB flash disk (U208, 4G, USB2.0)
02.01.210633	Unicode serial/parallel port recorder assembly
01.23.068023	Linear Barcode Scanner
02.04.241690	Patient monitor mounting arm assembly kit (M3/iM50)
02.04.101976	Rolling Stand Basket (in the bottom)

<b>Part Number</b>	<b>Accessories</b>
83.60.261069	M3\iM50 Trolley
83.60.261116	M3\iM50 Trolley
02.04.243472	Patient monitor mounting arm assembly kit (M3/iM50)
02.04.241699	Patient monitor mounting arm assembly kit (M3/iM50)
01.13.037122	Power cable, length 1.8 m, American standard, medical grade
01.13.036638	Power cable, length 1.8 m, VDE
01.13.114214	Ground Cable
01.17.052452	SD Memory Card (8GB, Class4)
01.13.036099	Power cable, Australia
01.13.036389	Power cable, English standard
01.13.036550	Power cable, Argentina
01.13.036551	Power cable, Argentina
01.13.036641	Power cable, English standard
01.13.036750	Power cable, Brazil
01.13.036751	Power cable, Argentina
01.13.036752	Power cable, Argentina
01.13.036754	Power cable, South Africa
01.13.036756	Power cable, Israel
01.13.036759	Power cable, India
21.13.036630	Power cable, Thailand

**NOTE:**

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

## A Product Specification

### NOTE:

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

### A.1 Classification

Anti-electroshock type	Class I equipment and internal powered equipment
Anti-electroshock degree	SpO <sub>2</sub> , NIBP, TEMP: BF
Ingress Protection	IPX1 With T2A, TH or F3000 TEMP module: Ordinary equipment (Sealed equipment without liquid proof)
Disinfection/sterilization method	Refer to <i>Chapter Care and Cleaning</i> for details.
Working system	Continuous operation equipment
Compliant with Standards	IEC 60601-1: 2005+A1 :2012; IEC 60601-1-2: 2014; EN 60601-1: 2006+A1 :2013; EN 60601-1-2: 2015; IEC 60601-2-49: 2011

### A.2 Physical Specifications

#### A.2.1 Size and Weight

Size	(159±1) mm (W) × (262±1) mm (H) × (166±1) mm (D)
Weight	<2.5kg (standard configuration, without accessories)

#### A.2.2 Environment Specification

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 to +40 °C (32 °F ~ 104 °F) With TEMP: +10 °C ~ +40 °C (50 °F ~ 104 °F)

Transport and Storage	-20 °C to +55 °C(-4 °F ~131 °F) With TH TEMP module: -20 °C ~ +50 °C (-4 °F ~122 °F)
Humidity	
Working	15%RH ~ 95%RH (non-condensing)
Transport and Storage	15%RH ~ 95%RH (non-condensing)
Altitude	
Working	86 kPa ~ 106 kPa
Transport and Storage	70 kPa ~ 106 kPa
Power Supply	100 V-240 V~, 50 Hz/60 Hz
	Current: 0.7 A-0.35 A; Fuse: T2.5AH, 250VAC

### A.2.3 Display

Display	Messages
Display screen: 8-inch color TFT, supporting touch screen Resolution: 800×600	One power on/off LED, green One battery charge LED, yellow/green One AC power LED, green One alarm LED, red/yellow/blue

### A.2.4 Battery Specification

Number	1
Battery Type	Lithium battery
Capacity	≥2400 mAh
Condition	Stand configuration, at 25 °C±2 °C, with (a) new fully charged battery/batteries, continuous SpO <sub>2</sub> measurement and NIBP automatic measurement mode at interval of 15 minutes, recording at interval of 10 minutes
Operating Time	≥3.5 hrs
Charging Time	≤14 hrs, at 25 °C±2 °C; the monitor is on or in standby mode
Fast Charging Time	<3 hrs, when the monitor is off

## A.2.5 Recorder

Record Width	49 mm~50 mm.
Paper Speed	12.5 mm/s, 25 mm/s, 50 mm/s
Trace	1
Recording types	Continual real-time recording 8 seconds real-time recording Recording manually Physiological Alarm recording Trend graph recording Trend table recording NIBP review recording Alarm review recording Recording automatically NIBP auto triggered recording

## A.2.6 Data Storage

### Monitor Mode

Trend graph/trend table review	1 hour, at 1 Second Resolution by default 120 hrs, at 1 min. Resolution by default
Alarm/Monitoring Event data	Up to 200 sets
NIBP Measurement Review	1200 sets
Each 1 GB extension space for data storage: $\geq 400$ hrs With all parameters on, storage interval of 1 s, one SpO <sub>2</sub> wave, and one alarm event occurring for each 10 s.	

### Round Mode

Round record	Up to 800 thousand sets
SpO <sub>2</sub>	Up to 20 sets for a single patient
NIBP	Up to 20 sets for a single patient
TEMP	Up to 20 sets for a single patient
Each 1 GB space for data storage: $\geq 100$ thousand sets of round records. Up to 800 thousand sets of round records are supported (one round record has 20 original records).	

### Spot-checking mode

Storage data maximally contains 16 million sets of spot-checking data for multiple patients.



## A.3 NIBP

Complies with IEC 80601-2-30: 2009.

### EDAN Module

Technique	Oscillometry	
Mode	Manual, Auto, Continuous, Average	
Measuring Interval in AUTO Mode (unit: minutes)	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480	
Continuous	5 min, interval is 5 s	
Measuring Type	SYS, DIA, MAP, PR	
Average measurement	Interval (unit: minutes)	1/2/3/4/5
	times	3/5
☆Measuring Range		
☆Adult Mode	SYS: 40 mmHg to 270 mmHg DIA: 10 mmHg to 215 mmHg MAP: 20 mmHg to 235 mmHg	
☆Pediatric Mode	SYS: 40 mmHg to 230 mmHg DIA: 10 mmHg to 180 mmHg MAP: 20 mmHg to 195 mmHg	
☆Neonatal Mode	SYS: 40 mmHg to 135 mmHg DIA: 10 mmHg to 100 mmHg MAP: 20 mmHg to 110 mmHg	
☆Alarm Type	SYS, DIA, MAP	
☆ Cuff Pressure Measuring Range	0 mmHg to 300 mmHg	
Pressure Resolution	1 mmHg	
☆Maximum Mean Error	±5 mmHg	
☆Maximum Standard Deviation	8 mmHg	
Maximum Measuring Period		
Adult/Pediatric	120 s	
Neonate	90 s	
Typical Measuring Period	20 s to 35 s (depend on HR/motion disturbance)	

Dual Independent Channel Overpressure Protection	
Adult	(297 ±3) mmHg
Pediatric	(245 ±3) mmHg
Neonatal	(147 ±3) mmHg
PR	
☆Measuring Range	40 bpm to 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

### SunTech Module

Method	Oscillometric	
Mode	Manual, Auto, Continuous, Average	
Measuring Interval in AUTO Mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480	
Continuous	5 min, interval is 5 s	
Average measurement	Interval (unit: minutes)	1/2/3/4/5
	times	3/5
PR		
☆Measuring range	30 bpm to 220 bpm	
☆Accuracy	±3 bpm or ±2%, whichever is greater	
☆Measuring Type	SYS, DIA, MAP, PR	
☆Measuring Range		
☆Adult Mode	SYS: 40 mmHg ~ 260 mmHg DIA: 20 mmHg ~ 200 mmHg MAP: 26 mmHg– 220 mmHg	

☆Pediatric Mode	SYS: 40 mmHg– 230 mmHg DIA: 20 mmHg– 160 mmHg MAP: 26 mmHg– 183 mmHg
☆Neonatal Mode	SYS: 40 mmHg – 130 mmHg DIA: 20 mmHg– 100 mmHg MAP: 26 mmHg – 110 mmHg
☆Alarm Type	SYS, DIA, MAP
Pressure Resolution	1 mmHg
☆Maximum mean error	±5 mmHg
☆Maximum standard deviation	8 mmHg
Maximum measuring period	
Adult	130 s
Pediatric	90 s
Neonate	75 s
Overpressure protection	
Adult/Pediatric	<300 mmHg
Neonate	<150 mmHg
Pre-inflation Pressure	
Adult Mode	120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 240 mmHg, 260 mmHg, 280 mmHg Default: 160 mmHg
Pediatric Mode	80 mmHg, 100 mmHg, 120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 250 mmHg Default: 140 mmHg
Neonatal Mode	60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 120 mmHg, 140 mmHg Default: 90 mmHg

## A.4 SpO<sub>2</sub>

Complies with ISO 80601-2-61: 2011.

### EDAN Module

Measuring Range	0% to 100%
Resolution	1%
☆Data Update Period	1 s
☆Accuracy	
☆Adult /Pediatric	±2% (70% to 100% SpO <sub>2</sub> )
	Undefined (0% to 69% SpO <sub>2</sub> )
☆Neonate	±3% (70% to 100% SpO <sub>2</sub> )
	Undefined (0% to 69% SpO <sub>2</sub> )
SpO <sub>2</sub> Storage Interval	In round or spot-checking mode 30 S (default), 1 min, 2 mins, 5 mins
Pulse Rate	
Measuring Range	25 bpm to 300 bpm
☆ Adjustable Range of Alarm Limits	30 bpm to 300 bpm
Resolution	1 bpm
☆Accuracy	±2 bpm
Sensor	
Red Light	(660±3) nm
Infrared Light	(905±10) nm
Emitted Light Energy	< 15 mW
PI	
Measuring Range	0-10, invalid PI value is 0.
Resolution	1

### Nellcor Module

Measuring Range	1% to 100%
Resolution	1%
☆Data Update Period	1 s

☆Accuracy	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST	±2 (70% ~ 100% SpO <sub>2</sub> )
	D-YS (from infant to adult), DS-100A, OXI-A/N (adult), OXI-P/I	±3 (70% ~ 100% SpO <sub>2</sub> )
	If sensor is used for neonate as recommended, the accuracy will be larger than adult by ±1.	
SpO <sub>2</sub> Storage Interval	In round or spot-checking mode 30 S (default), 1 min, 2 mins, 5 mins	
Pulse Rate		
Measuring Range	20 bpm to 300 bpm	
Resolution	1 bpm	
☆Accuracy	± 3 bpm (20 bpm to 250 bpm)	
Sensor	Wave length: approximately 660 nm and 900 nm	
	Emitted light energy: <15 mW	

**NOTE:**

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

**A.5 TEMP**

Complies with ISO 80601-2-56: 2009.

**T2A Module:**

☆Measuring range	Monitor mode: 25 °C~45 °C Predict mode: 35.5 °C~42 °C
Working temperature	10 °C ~40 °C
Transport and Storage	-20 °C ~ 55 °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)
Response time	< 60 s

Update time	1 s~ 2 s
Warm-up time	<10 s
Time for predicting	<30 s
Calibration	Self-test interval: $\leq 5$ min
Measuring Mode	Direct Mode/ Adjusted Mode
Transient Response Time	$\leq 30$ s
Clinical Bias	(-0.2 to -0.4) °C
Limits of Agreement	0.49
Stability	0.14 °C

**NOTE:**

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

**TH Module:**

☆Measuring range	34 °C~ 42.2 °C
Working temperature	10 °C~ 40 °C
Transport and Storage	-20 °C ~ 50 °C
☆Adjustable range of alarm limits	35.5 °C~ 42 °C
Resolution	0.1 °C
Response time	1 s
Measuring Mode	Adjusted Mode
Clinical Accuracy	$\pm 0.2$ °C (0.4 ° F) (35.5 °C ~42 °C) (95° F ~107.6° F) $\pm 0.3$ °C (0.5° F) (out of the range mentioned above)
Laboratory Accuracy	$\pm 0.2$ °C

**F3000 Module:**

☆Measuring range	30 °C~43 °C
Prediction measurement range	35 °C~43 °C
Cold mode prediction measurement range	33 °C~43 °C
Working temperature	10 °C ~ 40 °C
Transport and Storage	-20 °C ~ 55 °C
Sensor type	Oral /axillary /rectal

☆ Adjustable range of alarm limits	35.5 °C ~42 °C
Resolution	0.1 °C
☆ Accuracy	Monitoring Mode and Predictive Mode: ±0.1 °C Quick Predictive Mode: ±0.3 °C
Typical measurement time (after insertion into measurement site)	Oral (Quick Predictive Mode): (3~5) s (non-fever temps); (8~10) s (fever temps)
	Oral (Predictive Mode): (6~10) s
	Axillary: (8~12) s
	Rectal: (10~14) s
	Monitoring Mode (all sites): (60~120) s
Measuring Mode	Direct Mode /Adjusted Mode
Transient Response Time	≤30 s monitoring mode
Clinical Bias	(-0.2 to -0.4) °C
Limits of Agreement	0.49
Stability	0.14 °C

**NOTE:**

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

## A.6 Adjustable Range of Alert Limits

SpO <sub>2</sub>	20% ~ 100%		
PR	30 bpm ~ 300 bpm		
NIBP mmHg (1 mmHg=0.133 kPa)			
<b>EDAN NIBP</b>			
Patient Type		High Limit	Low Limit
ADU	SYS	270	40
	DIA	215	10
	MAP	235	20
PED	SYS	230	40
	DIA	180	10
	MAP	195	20

NEO	SYS	135	40
	DIA	100	10
	MAP	110	20
<b>SunTech NIBP</b>			
Patient Type		High Limit	Low Limit
ADU	SYS	260	40
	DIA	200	20
	MAP	220	26
PED	SYS	230	40
	DIA	160	20
	MAP	183	26
NEO	SYS	130	40
	DIA	100	20
	MAP	110	26
<b>TEMP</b>			
Patient Type	High Limit		Low Limit
ADU/PED	+42 °C (+107.6 °F)		+35.5 °C (+95.9 °F)

## A.7 Wi-Fi

IEEE	802.11b/g/n
Frequency Band	2.4 GHz ISM band
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Typical Transmit Power (± 2 dBm)	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM

## A.8 E-link

Transmit Frequency	2402 MHz ~ 2480 MHz
Frequency Band	2402 MHz ~ 2480 MHz
Modulation	FHSS, GFSK, DPSK, DQPSK
Transmit Power	≥ 0 dBm



## A.9 Interfaces

### A.9.1 Nurse Call

Drive Mode	Voltage output
Power Supply	3.14 V ~ 3.46 V, 8 mA MAX
Interface Signal	3.3 V power supply and PWM waveform
Interface Type	Micro USB

### A.9.2 USB Interfaces

Number of USB Interfaces	Standard: 1
Drive Mode	HOST interface, USB1.0/2.0 protocol
Power Supply	5 VDC $\pm$ 5%, 500 mA Max.
Interface Type	USB A-type port

### A.9.3 OTG Interfaces

Number of USB Interfaces	Standard: 1
Drive Mode	USB OTG interface, USB1.0/2.0 protocol
Power Supply	Output: 5 VDC $\pm$ 5%, 500 mA Max. Input: 5 VDC $\pm$ 5%, 100 mA Max.
Interface Type	Micro USB port

### A.9.4 Network Interface

Bandwidth	10 Mbps
Interface Type	Standard RJ-45 network interface

## B EMC Information

### - Guidance and Manufacture's Declaration

#### B.1 Electromagnetic Emissions

<b>Guidance and manufacture's declaration – electromagnetic emission</b>		
iM3 is intended for use in the electromagnetic environment specified below. The customer or the user of iM3 should assure that they are used in such an environment.		
<b>Emission test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
RF emissions CISPR 11	Group 1	iM3 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	iM3 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 iM3 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) iM3 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.

#### B.2 Electromagnetic Immunity

<b>Guidance and manufacture's declaration – electromagnetic immunity</b>			
iM3 is intended for use in the electromagnetic environment specified below. The customer or the user of iM3 should assure that they are used in such an environment.			
<b>Immunity test</b>	<b>IEC/EN 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment guidance</b>
			-


Electrostatic discharge (ESD) IEC/EN 61000-4-2	$\pm 8$ kV contact $\pm 15$ kV air	$\pm 8$ kV contact $\pm 15$ 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	$\pm 2$ kV for power supply lines	$\pm 2$ kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	$\pm 1$ kV for line to line $\pm 2$ kV for line to ground	$\pm 1$ kV for line to line $\pm 2$ 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 iM3 requires continued operation during power mains interruptions, it is recommended that iM3 be powered from an uninterruptible power supply or a battery.
<b>NOTE</b> $U_T$ is the a.c. mains voltage prior to application of the test level.			

## B.3 Electromagnetic Immunity

### Guidance and manufacture's declaration – electromagnetic immunity

iM3 is intended for use in the electromagnetic environment specified below. The customer or the user of iM3 should assure that they are used in such an environment.

Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC/EN 61000-4-6</p> <p>Radiated RF IEC/EN 61000-4-3</p>	<p><math>3 V_{\text{rms}}</math> 150 kHz to 80 MHz <math>6V_{\text{rms}}^{\text{c}}</math> in ISM bands between 0,15 MHz and 80 MHz</p> <p><math>3 V/\text{m}</math> 80 MHz to 2.7 GHz</p> <p>See table 1</p>	<p><math>3 V_{\text{rms}}</math> 150 kHz to 80 MHz <math>6V_{\text{rms}}^{\text{c}}</math> in ISM bands between 0,15 MHz and 80 MHz</p> <p><math>3 V/\text{m}</math> 80 MHz to 2.7 GHz</p> <p>Comply with table 1</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of iM3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b> <math>d = 1.2\sqrt{P}</math> 150KHz to 80MHz</p> <p><math>d = 1.2\sqrt{P}</math> 80 MHz to 800 MHz <math>d = 2.3\sqrt{P}</math> 800 MHz to 2.7 GHz <math>d=6 \sqrt{P}/E</math> 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 iM3, including cables specified by the manufacturer).</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF</p>

			<p>transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p><b>NOTE 1</b> At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p><b>NOTE 2</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV 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 iM3 is used exceeds the applicable RF compliance level above, iM3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating iM3.</p> <p><sup>b</sup> Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.</p> <p><sup>c</sup> 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.</p>			

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

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM <sup>c)</sup> ± 5 kHz deviation 1 kHz sine	2	0,3	28

710	704-787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 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 <sup>b)</sup> 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 <sup>b)</sup> 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 <sup>b)</sup> 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 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.

## B.4 Recommended Separation Distances

### Recommended separation distances between portable and mobile RF communications equipment and iM3

iM3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of iM3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iM3 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.

## C Default Settings

This appendix documents the most important default settings of your monitor as it is delivered from the factory.

Note: If your monitor has been ordered preconfigured to your requirements, the settings at delivery will be different from those listed here.

### C.1 Patient Information Default Settings

Patient Information Settings	
Patient Type	Adult

### C.2 Alarm Default Settings

Alarm Settings	
Pause Time	120 s
Alarm Latch	Off

### C.3 SpO<sub>2</sub> Default Settings

SpO <sub>2</sub> Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	100	100	95
Alarm Low Limit	90	90	88
NIBP/SpO <sub>2</sub> Simul Measurement	Off		
Pitch Tone	On		
Sensitivity	Medium		
SatSeconds (Nellcor Module)	Off		
Sweep	12.5 mm/s		
Alert Switch	On		
Alert High Limit	100	100	95
Alert Low Limit	90	90	88



## C.4 PR Default Settings

PR Settings	ADU	PED	NEO
PR Source	SpO <sub>2</sub>		
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
Pulse Volume	3		
Alarm Source	SpO <sub>2</sub> or NIBP		

## C.5 NIBP Default Settings

NIBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (SYS)	160	120	90
Alarm Low Limit (SYS)	90	70	40
Alarm High Limit (Map)	110	90	70
Alarm Low Limit (Map)	60	50	30
Alarm High Limit (Dia)	90	70	60
Alarm Low Limit (Dia)	50	40	20
EDAN Module			
Inflation value	160	140	100
SunTech Module			
Inflation value	160	140	90
Unit	mmHg		
Interval	1 minute		
Interval (Average)	1 minute		
Measurement times (Average)	3		
PR Switch	On		

Auto Recording	Off		
Alert Switch	On		
Alert High Limit (SYS)	160	120	90
Alert Low Limit (SYS)	90	70	40
Alert High Limit (MAP)	110	90	70
Alert Low Limit (MAP)	60	50	30
Alert High Limit (DIA)	90	70	60
Alert Low Limit (DIA)	50	40	20

## C.6 TEMP Default Settings

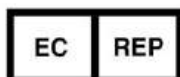
TEMP Settings	ADU	PED
Alarm Switch	On	
Alarm Record	Off	
Alarm Level	Medium	
Measurement Mode	Predictive	
Measurement Position	Oral or rectal	
Cold Mode	Off	
Alarm High Limit	39.0	39.0
Alarm Low Limit	36.0	36.0
Alert Switch	On	
Alert High Limit	39.0	39.0
Alert Low Limit	36.0	36.0
Unit	°C	

## D Abbreviations

Abbr	English Full Name/Description
AC	Alternating current
Adu	Adult
Art	Arterial
BP	Blood pressure
BTPS	Body temperature and pressure, saturated
CI	Cardiac index
CISPR	International Special Committee on Radio Interference
CMS	Central monitoring system
COHb	Carboxyhemoglobin
DC	Direct current
Dia	Diastolic
EEC	European Economic Community
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
ESU	Electrosurgical unit
Hb	Hemoglobin
Hb-CO	Carbon mono-xide hemoglobin
HR	Heart rate
ICU	Intensive care unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
LCD	Liquid crystal display
LED	Light emitting diode
MAP	Mean arterial pressure
MDD	Medical Device Directive
MetHb	Methemoglobin
MRI	Magnetic resonance imaging
N/A	Not applied

Neo	Neonate
NIBP	Non-invasive blood pressure
O <sub>2</sub>	Oxygen
Ped	Pediatric
Pleth	Plethysmogram
PR	Pulse rate
PVC	Premature ventricular complex
R	Right
RA	Right arm
RAP	Right atrial pressure
RHb	Reduced hemoglobin
RL	Right leg
RR	Respiration Rate
Sev	Sevoflurane
SYS	Systolic pressure
TB	Blood Temperature
TD	Temperature difference
TEMP	Temperature
USB	Universal serial bus
SpO <sub>2</sub>	Pulse Oxygen Saturation

P/N: 01.54.457703  
MPN: 01.54.457703011



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