

iM3

Vital Signs Monitor

Version 2.0

User Manual

CE₀₁₂₃


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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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, SpO₂, 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.

WARNING

- 1 To ensure that the monitor works properly, please read the user manual and follow the steps before using the monitor.
 - 2 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.
 - 3 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.
 - 4 EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
 - 5 SHOCK HAZARD-To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.
 - 6 Do not come into contact with the patient, table, or the monitor during defibrillation.
 - 7 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.
 - 8 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.
-

WARNING

- 9 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.
 - 10 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.
 - 11 Devices connecting with monitor should be equipotential.
 - 12 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.
 - 13 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.
 - 14 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.
 - 15 When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.
 - 16 If several items of medical equipment are interconnected, pay attention to the sum of the leakage currents, otherwise it may cause shock hazard. Consult your service personnel.
 - 17 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.
-

WARNING

- 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.
 - 19 If leakage or foul odor is detected, ensure that there's no fire around.
 - 20 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.
 - 21 This equipment is not intended for home usage.
 - 22 Do not service or maintain the monitor or any accessory which is in use with the patient.
 - 23 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.
 - 24 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
 - 25 The monitors are MR Unsafe. The monitors are not intended for use in an MRI environment.
 - 26 Only recommended batteries can be used for the monitor.
 - 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.
-
-

WARNING

- 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.
 - 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 wireless AP/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.
-
-

WARNING

- 44 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 before installation and any time new medical equipment is added to the Wireless LAN coverage area.
 - 45 If the protective grounding (protective earth) system is doubtful, the monitor must be supplied by internal power only.
 - 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 The monitor is suitable for use in the presence of electrosurgery. When the monitor is used with HF surgical equipment, user (doctor or nurse) should be cautious about patient safety.
 - 48 Make sure networking function is used in a secure network environment.
-
-

CAUTION

- 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.
 - 11 Do not touch the touch screen with a sharp object.
-
-







CAUTION















- 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 light 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.


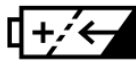









NOTE:

- 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 When there's measurement beyond range, invalid measurement or no measurement value, it will display -?-.
- 8 In normal use, the operator shall stand in front of the monitor.

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		Equipotentiality
6		Power Supply switch

7		Serial number
8		Network port
9		USB (Universal Serial Bus) Connection
10		CE marking
11		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
12		Date of manufacture
13		Manufacturer
14	P/N	Part Number
15		General symbol for recovery/recyclable
16		Disposal method
17		Operating instructions
18		Refer to instruction manual/booklet (Background: Blue; Symbol: White)
19		Warning (Background: Yellow; Symbol & outline: black)
20	IPX1	Ingress Protection IPX1 (Protected against vertically falling water drops)
21	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
22		Non-ionizing electromagnetic radiation
23		Alternating Current

24		Output/ Nurse call
25		Chargeable battery
26		Battery check
27	Contains FCC ID	Federal Communications Commission: Contains FCC ID: SMQ9113EDAN, or Contains FCC ID: 2AMWOFSC-BT836B
28	<p>ETL CLASSIFIED</p>  <p>Intertek 4005997</p>	<p>Conforms to AAMI Std. ES60601-1, IEC Std. 80601-2-30, IEC Std. 60601-2-49, ISO Std. 80601-2-56, ISO Std. 80601-2-61</p> <p>Certified to CSA Std. C22.2 No. 60601-1, No 80601-2-30, No 60601-2-49, No 80601-2-56, No 80601-2-61</p>
29		This way up
30		Fragile, handle with care
31		Keep dry
32		Stacking limit by number
33		Handle with care
34		Do not step on
35		Use-by date

NOTE:

The user manual is printed in black and white.

Chapter 2 Installation

NOTE:

The monitor installations and settings must be configured by the authorized hospital personnel.

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*.

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*.

WARNING

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.

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. **Display Second** can be set to **On** or **Off** as needed.
4. Set **Sync Time**: default selection is **Off**.
 - ◆ **CMS**, is used for time synchronization with MFM-CMS.
 - ◆ **NTP** (Network Time Protocol), is used for time synchronization with the server with NTP function in hospital. Then, set the **Time Zone** of the monitor and **NTP Server IP**.

NOTE:

- 1 If the system is not used for a longer period of time, its system time may be inaccurate. In this case, readjust the system time after powering on.
- 2 If the system time cannot be saved and resumes the default value after restart, contact the service department of EDAN to replace the button cell in main board.

WARNING

Changing date and time will affect the storage of trend data.

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.

2.9 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE:

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate this equipment.

2.10 FCC RF Radiation Exposure Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

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.

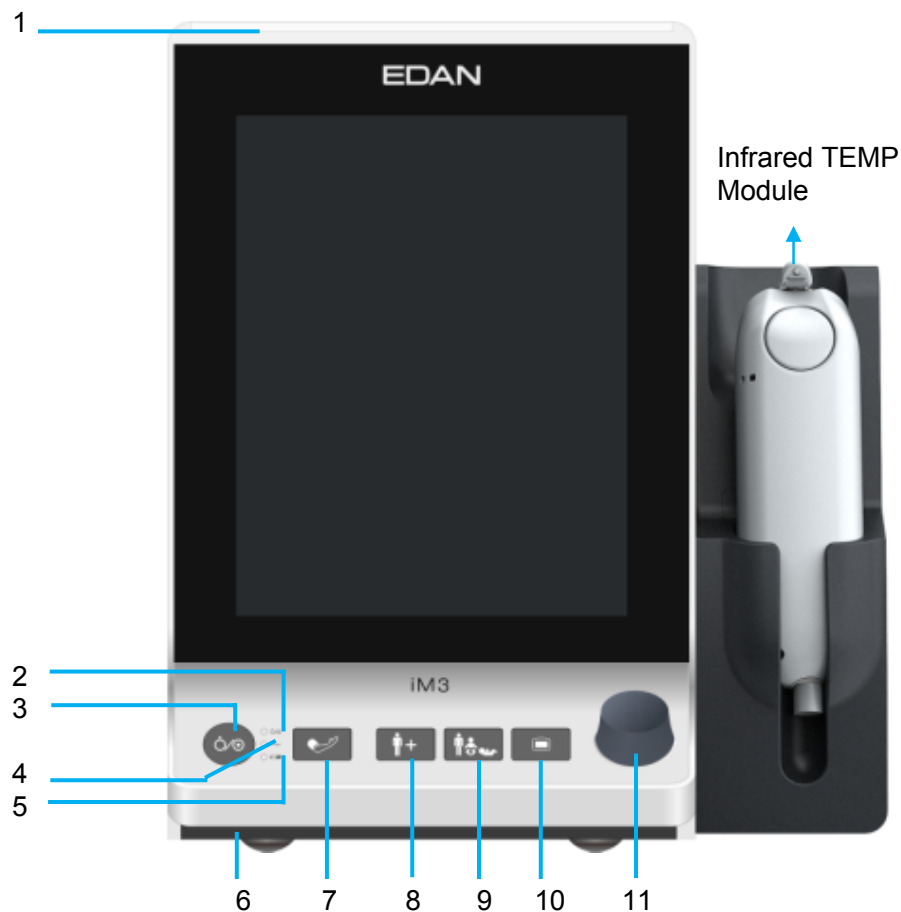
You may frequently use the follow functions:

- ◆ SpO₂ monitoring (Refer to *Monitoring SpO₂* 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 System Components

3.1.1 Front View

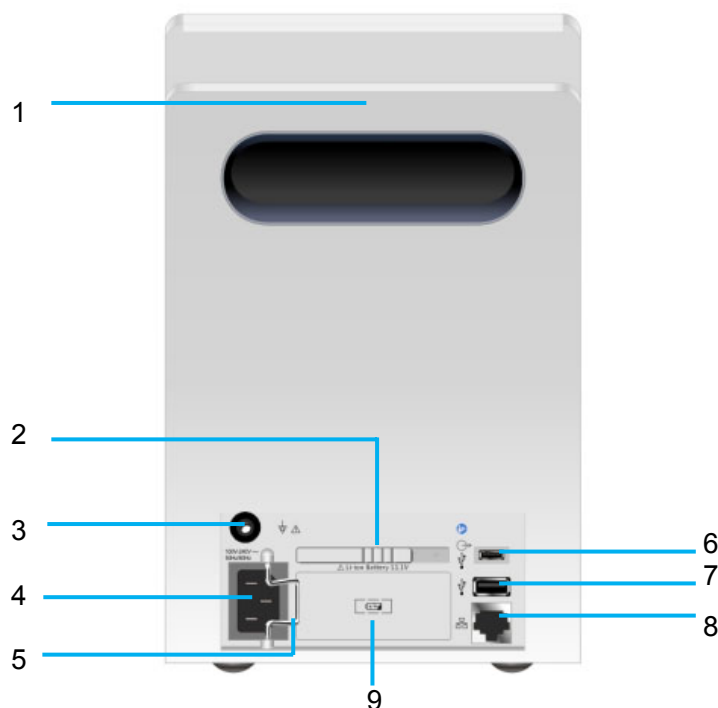




1	Alarm indicator/Standby indicator	When an alarm occurs, the alarm indicator will light or flash. The color of light represents the alarm level. High level alarm: flashes in red; Medium level alarm: flashes in yellow; Low level alarm: constantly yellow for physiological alarm and constantly blue for technical alarm. The indicator will light 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	<p>Admitting or creating new patient will clear the data in main interface.</p> <ul style="list-style-type: none"> • In Monitor mode, press the button to admit a new patient. • In Ward round mode, press the button to create a new patient. • In spot-checking mode, press the button to admit a new patient. Series No. will be automatically added by one and other setting items are empty by default. <p>In all interfaces (except main interface), pressing this button can only close the current window and return to main interface.</p>
9	Switch patient type	<p>In main interface, press it to pop up a patient type selection window. The relevant configuration will be updated after selection.</p> <p>In other interfaces, press it to close the current window and return to main interface.</p>
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>

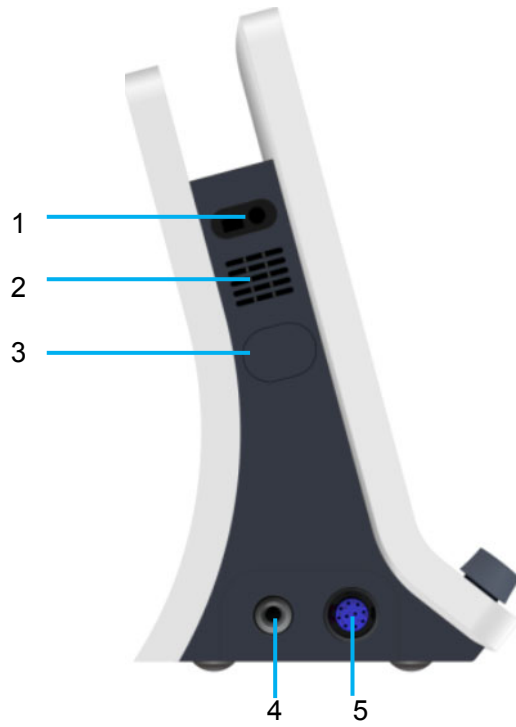
3.1.2 Rear View



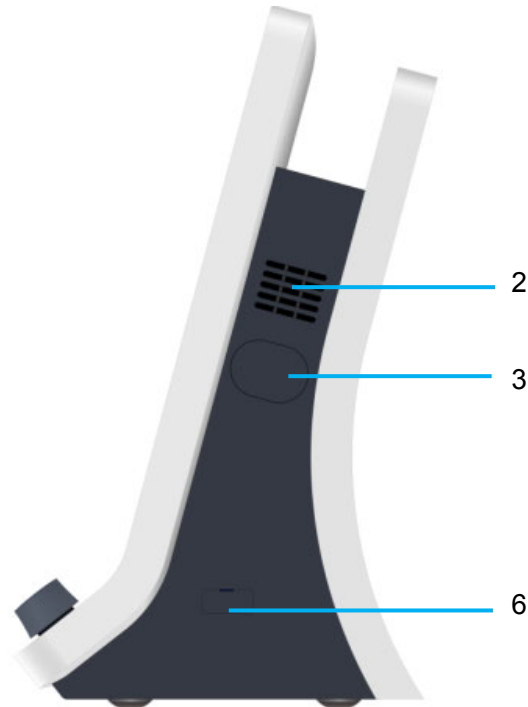
1	Portable handle/Accessory collecting: for lifting or moving the monitor or collecting the accessories
2	Battery compartment latch: for opening or closing battery door.
3	Equipotential grounding terminal. If the monitor is used together with other devices, connect this terminal to eliminate potential ground differences between devices.
4	AC power input: for connecting AC power cable
5	Power cable safety latch. Used to prevent the power cable from loosing or falling. Place the latch on the power cable and fasten it firmly from right to left to ensure that it secures the power cable.
6	OTG interface/nurse call port. <ul style="list-style-type: none">• OTG interface: it connects the monitor to computer via data-line. The data in monitor can be transmitted to computer.• 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.
NOTE: During connecting USB flash drive via OTG interface, if the USB flash drive cannot be recognized, please try to re-plug USB flash drive.	
7	USB interface: for connecting the approved USB device.
8	Network interface. It connects the monitor to the central monitoring system (also named as MFM-CMS, and MFM-CMS V2.64 or above is recommended) or to Gateway (V1.21 or above) via standard network cable.
9	Battery door: for fixing or replacing the battery.

3.1.3 Side View

Left side



Right side



1	Built-in barcode scanner window
---	---------------------------------

2	Heat sink
---	-----------

3	Plug-in interface (there is dustproof vent for NIBP on the left side.)
4	NIBP interface: for connecting the parameter sensor and cables
5	SpO ₂ interface: for connecting the parameter sensor and cables
6	TEMP communication interface: : for connecting TEMP parameter

NOTE:

To avoid blocking and affecting NIBP measurement, user can open the built-in interface coverplate and clean dustproof vent routinely (don't use wet cotton swab to clean the vent). 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	
General information area (Left is function info.; Right is symbol area, from right to left, including data storage status, USB flash disk, e-link, Wi-Fi network, battery status, wired network, date & time)	
Permanent key & Shortcut key area	




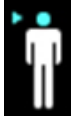








1	Bed No.
2	Patient name; ID number: in Monitor or Spot-checking mode, it is MRN; in Ward round mode, it is the 1 st patient information item (such as MRN, Medical Card, etc. Please refer to chapter <i>Patient Information Item Management</i> for more details.)
3	Patient type (click this area to view/edit patient information)
4	Physiological alarms area (click this area to enter Review window)
5	Technical alarms area (click this area to enter technical alarms window)
6	Measurement value
7	Parameter waveform
8	Alarm reset key

9	Scroll left to display more shortcut keys
10	Shortcut key area
11	Storage status indicator of the storage device
12	Removable storage device symbol of USB flash disk
13	e-link connection symbol
14	Wi-Fi network symbol
15	The picture sample above: single battery status symbol  : dual batteries status symbol
16	Wired network symbol
17	Scroll right to display more shortcut keys
18	Date and time
19	Menu
20	TEMP 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
	NIBP SYS alarm off
	NIBP MAP alarm off
	NIBP DIA alarm 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	

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.



Menu, to display the main setup menu



Alarm Reset, to reset the alarm for monitor mode only



New Patient, to create new patient for spot-checking mode only



Select Patient, to select patient for Ward 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 > Common > Shortcut** to choose and configure.

In monitor mode, the displayed keys are: Alarm Mute, Admission, Review, NIBP measurement, General, Standby mode, Record, Barcode scanning, Night Mode and Score.

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

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



Audio alarm paused/off



Quickly admit a patient



Enter score interface



NIBP measurement



General setup



Standby mode



Record output



NIBP average measurement



Review (in monitor or spot-checking mode)



Night mode



Barcode scanning



Review (in Ward round mode)



Select this item by the rotary knob to enable the touch screen operation

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 Work Modes

The monitor offers multiple work modes, including Monitor (also called Monitoring), Ward Round, and Spot-checking.

Monitoring mode is designed for continuous bedside single patient monitoring and management. Ward round mode is used for parameter measurement and for multiple patients' ward round data management. Spot-checking mode is used for spot-checking measurement and for management of multiple patients' spot-checking data.

Select **Menu > System Setup > Mode** to choose **Monitoring**, **Spot-checking** or **Ward Round**. The selected working mode will be displayed in left part of general information area. Refer to specific chapter for details of these 3 modes.

NOTE

1. The history data in each mode can be viewed only in corresponding mode.
2. In these 3 modes, each setting item is respectively independent, except language and network setups. For instance, in monitoring 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 ward round mode.

3.4 Operating Modes

3.4.1 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**.

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.

3.4.2 Standby Mode

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

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

Function > Standby.

2: Automatic standby: In spot-checking or Ward 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 **Off**. **30 min** is default setting. In monitor mode, permanent setting is **Off**.

Standby Indicator can be turned **On** or **Off**, and the indicator will light or not accordingly.

■ In standby mode:

1. The monitor stops monitoring and measuring. The monitoring data before entering standby will be stored.
2. The monitor won't respond to any 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. Stop the recording work in progress.
5. Disconnected with MFM-CMS. MFM-CMS won't update monitoring data, and will display monitor's Offline status. When the monitor exits standby, it will reconnect with MFM-CMS.

■ 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 sends exit order to monitor.

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

NOTE:

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

3.4.3 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.

3.5 Changing Monitor Settings

3.5.1 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.

3.5.2 Adjusting Volume

3.5.2.1 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. Default is volume off.

3.5.2.2 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.

3.5.2.3 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.

3.6 Checking Your Monitor Information

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

Config includes: the configuration monitor supported (such as Wi-Fi, Wired, USB, Barcode, etc.), the currently used configurations are marked with \surd .

About includes: software version, serial number, device name and so on.

Network includes: Network type, Local Net No., Server IP (such as MFM-CMS), Local Mask No., Local Gateway No., Mac address, Communication protocol and so on.

NOTE:

The contents related with network can be set in **User Maintain > Network**.

3.7 Device Settings

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




Device settings include: Department, Device name, Language, Chinese Input (when it is on, the virtual keyboard of the monitor can be switched to Chinese input method), Format Internal

Storage Device and so on.

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, select **Common > Barcode Setup**. Then the user can set MRN (in Monitor or Spot-checking mode) or the 1st patient information item (in Ward Round mode), last Name, first Name and so on.

If internal scanner is configured (please contact EDAN service personnel for activation), user can choose **Manual** or **Auto** for **Internal Scanner Mode** in **User Maintain** to scan the barcode.

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

If the scanner is connected for the first time, the monitor will pop up a confirmation message to ask user whether the new USB device is added as scanner. Choose **Yes** to add as scanner, choose **No** to add as USB device. Please refer to chapter *Accessories* for the recommended scanner.

NOTE:

- 1 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.
- 2 In order to correctly read and input barcode information, set the barcode scanner to USB PC Keyboard. For detailed settings, please refer to the user manual of the scanner.

3.10 Using Mouse

The monitor supports mouse operation via USB port. Mouse is used for controlling cursor.

Chapter 4 Monitor Mode

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

4.1 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, 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.:** supports up to 8 numbers. Chinese, English, number and special characters can be input.
- **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**.
- **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 (admission or admission by barcode) and updating patient will clear the history data in the monitor associated with the patient.

4.1.1 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.

WARNING

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.

4.2 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** to the correct setting and click **Yes** to finish the quick patient admission operation. If you want to quit the operation, click **No**.

4.3 Admit by Barcode

The barcode is based on patient MRN. To admit a patient by barcode,

- In the interface of creating new patient

The patient information from barcode is directly updated to the interface. User can input relevant information and click **confirm** to finish.

- In other interfaces

If the monitor is connected with network server and **ADT Query** (in **User Maintain**) is also set to on, the monitor will automatically inquire for patient information from the server via MRN and update the information to the interface of creating new patient in which the items are grey and can't be modified (except bed No.), and user should click **confirm** to finish; if network server is not connected, monitor can not inquire for patient information from the server, and then monitor will update the patient information to the interface of creating new patient according to barcode information, and user can input relevant information and click **confirm** to finish.

4.4 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.


4.5 Monitoring Data Review

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.

Data Review





Trend graph/trend table review	3 hour, at 1 Second Resolution 120 hrs, at 1 min. Resolution
Alarm/Monitoring Event data	Up to 200 sets
NIBP Measurement Review	1200 sets

4.5.1 Trend Graph Review

To review Trend Graph, please press the **Review** shortcut key  on the screen or select **Menu > Review > Trend Graph**.

In the trend graph, the y-axis stands for the measurement value and x-axis stands for the time. With the exception of NIBP and TEMP, other trends are displayed as continuous curves.

In the trend graph review window:

- Select  beside the parameter name and choose the desired parameter.
- Select **Zoom** to adjust the trend scale.
- Select **Interval** to change the length of trend data displayed on the current screen. **1 s, 5 s, 1 min, 5 min** and **10 min** are optional.
- Select  beside **Cursor** to move the cursor left or right.
- Select  and  to scroll the screen left and right manually to browse the trend graph.
- Select **Record** to print out the currently displayed trends by the recorder.



NOTE:

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


4.5.2 Trend Table Review

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



In the trend table review window:

- Select **Interval** to change the interval of the trend data. **1 s, 5 s, 30 s, 1 min, 3 min, 5 min, 10 min, 15 min, 30 min, 60 min** and **NIBP** are optional. Select **NIBP** to view the trend data according to the NIBP measurement time.
- Select  and  to scroll the screen manually to browse the trend table.
- Select **Record** to print out the currently displayed trends by the recorder.
- Select **Record All** to print out all the trends by the recorder.

4.5.3 NIBP Review

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



In the NIBP review window:

- Select **Unit** to change the pressure unit.
- Select  and  to browse more NIBP measurement data.
- Select **Record** to print out the NIBP measurement data by the recorder.

4.5.4 Alarm Review

To review the alarm event, please press the **Review** shortcut key  on the screen or select **Menu > Review > Alarm**.

In the alarm review window:

- Select **Event Type** to choose the required parameter from the popup list and the user can review alarm event of the specific parameters.
- Select **Time Index** to set end time of alarm review.
- **Current Time**: the alarm events occurring before the current time are displayed on the alarm event review interface.
- **User Define**: the user 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.
- Select  and  to browse more alarm events.

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.

4.5.5 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.

4.5.6 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 Marker** to check event mark. Besides, these areas can also display event mark: trend graph window, trend table window and alarm review window.


Chapter 5 Ward Round Mode

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

5.1 Patient Information Item Management

Before creating new patient, user can set the patient information item as needed. Select **Menu > User Maintain > Manage Patient Info. Items** to enter the window:

Bed No.	Show
First Name	Show
Middle Name	Show or hide
Last Name	Show
Type	Show
The 1 st patient info. item (optional)	Show
The 2 nd patient info. item (optional)	Show or hide

- 1 MRN, driver licence, passport No., medical card and so on can be selected as the 1st or 2nd patient info. Item.
- 2 Except **Bed No.**, **First Name**, **Last Name**, **Type** and the 1st patient info. item, other items can be set to show or hide. 10 items at most can be set to show.
- 3 User also can **Add** new patient info. item, or delete the item by clicking icon .

Click **Confirm** to finish the operation. Then, the patient information items will be accordingly displayed in the patient information window and the window of creating new patient.

NOTE:

The changes of patient information items do not affect the data stored in Review.

5.2 Patient Management


Select **Menu > Patient Management** to enter Patient Management window where patients information are listed, including bed No., name, patient type and the 1st patient info. item. 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.

5.2.1 Create New Patient

To create new patient, you may:

1. Select **Menu > Patient Management > New Patient**, or

2. Press Admit/Create new patient hardkey  on the front panel, or
3. Use **Select Patient** permanent key, and then click icon + in popup window, or
4. Scan patient barcode by using barcode scanning shortcut key. The barcode is based on the 1st patient info. item.
 - 1) In the interface of patient management, scan the barcode:

The monitor will update the patient information based on the 1st patient info. item. In this interface, user can complete relevant information inputting.
 - 2) In other interfaces, scan the barcode:
 - a) If the patient based on the 1st patient info. item has been stored in the monitor before, this patient information will be inquired from the monitor and be updated as current patient who needs to be measured. Measurement can be started without **Select Patient** operation.
 - b) If the patient based on the 1st patient info. item hasn't been stored in the monitor before:

When monitor is connected with network server and **ADT Query** (in **User Maintain**) is also set to on, the monitor will automatically inquire for patient information from the server based on the 1st patient info. item and update the information to the interface of creating new patient in which the items are grey and can't be modified (except bed No.); when network server is not connected, monitor can not inquire for patient information from the server, and then monitor will update the patient information to interface of creating new patient according to barcode information.

After input and **Confirm** patient information in the interface of creating new patient, user can start the measurement. When the total patients in the monitor exceed the upper limit 1000, monitor will pop up a prompt. The patients created can be viewed in **Patient Management**.



NOTE:

Either Bed No. or Medical Card number should be input.

5.2.2 Import Patient

■ Import patient

Select **Patient Management** > **Import** to choose **Source** (**USB flash disk** or **Network**). For

querying patient from **Network**, user can also directly click shortcut key  > icon  to set query condition (such as **Admission Date**, **Department**) to import patient.

If **USB flash disk** is selected, before importing, please set the import data file as following steps:

Step 1: use Excel to input the patient information with the format as shown below. Patient type can only be numbers, 1 for Adult, 2 for Pediatric and 3 for Neonate.

Patient information should include:


bed No. first name last name patient type the 1st patient info. item

bed No.	first name	last name	patient type	the 1 st patient info. item
23	Xiaoming	Wang	1	12345
...

Step 2: Save the file as CSV with comma delimiter format. The file name should be fixed as 'ImportPatientList.csv', and the encoding format of the file should be UTF-8.

NOTE:




- 1 In the patient list of CSV data file, first name, last name and the 1st patient info. item cannot be more than 63 bits for each.
- 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.

If **Network** is selected and the monitor is connected with network server, user can set the query conditions (**Admission Date**, **Department**), and click query icon  to show the patients.

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 user should delete part of existing patients, then return to import patient window to import again. Choose **NO** to return to **Import Patient** window, and user should delete part of patients who need to be imported, then import again.

■ Refresh patient list

If monitor is connected with network server and **ADT Query** (in **User Maintain**) is also set to on, click shortcut key  > icon  to set query condition (such as **Admission Date**, **Department**) > click query icon  to show the patients > click **Refresh List**, and then all eligible patients will be refreshed to the window of **Select Patient**.

NOTE:

- 1 The operation of importing will keep "the patients those exist in the monitor but not found in network". However, the operation of refreshing will delete those patients.
- 2 During importing or refreshing, if the 1st patient information item or the bed No. has conflict, the monitor will replace all conflicting patient information. But the patient measurement status will keep unchanged as the previous patient for the conflict of the 1st patient information item, and recover to the initial unmeasured status for the conflict of bed No..

5.2.3 Delete Patient

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

This operation can only delete the patient information in **Patient Management** window but cannot delete patient history data.

If the selected patients are in measurement, there will be a confirmation '**Delete the currently measured patient, confirm?**'. Choose Yes to delete and the monitor will return to no patient status. Choose No to stop and the monitor will return to **Delete Patient** window.

5.3 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** permanent key to enter select patient window:

- All patients' bed No., name, measurement time and measurement status will be displayed. The circle near bed No. shows measurement status by colour. Green means a measured patient has normal measurement value; no color means a measured patient has invalid measurement value or no measurement value.
- 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.
- **New Round**: when new round is needed, press this key to clear all patients' measurement status and measurement time. Measurement status will return to 'not measured' status, and when user set **Time Span** to **Current** in **Review** window, **Current** measurement data will be cleared.

If monitor is restarted, it will return to no patient status in main interface and keep the previous measurement status in **Select Patient** interface.

5.4 Ward Round Record

5.4.1 Data Update

In main interface, for quick TEMP module, only measurement data in predict/quick predict will be updated.

SpO₂ data will be updated by following ways:

- By time interval: Click SpO₂ parameter area to enter SpO₂ parameter setup menu > **SpO₂ Storage Interval**, choose from **30 S**, **1 min**, **2 mins** and **5 mins**. **30 S** is default setting. Then the monitor will store SpO₂ original data or SpO₂ spot-checking data according to the selected interval.
- By spot-checking data: when TEMP value or NIBP value is obtained.

5.4.2 Ward Round Record Confirmation

In main interface:

User clicks **Save**, and the measurement data in main interface will be stored as a Ward round record in **Review** menu. User can **Save** multiple ward round records for a patient.

The time of Ward round record is subject to the time of clicking **Save**.

In User Maintain:

If **Clear Data After Save** is set to On (default is Off), the data in main interface will be immediately cleared after user clicks **Save**.

5.5 Operator Information & Custom Parameters

In Ward round mode, user can file the operator information and the custom parameters uniformly. The filed information can be viewed in **Menu > Review >** clicking the symbol on the right of Ward round record to enter **Patient Measurement Data** window **> Custom Parameters**, and can also be uploaded along with the Ward round record. (For details about uploading, please refer to chapter *Uploading Data to Network Server*)

To file the operator information and the custom parameters:

- Add new custom parameters or set the attribute

In **Menu > User Maintain > Custom Parameter Setup**, user can **Add, Import, Export** or **Delete** the custom parameters.

In the window of **Add Custom Parameters**, the basic attribute (such as **Name, Unit** and **Type**) should be set. When **Type** is selected as **Numeric**, user should set the **Upper Limit, Lower Limit** and **Resolution** according to the prompts. When **Type** is selected as **Option**, user should set **Option Counts** and detailed option contents according to the prompts. Click **Confirm** to finish the operation.

After adding, user can modify all attributes (except for the basic attributes) by clicking the small icon on the right of custom parameters.

NOTE:

- 1 The total number of Custom Parameters allowed in the device is 20. If exceeds, please delete before adding or importing.
- 2 In **Custom Parameters Setup** window, if the existing custom parameters are deleted, the corresponding custom parameters data stored in **Review** will also be deleted accordingly.

- Sort the custom parameters by positions

After adding and setting attribute, all custom parameters will be displayed accordingly in **Menu > Parameters Setup > Custom Params Switch**. Among which, **RR, Consciousness** and **Oxygen** are fixed in this window, and there is no need to **Add** them in **User Maintain > Custom Parameter Setup**.

Click **Select All, Clear All** or Select as needed to sort the selected parameters by position. The sorting of up to 6 positions is supported. Click **Confirm** to finish the operation. After

sorting, the custom parameter area in the main interface will be displayed accordingly.

- Set detailed data information for the custom parameters

Set and input detailed data information in in the main interface > click **Save** to store them. The saved custom parameters data details can be viewed in **Review** menu.

If more than 6 custom parameters are the displayed in main interface, click **More** to enter a submenu. User can modify and input detailed data information, and also can **Clear All** data. Click **Confirm** to finish the operation.

- Filing Time & Operator ID: in main interface, directly click **Filing Time** or **Operator ID**.

User can select the **Filing Time Source** (**System** or **Manual Setting**), set **Operator ID** and **Operator Name**, and then click **Confirm**.

The **Filing Time** can be turned On or Off in **User Maintain**. Default is On.

- Save: by clicking **Save**, the data (Ward round record, operator information, custom parameters, etc.) will be filed and viewed in **Review** menu.

5.6 Ward Round Record Review

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

- Set **Time Span** to display Ward round record in specified period. The **Current** Ward round record will be displayed by default.
- **Filter** operation: is to display Ward round records in specified period. Abnormal value is displayed in red. Choose **Alert** to display abnormal value in specified period. Choose **Not Uploaded** to display data not uploaded in specified time. All ward rounds are displayed by default. The default display will be restored if user exits and enters this interface again.
- The Ward round record can be in order by **Bed No.** or **Time**. Time order is the default setting which will be recovered if user exits and enters this window again.
- **Upload**, **Record**, **Export** or **Delete** is used for uploading, record outputting, exporting or deleting the selected Ward round records (not including its original data). Please refer to chapter *Uploading Data to Network Server* and *Exporting Data Stored in the Internal Storage Device* for details about uploading and exporting.
- Click the icon on the right of one Ward round record to enter **Patient Measurement Data** window. In this window, user can view the corresponding original data (20 groups at most), including patient information, parameters value and this Ward round record. User can also click **Record** to output the original data in this window, or modify the Ward round record and click **Save** to complete.

If monitor is powered off, Ward round record will be stored. Each 1 MB space can store 100 groups of Ward round records at least, including patient information and 20 original records.


Chapter 6 Spot-checking Mode

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

6.1 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 **New Patient** permanent key, or press Admit/create new patient hardkey  (without key sound), 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).

3. Scan patient barcode by using barcode scanning shortcut key.

- In creating new patient interface, user can scan the barcode through scanner. The patient information is directly updated to this interface according to barcode information, and user should **Confirm** it.
- In other interfaces, series No. will be automatically added by one, and the patient information is directly updated to main interface according to barcode information.

6.2 Modify Patient Information

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

If the monitor is powered off and restarted, the patient 1 will be automatically selected as current measured patient, the patient type is adult and the other information is blank.

6.3 Spot-checking Data Review

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

- Click page button to turn page.
- Set **Time Span** 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.
- **Filter** operation: is to display spot-checking data in specified period. Abnormal value is displayed in red. Choose **Alert** to display abnormal value in specified period. Choose **Not Uploaded** to display data not uploaded in specified time. All spot-checking data are displayed by default. The default display will be restored if user exits and enters this interface again.
- **Upload, Record, Export** or **Delete** is used for uploading, record outputting, exporting or deleting all spot-checking data in specified period. User can choose patient data manually and upload as needed, including the data which have been uploaded. Please refer to chapter *Uploading Data to Network Server* and *Exporting Data Stored in the Internal Storage Device*

for details about uploading and exporting.

6.4 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. Each 1 MB space can store 1000 groups of spot-checking data at least.

Chapter 7 Networking

The 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, check the IP address from MFM-CMS.

7.1 Cybersecurity Measures

7.1.1 Personal Information Safety

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

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

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

CAUTION

- 1 The access/operation of the monitor is restricted to authorized personnel only. Assign only staff with a specific role the right to use the monitor.
 - 2 Ensure that all device components maintaining personal information (other than removable media) are physically secure.
 - 3 Ensure that the data are deleted after the patient is discharged (Refer to Section *Deleting Data Stored in the Storage Device*).
 - 4 Ensure that the monitor is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported monitors within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.
 - 5 Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the Factory Maintain settings.
-

CAUTION

- 6 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.
 - 7 Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against DoS and DDoS attacks, and keep it up to date.
 - 8 DoS and DDoS protection of the router or switch must be turned on for defending against attacks.
 - 9 When the monitor is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the monitor (Refer to Section *Deleting Data Stored in the Storage Device*).
 - 10 To avoid malicious tampering and theft of data transmitted by the network, it is recommended to switch on the encryption function. After the encryption function is turned on (it is set to on by default), the monitor will authenticate the accessed MFM-CMS and GATEWAY devices and encrypt the transmitted data to ensure the security.
 - 11 Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the monitor.
 - 12 When building the networking environment: 1) If a wireless router is used, please turn on the MAC address filtering function of the wireless router and add the MAC address of the monitor to the rule list. The wireless router only allows devices in the rule list to access the wireless network. 2) It is suggested to build a VLAN, assign the LAN ports where the approved switch port, monitor and MFM-CMS are into the same VLAN, and isolate them from other VLANs.
-
-

NOTE:

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

7.1.2 Network Security

For more security operations, please enter **Menu > User Maintain**, input user maintain password > **Security**. In this window:

- Click **User Password** box to enter **Modify User Password** subwindow, user can change the password according to the prompts displayed on the interface. For safety consideration, please change the password periodically, and a combination of words and numbers is recommended. If **Old User Password** is forgotten, please contact the service personnel of EDAN.

NOTE:

When the monitor is turned on for the first time or after upgrading software, please modify User Maintain password according to the prompts. The default initial User Maintain password is **ABC**.

- Set **CMS/Gateway Encryption** to **Off**, **AES** (default) or **TLS** when user connects the monitor with network server (MFM-CMS or gateway).
- Click **Load Certificate** to install/upgrade the **Certificate** via USB flash drive. The certificate issued by Certificate Authority (CA) is recommended and self-signed certificate should be avoided.

Steps of importing certificate for MFM-CMS and Gateway:

- ✓ Step 1, in CA Certificate column, select corresponding CA certificate whose suffix should be '.cer'.
- ✓ Step 2, in Client Certificate column, select corresponding client certificate whose suffix should be '.cer'.
- ✓ Step 3, in Private Key Certificate column, select corresponding private key whose suffix should be '.pem'.
- ✓ Step 4, in Password column, input corresponding password.
- ✓ Step 5, click **Confirm**.

NOTE:

- 1 CA certificate is the root certificate of CA institution.
 - 2 Client certificate/Server certificate are the SSL certificate obtained from CA institution and it is recommended to use OV-SSL certificate type.
 - 3 The private key shall be generated by the RSA-2048 algorithm and be encrypted by using the AES-256 algorithm. The password for encryption shall be at least 8 characters (a combination of letters and numbers).
 - 4 The certificate format is as follows: For CA and Client certificate/Server certificate, '.cer' is supported; for private key, '.pem' is supported. All the certificates should comply with X.509 format.
 - 5 The storage path for certificate related to TLS enterprise-level encryption method:
For MFM-CMS\gateway: root directory of USB flash drive\certs\cms\
- Set **Firewall** to **On** to protect against hacker attacking.
 - Click **Firewall Rules** to check rule details.
 - Set **Packets Limit** value for traffic monitoring. If the data traffic into the monitor in Per minute exceeds the threshold, the monitor will remind the user of the exceeding and the risk of network attack.
 - Set **Auto Login** to On/Off.

When it is set to **On**, the user can directly enter the main interface; otherwise, the user needs to enter a password for identity authentication.

- Setting **User Login Timeout** allows the user to lock the screen when the monitor has been idle for a certain amount of time, so that others cannot access the monitor without entering the password. If **Never** is chosen, the user has no need to login again once the authorization is successful. Default selection is **Never**.

NOTE:

In screensaver status, if password entered is incorrect, user can directly click **Factory Entrance** and send the verification code to the service personnel to retrieve the password.


7.2 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.
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.

Click the desired network to check the encryption information (such as **Security**). Input relevant network information (such as **Password, IPv4 Address**) to make the network connected.

If the encryption type of the currently connected network is modified, the network will

automatically disconnect and attempt to reconnect. At this time, please click  first to ignore this network and then connect manually. For an unconnected network, if the encryption information or SSID is modified and the user attempts to connect it, the user needs to disconnect the currently connected network and click Update icon to select the updated network.





Icons function:

 Connect to hidden networks.	 View historically connected networks.	 Refresh network list.
 Turn the page left and right. to view more networks	 Secure network	 Insecure network (not recommended). Icon color is red.

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 Use the wireless device recommended by EDAN, otherwise some exceptional situations such as frequent network disconnection may occur on the monitor.
- 4 When signal intensity is level 2 or less, signal may be unstable and quality of the signal transmission may be degraded.
- 5 When the monitor is connected to MFM-CMS/GATEWAY via the wireless network, the user should set the router to a secure encryption/authentication mode and use the non-dictionary password.
 - ◆ Recommended options: WPA2-PSK (supports AES / TKIP);
 - ◆ Other options: WPA-PSK, WPA2-Enterprise (includes EAP-TLS / EAP-TTLS / EAP-PEAP).
- 6 The storage path for certificate related to EAP-TLS enterprise-level encryption method: root directory of USB flash drive\certs\wlan\

WARNING

- 1 Before monitoring patient, the Network Type (wired or Wi-Fi) should be selected, it is not allowed to be switched during monitoring. Otherwise, the Wi-Fi may be unavailable.
- 2 If Wi-Fi is unavailable, please restart the monitor (refer to Section *Front View*) to restore Wi-Fi function under the precondition of ensuring patient's safety.

7.3 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**.

7.4 e-link Function

A monitor with e-link module can transmit data through e-link and also displays the connection status between the monitor and the communication device in the general information area.

To enable/disable the function, select **User Maintain** > input password > select **Network** > set **e-link to Active Connection, Passive Connection** or **Off** (default).

- **Active Connection:** used to actively receive data from external module.

In **System Setup** > **e-link**, user can view **Paired Devices** list and **Available Devices** list. Select from the **Available Devices** list to **Connect** with communication device.

In **Paired Devices** list, up to 10 recently connected devices can be displayed. Select one of them to view details (such as Device Name, Alias, MAC address, etc.) or to delete. User can also modify Alias which supports 1~20 English characters.

- **Passive Connection:** used to send data to the network in response to HL7 requirement.

In **User Maintain** > **Network**, user can set **e-link Name** and **e-link Key**.

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".

Connection permission (e.g. pairing code) is needed for the first connection. Pairing code supports 6 numbers at most. Default pairing code is 123456.

For Passive Connection, the transmitted data include: patient information (in monitor/Ward round/spot-checking mode, doctor, blood type and department information are excluded), parameter measurement data.

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, SpO₂, TEMP (prediction data of Quick TEMP and infrared TEMP data), transmission time.

NOTE:

For Passive Connection, the supported data transmission format is XML or ER7, and the supported e-link version is BLE4.0, which is applicable in 3 system environments: iOS, Android and Windows. For Active Connection, only version below 4.0 is supported.

7.5 Connecting the Monitor to MFM-CMS

The monitor can be connected to the central monitoring system only when it is in monitor mode and also the encryption method is not TLS. 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 HL7 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 MFM-CMS is in good condition when the time synchronization function (refer to section *Setting Date and Time*) on the monitor is active. 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.
- 4 The monitor and MFM-CMS/Gateway will pack and transmit the data via their own protocol. When receiving the data, they will confirm the correctness of the data package. Only the data that meets the protocol's requirements will be received.
- 5 When deploying the network of the monitor and MFM-CMS/Gateway, it is recommended to isolate the network and the Intranet system of the hospital by using VLAN so as to ensure the network security. Only trusted devices are allowed to join the VLAN network.
- 6 For more instructions on how to connect or install and disconnect or uninstall the MFM-CMS/Gateway, please refer to *MFM-CMS Central Monitoring System Installation Guide/GW1 Gateway User Manual*.

7.6 Connecting the Monitor to CMS-LITE

The monitor can be connected to the CMS-LITE Data Management Software only when it is in monitor mode and also the encryption method is not TLS. Through the network:

1. The monitor sends patient information, monitoring or measurement data to the CMS-LITE Data Management Software.
2. The monitoring information is displayed on the CMS-LITE Data Management Software as

the same to the monitor.

For detailed information, please refer to *CMS-LITE Data Management Software User Manual*.

7.7 Gateway Communication

The monitor can be connected to the Gateway (V1.21 or above), which provides clinicians with the capability of viewing and collecting patient data remotely and the data exchange of selected clinical and administrative information between the monitor and the hospital network.

To set the monitor server IP address, select **User Maintain > Network > Server IP**. Make sure the monitor share the same server IP with the computer in which the MFM-CMS software is installed.

For more information about Gateway communication, refer to *GW1 Gateway User Manual*.

7.8 HL7 Communication

The monitor supports HL7 protocol to upload data. Select **User Maintain** and input user maintain password > **Security**. In this menu:


- Set **HL7** to On/Off. To avoid hacker attacking, setting HL7 to Off is normally recommended.

To set HL7 IP address of the client-side, select **User Maintain > Network > HL7 IP**.

For more information about HL7 communication, refer to *HL7 Communication Protocol Service Manual*.

7.9 Inquire for Patient Information via Network (ADT)

If the monitor is connected to network server and **ADT Query** (in **User Maintain**) is also set to **On** (default is Off), the monitor can inquire for patient information from the server.

- 1 In Monitor mode or Ward round mode, press Admit/Create new patient hardkey  on the front panel to enter **New Patient** interface;

In Spot-checking mode, select **Menu > Patient Management > New Patient** to enter **New Patient** interface;

- 2 In Monitor or Spot-checking mode, input MRN for query;

In Ward round mode, input the 1st patient information item, Or, directly scan barcode to get patient information. The patient information can be updated to the monitor.

NOTE:

- 1 If the patient information inquired from Network server is modified on the network server, the monitor can update the modified contents correspondingly only when the monitor is in the monitor mode and relevant settings on the network server have also been set to on; If patient information is modified on the monitor only in the monitor mode, the modified contents can be updated to network server.
- 2 When the monitor is in the on-screen keyboard interface, scanning barcode is used only for information input. After information input, user should complete the new

creation according to the normal operation

7.10 Uploading Data to Network Server

Ward round records and spot-checking data 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 Ward round records/spot-checking data. The upload result will be prompted by pop-up window, and in review window, a symbol will be displayed near the data which have been uploaded successfully.

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, the monitor will upload the Ward round record which has been saved by user or the real-time spot-checking measurement data to network server in real time. The upload result will be prompted in the general information area of main interface, and in review window, a symbol will be displayed near the data which have been uploaded successfully.

In **User Maintain > Network**, If **Delete Data After Upload** is set to On (default is Off), the data successfully uploaded will be deleted in the device.

7.10.1 Continue to Upload from Breakpoint

When the monitor is in idle and there are data failed to be uploaded, the monitor can automatically upload those data from the breakpoint if the network server is connected.

Chapter 8 Alarms

WARNING

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

8.1 Alarm Category

- In monitor mode:

the monitor provides two types of alarm, physiological alarms and technical alarms. Also, the monitor provides prompts.

- In Ward round or spot-checking mode:

The monitor provides vital signs alarms (such as **SpO₂ No Pulse**, **SpO₂ Desat**), and also provides alert information (please refer to chapter *Alert Setup* for details) instead of physiological alarms. Parameter area displays alarm off symbol.

Battery Low is acted as low-level technical alarm. Some technical alarms are acted as prompts.

8.1.1 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*.

8.1.2 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*.

8.1.3 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*.

8.2 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.

The sound pressure range for standard audible alarm signals is from 45 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

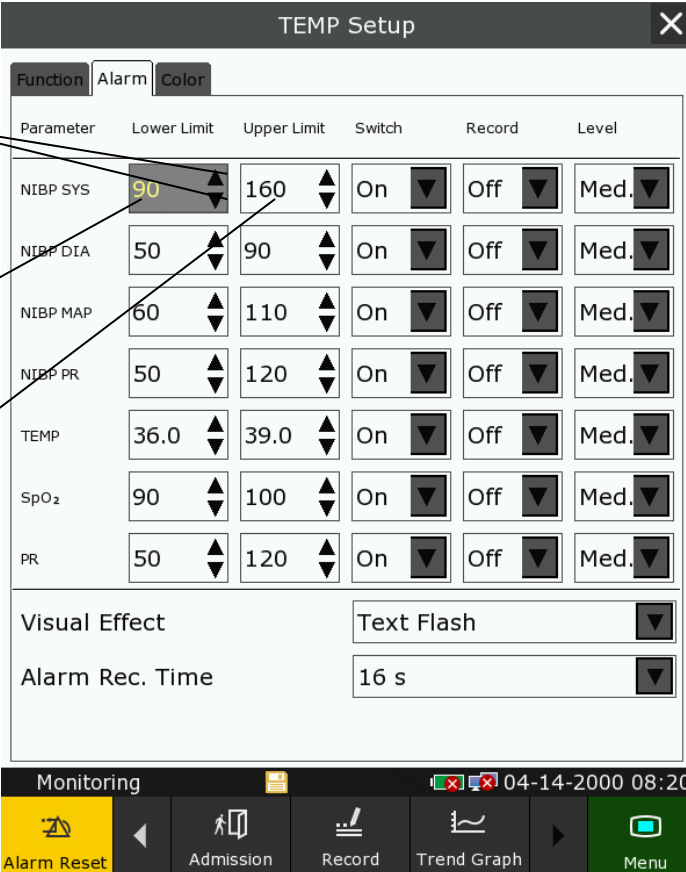
- 1 Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation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

8.3 Controlling Alarm

8.3.1 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

Function	Alarm	Color			
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 ₂	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.

8.3.2 Audio Alarm Paused


In monitor mode, 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.
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.

8.3.3 Audio Alarm off

In monitor mode, 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.

8.3.4 Alarm Reset

In monitor mode, select the shortcut key  on the screen directly. 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.

8.4 Latching Alarms

In monitor mode, 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 audio 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.

8.5 Alarm of SpO₂ Sensor Off

In monitor mode, user can enter **Menu > User Maintain > Alarm** to set the alarm level of **SpO₂ Sensor Off** to **High**, **Med.** or **Low**. It is set to **Low** by default.

In Ward round or spot-checking mode, it is acted as prompt and the level is not user-selectable.

8.6 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.

8.7 Testing Alarms

When you switch the monitor on, the monitor will prompt two “Di” tone that means the audio in selftest is normal. You must check that the alarm indicator light is normal (it lights in red, yellow and blue in turn during starting up). 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.

8.8 Alert Setup

In Ward round mode or spot-checking mode, the monitor provides vital signs alarms (such as **SpO₂ No Pulse**, **SpO₂ Desat**), and 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 **Alert Method**.
- ◆ 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.

8.9 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 **Off** (default), **High**, **Medium**, **Low**, **High+Med.** or **All**. When the corresponding level of physiological alarm occurs, the nurse call signal will be sent to remind the nurse.

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.

Chapter 9 Alarm Information

9.1 Physiological Alarm Information

WARNING

During monitoring, the physiological alarms **SpO₂ No Pulse** and **SpO₂ Desat** are preset to be on and cannot be turned off.

Message	Cause	Alarm level
SpO₂		
SpO₂ High	SpO ₂ measuring value is above upper alarm limit.	User-selectable
SpO₂ Low	SpO ₂ measuring value is below lower alarm limit.	User-selectable
SpO₂ 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
SpO₂ Desat	SpO ₂ measuring value is below the SpO ₂ Desat Limit.	High
PR		
PR High	PR measuring value is above upper alarm limit.	User-selectable
PR Low	PR measuring value is below lower alarm limit.	User-selectable
NIBP		
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
TEMP		
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

9.2 Technical Alarm Information

Message	Cause	Alarm Level	Action Taken
SpO ₂			
SpO₂ Sensor Off	SpO ₂ 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.
SpO₂ Sensor Err	Malfunction in the SpO ₂ sensor or in the extension cable.	Low	Replace the SpO ₂ sensor or the extension cable.
SpO₂ No Sensor	No SpO ₂ sensor was connected to the monitor.	Low	Make sure the monitor and sensor are well connected, reconnect the sensor.
SpO₂ Comm Fail	SpO ₂ module failure or communication failure	High (monitor mode) Low (spot-checking or Ward round mode)	Stop using measuring function of SpO ₂ module, and notify biomedical engineer or manufacturer's service staff.
SpO₂ Low Perfusion (EDAN SpO ₂)	The pulse signal is too weak or the perfusion of the measurement site is too low.	Low	Reconnect the SpO ₂ sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.
SpO₂ Noisy Signal (EDAN SpO ₂)	There is interference with SpO ₂ measurement signals due to patient movement, ambient light, electrical interference or else.	Low	Check the condition of patient and avoid patient movement; make sure the cable is well connected.

Message	Cause	Alarm Level	Action Taken
SpO₂ Interference (EDAN SpO ₂)	Light Ambient light around the sensor is too strong.	Low	Reduce interference of the ambient light and avoid sensor's exposure to strong light.
NIBP			
NIBP Comm Fail	NIBP module failure or communication failure	High (monitor mode) Low (spot-checking or Ward round mode)	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.	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 Pressure	Excessive 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	

Message	Cause	Alarm Level	Action Taken
NIBP Aux Excessive Pressure	Pressure has exceeded the second safety limit as specified.	High	Notify biomedical engineer or manufacturer's service staff.
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.	High	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP Cuff Type Error (EDAN NIBP)	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.
NIBP SystemPress.Abnormal	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.

Message	Cause	Alarm Level	Action Taken
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.
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.
T2A TEMP			
Temp Comm Fail	TEMP module failure or communication failure.	High (monitor mode) Low (spot-checking or Ward round mode)	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	

Message	Cause	Alarm Level	Action Taken
Probe Is Missing	The probe connected cannot be identified.	Medium	Please change probe or contact Manufacturer's service staff.
Probe TEMP Too High	The original temperature of sensor $>+33\text{ }^{\circ}\text{C}$ and $\leq+40\text{ }^{\circ}\text{C}$.	Low	Please wait for probe temp drop and start measuring.
Probe Heater Error	Heater error.	Medium	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
Temp SENSOR OFF	The probe is disconnected from the patient.	Low	Connect the sensor and the patient well, and measure again.
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.
TH TEMP			
Temp exceed limit	The TEMP value is beyond the range of $34\text{ }^{\circ}\text{C}$ ~ $42.2\text{ }^{\circ}\text{C}$	Medium	Check the integrity of the probe cover, make sure it is clean, and take a new measurement.

Message	Cause	Alarm Level	Action Taken
F3000 TEMP			
TEMP Error E1	System error during synchronization.	Medium	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
TEMP Error E2	System error during patient thermistor calibration.	Medium	
TEMP Error E3	System error during heater thermistor calibration.	Medium	
TEMP Error E4	System timing error.	Medium	
Probe Heater error	Heater error.	Medium	
TEMP Error P2	Monitor Mode patient thermistor unstable or out of range.	Low	
TEMP Error P3	Monitor Mode heater thermistor unstable or out of range.	Low	
TEMP Error P4	Predict Mode patient thermistor unstable or out of range.	Low	
TEMP Error P5	Predict Mode heater thermistor unstable or out of range.	Low	

Message	Cause	Alarm Level	Action Taken
TEMP Error P6	Unable to pre-heat probe tip.	Low	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff. NOTE: Measure readings displayed on the screen are unreliable when the monitor indicates Temp Error P06.
Temp COMM Fail	TEMP module failure or communication failure.	High (monitor mode) Low (spot-checking or Ward round mode)	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.
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.
Probe TEMP Too High	The original temperature of sensor >+33 °C and ≤+40 °C.	Low	Please wait for probe temp drop and start measuring.

Message	Cause	Alarm Level	Action Taken
Others			
Battery Low	Battery Low	High (monitor mode) Low (spot-checking or Ward round mode)	Please change the battery or charging.
Battery Error	Malfunction in Battery	Low	Replace the battery and restart the monitor. If the problem persists, notify the manufacturer's service staff.
Recorder Out Of Paper	Recorder Out Of Paper	Low	Please install the paper.
Recorder Setup Needed	The user presses the RECORD button when Recorder is not configured.	Low	Notify the manufacturer's service staff to install and set the recorder.
Insufficient storage space	Less than 10M space is left in the device.	Low	Delete some data in the device or use another device.
Read-only storage device	The device is read-only.	Low	Repair the device or replace it with a new one.

Message	Cause	Alarm Level	Action Taken
Network Disconnect	In distributed alarm system, the monitor's network is disconnected.	Low	<ol style="list-style-type: none"> 1) Check if the network cable is well connected. 2) Check if the MFM-CMS is turned on. 3) Check if the IP of bedside monitor and MFM-CMS are on the same network segment. 4) Contact the professionals authorized by manufacturer to check the network problem.
Network Traffic Abnormity	Abnormal network traffic has been detected. The data traffic exceeds the limit.	High	Disconnect the network to make the monitor work properly, and then contact the professionals authorized by manufacturer to check the network problem.

9.3 Prompts

Message	Cause
SpO₂ Search Pulse	SpO ₂ module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.
SpO₂ Noisy Signal	There is interference with SpO ₂ measurement signals due to patient movement, ambient light, electrical interference or else. (Nellcor SpO ₂)
Manual Measuring	In manual measuring mode
Continual Measuring	In continuous measuring mode

Message	Cause
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.
TEMP Is Warming Up	User takes the sensor out of the bracket and TEMP is warming up
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 Warning-Score System interface, parameters are not completely input.
No WIFI module detected	No Wi-Fi module is detected.
Quick Predict Over	Quick prediction measurement is completed.
PlaceProbeOnMeasurePlace	Probe isn’t placed on the measurement site.

9.4 Adjustable Range of Alarm Limits

SpO₂ alarm limits are listed as follows (unit %):

	Adjustable Range
SpO ₂	20~100

SpO₂ Desat Limits are listed as follows (unit %):

	Adjustable Range
SpO ₂ Desat Limit	20~99

NOTE:

User can set the range through **User Maintain > Alarm > SpO₂ Desat Limit**. SpO₂ Desat Limit should be less than or equal to SpO₂ alarm low limit.

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

		Adjustable Range
PR (SpO ₂)	EDAN	30~300
	Nellcor	30~300
PR (NIBP)	EDAN	40~240
	SunTech	30~220

NIBP alarm limits are listed as follows:

EDAN module:

Patient Type		Adjustable Range (mmHg)
ADU	SYS	40~270
	DIA	10~215
	MAP	20~235
PED	SYS	40~230
	DIA	10~180
	MAP	20~195
NEO	SYS	40~135
	DIA	10~100
	MAP	20~110


SunTech module:

Patient Type		Adjustable Range (mmHg)
ADU	SYS	40~260
	DIA	20~200
	MAP	26~220
PED	SYS	40~230
	DIA	20~160
	MAP	26~183
NEO	SYS	40~130
	DIA	20~100
	MAP	26~110

TEMP alarm limits are listed as follows:

Patient Type	Adjustable Range	Step
ADU/PED	+35.5 °C (+95.9 °F) ~ +42 °C (+107.6 °F)	+0.1 °C (32.2 °F)

9.5 Known Issues and Directions

No.	Known issues	Directions
1	When recording the trend graph in monitor mode, if the Record shortcut key is pressed to stop recording in the process of recording the second parameter trend graph, the paper for recording will not be left blank after the second parameter trend graph.	Re-print trend graph, and do not press Record shortcut key in printing process.
2	When USB flash drive is inserted via OTG interface, it may not be recognized.	Re-plug USB flash drive
3	In spot-checking mode, press Admit/Create new patient hardkey  , there is no key sound.	N/A
4	Switching Network Type may lead to Wi-Fi unavailable.	If Wi-Fi is unavailable, please restart the monitor (refer to Section Front View) under the precondition of ensuring patient's safety.
5	In Ward round or spot-checking mode, the Removable Device can be selected, while storage device is fixed as Internal Storage Device .	N/A

Chapter 10 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.

10.1 Setting Interface Style

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

10.2 Selecting Display Parameters

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

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

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

10.3 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.

NOTE:

The colors won't be affected by the default factory Settings.

10.4 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.

10.5 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 11 Monitoring SpO₂

11.1 Overview

SpO₂ is used to measure arterial blood oxygen saturation, which is the percentage of oxyhemoglobin in the arterial blood. SpO₂ parameter can also provide pulse rate (PR) and a plethysmogram wave (Pleth).

11.2 SpO₂ Safety Information

WARNING

- 1 Do not use the SpO₂ sensors if the packaging or the sensor is damaged and return them to the vendor.
- 2 If the SpO₂ sensor cannot work properly, please reconnect the sensor or change a new one.
- 3 Correct and proper sensor application: if the sensor is too loose, it might compromise the optical alignment, and even cause the sensor to fall off. If the sensor is too tight, (such as the application site is too large or becomes too large due to edema), excessive pressure and local tissue ischemia, hypoxia and lack of nutrition may occur on the application site. Prolonged and continuous monitoring may increase the risk of Skin irritations or lacerations. To avoid these damages, users should periodically check surrounding skin of application site according to the patient's condition and pressure sensor, inspect the if there is sign of stress-related damage in surrounding tissue, and regularly change the application site. For the patients whose fluid is easy to transfer and/or the patients with systemic or localized edema, users should inspect the skin and change application site more frequently.
- 4 Use only EDAN permitted sensors and extension cables with the monitor. Other sensors or extension cables may cause improper monitor performance and/or minor personal injury.
- 5 High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the high limit alarm off.
- 6 When serious arrhythmia is present, the SpO₂ pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO₂) value.
- 7 Misapplied sensor or sensor that becomes partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

NOTE:

- 1 Avoid placing the sensor on extremities with an arterial catheter, intravascular venous infusion line, or inflated NIBP cuff. When measuring SpO₂ on the limb with inflated NIBP cuff, please turn on the **NIBP Simul** function.

- 2 When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.
- 3 SpO₂ waveform is not directly proportional to the pulse volume.
- 4 The device is calibrated to display functional oxygen saturation.
- 5 Functional tester or simulator can not be used to assess the SpO₂ accuracy. However, it can be used to demonstrate that a particular monitor reproduces a calibration curve that has been independently demonstrated to meet a particular accuracy.
- 6 If the surrounding temperature increases, the operator should pay attention to the site of poor perfusion, and increase the frequency of checking the skin and changing the measurement site to prevent burns. If the initial skin temperature is less than 35 °C, the temperature of all the listed sensors on the skin will not exceed 41 °C during working.
- 7 The cumulative use time for SpO₂ sensor in a single patient should be less than 30 days.

11.3 Measuring SpO₂

1. Select the correct patient category setting (adult/pediatric and neonatal), as this is used to optimize the calculation of the SpO₂ 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.

Before Applying the Sensor

Be sure to understand all warnings listed in the previous section before applying any sensor to a patient. Also, check the sensor as follows:

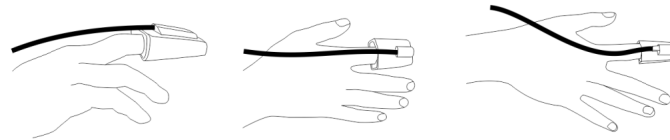
- ◆ Check the sensor outside and inside. To inspect the inside, gently open the sensor cavity and check splits on or next to the transparent silicone that covers the optical elements.
- ◆ Any sensor showing signs of damage or alteration must not be used for further patient monitoring; instead, dispose of it using proper disposal procedures.

Applying Finger/Soft-tip Sensors:

- ◆ Nip the clamp, and choose a site that is well perfused and restricts a conscious patient's movements least. The right finger of the non-dominant hand is preferred. Alternatively, the other digits on the non-dominant hand may be used.
- ◆ The grate toe or long toe (next to the grate toe) may be used on restrained patients or patients

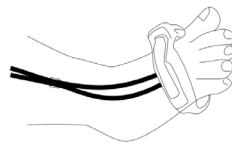
whose hands are unavailable.

- ◆ Place the finger into the sensor according to the direction of the symbol on the sensor. The fleshiest part of digit should be covering the detector window.
- ◆ Orient the sensor so that the cable will be running towards the top of the patient's hand.
- ◆ Connect the sensor with the monitor (or with the extension cable if needed).



Applying Neonatal Finger (or Toe) Wrap Sensors:

- ◆ When you perform the measurement, position the sensor over the hand or foot with optical components opposite each other.
- ◆ Hold the sensor, and insert stretched strap into slot, hold it there while threading end through latch. If strap is too long, thread it through second latch.
- ◆ Connect the sensor with the monitor (or with the extension cable if needed).



Applying Adult/Pediatric Ear Clip Sensor:

- ◆ When you perform the measurement, clip the plastic fixing mechanism on top of the ear; make the ear afford the sensor's weight to avoid the sensor getting loose.
- ◆ Clip the probe onto fleshy part of the lobe with optical components opposite to each other.
- ◆ Connect the sensor with the monitor (or with the extension cable if needed).



3. Plug the connector of the sensor extension cable into the SpO₂ socket.

WARNING

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

NOTE:

- 1 Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.
- 2 Inspect the sensor to ensure that the light emitter and receiver are aligned with each other and there is no gap between the sensor and the finger. All the light emitted by the light emitter must pass through the patient's tissue. The sensor cable should be placed on the back of the hand.
- 3 Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

11.4 Measurement Limitations

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

Inaccurate measurements can be caused but not limited by:

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

Loss of pulse signal can occur for the following reasons:

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

NOTE:

- 1 To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.
- 2 Adjacent SpO₂ sensors may interfere with each other (eg, multiple SpO₂ measurements in the same patient). Be sure to cover the sensor with opaque material to reduce cross-interference.
- 3 Move the sensor to a less active site, and keep the patient still, if possible.
- 4 For Nellcor SpO₂ module, the algorithm automatically extends the amount of data required for measuring SpO₂ 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 “SpO₂ Search Pulse” and SpO₂ 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 “SpO₂ No Pulse” indicating a loss-of-pulse condition.

11.5 Assessing the Validity of a SpO₂ Reading

You can check the quality of the pleth wave and the stability of the SpO₂ values to assess whether the sensor functions properly and whether the SpO₂ readings are valid. Always use these two indications simultaneously to assess the validity of a SpO₂ reading.

Generally, the quality of the SpO₂ 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 SpO₂ values also reflects the signal quality. Different from varying SpO₂ readings caused by physiological factors, unstable SpO₂ 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 SpO₂ readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

- 1 The SpO₂ accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. SpO₂ 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 healthy men and women from age 19 to 37 (for EDAN SpO₂ module), from 18 to 50 (for Nellcor SpO₂ 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).
- 3 During monitoring, if the monitor's reading differs significantly from the patient's physiological condition, it indicates that the signal may be disturbed, resulting in an inaccurate reading. In this case, the artifact can disguise as a similar reading, causing the monitor to fail to send an alarm. In order to ensure reliable monitoring, it is necessary to regularly check whether the sensor is wearing properly and the signal quality is good.

11.6 SpO₂ 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.

11.7 Perfusion Index (PI)*

* Only applicable to the EDAN SpO₂ module.

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

As the measurement of SpO₂ 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 SpO₂.

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 SpO₂ parameter area.

11.8 Setting Pitch Tone

If tone modulation is on, the PR sound lowers when the SpO₂ level drops. In the **SpO₂ Setup** menu, select pitch tone to toggle between **On** and **Off**. The lower SpO₂ value is, the lower the frequency of Pitch tone is.

11.9 Setting Sensitivity

The different sensitivity indicates different refresh frequency. **High** indicates the refresh frequency of SpO₂ value is the most frequent. To change the sensitivity, please follow the steps:

- 1 Select the **SpO₂ Setup** menu;
- 2 Select **Sensitivity** on the interface and select the desired sensitivity from the popup list.

11.10 Measuring SpO₂ and NIBP Simultaneously

While measuring SpO₂ and NIBP on the same limb simultaneously, the user can enter **SpO₂ Setup > NIBP Simul** to choose **ON** or **OFF**. t1~t2 is the duration time of NIBP/SpO₂ Simul measurement. T1 and t2 respectively means beginning and ending (cuff deflation over) NIBP measurement.

When NIBP/SpO₂ Simul measurement is set to on:

- General information area displays **NIBP Simul**;
- During t1~t2: in monitor mode, there are no SpO₂ and PR (when PR is from SpO₂) physiological alarms; in Ward round or spot-checking mode, there are no SpO₂ and PR (when PR is from SpO₂) alert information;
- Before t1 and after t2, there are normal SpO₂ physiological alarms/alert information and PR physiological alarms/alert information;
- It will not influence other functions of the monitor.

11.11 SatSeconds Alarm Management*

* Only applicable to the Nellcor SpO₂ module.

11.11.1 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 SpO₂ 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 SpO₂ alarm limits are set in the same way as traditional alarm management. However, you can also set a SatSeconds limit that allows monitoring of SpO₂ 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 SpO₂ falls outside the alarm limit is multiplied by the number of seconds that the SpO₂ level remains outside that limit. This can be stated as an equation:

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

Where:

Points = SpO₂ percentage points outside of the limit

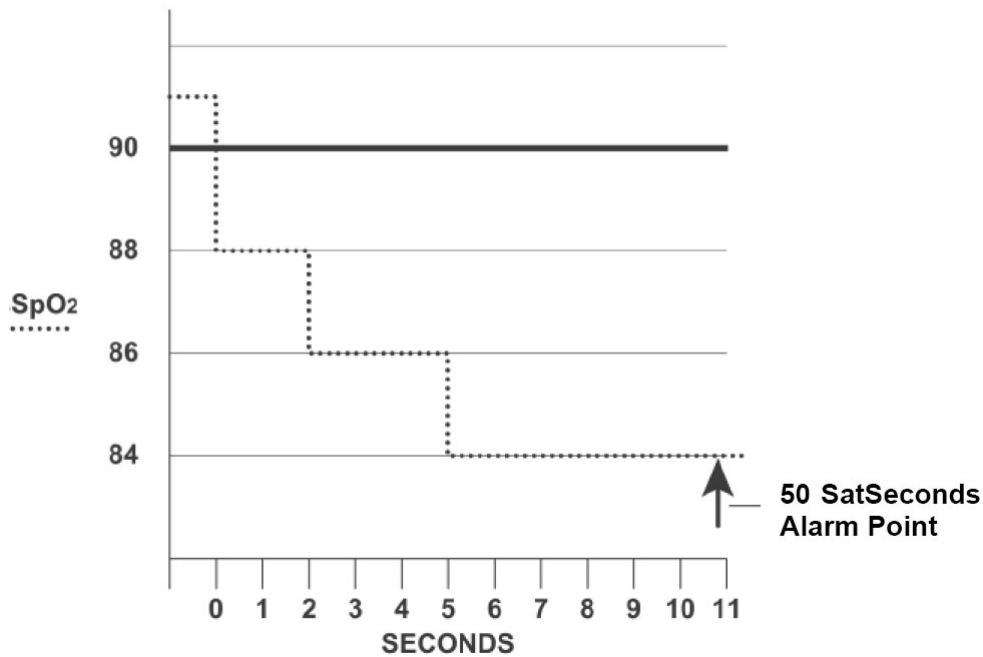
Seconds = number of seconds that SpO₂ remains at that point outside of the limit

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 SpO₂ level drops to 88 (2 points below the limit) and remains there for a period of 2 seconds (2 points × 2 seconds = 4 SatSeconds). The SpO₂ then drops to 86 for 3 seconds and then to 84 for 6 seconds. The resulting SatSeconds values are shown below:

SpO ₂		Seconds	=	SatSeconds
2	×	2	=	4
4	×	3	=	12
6	×	6	=	36
Total SatSeconds			=	52

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



Alarm Response with SatSeconds

Saturation levels may fluctuate rather than remaining steady for a period of several seconds. Often, the patient SpO₂ 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 SpO₂ points, both positive and negative, until either the SatSeconds limit is reached, or the patient SpO₂ returns within a normal range and remains there.

11.11.2 SatSeconds “Safety Net”

The SatSeconds “Safety Net” is for patients whose saturation makes frequent excursions below or above the SpO₂ limit but does not remain in violation long enough for the SatSeconds limit to be reached. If three or more SpO₂ alarm limit violations occur within a 60-second period, an alarm will be triggered even if the SatSeconds limit has not been reached.

11.11.3 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 **SpO₂ Setup** menu and select the desired SatSeconds setting from the **SatSeconds** list.

Chapter 12 Monitoring PR

12.1 Overview

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm). You can obtain a pulse from any measured SpO₂ signal or NIBP measurement.

12.2 PR Source

PR source can be from SpO₂ or NIBP, and is not selectable. SpO₂ is preferred source if PR from SpO₂ is valid. If PR is on, and SpO₂ & NIBP both are off, PR parameter area will display **No source**.

12.3 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 13 Monitoring NIBP

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

The invasive blood pressure is used to determine the neonate pressure in clinical investigation, and the arterial reference sites include umbilical artery, arteria cruralis, axillary artery, brachial artery, dorsalis pedis, and radial artery.

13.2 NIBP Safety Information

WARNING

- 1 Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
 - 2 Do not measure NIBP on the arm of the same side with a mastectomy.
 - 3 Use clinical 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 Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
 - 5 Do not attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to patient.
 - 6 Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.
 - 7 Ensure that the correct patient type is selected before performing measurements. Do not apply the higher adult inflation, overpressure limits and measurement duration for neonatal patients. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.
 - 8 Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
-

WARNING

- 9 Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.
 - 10 NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.
 - 11 Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.
 - 12 Verifying the calibration is only applicable for adults, and it cannot be operated in automatic measuring interval. Continuous measuring cannot be operated in automatic measuring interval either.
-
-

NOTE:

- 1 It is suggested that the user should not start NIBP measuring when the low battery displays, or the monitor may be turned off automatically.
- 2 If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.
- 3 Continuous use of the automatic measuring mode for short intervals may lead to the discomfort of patient. Continuous measuring and automatic measuring in neonatal or pediatric mode may result in tissue damage or ischemia to the patient.
- 4 NIBP measurement can be affected by extremes of temperature, humidity and altitude.
- 5 NIBP measurement value should be explained by qualified professionals.
- 6 The pulse rate based on the NIBP measurement may differ from the heart rate based on the ECG waveform. NIBP measures the number of peripheral pulse pulsations, and the heart rate is measured by the electrical signal of the heart. When the electrical signals of the heart occasionally fail to cause the peripheral blood vessels to pulse or the patient's peripheral perfusion is poor, the difference happens.
- 7 The cumulative use time for NIBP cuff in a single patient should be less than 30 days.

13.3 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.

13.4 Measurement Methods

There are four methods of measuring NIBP:

- Manual - measurement on demand. Manual is the default setting in Ward round and spot-checking mode.
- Auto - continually repeated measurements (between 1 and 480 minute adjustable interval). After the first measurement starts manually, the monitor will automatically measure NIBP as preset 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 Ward round or spot-checking mode only. After finishing average measurement, the monitor enters manual mode.

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

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.

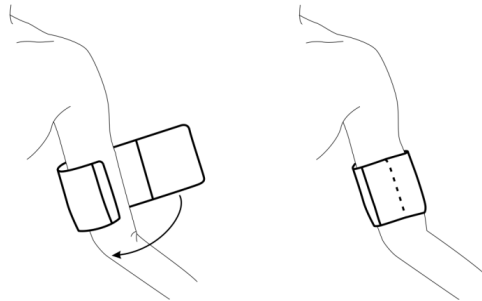
13.5 Measurement Procedures

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, legs uncrossed;
 - ◆ Feet flat on the floor
 - ◆ Back and arm supported
 - ◆ During the measurement, relax as much as possible, neither talking nor applying external pressure against the cuff. Rest for five minutes in a quiet environment.
2. Connect the air hose and switch on the monitor. Apply the blood pressure cuff to the patient's arm and follow the instructions below. Ensure that middle of the cuff is at the level of the

right atrium of the heart and 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.



Cuff Usage

3. Check whether the patient type is appropriately selected. Clicking patient information area or pressing Switch Patient Type hardkey can change patient **Type**.
4. Select a measurement mode and unit (mmHg, cmH₂O or kPa, 1 mmHg = 0.133 kPa, 1 mmHg=1.36 cmH₂O) in the **NIBP Setup** menu. Refer to section *Operation Prompts* for details.
5. Press the  button on the front panel to start a measurement.
6. Wait until the first reading is taken.


NOTE:

- 1 The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.
- 2 If an NIBP measurement is suspect, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.
- 3 Please make sure the cuff is well connected. A leak of air may cause measurement error.
- 4 Please select the cuff with the suitable size. An unsuitable cuff may cause incorrect measurements.
- 5 Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.
- 6 NIBP parameter area can display real-time cuff pressure value till displaying SYS value.
- 7 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.

13.5.1 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. Automatic Measurement

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

interval as need, then press the  button on the front panel. 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 **Continuous** to start a continuous measurement. The continuous measurement will last 5 minutes.

4. AVG measurement


Access **NIBP Setup > Function** menu, set **AVG Measurement interval** and **AVG Measurement**

times, and click **NIBP AVG**; or click AVG shortcut key  directly to start measurement. During 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. Meanwhile, alert information of the last measurement 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 Ward 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 Ward round of average measurement will be started with prompt **NIBP AVG-1 (n)** and NIBP average value of the last Ward round will not be displayed. '-1 (n)' means the first measurement of N 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.

13.5.2 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

13.6 NIBP Multi-Review Window

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

13.7 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.

13.8 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.

13.9 Leakage Test

Leakage test is used to detect the air tightness of the NIBP pump, valve, and trachea. If not, the system will display NIBP leakage. NIBP leak detection should be performed at least once every two years or when you think the measurement is inaccurate.

WARNING

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

Procedure of 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; don't wrap the cuff around limbs.
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.

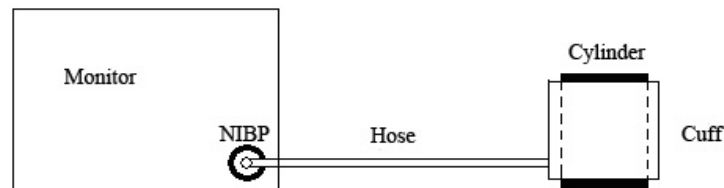


Diagram of NIBP Air Leakage Test

13.10 Setting Inflation Value

To change the inflation value:

- Select **NIBP Setup > Function > 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.

13.11 Measuring PR

Access **NIBP Setup > Function**, 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.

13.12 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 14 Monitoring TEMP

14.1 Quick TEMP with T2A Module

14.1.1 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.

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.

14.1.2 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.

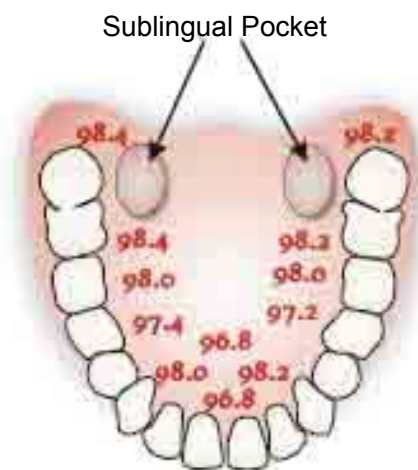


Figure 11-1 Measuring position in mouth

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

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.

14.1.3 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 **RECTAL**. 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.

14.2 Quick TEMP with F3000 Module

14.2.1 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: 2015 requirements.

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.

NOTE:

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

3. The reference body site temperature is the same as the temperature of the measuring site.
4. The cumulative use time for the oral or rectal temperature probe in a single patient should be less than 24 hours.

14.2.2 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.

14.2.3 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.

14.2.4 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 Low Temp. Mode.

Monitoring Mode

When **MEASURE MODE** is set to **MONITOR**, the monitor will perform continual temperature measurement for a maximum of 10 minutes. Only measure mode ‘**MONITOR**’ can be displayed in TEMP parameter area.

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).

Low Temp. Mode

Low Temp. 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 Low Temp. Mode measurements are equivalent to standard prediction measurements at the respective body sites.

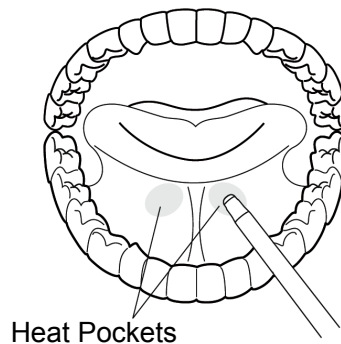
14.2.5 Measuring Procedure

Oral and Axillary Temperature Taking

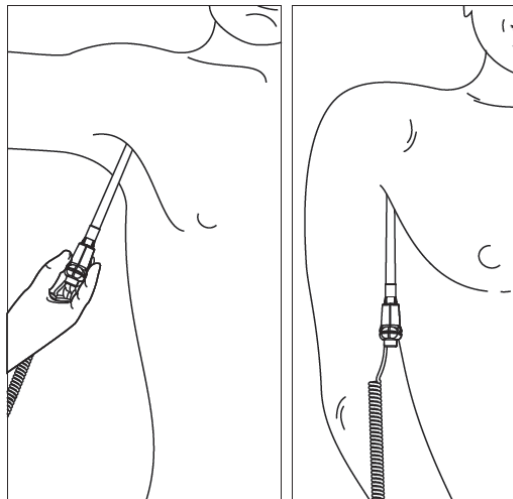
1. Make certain that the Blue isolation chamber /probe unit is attached.
2. Withdraw probe and apply a probe cover. The thermometer turns on automatically and a beep will be heard when the probe completes warm-up.
3. For Oral temperatures, insert the probe tip deep into the sublingual pocket next to 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.

14.2.6 TEMP Setup for F3000 Module

In **TEMP SETUP** window, 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 **RECTAL**.

Low Temp. Mode: Activate /deactivate the Low Temp. Mode by setting it to **ON/OFF**.

NOTE:

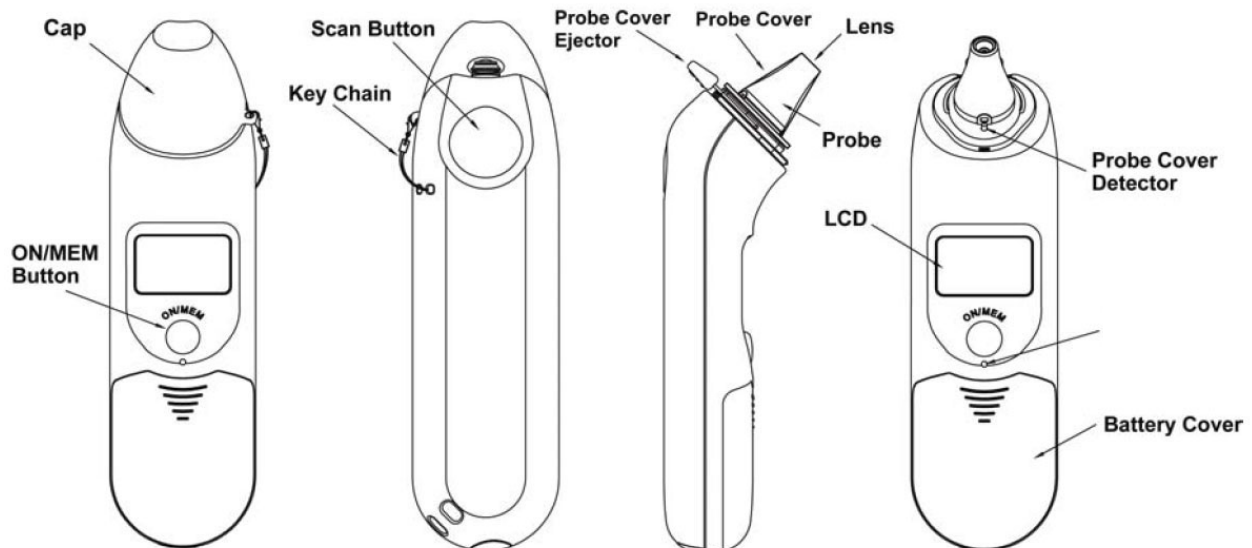
- 1 The **QUICK PREDICT** mode is for oral measurement only.
- 2 **Low Temp. Mode** can be set to **ON** only when measure mode is **PREDICT**.
- 3 Make sure all settings of TEMP Setup are properly set up every time before you withdraw the probe from the probe well. If you modify the settings immediately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

14.3 Infrared TEMP with TH Module

14.3.1 Introduction

iM3 with the TH module (Infrared Ear Temperature Module) takes a temperature in the ear.

Diagram of the Infrared Ear Thermometer:



WARNING

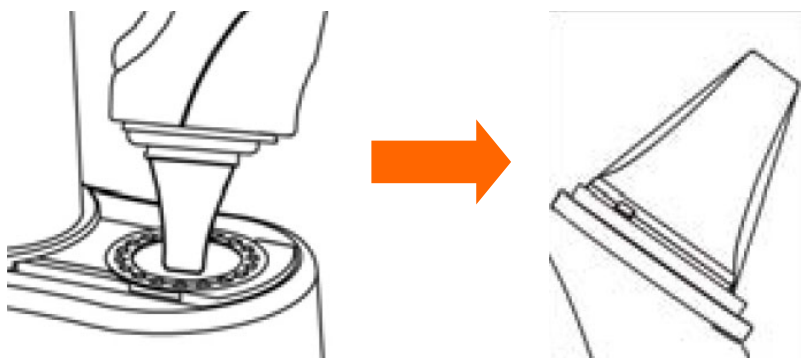
- 1 The infrared ear thermometer is not intended for neonatal patients.
- 2 Only use the disposable probe covers supplied or recommended by EDAN. Use of other manufacturer's probe covers, reuse of disposable probe covers or absence of probe covers may produce temperature measurement errors and/or inaccuracies.
- 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.
- 12 Remove the batteries from TH module if TH module is not used for a longer period of time.


14.3.2 Measuring Procedure

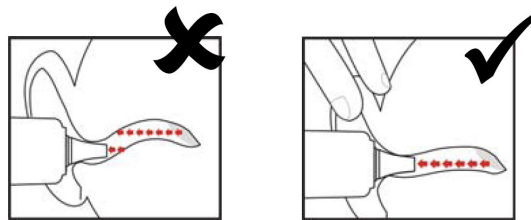
1. Align the center of the probe to the center of the probe cover. Make sure to place the adhesive side of probe cover upward.
2. Insert the probe into the probe cover on the probe cover loader until the probe cover clicks in place.



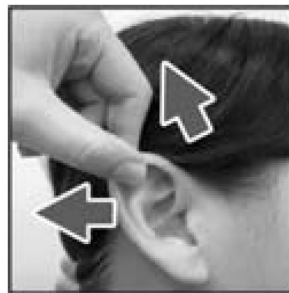
NOTE:

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.

14.3.3 Replacing the Battery

The device is supplied with one lithium cell CR2032x1.

To replacing the battery, follow the procedure:

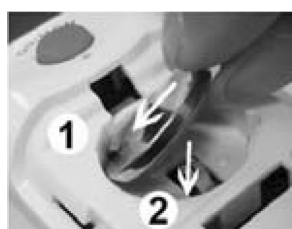
1. Open the battery cover by inserting a pointed object into the battery cover pin hole; meanwhile, use thumb to push battery cover out.



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.



WARNING

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

Chapter 15 Warning-Score System

Click **User Maintain** > **Score Type** to turn on one of the warning-score function.

User can use warning-score system to get score and sum up based on measurement value or input value of each vital sign. Warning-score system includes EWS (Early Warning Score), NEWS (National Early Warning Score System) and MEWS (Modified Early Warning Score) system, which are mutual excluded. That is, only one system can be used at the same time.

NOTE:

- 1 MEWS, EWS and NEWS are not available in USA.
- 2 The score results are for reference only and the score significance must be determined by the physician.

15.1 Warning-Score Interface

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

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

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.

15.2 Warning-Score Method

Warning-Score method includes score calculator (default) and auto score. If score calculator is selected, user needs to input **HR/PR**, **TEMP**, **RR**, **SYS**, **SpO₂**, **Oxygen**, **Age** and **Consciousness** manually, if auto score is selected, user needs to input **TEMP**, **RR**, **Oxygen**, **Consciousness** and **Age** manually (**HR/PR**, **SYS**, **SpO₂** value will be obtained automatically), and then click **Start**. The monitor will calculate and display score result.

NOTE:

- 1 If any of above information is not completely input, the monitor will prompt information: **Incomplete parameter input, unable to score.**
- 2 In Ward Round mode, **RR**, **Oxygen** and **Consciousness** can be obtained according to Custom Parameters, which are consistent with the data of Custom Parameters entered by the user in the main interface.

15.3 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 ₂ (%)	<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 ₂ (%)	≤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	101~199		≥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

15.4 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.

15.5 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, score value. 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.

In Ward round mode:

If **User Maintain > Network > Real-time Upload** is turned on, the score data will be uploaded in real time. Otherwise, user should select as needed and click **Upload** in trend table to manually upload the score data.

Chapter 16 Storing Data in the Storage Device

16.1 Setting Storage Mode (For Monitor Mode Only)

NOTE:

The storage time varies according to the patient's parameter data volume. When store time for single patient data reaches 240 hours, the monitor will create a new folder for continuous data store.

Refer to Section *Data management* for more information about data volume in each work mode.

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.

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

NOTE:

In ward round or spot-checking mode, if storage space of the system is <200 M, a prompt will be given out. In order to store data normally, please clean the space in time.

In monitor mode, **Internal Storage Device** (default) and **Removable Device** can be selected. If **Removable Device** is selected, data storage can be operative after user inputs User Maintain password.

When you choose **Internal Storage Device** as the storage medium, if configured, the storage device name will automatically become **Internal Storage Device**. 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 not 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.

CAUTION

- 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.
 - 4 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.
-

16.3 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 Ward round or spot-checking mode:

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

16.4 Deleting Data Stored in the Storage Device

CAUTION

When the lifecycle of the device ends, delete all patient information before disposal of the 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 Ward round or spot-checking mode:

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

16.5 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**, click **Export Data** on the **Review** menu, and then input User Maintain password.

To export data of all patients, select **Menu > Review > History Patient**, click **Export all data**, and then input User Maintain password.

If the monitor is connected with the PC via OTG interface, you can copy the data which stored in internal storage device through the PC.

NOTE:

In monitor mode, the data in internal storage device is not encrypted. Please protect privacy information.

- In Ward round or spot-checking mode, User Maintain password is necessary for exporting Ward round records/spot-checking data in the specified time to the removable device, and also to the internal storage device. If no removable device is used, the data will be exported to internal storage device directly, and user can copy the data vial OTG interface.

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

In Ward 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.

16.6 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.

CAUTION

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

16.7 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 Ward round or spot-checking mode:

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

16.8 Formatting the Internal Storage Device

To format the internal storage device, select **Menu > User Maintain > Device > 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.

Chapter 17 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

17.1 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 SpO₂ 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.

17.2 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 Menu > System Setup > Recorder , select Continual in R-T Rec Time , and press Record shortcut key to start or stop recording.
8-second real-time recording	In monitor mode, select 8 s in R-T Rec Time , set Record Interval 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: Off, 10 min, 20 min, 30 min, 40 min, 50 min, 1 h, 2 h, 3 h, 4 h .
Trend recording graph	In monitor mode, select Menu > Review > Trend Graph , click Record in trend graph window to start recording. Press Record shortcut key to stop the recording. NOTE: When recording the trend graph in monitor mode, if user presses the Record shortcut key to stop recording in the process of recording the second parameter trend graph, the paper for recording will not be left blank after the second parameter trend graph.
Trend recording table	In monitor mode, select Menu > Review > Trend Table , click Record in trend table window to start recording. Press Record shortcut key to stop the recording.
NIBP recording review	In monitor mode, select Menu > Review > NIBP , click Record in NIBP review window to start recording. Press Record shortcut key to stop the recording.
Alarm recording review	In monitor mode, select Menu > Review > Alarm , select one alarm and click Record in alarm review window to start recording. Press Record shortcut key to stop the recording.
Recording manually	In spot-checking mode, press Record shortcut key in main interface to output current measurement value and patient information; In spot-checking or Ward round mode, click Record or press Record shortcut key in Review window to output corresponding spot-checking data or Ward round record. Pressing Record shortcut key again can stop recording.
NIBP auto triggered recording	In monitor mode, support NIBP auto triggered recording. Please refer to <i>NIBP Auto Recording</i> for details.

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.
- The monitor enters Standby mode.

NOTE:

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

17.3 Recorder Operations and Status Messages

17.3.1 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.

17.3.2 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.

17.3.3 Paper Out

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

17.3.4 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.

17.3.5 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 configured with the recorder function, it will indicate **Recorder Setup Needed** after the **Record** button is pressed.
2. Do not touch the thermo-sensitive print head when performing continuous recording.

Chapter 18 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.

18.1 Battery Safety Information

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. If the battery life is exhausted and not replaced in time, it may cause damage or heat to the device.
 - 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 The recommended battery can only be used for this 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.
-

WARNING

- 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 For the monitor equipped with dual batteries, if the battery temperature is too high during the charging process, the monitor will automatically stop charging. For continuing charging, please unplug the AC power supply, shut down the monitor, place the monitor in environment of 0~30 °C to cool down the battery, and then plug the AC power supply.
 - 18 To improve the battery charging efficiency, it is recommended to charge the battery when the device is off or in standby mode.
-
-

18.2 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.

18.3 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: 75%~100%.



Remaining battery power: 50%~75%



Remaining battery power: 25%~50%



Remaining battery power: 4%~25%



Batteries are almost depleted and need to recharge immediately.



No battery is installed.



Battery Error

18.4 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery maintenance as

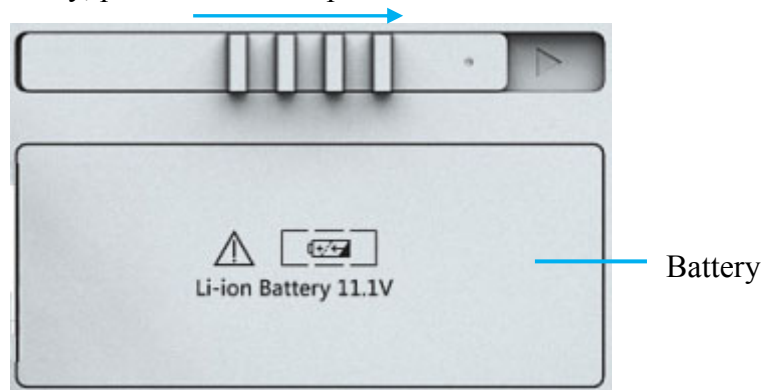
recommended here can help to slow down this process.

1. Disconnect the patient from the monitor and stop all monitoring and measurement.
2. Switch the monitor power on and fully charge the battery.
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. If the running time meets the specification, fully charge the battery again for use or charge it to 40%-60% for storage.

18.5 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.

18.6 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.

18.7 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. Avoid

charging the battery for a longer period of time.

It is recommended to check and maintain the batteries regularly every 3-6 months if they are not in use for a long time. And recharge the batteries to 40%~60% every 3-6 months when they are stored. Refer to the steps in section *Checking Battery Performance*. If the running time meets the specification, fully charge the battery again for use or charge it to 40%-60% for storage.

Chapter 19 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.

19.1 Safety Instructions

Reusable products

Reusable products must be reprocessed, otherwise there is an increased risk of infection.

- ▶ Follow the infection prevention policies and reprocessing regulations of the health-care facility.
- ▶ Follow the national infection prevention policies and reprocessing regulations.
- ▶ Use validated procedures for reprocessing.
- ▶ Reprocess reusable products after every use.
- ▶ Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices. Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.
- ▶ Check the products for signs of wear and replace them if necessary.

Disposable products

Disposable products have been designed, tested, and manufactured exclusively for single use. Reuse, reprocessing, or sterilization can result in failure of the accessory, incorrect measurements, and injury to the patient.

- ▶ Do not reuse disposable products.
- ▶ Do not reprocess disposable products.
- ▶ Do not use any disinfectants.

19.2 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.

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.

19.3 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:

1. Mild near neutral detergent
2. Ethanol (75%)
3. Isopropanol (70%)

Cleaning agents should be applied and removed by using a clean cotton swab or a clean, soft, non-abrasive cloth or paper towel each time. Refer to the cleaning agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

19.3.1 Cleaning the Monitor

WARNING

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

To surface-clean the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Remove all residual foreign matters from the surface of the monitor using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Use a clean cotton swab dampened with the cleaning solution to wipe the surface apertures of the equipment, until no visible contaminants remain.
4. Use a soft clean cloth dampened with the cleaning solution to wipe the entire exterior surface of the equipment, until no visible contaminants remain.
5. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
6. Dry the monitor in a ventilated and cool place.

7. If the monitor is not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 4 to step 7.
8. Inspect the monitor to ensure that there is no damage.

19.3.2 Cleaning the Reusable Accessories

19.3.2.1 Cleaning the Blood Pressure Cuff

Cleaning the Cuff:

1. Disassemble NIBP Cuff from the monitor, and take out the air bladder.
2. Remove all residual foreign matters from the surface of cuff and air bladder using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution. Clean the surface of the cuff and the air bladder thoroughly until no visible contaminants remain.
4. 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.
5. Wipe off residual moisture with a dry cloth.
6. Air dry the cuff thoroughly after cleaning.
7. If the cuff and the air bladder are not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 4 to step 6.
8. Inspect the cuff and the air bladder to ensure that there is no damage.

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.

19.3.2.2 Cleaning the SpO₂ Sensor

1. Disassemble SpO₂ sensor from the monitor.
2. Remove all residual foreign matters from the surface of SpO₂ Sensors, including cables, using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
4. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution. until no visible contaminants remain

5. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
6. Wipe off residual moisture with a dry cloth.
7. Leave the sensor to air dry.
8. If the SpO₂ Sensors, including cables, are not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 4 to step 6.
9. Inspect the SpO₂ Sensors, including cables, to ensure that there is no damage.

19.3.2.3 Cleaning the TEMP Sensor

1. Disassemble quick TEMP module from the monitor.
2. Remove all residual foreign matters from the surface of TEMP Sensors using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the sensor/probe with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
4. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
5. Wipe off residual moisture with a dry cloth.
6. Leave the sensor/probe to air dry.
7. If the TEMP Sensors are not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 4 to step 6.
8. Inspect the TEMP Sensors to ensure that there is no damage.

19.4 Disinfection

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

- Ethanol (75%)
- Isopropanol (70%)

Disinfecting agents should be applied and removed by using a clean cotton swab or a clean, soft, non-abrasive cloth or paper towel each time. Refer to the disinfecting agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

CAUTION

- 1 Do not use any disinfectant containing additional active ingredients other than those listed, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.
 - 2 Although the monitor is chemically resistant to most common hospital cleaners, disinfectants and non-caustic detergents, unverified cleaners or disinfectants are not recommended and may stain the monitor, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.
 - 3 Do not use phenol disinfectants because vinyl absorbs them. Do not use strong aromatic, chlorinated, ketone, ether or ester solvents. Do not immerse the cables for any prolonged period in alcohol, mild organic solvents, or highly alkaline solutions. Never boil or autoclave the cable. Vinyl withstands temperatures up to 100 °C but begins to soften at around 90 °C. Handle gently when hot and wipe away from the tip toward the cable.
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WARNING

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

19.4.1 Disinfecting the Monitor

WARNING

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

To disinfect the monitor, follow these steps:

- 1 Switch off the monitor and disconnect it from the power line.
- 2 Clean and dry the monitor, according to the methods in section *19.3.1* prior to disinfection.
- 3 Prepare the disinfectant solution.
- 4 Use a clean cotton swab dampened with the disinfectant solution to wipe the surface apertures of the equipment. Follow the disinfectant manufacturer's recommended contact time and mode.
- 5 Use a soft clean cloth dampened with the disinfectant solution to wipe the entire exterior surface of the equipment. Follow the disinfectant manufacturer's recommended contact time and mode.
- 6 After disinfection, wipe off the disinfecting agent with a new sterile cloth dampened with sterile water.
- 7 Dry the monitor for at least 30 minutes in a ventilated and cool place.
- 8 Inspect the monitor to ensure that there is no damage.

19.4.2 Disinfecting the Reusable Accessories

19.4.2.1 Disinfecting the Blood Pressure Cuff

Disinfecting the Cuff:

1. Disassemble NIBP Cuff from the monitor, and take out the air bladder.
2. Clean and dry the NIBP Cuff and air bladder according to the methods in section *19.3.2.1* prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.
5. Leave the cuff and air bladder to air dry for at least 30 minutes.
6. Inspect the cuff and the air bladder to ensure that there is no damage.

Replacing the Air Bladder:

After disinfection, replace the air bladder into the cuff. Refer to Section *19.3.2.1* for more information.

NOTE:

Prolonged use of disinfectant may cause discoloration of the cuff.

19.4.2.2 Disinfecting the SpO₂ Sensor

1. Disassemble the SpO₂ sensor from the monitor.
2. Clean and dry the SpO₂ sensor according to the methods in section *19.3.2.2* prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
5. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
6. Wipe off the disinfection solution with a dry cloth after disinfection.
7. Leave the sensor to air dry for at least 30 minutes.
8. Inspect the SpO₂ Sensor, including the cable, to ensure that there is no damage.

19.4.2.3 Disinfecting the TEMP Sensor

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

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

1. Disassemble quick TEMP module from the monitor.
2. Clean and dry the TEMP Sensor according to the methods in section 19.3.2.3 prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the sensor with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).
5. Wipe off the disinfectant solution with a dry cloth after disinfection.
6. Leave the sensor to air dry.
7. Inspect the TEMP Sensor, to ensure that there is no damage.

19.5 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.

19.6 After Reprocessing

- After reprocessing, the equipment, cables, cuffs, sensors and other accessories should be checked to ensure there are no signs of aging, wear, cracks, deformation, discoloration or peeling, etc. Replacement should be taken or contact the service personal of the manufacturer if necessary.
- Assembling and attaching device-specific components

Prerequisite:

All components have been reprocessed and are dry.

- Preparation before next use of device

Assembling and fitting patient-specific accessories and consumables, i.e. SpO₂ sensors and NIBP Cuffs.

19.7 Storage and Transport

After reprocessing, there are no special requirements for storage and transport of the product. However, the following must be observed:

- Store dry and free of dust
- Avoid recontamination and damage during transport

All further information on storage and transport included in the accompanying documents must be observed.

Chapter 20 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.
 - 3 The maintenance operations like software upgrade of the device can only be completed by EDAN-qualified service professionals. The history data in monitor may be deleted due to software upgrade. Before software upgrade, please backup the data in the monitor to avoid data loss. For data backup methods, please refer to the section *Exporting Data Stored in the Internal Storage Device* to export the data, or refer to the section *Uploading Data to Network Server* to load the data to HIS system.
 - 4 Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
-

20.1 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.

20.2 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 21 Warranty and Service

21.1 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.

21.2 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.

Chapter 22 Accessories

You can order accessories from EDAN supplies at www.edan.com.cn or consult your local EDAN representative for details.

WARNING

- 1 Never reuse disposable transducers, sensors, accessories and 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.

22.1 SpO₂ Accessories

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

Part Number	Accessories
01.57.471747	SHD-P SpO ₂ Sensor, pediatric, disposable
01.57.471748	SHD-I SpO ₂ Sensor, Infant, disposable
01.57.471749	SHD-N SpO ₂ Sensor, Neonate, disposable
For Nellcor Module	
01.15.30043	Nellcor Reusable Adult SpO ₂ Sensor (DS-100A OxiMax)
01.15.40096	Nellcor Reusable Adult/Neonate SpO ₂ Sensor (OXI-A/N OxiMax)
01.57.471069	Nellcor SpO ₂ Extension cable (Compatible with Nellcor OXI-Max SpO ₂ 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

22.2 NIBP Accessories

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

Part Number	Accessories
01.57.471324	NIBP Cuff, Neonate, 6 cm-11 cm, reusable
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-11 cm, disposable
01.57.471160	NIBP Cuff, neonatal #4, 7 cm-13 cm, disposable
01.57.471161	NIBP Cuff, neonatal #5, 8 cm-15 cm, disposable
For SunTech Module	
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 -11 cm, disposable
01.57.471160	NIBP Cuff, neonatal #4, 7 cm -13 cm, disposable
01.57.471161	NIBP Cuff, neonatal #5, 8 cm -15 cm, 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 -19 cm
01.57.000976	OPC Cuff, Small Adult, rang: 17 cm -25 cm
01.57.000977	OPC Cuff, Adult, rang: 23 cm -33 cm
01.57.000978	OPC Cuff, Large Adult, rang: 31 cm -40 cm

22.3 TEMP Accessories

Part Number	Accessories
TEMP (For T2A Module)	
02.01.110131	Temperature Probe, Oral/Axillary, FT10

02.01.110130	Temperature Probe, Rectal, FT20
01.57.471871	Disposable Probe Covers
TEMP (For TH Module)	
01.13.036415	Infrared Ear Thermometer Communication Cable
01.57.208057	Infrared Ear Thermometer
01.57.208058	Probe Cover
01.57.208059	Probe Cover Loader
TEMP (For F3000 Module)	
01.57.471312	Filac 3000 Oral Probe 4ft
01.57.471313	Filac 3000 Oral Probe 9ft
01.22.066159	Filac 3000 Oral Isolation Chamber
01.57.471314	Filac 3000 Rectal Probe 4ft
01.57.471315	Filac 3000 Rectal Probe 9ft
01.22.066160	Filac 3000 Rectal Isolation Chamber
01.57.471316	Filac 3000 Probe Covers
01.51.413192	Filac 3000, Isolation Chamber, blue
01.51.413270	Filac 3000, Isolation Chamber, red

22.4 Other Accessories

Part Number	Accessories
02.21.064365	Rechargeable Lithium-Ion Battery /TWSLB-012, 11.1 V, 2400 mAh
01.57.078035	Recorder paper
01.18.052245	USB flash disk (U208, 4 G, USB2.0)
02.01.210633	Unicode serial/parallel port recorder assembly

Part Number	Accessories
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)
83.60.261069	M3\iM50 Trolley, metal caster
83.60.261116	M3\iM50 Trolley, plastic caster
83.60.261648	MT-206 (S) Trolley
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 ₂ , 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) <ul style="list-style-type: none"> With TEMP: +10 °C ~ +40 °C (50 °F ~104 °F)

	<ul style="list-style-type: none"> When charging the monitor which is equipped with dual batteries: +0 °C to +30 °C (32 °F~86 °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
Charge/discharge cycle	300 times
Condition	Standard configuration, at 20 °C~30 °C, with (a) new fully charged battery/batteries, continuous SpO ₂ 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 20 °C~30 °C; the monitor is on
Fast Charging Time	<3 hrs, when the monitor is off or in standby mode

Number	2
Capacity	≥4800 mAh
Condition	Standard configuration, at 20 °C~30 °C, with (a) new fully charged battery/batteries, continuous SpO ₂ measurement and NIBP automatic measurement mode at interval of 15 minutes, recording at interval of 10 minutes
Operating Time	≥8 hrs
Charging Time	≤20 hrs, at 20 °C~30 °C; the monitor is on
Fast Charging Time	≤8 hrs, when the monitor is off or in standby mode

A.2.5 Recorder

Record paper 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 NIBP auto triggered recording

A.2.6 Data Management

Data storage

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

Each 1 GB extension space for data storage: ≥ 400 hrs

With all parameters on, storage interval of 1 s, one SpO₂ wave, and one alarm event occurring for each 10 s.

In Ward round mode, storage data maximally contains the following information:

Ward Round record	Patient information items (such as MRN, bed No., patient type, etc.), Ward round data	Up to 800 thousand sets
SpO ₂	Storage starting time, SpO ₂ 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
Custom parameters	The custom parameters data	Up to 20 sets for a single patient

Each 1 GB space for data storage: ≥ 100 thousand sets of Ward round records. Up to 800 thousand sets of Ward round records are supported (one Ward round record has 20 original records).

In spot-checking mode, storage data maximally contains the following information:

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

A.3 NIBP

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

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 Parameter	SYS, DIA, MAP, PR	
Pressure Unit	kPa, mmHg, cmH ₂ O	
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
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
☆Measuring Parameter	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: 120 mmHg
Neonatal Mode	60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 120 mmHg, 140 mmHg Default: 90 mmHg

A.4 SpO₂

Complies with ISO 80601-2-61: 2017.

EDAN Module

Measuring Range	0% to 100%
Resolution	1%
☆Data Update Period	1 s
☆Accuracy	
☆Adult /Pediatric	±2% (70% to 100% SpO ₂)
	Undefined (0% to 69% SpO ₂)
☆Neonate	±3% (70% to 100% SpO ₂)
	Undefined (0% to 69% SpO ₂)
SpO ₂ Storage Interval	In Ward round or spot-checking mode 30 S (default), 1 min, 2 mins, 5 mins
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	DS-100A, OXI-A/N (Adult) D-YS (Adult and Pediatric) OXI-P/I (Pediatric)	± 3% (70% to 100% SpO ₂)
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±2% (70% to 100% SpO ₂)
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±3% (60% to 80% SpO ₂)
	If sensor is used for neonate as recommended, the accuracy will be larger than adult by ±1.	
SpO ₂ Storage Interval	In Ward round or spot-checking mode 30 S (default), 1 min, 2 mins, 5 mins	
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 PR

		Measuring range	Accuracy	Resolution
PR (SpO ₂)	EDAN	25 bpm to 300 bpm	±2 bpm	1 bpm
	Nellcor	20 bpm to 300 bpm	±3 bpm (20 bpm to 250 bpm)	1 bpm
PR (NIBP)	EDAN	40 bpm to 240 bpm	±3 bpm or 3.5%, whichever is greater	1 bpm
	SunTech	30 bpm to 220 bpm	±3 bpm or ±2%, whichever is greater	1 bpm

A.6 TEMP

Complies with ISO 80601-2-56: 2017+A1:2018.

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: ≤5 min
Measuring Mode	Direct Mode/ Adjusted Mode
Transient Response Time	≤30 s
Clinical Bias	(-0.2 to -0.4) °C
Limits of Agreement	0.49
Stability	0.14 °C

NOTE:

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

TH Module:

☆Measuring range	34 °C~ 42.2 °C
Working temperature	10 °C~ 40 °C
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	± 0.2 °C (0.4 ° F) (35.5 °C ~42 °C) (95° F ~107.6° F) ± 0.3 °C (0.5° F) (out of the range mentioned above)
Laboratory Accuracy	± 0.2 °C

F3000 Module:

☆Measuring range	30 °C~43 °C
Prediction measurement range	35 °C~43 °C
Low Temp. 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.7 Adjustable Range of Alert Limits

SpO ₂	20% ~ 100%		
PR	30 bpm ~ 300 bpm		
NIBP mmHg			
EDAN NIBP			
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
SunTech NIBP			
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
TEMP			
Patient Type	High Limit		Low Limit
ADU/PED	+42 °C (+107.6 °F)		+35.5 °C (+95.9 °F)

A.8 Wi-Fi

IEEE	802.11a/b/g/n
Frequency Band	2.4 GHz & 5 GHz ISM band
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Max. Transmit Power (± 2 dBm)	2.4 GHz 17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 17 dBm for 802.11g OFDM 16 dBm for 802.11n OFDM 5 GHz (not available in USA and in Canada) 10 dBm for 802.11a OFDM 9 dBm for 802.11n OFDM
I/U Ratio (co-channel)	≤ 20 dB
I/U Ratio (adjacent channel)	≤ 1 dB
Throughput	≥ 0.01 Mbps
Latency	≤ 1 s
Jitter	≤ 1 s
PER	$\leq 10\%$

A.9 e-link

Transmit Frequency	2402 MHz ~ 2480 MHz
Frequency Band	2402 MHz ~ 2480 MHz
Modulation	FHSS, GFSK, DPSK, DQPSK
Transmit Power	≥ 0 dBm
I/U Ratio	≤ 1 dB
Throughput	≥ 0.01 Mbs
Latency (one way delay)	≤ 1 s
Jitter (latency variation)	≤ 1 s
PER	$\leq 10\%$

A.10 Interfaces

A.10.1 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.10.2 USB Interfaces

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

A.10.3 OTG Interfaces

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

A.10.4 Wired Network Interface

Specification	100-Base TX (IEEE802.3)
Interface Type	Standard RJ-45 network interface

B EMC Information

- Guidance and Manufacture's Declaration

B.1 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emission		
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.		
Emission test	Compliance	Electromagnetic environment – guidance
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

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
			-

Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	± 2 kV for power supply lines	± 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	± 1 kV for line to line ± 2 kV for line to ground	± 1 kV for line to line ± 2 kV for line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % 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	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.
NOTE 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
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 V _{rms} 150 kHz to 80 MHz 6V _{rms} ^c in ISM bands between 0.15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz See table 1	3 V _{rms} 150 kHz to 80 MHz 6V _{rms} ^c in ISM bands between 0.15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz Comply with table 1	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. Recommended separation distance $d = 1.2\sqrt{P}$ 150KHz to 80MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d=6 \sqrt{P} /E$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iM3, including cables specified by the manufacturer). Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF


			<p>transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which 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>^b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.</p> <p>^c The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.</p>			

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

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28

710	704-787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						

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

- a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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 preconfigured according to your requirements, the settings at delivery will be different from the default settings 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 SpO₂ Default Settings

SpO ₂ 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 ₂ 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
SpO ₂ Desat Limit	80%		

C.4 PR Default Settings

PR Settings	ADU	PED	NEO
PR Source	SpO ₂		
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 ₂ 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 (Auto)	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	
Low Temp. 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
FCC	Federal Communication Commission
FDA	Food and Drug Administration
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

Abbr	English Full Name/Description
MRI	Magnetic resonance imaging
N/A	Not applied
Neo	Neonate
NIBP	Non-invasive blood pressure
O ₂	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 ₂	Pulse Oxygen Saturation
oxyCRG	Oxygen cardio-respirogram
DoS	Denial of Service
DDoS	Distributed Denial of Service

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