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X8/X10/X12

Patient Monitor

Version 1.7

User Manual

CE 0123

EDAN

About this Manual

P/N: 01.54.458083

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Release Date: August, 2023

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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The user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of EDAN.

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

Responsibility of the Manufacturer

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

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

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

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

Terms Used in this Manual

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

WARNING

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

CAUTION

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

NOTE

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

Table of Contents

Chapter 1 Intended Use and Safety Guidance

1.1 Intended Purpose

The product is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters.

1.2 Intended Use/Indications for Use

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

The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO_2), cardiac output (C.O.).

The arrhythmia detection and ST Segment analysis are intended for adult patients.

The monitors are not intended for MRI environments.

1.3 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 electrodes 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. **EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.**
4. **SHOCK HAZARD-To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.**
5. **Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, 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

6 **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.**

7 **Do not come into contact with the patient, table, or the monitor during defibrillation.**

8 **The simultaneous use of a cardiac pacemaker or other electrical stimulators may cause safety hazard.**

9 **Devices connecting with monitor should be equipotential.**

10 **If leakage or foul odor is detected, ensure that there's no fire around.**

11 **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.**

12 **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.**

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

14 **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.**

15 **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.**

16 **Always remove non-defibrillation-proof accessories during defibrillation.**

WARNING

17 **The monitor is equipped with Wi-Fi to receive RF electromagnetic energy. Therefore, any other equipment complying with CISPR radiation requirements may also interfere with the wireless communication and make it interrupted.**

18 **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 or sterilized accessory is intact. Do not use it if its casing is damaged.**

19 **When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.**

20 **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.**

21 **During monitoring, 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.**

22 **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.**

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

24 **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.**

25 **After defibrillation, the ECG display recovers within 10 seconds if the correct electrodes are used and applied based on the manufacturers' instructions.**

WARNING

26 Clinical decision making based on the output of the device is left to the discretion of the provider.

27 This equipment is not intended for home usage.

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

29 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.

30 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.

31 The monitors are MR Unsafe. The monitors are not intended for use in an MRI environment.

32 Additional multiple socket-outlets or extension cords can't be connected to the system.

33 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.

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

35 Portable and mobile RF communications equipment can affect medical electrical equipment; refer to the recommended separation distances provided in this user manual.

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

37 Only recommended batteries can be used for the monitor.

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

39 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.

WARNING

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

41 **The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start monitoring patients.**

42 **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.**

43 **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.**

44 **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.**

45 **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.**

46 **When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.**

47 **To protect the monitor from damage during defibrillation, for accurate measurement information and to protect against noise and other interference, use only accessories specified by EDAN.**

48 **No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.**

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

50 **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.**

51 **If the accessory is accidentally disconnected, it shall be reconnected by a trained healthcare professional.**

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 **Avoid liquid splashing on the device.**

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.**

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 the signal interference.**

14 **Poor connection might be caused by frequently plugging and unplugging the power cord. Check the power cord regularly and replace it in time.**

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

16 **Ensure that the monitor is supplied with continuous electric power during operation from the main source power or batteries. Sudden power failure may cause failure to monitor parameters.**

NOTE:

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

2 **This monitor is not a device for treatment purposes.**

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

4 **If the monitor gets damp or liquid pours on the monitor, please contact the service personnel of EDAN.**

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.**

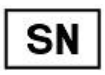
7 **It is recommended to format the USB flash drive to the FAT file type via PC prior to use.**

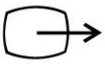
8 **When there's measurement beyond range, invalid measurement or no measurement value, it will display -?-.**

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

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

1.4 Explanation of Symbols

1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		Caution
3		MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
4		Equipotentiality
5		Alternating Current
6		Power Supply switch
7		Serial number
8		Network port

9		USB (Universal Serial Bus) Connection
10		Bell cancel
11		NIBP measurement
12		Trend
13		Screen or video image, freeze
14		Menu
15		Video output
16		Defibrillator synchronization/Signal output port
17		Output
18		Date of manufacture
19		MANUFACTURER
20	P/N	Part Number
21		General symbol for recovery/recyclable
22		The products marked with this symbol apply to the European WEEE directive. This symbol Indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning of your equipment.
23		Operating instructions

24		Refer to instruction manual/ booklet (Background: Blue; Symbol: White)
25		Warning (Background: Yellow; Symbol & outline: black)
26		Gas inlet
27		Gas outlet (evac)
28	IPX1	Ingress Protection IPX1 (Protected against vertically falling water drops)
29	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
30	 (Optional)	Non-ionizing electromagnetic radiation
31	Contains FCC ID	Federal Communications Commission: Contains FCC ID: SMQ9113EDAN
32		Do not reuse
33		This way up
34		Fragile, handle with care
35		Keep dry
36		Stacking limit by number
37		Handle with care
38		Do not step on
39	CE 0123	CE marking
40	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

41		Use-by date
42	 (Optional)	CONFORMS TO AAMI STD ES60601-1, IEC STD 60601-1-6, AAMI/IEC STD 60601-1-8, AAMI/IEC STD 60601-2-25, AAMI/IEC STD 60601-2-27, IEC STD 80601-2-30, IEC STD 80601-2-49, ISO STD 80601-2-55, ISO STD 80601-2-56, ISO STD 80601-2-61 CERTIFIED TO CSA STD C22.2 NO. 60601-1, CSA STD C22.2 NO. 60601-1-6, CSA STD C22.2 NO. 60601-1-8, CSA STD C22.2 NO. 60601-2-25, CSA STD C22.2 NO. 60601-2-27, CSA STD C22.2 NO. 60601-2-49
43		Medical Device
44		Unique Device Identifier
45		Protective earth (ground)

NOTE:

The user manual is printed in black and white.

1.5 Contraindication

None known.

Chapter 2 Installation

NOTE:

The monitor 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

Place the monitor on a flat, level surface, mount it on a wall or install it on a trolley. For detailed information about how to install the wall mount and trolley for the monitor, please refer to the *Wall Mounting Bracket Assembly Instruction* and *Trolley Installation Guide*.

WARNING

The wall mounting bracket can be fixed only on a concrete wall.

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 the Section *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 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.

2.6 Setting Date and Time

To set the date and time:

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

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.**
3. **The default clock format is 24 hours. When Clock Format is set to 12 hours, please select AM or PM according to actual situation.**

2.7 Handing Over the Monitor

If you are handing over the monitor to the end-users directly after configuration, make sure that it is in the monitoring mode.

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 Guide – for quick reminders during use.

2.8 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.

NOTE:

"Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

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.

2.9 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 manual is for clinical professionals using the X8 X10 and X12 patient monitors. Unless otherwise specified, the information here is valid for all the above products.

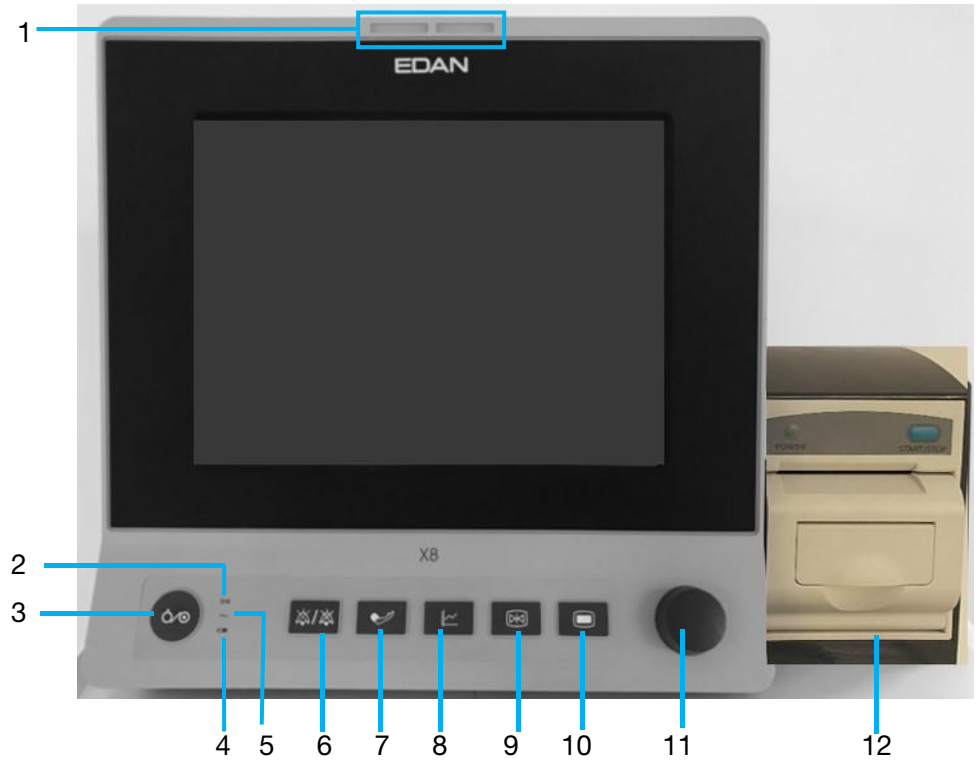
This user manual describes all features and options. Your monitor may not have all of them; they are not all available in all geographies. Your monitor is highly configurable. What you see on the screen, how the menus appear and so forth, depend on the way it has been tailored for your hospital and may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

You may frequently use the follow functions:

- ECG monitoring (Refer to *Monitoring ECG* for more information.)
- SpO_2 monitoring (Refer to *Monitoring SpO_2* for more information.)
- PR monitoring (Refer to *Monitoring PR* for more information.)
- NIBP monitoring (Refer to *Monitoring NIBP* for more information.)
- Alarm (Refer to *Alarms* for more information.)

3.1 System Components

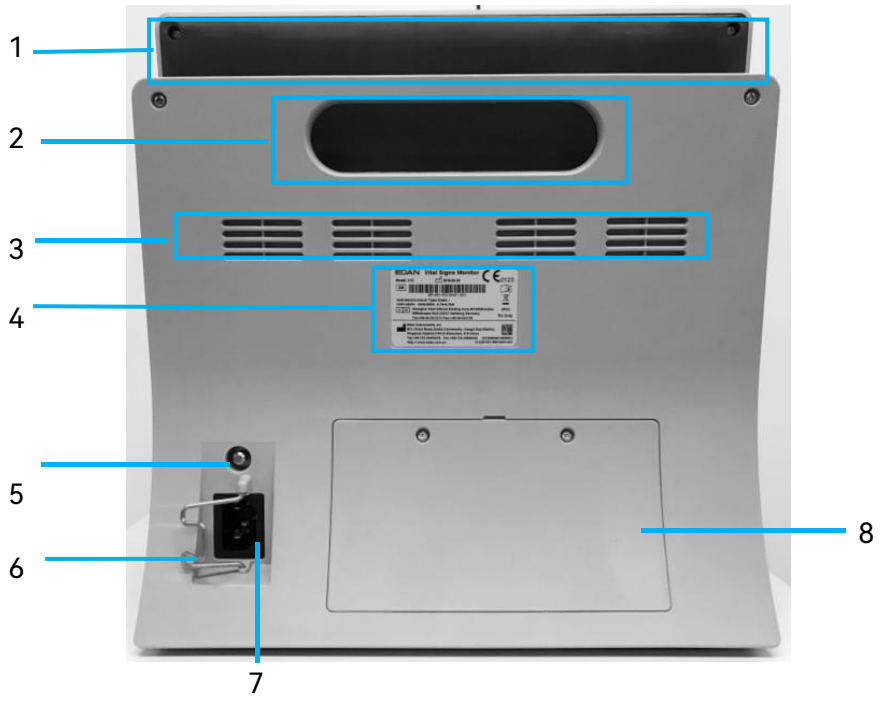
3.1.1 Front View



1	Alarm indicator — when an alarm occurs, the alarm indicator will light or flash. The color of light represents the alarm level. High level alarm: flashes red; Medium level alarm: flashes yellow; Low level alarm: constantly yellow for

	physiological alarm and constantly blue for technical alarm.
2	Power supply indicator — On: the monitor is turned on; Off: the monitor is turned off.
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 to turn the monitor off.
4	Battery indicator, refer to Section *Battery Power Indicator* for details.
5	Alternating current indicator— On: AC power is connected; Off: AC power is not connected.
6	Mute — Press it to suspend the output of all audible alarm signals. Upon the configuration, pressing this button to pause or turn off the audio alarm. Further information can be found in Section *Audio Alarm Paused* and Section *Audio Alarm Off*.
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	Trend Key — Press this button to enter trend table review interface.
9	Start / Stop Recording — Press this button to start a real-time recording. During the recording, press this button again to stop recording.
10	Menu —Press this button to open the main menu when there is no menu open. Press it again to exit.
11	Rotary Knob (hereinafter called knob) — 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.
12	Recorder, refer to Section *Recording* for details.

3.1.2 Rear View



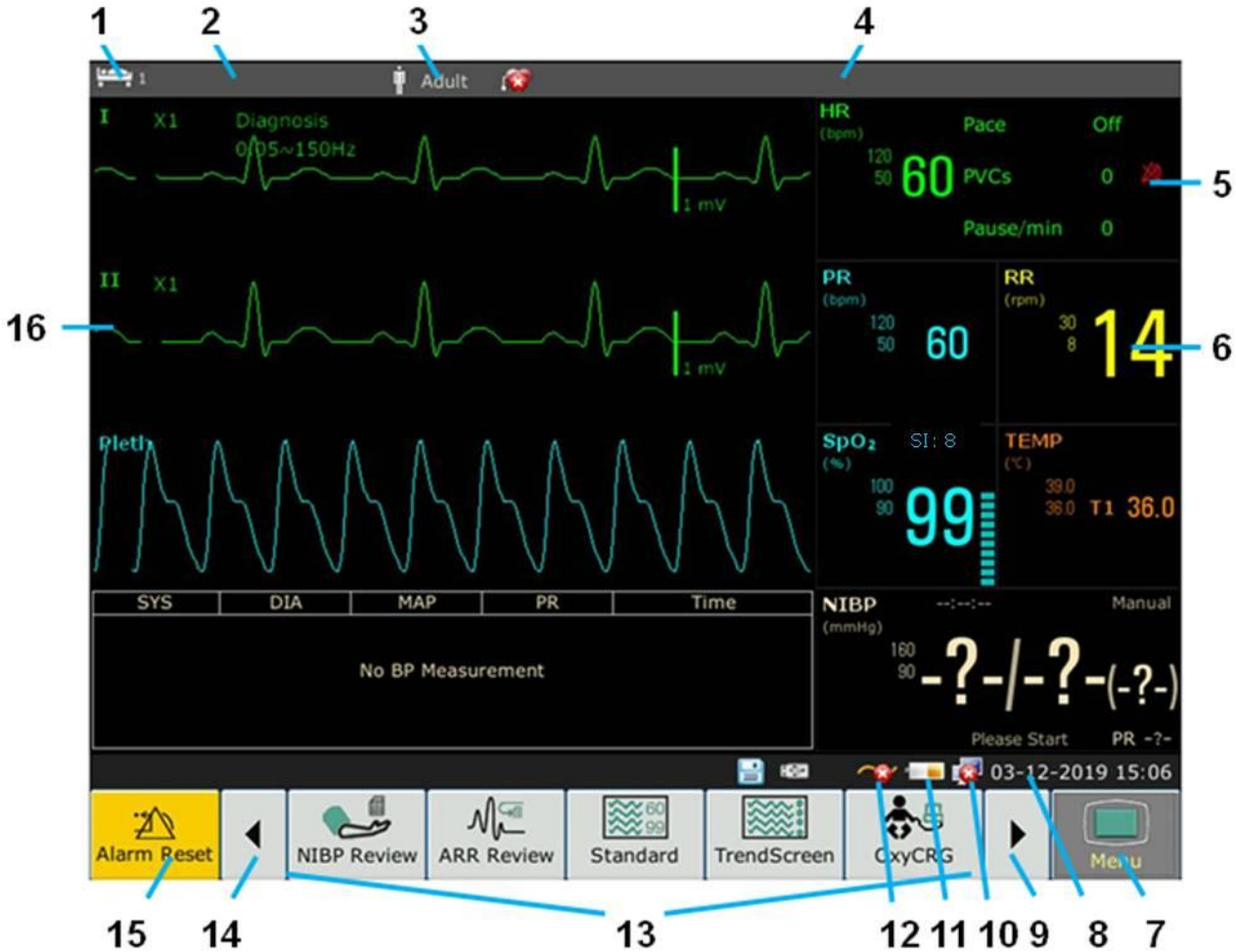
1	Accessory storage area: the accessories can be wrapped around this area to prevent the patient from being entangled or suffocated.
2	Handle: for lifting or moving the monitor, which is convenient, comfortable and fast.
3	Heat sink: Adopt No-fan design, which is dust-free, low noise and low consumption.
4	Label
5	Equipotential grounding terminal, if the monitor or other processing unit are used in internal examinations on the heart, ensure that the room incorporates an equipotential grounding system to which the monitor and other processing unit have separate connection.
6	Power cable safety latch. Used to prevent the power cable from loosening or falling. Place the latch on the power cable and press it down firmly to ensure that it secures the power cable.
7	Power supply interface: for connecting AC power cable.
8	Battery door: for fixing and replacing the battery.

3.1.3 Side View

1	Sensor interface: enables the parameter measurement.
2	CO_2 water trap: removes liquid water from the patient's airway during CO_2 monitoring.
3	USB interface: supports USB 2.0 output. It connects approved USB devices, for example, USB flash disk, barcode scanner, mouse and keyboard.
4	Multifunctional port: Nurse call / analog output/ defibrillator synchronization port. 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. Analog output: the monitor outputs the waveform through the port. Defibrillator synchronization: the monitor outputs the defibrillator synchronization signal through the port.
5	Network interface, it connects the monitor to the central monitoring system (MFM-CMS) or gateway via standard network cable, which enables MFM-CMS or gateway to achieve bidirectional communication with the monitor.
6	VGA output: it enables the VGA video output.

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.



1	Bed number
2	Patient name
3	Patient type
4	Alarm area
5	Alarm off
6	Measurement value

7	Menu
8	Date and time
9	Scroll right to display more shortcut keys
10	Networking symbol
11	Battery status symbol
12	AC power supply symbol
13	Shortcut key area
14	Scroll left to display more shortcut keys
15	Alarm reset key
16	Parameter waveform

3.2.1 Using Keys

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

3.2.1.1 Permanent Keys

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

To display the main setup menu.

To reset the alarm.

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. You can select the shortcut keys those need to be displayed on the main screen through **Menu** > **Maintenance** > **User Maintain** > **Shortcut Setup**. You can adjust the shortcut key sequence as need.

Perform a 12-lead analysis

Switch to the standard screen

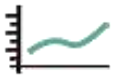
Exit from 12-lead analysis

Switch to the OxyCRG screen


Access the 12-lead review


Perform 12-lead record (in 12-lead interface)

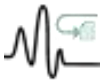

Admit a patient

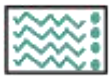

Review the trend graph


Review the trend table


Review the alarm event


Access the NIBP review


Access the ARR review


Switch to the trend screen

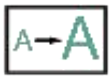

Switch to the vital screen


Printer Setup


Enter privacy mode


Freeze or unfreeze waveforms


Start or stop NIBP measurement


Switch to the large font screen


Set the module switch


Change the key volume


Adjust the screen brightness


Zero the IBP sensor


Alarm setup


Change the beat volume


Enter standby mode


Enter night mode


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


Enter warning score interface


Start/stop recording


Audio alarm paused/off

3.2.1.3 Hardkeys

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

3.2.1.4 Pop-up Keys

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

to confirm a change.

3.3 Operating Mode

3.3.1 Demo Mode

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

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

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

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.

3.3.2 Standby Mode

To enter into standby mode, select **Menu** > **Common Function** > **Standby**, or press the shortcut key  on the screen directly, the monitor enters into standby mode after user's confirmation.

In standby mode:

1. The monitor stops monitoring patients and stores previous monitoring data.
2. The monitor won't respond to all alarms and prompts, except Battery Low alarm.
3. Audio alarm paused status discontinues. Audio alarm off status is not influenced.
4. All recording and printing tasks will stop.
5. MFM-CMS won't update monitoring data, and will display monitor's standby mode. If network is disconnected, monitor will make request for connection.

The monitor exits standby mode in any of the conditions:

1. The user clicks anywhere on the screen or presses any key (except Power ON/OFF key).
2. Battery Low alarm occurs.

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

NOTE:

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

3.3.3 Night Mode

To switch to night mode, you may:

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

NOTE:

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

3.3.4 Privacy Mode

Only if the monitor is connected and admitted by MFM-CMS, the privacy mode can be activated. To enter into privacy mode, you can select **Menu** > **Maintenance** > **User Maintain** > **Shortcut Setup** > **Privacy Mode** (it is defaulted to be off). Press the shortcut key  on the screen, the monitor enters into privacy mode after user's confirmation.

In privacy mode:

1. The screen displays message: **Privacy mode** and **Patient is in monitoring without audio alarm and alarm indicator lighting. Please click screen or hard key to exit**.
2. Monitoring data, alarm information, stored data and monitor status are transmitted to MFM-CMS.
3. Audio alarm paused status discontinues. Audio alarm off, alarm off, alarm reset and alarm latch status are not influenced.

The monitor exits privacy mode in any of the conditions:

1. The user clicks anywhere on the screen or presses any key (except Power ON/OFF key).
2. Battery Low alarm occurs.
3. The monitor is disconnected with MFM-CMS.

NOTE:

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

3.3.5 NFC Mode

NFC mode is designed when users need to constantly observe HR physiological alarm. In NFC mode, the HR physiological alarm is automatically or always switched on, and user cannot turn it off. To configure NFC mode, select **Menu** > **Maintenance** > **User Maintain** > **Alarm Setup** > **NFC Mode**, set it to **On** or **Off**. NFC mode is off by default.

In NFC mode:

1. The HR physiological alarms are always on and can't be set to off by the user.
2. The user can't turn off the audio alarm permanently.
3. The audio alarm off status will be finished and the monitor enters normal alarm response status. **Pause Time** will automatically switch to **120 s**, which can be set to **60 s**, **120 s**, or **180 s** manually.
4. The audio alarm paused status is not affected by entering NFC mode.
5. Symbol NFC is displayed in the HR parameter area.
6. Monitoring data, alarm information, stored data and monitor status are transmitted to MFM-CMS.

After exiting NFC mode:

1. The HR physiological alarms are still on and can be set to off by the user.
2. **Pause Time** keeps no change and the user can set it to **Permanent**.
3. Symbol NFC gets disappeared.

3.4 Changing Monitor Settings

3.4.1 Adjusting Screen Brightness

To change the screen brightness:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu > Common Function > Brightness**, and select the appropriate setting for the screen brightness. **10** is the brightest, **1** is the least bright.

3.4.2 Changing Date and Time

To change the date and time, please refer to Section *Setting Date and Time*.

WARNING

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

3.5 Adjusting Volume

3.5.1 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:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu** > **System Setup** > **Key Volume**, then select the appropriate setting for the key volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the key volume will be off.

3.5.2 Adjusting Alarm Volume

To change the alarm volume:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu** > **Alarm Setup** and select the desired setting for the **AlarmVolume** item: five bars represent the maximum volume and one bar represents the minimum volume.

3.5.3 Adjusting Beat Volume

Beat volume is from HR or PR, depending on your setting of the beat source. To change the beat volume:

1. Select the shortcut key  on the screen directly, or
2. Select **ECG Setup** > **Beat Volume**, then select the appropriate setting for the beat volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the beat volume will be off. Beat frequency has positive correlation with measurement value.

3.6 Checking Your Monitor Version

To check the monitor version, please select **Menu** > **Common Function** > **About** to check the monitor software revision.

3.7 Setting Languages

To change the language, please:

1. Select **Menu** > **Maintenance** > **User Maintain**, then type the correct password into the displayed interface.
2. Select the **Language** option on the popup interface to open the language list.
3. Select the desired language from the list. To make the change validate, please restart the monitor.

3.8 Setting Keyboard Languages

The monitor is equipped with Chinese keyboard, English keyboard and Russian keyboard. To change the keyboard language, select **Menu** > **Maintenance** > **User Maintain** > **Keyboard Language**, then select the desired language from the list.

NOTE:

The keyboard language will restore to the default language when the system language changes. The default keyboard language varies in different system language. User can change the keyboard language as needed.

3.9 Calibrating Screens

To calibrate the screen, please refer to the following steps:

1. Select **Menu** > **Maintenance** > **User Maintain**, input the user password, and select **TouchScr Calibration** on the **User Maintain** menu. User can also enter into calibration interface through pressing shortcut key F9 in connected keyboard.
2. The symbol  appears on the screen.
3. Click on the central point of the symbol  .

NOTE:

1 If calibration file is lost or damaged, the monitor will automatically enter into screen calibration interface.

2 In the screen calibration interface, the screen turns gray and no measurement data can be displayed.

3.10 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 the

symbol  by using the knob.

3.11 Using the Barcode Scanner

To enter the barcode setup menu, please select **Menu** > **Maintenance** > **User Maintain**. After entering the required password, select **Other Setups** > **BarCode Setup**. Then the user can set MRN, last name, first name and so on.

User can also check relevant scanner device information in **User Maintain** > **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 **Scanner** to add the barcode scanner to the scanner management list and enable the barcode scanning. Choose **Keyboard** to enable the keyboard entry. Please refer to Chapter *Accessories* for the recommended scanner.

NOTE:

1 **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.**

2 **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.**

Chapter 4 Networked Monitoring

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

NOTE:

1 **Be aware that some network-based functions may be limited for monitors on wireless networks in comparison to those on wired networks.**

2 **When selecting dynamic IP mode, please check the IP address from MFM-CMS.**

4.1 Cybersecurity Measures

4.1.1 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 security practices or measures that include:

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

CAUTION

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

2 **Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).**

3 **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.**

CAUTION

4 **Ensure that the data are deleted after the patient is discharged. (Refer to Section *Deleting Data Stored in the Storage Device*).**

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

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

7 **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 defensing 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 **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 it from other VLANs.**

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 **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 off by default), the monitor will authenticate the accessed MFM-CMS devices and encrypt the transmitted data to ensure the security.**

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

4.1.2 Network Security

For more security operations, select **Menu** > **User Maintain** and input user maintain password > **Security**. In this menu:

- Select **Modify User Password**, the user can change the password according to the prompts. For safety considerations, change the password periodically, and a combination of words and numbers is recommended. If **Old Password** is forgotten, contact Service personal for help.
- Click **Firewall Rules** to check rule details.
- Set **Auto Login** to On/Off.

  When it is set to **On**, the monitor can enter the normal working interface after start-up; when it is set to **Off**, after start-up, a password window will be displayed, and the monitor can enter the normal working interface until correct password is input. Default setting is **On**.
- Select the minutes in **User login Timeout**. If there are no any operations to the monitor for XX minutes (**5**, **15**, **30**, **60** and **Never**), the screen will enter into the screensaver status. User Maintain password should be correctly input before user operates the monitor again. The selection **Never** means the monitor will never enter into screensaver status and still in the normal working status. Default setting is **Never**.
- Set **Firewall** to **On** to protect against hacker attacking.
- Set **Packets Limit** value for traffic monitoring. If the data traffic per minute exceeds the preset threshold, the monitor will trigger the alarm "**Network Traffic Abnormity**" to remind the user, and at the same time, the network will disconnect for 5 minutes. After 5 minutes, the network will be re-connected and alarm disappears.

NOTE:

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

2 **When any password is input incorrectly for more than 5 times consecutively, the monitor will display the information: More than five consecutive password errors.**

4.2 Connecting the Wireless Network

Wi-Fi modules are optional to be configured in the monitors. Please contact the EDAN service personnel for activation. To configure the settings on the monitor, follow the steps below before connecting the monitor to a wireless network:

1. Select **Menu** > **Maintenance** > **User Maintain**, and input the password.
2. In the **User Maintain** menu, select **Network Maintain**.
3. In the **Network Maintain** menu, select **Wi-Fi** from the **Network Type** list. And click **Config** to open the **Wi-Fi Setup** window. The available networks will be listed in this window.
4. Choose a network from the window, in which the user can check the network's encryption information (**Security**). The user will be prompted to enter the password of that network if a password is required. After entering the password and setting the IPv4 address, the user can click to connect the network.
5. Or select to connect the hidden networks. After entering **Network Name**, **Security**, password and setting the IPv4 address, the user can click to connect the hidden network.

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

Click to review the historically connected networks. After choosing certain network, the user can select **Forget This Network** or **Join This Network**.

If the encryption information of the currently connected network is modified, the network will automatically disconnect and attempt to reconnect. At this time, 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 to select the updated network.

The following symbols may appear when configuring Wi-Fi:

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

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. **If the monitor fails to connect to any wireless network or no available wireless network is in the Wi-Fi Setup window, switch the Network Type from Wi-Fi to Wired and then to Wi-Fi again. Then retry to connect to a wireless network. If the wireless network still fails to be connected, please try to restart the monitor and connect again.**
4. **Use the wireless device recommended by EDAN, otherwise some exceptional situations such as frequent network disconnection may occur on the monitor.**
5. **The wireless driver is compatible with channels 1-11 only.**
6. **When signal intensity is level 2 or less, signal may be unstable and quality of the signal transmission may be degraded.**
7. **When the monitor is connected to MFM-CMS/Gateway via the wireless network, the user should set the router to a secure encryption/authentication and use the non-dictionary password.**
   - **Recommended options: WPA/WPA2 Personal (supports AES/TKIP);**
   - **Other options: none or WPA/WPA2 Enterprise (includes TLS/TTLS /PEAP).**
8. **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, Network Type (Wired or Wi-Fi) should be selected and is not allowed to switch during monitoring. Otherwise, Wi-Fi may be unavailable.**

2 **If Wi-Fi is unavailable, please restart the monitor to restore Wi-Fi function under the precondition of ensuring patient's safety.**

4.3 Network Disconnected Alarms

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

NOTE:

1 **When the monitor is connected with the central monitoring system, you must set Disconnect Alarm to On.**

2 **If Disconnect Alarm occurs during audio alarm paused or audio alarm off status, the monitor will prompt a sounding alarm with information of NetWork Disconnect. During the network disconnected status, activating audio alarm paused or audio alarm off function can disable the audio alarm signal of Disconnect Alarm.**

4.4 Connecting the Monitor to MFM-CMS

The monitor can be connected to the central monitoring system (V2.65 and above). 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, admitting patient, discharging patient and so forth.

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

And the monitor supports HL 7 protocol.

WARNING

Due to the delay of network transmission, data viewed at the MFM-CMS has a delay of less than 10 seconds compared with data generated at the corresponding monitoring device. To avoid potential patient injury, do not rely on MFM-CMS screen for unrestricted real time data.

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 on the monitor is active. (Default setting is on. Setting path: Menu > Common Function > Date/Time Setup > Sync Time). If the setting is on, the monitor will accept time synchronization from MFM-CMS.**

3 **The time synchronization function might not be available to all software versions of MFM-CMS. Consult our technical service department or your local distributor for more information.**

4 **When deploying the network of the monitor and MFM-CMS, it is recommended to isolate the network and the Intranet system of the hospital by using VLAN so as to ensure the network security. Only trusted devices are allowed to join the VLAN network.**

4.5 Connecting the Monitor to CMS-LITE

The monitor can be connected to the CMS-LITE Data Management Software. Through the network:

1. The monitor sends patient information, monitoring or measurement data to the CMS-LITE Data Management Software.
2. The real-time 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*.

4.6 Connecting the Monitor to Gateway

The monitor can be connected to the Gateway (V1.1 and 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 X series Network and the hospital network.

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

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

4.7 HL7 Communication

The monitor supports HL7 protocol to upload data. Select **Menu** > **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. When the monitor serves as the server, set **HL7** to **On** and the format is XML.
- Set **HL7(Client)** to **On**/**Off**. When the monitor serves as the client, set **HL7(Client)** to **On** and the format is ER7.
- Set **CMS/Gateway Encryption** to **Off** (default), **TLS** or **AES,** when user connects the monitor with network server (MFM-CMS/gateway).
- Set **HL7 Encryption** method to **Off** or **TLS** (default).
- When **HL7 Encryption** or **CMS/Gateway Encryption** is set to TLS, certificate is required to import. Click **Import 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. For detailed steps of importing certificates, please refer to service manual.

In addition, select **Menu** > **User Maintain** > **Network Maintain** > **HL7** > **Config**. In this menu:

- Set HL7 IP address.
- When **HL7(Client)** is **On**, set the **Server Port, Data Sent Interval** and **Connection Type**.

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

NOTE:

If TLS is selected, the monitor will prompt the expiry date to remind updating the

certificate in the lower right corner of the screen.  **indicates that the certificate is about to expire and**  **means the certificate is invalid. Update the certificate in time, otherwise the monitor will be unable to connect with MFM-CMS/Gateway or HL7 communication will be failed.**

Chapter 5 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.

NOTE:

The delay time from onset of ALARM CONDITION to the point where representation of ALARM CONDITION leaves the SIGNAL OUTPUT PART is less than 1 second.

5.1 Alarm Category

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

5.1.1 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*.

5.1.2 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*.

5.1.3 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*.

5.2 Selecting Alarm Tone Type

The user can select the alarm tone type as desired.

1. Select **Menu** > **Maintenance** > **User Maintain**, and enter the required password.

2. If configured, select **Alarm Setup**, and set **Alarm Tone** to **Standard** or **Mode 1**.
   - **Standard**: Standard alarm sound according to IEC 60601-1-8.
   - **Mode 1**: User customized alarm sound according to clinical applications.

5.3 Alarm Levels

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

1. High level alarms

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

2. Medium level alarms

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

3. Low level alarms

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

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

Standard:

Alarm Level	Prompt
High	Mode is "DO-DO-DO------DO-DO, DO-DO-DO------DO-DO", which is triggered once every 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 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.

Alarm Level	Prompt
Low	Mode is “DO-”, which is triggered once every 30 seconds. When physiological alarm is triggered, the alarm indicator is constantly yellow. While for technical alarm, the alarm indicator is constantly cyan. The alarm message flashes with yellow background, and the symbol * is displayed at the alarm area.

Mode 1:

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

The sound pressure range for standard audible alarm signals is from 45 dB to 85 dB, and for Mode 1 is from 30 dB to 85 dB, with the measurement radius of 1 meter.
The sum of the mean alarm condition delay plus the mean alarm signal generation delay is less than 10 s.
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 select one method from **Menu** > **Alarm Setup** > **Visual Effect**:

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

Meanwhile, the alarm level icon is displayed in the parameter area.  stands for medium or low level alarm and  for high level alarm.

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.**

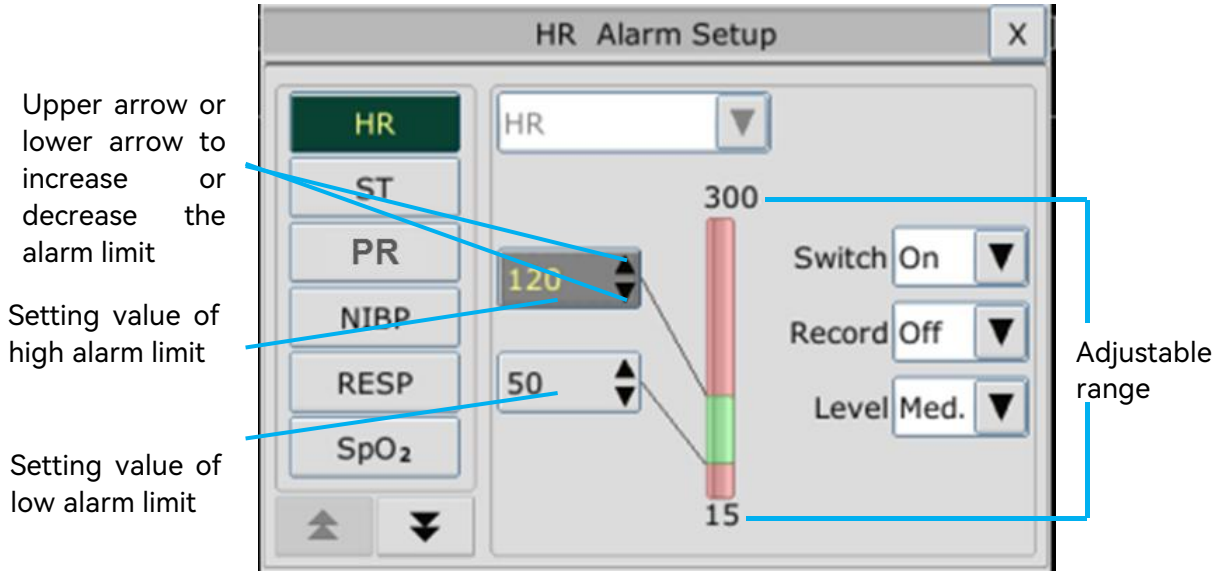
3 **During monitoring, please avoid quick and frequent illegal operations. If the monitor suddenly becomes stuck and produces a harsh prompt sound, the user should press the switch button to shut down the monitor.**

5.4 Controlling Alarm

5.4.1 Setting Parameter Alarm

Parameter alarm settings including alarm switch, alarm record, alarm level and alarm limit are available on the respective alarm setup menu for each parameter. To access the menu for parameter alarm settings, use the shortcut key or select **Menu** > **Alarm Setup**, and then click **Alarm Options** to open the menu shown below for alarm settings of each parameter. Also, you can access this menu via the respective parameter setup menu.

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



WARNING

1 **When the alarm is set to Off, the monitor won't give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.**

2 **Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.**

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

4 **In HR alarm limit setting process, the bottom will display ExtremeTachy or ExtremeBrady threshold value that has been set. HR high alarm limit should be less than or equal to ExtremeTachy threshold value, and HR low alarm limit should be more than or equal to ExtremeBrady threshold value.**

5.4.2 Audio Alarm Paused

Audio alarm pause function can be activated in either of the following ways:

- You can temporarily prevent alarms from sounding by pressing the hardkey  on the front panel or pressing shortcut key  on the screen.
- The monitor receives the audio alarm pause command from MFM-CMS.

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

1. Select **Menu** > **Maintenance > User Maintain**, and enter the required password.
2. Select **Alarm Setup**, and set **Pause Time** to **60 s**, **120 s**, or **180 s**. The pause time on MFM-CMS will be updated accordingly.

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 or when the monitor receives the audio alarm pause command from MFM-CMS, the audio alarm paused status will be terminated and alarm is sounding. You can also terminate the alarm paused status by pressing

the hardkey  on the front panel or pressing shortcut key  on the screen.

NOTE:

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

5.4.3 Audio Alarm off

Audio alarm off function can be activated in either of the following ways:

- Set **Pause Time** to **Permanent**, press hardkey  or 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 monitor receives the audio alarm off command from MFM-CMS.

During the audio alarm off 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 the hardkey  or 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.

5.4.4 Alarm Reset

Alarm reset function can be activated in either of the following ways:

- Select the shortcut key 

on the screen directly.
- The monitor receives the alarm reset command from MFM-CMS.

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.

NOTE:

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

5.5 Latching Alarms

To configure the alarm latching setting, select **Menu** > **Maintenance** > **User Maintain** > **Alarm Setup** 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 alarm indication and audio alarm indication 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.

5.6 Disabling Sensor Off Alarms

To set sensor off alarm, please select **Menu** > **Maintenance** > **User Maintain** and enter the required password. Then select **Alarm Setup** and set **Sensor Off Alm** from the pull-down list. If it is set to **On**, and a sensor off alarm occurs, after pressing the hardkey  or permanent key 

the user can disable the audio alarm signal, however, the visual alarm indications are still displayed. If it is set to **Off**, and a sensor off alarm occurs, after pressing the hardkey  or permanent key 

, sensor-off status will be announced with a prompt message. It means there's no audio alarm signal and alarm indicator, but prompt information displayed.

In **Menu** > **Maintenance** > **User Maintain > Alarm Setup**, **SpO_2 Sensor Off** and **ECG Lead Off** alarm level can be adjusted as **High**, **Med.** or **Low**. These alarm levels are set to **Low** by default.

5.7 Testing Alarms

When you switch the monitor on, the monitor will prompt one "Di" tone that means the audio in selftest is normal. Meantime, you must check that the alarm indicator lights are normal. This indicates that the visible and audible alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

Chapter 6 Alarm Information

6.1 Physiological Alarm Information

WARNING

Physiological alarms including Asystole, RESP APNEA, SpO_2 No Pulse, SpO_2 Desat, and CO_2 APNEA cannot be turned off.

Message	Cause	Alarm Level
ECG		
HR High	HR measuring value is above the upper alarm limit.	User-selectable
HR Low	HR measuring value is below the lower alarm limit.	User-selectable
ST-X High	ST measuring value is above the upper alarm limit. (X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
ST-X Low	ST measuring value is below the lower alarm limit.(X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
PVCs High	PVCs measuring value is above the upper alarm limit.	User-selectable
Asystole	No QRS is detected for 4 consecutive seconds	High
V-Fib/V-Tach	4 consecutive seconds' fibrillation wave occurs; Or 5 consecutive ventricular beats, and ventricular HR ≥ 100 bpm.	High
Run PVCs	3 ≤ the number of consecutive PVCs < 5	User-selectable
Couplet	2 consecutive PVCs	User-selectable
PVC Bigeminy	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.	User-selectable
PVC Trigeminy	A dominant rhythm of N, N, V, N, N,V	User-selectable

Message	Cause	Alarm Level
R on T	A type of single PVC under the condition that HR < 100, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
PVC	Single PVC detected in normal heartbeats, and the number of consecutive single PVC ≥ 4 within 30 s.	User-selectable
Pacer not Capture	No QRS complex detected in 300ms after a pace pulse.	User-selectable
Pacer not Pacing	No pace pulse detected in 1.75 times RR interval after a QRS complex.	User-selectable
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.	User-selectable
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.	User-selectable
Missed Beat	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second.	User-selectable
Irr Rhythm	Consistently irregular heart rhythm	User-selectable
Vent Brady	5 consecutive ventricular beats, and ventricular HR < 20 bpm.	User-selectable
Vent Rhythm	5 consecutive ventricular beats, and 20 bpm ≤ ventricular HR < 40 bpm.	User-selectable
Sustain VT	The duration of ventricular tachycardia rhythm > the threshold value that has been set.	High
ExtremeTachy	HR > Extreme Tachycardia threshold value that has been set.	High

Message	Cause	Alarm Level
ExtremeBrady	HR < Extreme Bradycardia threshold value that has been set.	High
V-Tach	5 consecutive ventricular beats and ventricular HR ≥ 100 bpm.	High
Wide QRS Tachy	Meet tachycardia conditions, and QRS wave width ≥ 160 ms.	User-selectable
Non-Sustain VT	3 ≤ The number of consecutive ventricular beats < 5, and ventricular HR ≥ 100 bpm.	User-selectable
Afib	The RR interval of normal beats must be irregular, and it can be seen that the obvious f or P waves do not exist.	User-selectable
Acc. Vent Rhythm	5 consecutive ventricular beats, and 40 bpm ≤ ventricular HR < 100 bpm.	User-selectable
Pause	No QRS is detected within the heartbeat pause threshold value that has been set.	User-selectable
Pauses/min High	The measurement value of Pause/min is greater than high alarm limit that has been set.	User-selectable
PVCs High	The measurement value of PVCs is greater than high alarm limit that has been set.	User-selectable
VEB	The delayed ventricular beats detected in normal heartbeats occur more than or equal to 2 times within 30 s.	User-selectable
Multiform PVCs	Different forms of ventricular premature beats are detected in 15 beats.	User-selectable
IPVC	The single ventricular premature beat between 2 sinus beats with normal interval occurs more than or equal to 3 times within 30 s.	User-selectable
PAC Bigeminy	The dominant rhythm of N, A, N, A, N, A, and the rhythm number exceeds the number of threshold value that has been set (N = supraventricular beat, A = atrial beat).	User-selectable

Message	Cause	Alarm Level
PAC Trigeminy	The dominant rhythm of N, N, A, N, N, A, N, N, A, and the rhythm number exceeds the number of threshold value that has been set.	User-selectable
Low Voltage(Limb)	None of the signal amplitudes of I, II and III leads exceeds that of the alarm threshold that has been set. PS: this alarm is available for 5, 6 or 10 electrodes only, not available for 3 electrodes.	User-selectable
RESP		
RESP APNEA	RESP waveform cannot be detected within the set apnea alarm delay time.	High
RR High	RR measuring value is above upper alarm limit.	User-selectable
RR Low	RR measuring value is below lower alarm limit.	User-selectable
SpO_2		
SpO_2 High	SpO_2 measuring value is above upper alarm limit.	User-selectable
SpO_2 Low	SpO_2 measuring value is below lower alarm limit.	User-selectable
SpO_2 No Pulse	The signal of the measurement site is too weak due to insufficient blood supply and environmental factors, so the monitor can't detect the pulse signal.	High
SpO_2 Desat	SpO_2 measuring value is below the SpO_2 Desat limit.	High
PR High	PR measuring value is above upper alarm limit.	User-selectable
PR Low	PR measuring value is below lower alarm limit.	User-selectable
TEMP		
T1 High	Measuring value of T1 channel is above upper alarm limit.	User-selectable
T1 Low	Measuring value of T1 channel is below lower alarm limit.	User-selectable

Message	Cause	Alarm Level
T2 High	Measuring value of T2 channel is above upper alarm limit.	User-selectable
T2 Low	Measuring value of T2 channel is below lower alarm limit.	User-selectable
TD High	Measuring value of TD channel is above upper alarm limit.	User-selectable
TEMP High	Measuring value of TD-1261 is above upper alarm limit.	User-selectable
TEMP Low	Measuring value of TD-1261 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
PR (NIBP) High	PR measuring value from the NIBP module is above upper alarm limit.	User-selectable
PR (NIBP) Low	PR measuring value from the NIBP module is below lower alarm limit.	User-selectable
IBP		
Art SYS High	Art SYS measuring value is above upper alarm limit.	User-selectable
Art SYS Low	Art SYS measuring value is below lower alarm limit.	User-selectable
Art DIA High	Art DIA measuring value is above upper alarm limit.	User-selectable
Art DIA Low	Art DIA measuring value is below lower alarm limit.	User-selectable

Message	Cause	Alarm Level
Art MAP High	Art MAP measuring value is above upper alarm limit.	User-selectable
Art MAP Low	Art MAP measuring value is below lower alarm limit.	User-selectable
PA SYS High	PA SYS measuring value is above upper alarm limit.	User-selectable
PA SYS Low	PA SYS measuring value is below lower alarm limit.	User-selectable
PA DIA High	PA DIA measuring value is above upper alarm limit.	User-selectable
PA DIA Low	PA DIA measuring value is below lower alarm limit.	User-selectable
PA MAP High	PA MAP measuring value is above upper alarm limit.	User-selectable
PA MAP Low	PA MAP measuring value is below lower alarm limit.	User-selectable
CVP MAP High	CVP MAP measuring value is above upper alarm limit.	User-selectable
CVP MAP Low	CVP MAP measuring value is below lower alarm limit.	User-selectable
ICP MAP High	ICP MAP measuring value is above upper alarm limit.	User-selectable
ICP MAP Low	ICP MAP measuring value is below lower alarm limit.	User-selectable
LAP MAP High	LAP MAP measuring value is above upper alarm limit.	User-selectable
LAP MAP Low	LAP MAP measuring value is below lower alarm limit.	User-selectable
RAP MAP High	RAP MAP measuring value is above upper alarm limit.	User-selectable
RAP MAP Low	RAP MAP measuring value is below lower alarm limit.	User-selectable

Message	Cause	Alarm Level
P1 SYS High	P1 SYS measuring value is above upper alarm limit.	User-selectable
P1 SYS Low	P1 SYS measuring value is below lower alarm limit.	User-selectable
P1 DIA High	P1 DIA measuring value is above upper alarm limit.	User-selectable
P1 DIA Low	P1 DIA measuring value is below lower alarm limit.	User-selectable
P1 MAP High	P1 MAP measuring value is above upper alarm limit.	User-selectable
P1 MAP Low	P1 MAP measuring value is below lower alarm limit.	User-selectable
P2 SYS High	P2 SYS measuring value is above upper alarm limit.	User-selectable
P2 SYS Low	P2 SYS measuring value is below lower alarm limit.	User-selectable
P2 DIA High	P2 DIA measuring value is above upper alarm limit.	User-selectable
P2 DIA Low	P2 DIA measuring value is below lower alarm limit.	User-selectable
P2 MAP High	P2 MAP measuring value is above upper alarm limit.	User-selectable
P2 MAP Low	P2 MAP measuring value is below lower alarm limit.	User-selectable
CO_2		
$EtCO_2$ High	$EtCO_2$ measuring value is above upper alarm limit.	User-selectable
$EtCO_2$ Low	$EtCO_2$ measuring value is below lower alarm limit.	User-selectable
$FiCO_2$ High	$FiCO_2$ measuring value is above alarm limits.	User-selectable

Message	Cause	Alarm Level
CO_2 APNEA	In the set apnea delay, no breath can be detected using CO_2 module.	High
AwRR High	AwRR measuring value is above upper alarm limit.	User-selectable
AwRR Low	AwRR measuring value is below lower alarm limit.	User-selectable
C.O.		
TB High	TB measuring value is above upper alarm.	User-selectable
TB Low	TB measuring value is below lower alarm.	User-selectable

6.2 Technical Alarm Information

NOTE:

The ECG alarm information listed in the below table describes the electrode names in America. For the corresponding electrode names in Europe, please refer to the Section *Installing Electrodes*.

Message	Cause	Alarm Level	Action Taken
ECG			
ECG Lead Off	1) The drive electrode or more than one ECG limb electrode falls off the skin; 2) ECG cables fall off the monitor.	User-selectable	Make sure that all electrodes, leads and patient cables are properly connected.
ECG LL Lead Off	ECG electrode LL falls off the skin or the ECG cable LL falls off the monitor.	User-selectable	
ECG LA Lead Off	ECG electrode LA falls off the skin or the ECG cable LA falls off the monitor.	User-selectable	

Message	Cause	Alarm Level	Action Taken
ECG RA Lead Off	ECG electrode RA falls off the skin or the ECG cable RA falls off the monitor.	User-selectable	
ECG RL Lead Off	When electrode type is AUTO, ECG electrode RL falls off the skin or the ECG cable RL falls off the monitor, 5/6/10 electrodes switches to 3 electrodes;	User-selectable	
ECG V Lead Off	ECG electrode V falls off the skin or the ECG cable V falls off the monitor.	User-selectable	
ECG V1 Lead Off	ECG electrode V1 falls off the skin or the ECG cable V1 falls off.	User-selectable	Make sure that all electrodes, leads and patient cables are properly connected.
ECG V2 Lead Off	ECG electrode V2 falls off the skin or the ECG cable V2 falls off.	User-selectable	
ECG V3 Lead Off	ECG electrode V3 falls off the skin or the ECG cable V3 falls off.	User-selectable	
ECG V4 Lead Off	ECG electrode V4 falls off the skin or the ECG cable V4 falls off.	User-selectable	
ECG V5 Lead Off	ECG electrode V5 falls off the skin or the ECG cable V5 falls off.	User-selectable	
ECG V6 Lead Off	ECG electrode V6 falls off the skin or the ECG cable V6 falls off.	User-selectable	

Message	Cause	Alarm Level	Action Taken
ECG Signal Exceeded	ECG measuring signal is beyond measuring range.	Low	Check lead connection and patient condition
ECG Noise	ECG measuring signal is greatly interrupted.	Low	
ECG Comm Fail	ECG module failure or communication failure	High	Stop measuring function of ECG module, and notify biomedical engineer or manufacturer's service staff.
RESP			
RESP Comm Fail	RESP module failure or communication failure	High	Stop measuring function of RESP module, and notify biomedical engineer or the manufacturer's service staff.
RR Exceed	RR measuring value is out of the measure range.	Medium	Check whether interference to the respiratory signal exists. And check whether the patient is breathing normally; breathing too rapidly or too slowly may endanger patient's life.

Message	Cause	Alarm Level	Action Taken
RESP Cardiac Artifact	No RESP waveform can be detected due to apnea or shallow breathing of the patient.	High	Check whether the patient is breathing normally. Take measures to help the patient breathe normally when necessary. If the patient is breathing normally, try to adjust the electrode position on the patient in order to reduce the interference of cardiogenic artifact.
RESP Noise	RR cannot be measured due to patient movement.	Low	Check whether the RESP leads are well connected. Keep the patient calm for better monitoring.
SpO_2			
SpO_2 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.

Message	Cause	Alarm Level	Action Taken
SpO_2 Comm Fail	SpO_2 module failure or communication failure	High	Stop using measuring function of SpO_2 module, and notify biomedical engineer or manufacturer's service staff.
SpO_2 Sensor Err	Malfunction in the SpO_2 sensor or in the extension cable.	Low	Replace the SpO_2 sensor or the extension cable.
SpO_2 No Sensor	No SpO_2 sensor was connected to the monitor.	Low	Make sure the monitor and sensor are well connected, reconnect the sensor.
SpO_2 Low Perfusion	The pulse signal is too weak or the perfusion of the measurement site is too low. The SpO_2 value and PR value might be inaccurate then.	Low	Reconnect the SpO_2 sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.
SpO_2 Noisy Signal	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
SpO_2 Light Interference	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 Cuff Type Error	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.
NIBP Comm Fail	NIBP module failure or communication failure	High	Stop using measuring function of NIBP module, and notify biomedical engineer or manufacturer's service staff.
NIBP Leak	NIBP pump, valve, cuff or tube has a leakage.	Low	Check the connections and the wrapped cuff to see whether they are all prepared well.
NIBP Excessive Pressure	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP Init Pressure High	The initial pressure is too high during measuring	Low	

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 Airway Pressure Abnormality	Atmospheric pressure or system pressure is abnormal. The valve is occluded so that deflation is failed.	Low	Check whether the airway is occluded or pressure sensor works properly. If the problem still exists, contact your service personnel.
NIBP System Failure	NIBP is not calibrated.	High	Contact your service personnel.
NIBP Loose Cuff	Cuff is not properly wrapped or no cuff is connected.	Low	Properly wrap the cuff.
NIBP Weak Signal	Cuff is too loose or patient pulse is too weak.	Low	Use other methods to measure blood

Message	Cause	Alarm Level	Action Taken
NIBP Range Exceeded	All of SYS, DIA and MAP values are beyond the measurement range.	High	pressure.
SYS(NIBP) Overrange	SYS (NIBP) value is beyond the measurement range.	High	
DIA(NIBP) Overrange	DIA (NIBP) value is beyond the measurement range.	High	
MAP(NIBP) Overrange	MAP (NIBP) value is beyond the measurement range.	High	
NIBP Interference	Signal noise is too large or pulse rate is not regular due to the patient movement.	Low	Make sure that the patient under monitoring is motionless.
NIBP Leak Test Error	Fail to deflate normally during the leak test, so NIBP leak test cannot be finished.	Low	Test again. If the problem still exists, contact your service personnel.
TEMP			
TEMP T1 Sensor Off	Temperature cable of TEMP channe1 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected
TEMP T2 Sensor Off	Temperature cable of TEMP channe2 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected.
Excessive T1	TEMP1 measuring value is beyond measuring range.	High	Check sensor connection and patient condition

Message	Cause	Alarm Level	Action Taken
Excessive T2	TEMP2 measuring value is beyond measuring range.	High	
TEMP Overrange	TD-1261 TEMP measuring value is beyond measuring range (32℃~43℃).	Medium	
TEMP Comm Fail	TEMP module failure or communication failure.	High	Stop measuring function of TEMP module, and notify biomedical engineer or Manufacturer's service staff.
T1 Calibration Failed	T1 calibration failed.	High	Please check whether the module works properly.
T2 Calibration Failed	T2 calibration failed	High	
IBP			
YY Sensor Off (YY stands for the IBP label name: Art, PA, CVP, RAP, LAP, ICP, P1 and P2)	IBP sensor falls off.	Medium	Check the sensor connection and reconnect the sensor.
IBP Catheter Off	IBP catheter falls off due to patient movement.	High	Check the catheter connection and reconnect it.
IBP Sensor Err	Malfunction in the IBP sensor or in the extension cable.	Medium	Replace the IBP sensor or the extension cable.

Message	Cause	Alarm Level	Action Taken
YY Comm Fail (YY stands for the IBP label name: Art, PA, CVP, RAP, LAP, ICP, P1 and P2)	IBP module failure or communication failure	High	Stop measuring function of IBP module, and notify biomedical engineer or Manufacturer's service staff.
C.O.			
C.O. TI Sensor Off	C.O. TI sensor not connected	Low	Insert injective temperature sensor.
C.O. TB Sensor Off	C.O. TB sensor not connected	Low	Insert TB sensor.
C.O. Comm Fail	C.O. module failure or communication failure	High	Stop measuring of C.O. module, or notify biomedical engineer or Manufacturer's service staff.
C.O. TEMP Out Of Range	TI/TB measuring value is beyond measuring range.	High	Please check TI/TB sensor.
CO_2			
CO_2 Comm Fail	CO_2 module failure or communication failure	High	Check if the water tray has been fixed.
CO_2 Check Adapter	The water trap is disconnected or not properly connected.	Low	Properly connect the water trap.
CO_2 Sensor Over Temp	CO_2 sensor temperature exceeds +40 °C.	High	Stop using measuring

Message	Cause	Alarm Level	Action Taken
CO_2 Sensor Faulty	CO_2 module failure	High	function of CO_2 module, notify biomedical engineer.
$FiCO_2$ Overrange	The $FiCO_2$ concentration exceeds the measurement range.	High	Please check the monitor or patient status and adjust the gas concentration accordingly.
$EtCO_2$ Overrange	The $EtCO_2$ concentration exceeds the measurement range.	High	
CO_2 Occlude	Water trap of SideStream is occluded.	High	Make sure the gas exhaust works well
CO_2 Noisy Signal	The CO_2 signal is interfered by ambient or electromagnetic interference	Low	Check interference sources around the device.
Others			
Battery Low	The battery is low, and it at least lasts for 20 minutes.	Medium	Change or charge the battery.
Battery Low	Battery is nearly depleted, and the monitor will shut down soon.	High	

Message	Cause	Alarm Level	Action Taken
Battery Error	Battery failure or high temperature protection	Low	Replace the battery and restart the monitor. Or suspend charging until the battery cools and then continue charging. If the problem still exists, contact your service personnel.
Battery Current Too High	The battery current is too high.	Low	Stop using the battery, contact your service personnel.
Battery Charge Voltage Too High	The battery charging voltage is too high	Low	
Recorder Out Of Paper	Recorder Out Of Paper	Low	Please install the paper
Recorder Probe Overheated	The probe of recorder is overheated.	Low	Stop recording and retry after the probe cools.
Printer Unavailable	The selected printer is not available.	Low	Check whether the network connection is in good condition and whether the printer is malfunctioning.
Insufficient storage space	Less than 10 M space is left in the storage device.	Low	Delete some data in the removable device or use another removable device.

Message	Cause	Alarm Level	Action Taken
Read-only storage device	The storage device is read-only.	Low	Repair the removable device or replace it with a new one.
Storage device damaged	Storage device is damaged.	Low	
Network Disconnect	In distributed alarm system, the monitor's network is disconnected.	Low	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.
Audio Failed	Audio circuit connection is abnormal, or loudspeaker falls off.	High	Stop using the monitor and notify the manufacturer's service staff.
Network traffic anomaly	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.

6.3 Prompts

Message	Cause
ECG ARR Learning	The QRS template building required for Arr. Analysis is in process.
Unable to analyze ST	The ST algorithm cannot produce valid ST value, which may be caused by the large change in the measured value of connected cardiogram ST or ventricular pacing.
Unable to analyze QT	QT algorithm cannot generate valid QT for more than 10 minutes (or 1 minute during startup).
QT Baseline Overrange	After modifying the calculation formula, the QTc parameter value exceeds the range.
Unable to analyze ECG	The arrhythmia algorithm cannot analyze ECG data reliably.
V-Fib/V-Tach Off	V-Fib/V-Tach alarm is set to **Off**.
ExtremeTachy Off	Extreme Tachycardia alarm is set to **Off**.
ExtremeBrady Off	Extreme Bradycardia alarm is set to **Off**.
Key ARR Alarm Off	One of Key ARR alarms is set to **Off**.
Electrode Contact Poor	The electrode has bad contact with patient's body.
SpO_2 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.
Please Disable Pace Pulse Rejection!	In 12 leads analyzing interface, if Pace and Pace Pulse Rejection are both On, the monitor will prompt the user to set **Pace Pulse Rejection** to **Off**.
Manual Measuring	In manual measuring mode
Continual Measuring	In continuous measuring mode
Auto Measuring	In automatic measuring mode
Sequence Measuring	In sequence measuring mode.
Measurem. Canceled	Press the "Start/stop NIBP measurement" button or shortcut key  to stop the measurement.

Message	Cause
Calibrating	During calibrating
Calibrat. Canceled	Calibration is over.
Leak. Test Running	The leakage test is in process.
Leak.Test Canceled	Pneumatic test over
Module Self Test	The module is self-testing.
Manometer Mode	Calibrate in this mode.
Please Switch To Maintain Mode	Need to calibrate in this mode.
Please Switch To Normal Mode	Need to measure in normal mode.
Leakage Test Ok	There is no leak.
Resetting	NIBP module in resetting
Please Start	NIBP module is in idle status.
Done	NIBP measurement is completed.
Venipuncture Starting	Start the assisting venipuncture and the cuff begins to inflate.
In venipuncture process	Venipuncture in process
Venipuncture Ending	Finish the assisting venipuncture and the cuff begins to deflate.
NIBP Simul	**NIBP Simul** function is turned on.
Be sure the cuff is disconnected from monitor	In Cleaning Mode, the user clicks the **Start Cleaning** button.
Cleaning succeeded	Cleaning finished successfully.
Cleaning failed	Abnormal air pressure in cleaning mode.
Cleaning in progress	The monitor is in cleaning progress.
Place Probe On Measure Place	Probe isn't placed on the measurement site.
CO_2 Standby	Turn from measuring mode to standby mode, making the module in energy-saving status.
CO_2 Calibration OK	CO_2 module calibration succeeds.

Message	Cause
CO_2 Calibration Failed	CO_2 module calibration failed.
Please Press 'Zero'.	Enter the IBP zeroing menu, and zeroing is not performed yet.
Zero OK	IBP completes zeroing.
Pulsatile Pressure Zero Fail.	During the zeroing process, pressure fluctuation is excessive.
Pressure out of normal range,Fail.	During the zeroing process, pressure value is beyond the zeroing range.
Sensor Off, Fail!	Perform zeroing when the sensor is off.
Invalid Time,Zero Fail.	Time is not set up prior zeroing.
Unable to Calibrate in Demo Mode	Perform zeroing in Demo Mode.
Zeroing...	Zeroing is in progress.
Please Press 'Calibrate'.	Enter the Calibration menu, and Calibration is not performed yet.
Calibration OK	Calibration is completed.
Pulse Pressure Calibration Failed	During the Calibration process, pressure fluctuation is excessive.
Pressure out of range	During the Calibration process, pressure value is beyond the Calibration range.
Zeroing and Calibration Failed	Zeroing is not performed prior calibration.
Sensor Off, Fail.	Perform calibration when the sensor is off.
Invalid Time, Calibration Fail.	Time is not set up prior calibration.
Unable to Calibrate in Demo Mode	Perform calibration in Demo Mode.
Calibrating...	Calibration is in progress.
C.O. Lack Param	Parameter is not configured for C.O. measurement.

Message	Cause
Warm-up over	The monitor displays this message after taking the sensor out of the bracket and warm-up is over.
Measure over	After the Predict measuring is over, the data and message display on the interface.
Measure time out	No measuring result after the module entering Predict state for 30 s.
Printer Busy	The monitor is performing a print job.
Recorder Setup Needed	The user presses the **RECORD** button or shortcut key **Record** when Recorder is not configured.
No Default Printer	No default printer has been set.
Lack of parameter, unable to score	In Warning-Score System interface, parameters are not completely input.
No WIFI module detected	No Wi-Fi module is detected.
The space in U disk is less than 300 M. Please clean it up.	The remaining space of U disk is less than 300 M.
Attention! Private information included in the data.	When user exports data from the internal storage device.
More than five consecutive password errors	Continuously enter the wrong password for more than 5 times.

6.4 Adjustable Range of Alarm Limits

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

	Patient Type	Adjustable Range
HR	ADU	15~300
	PED/ NEO	15~350

ST analysis alarm limits are listed as follows: unit (mV)

	Adjustable Range
ST	-2.0~2.0

QTc and ΔQTc alarm limits are listed as follows: unit (ms)

	Adjustable Range
QTc	200~800
ΔQTc	30~200

RESP alarm limits are listed as follows: unit (rpm)

Patient Type	Adjustable Range	Source
ADU	6~120	ECG
PED/ NEO	6~150	
ADU/PED	4~70	SpO_2

SpO_2 alarm limits are listed as follows: unit (%)

	Adjustable Range
SpO_2	20~100

SpO_2 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 Setup > SpO_2 Desat Limit, SpO_2 Desat Limit should be less than or equal to SpO_2 alarm low limit.

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

	Adjustable Range
PR (SpO_2)	30~300
PR (NIBP)	40~240
PR (IBP)	30~300

NIBP alarm limits are listed as follows: unit (mmHg)

Patient Type		Adjustable Range
ADU	SYS DIA MAP	25~290 10~250 15~260
PED	SYS DIA	25~240 10~200

Patient Type		Adjustable Range
	MAP	15~215
NEO	SYS DIA MAP	25~140 10~115 15~125

TEMP alarm limits are listed as follows:

	Adjustable Range
T1	0 °C (32 °F)~50 °C (122 °F)
T2	0 °C (32 °F)~50 °C (122 °F)
TD	High limit: 0.1 °C (0.2 °F)~50 °C (90 °F)

IBP alarm limits are listed as follows: unit (mmHg)

	Adjustable Range
Art	0~300
RAP, LAP, CVP, ICP	-10~40
PA	-6~120
P1, P2	-50~300

CO_2 alarm limits are listed as follows:

	Adjustable Range
$EtCO_2$	0 mmHg~150 mmHg
$FiCO_2$	High limit: 3 mmHg~50 mmHg
AwRR	2 rpm~150 rpm

C.O. alarm limits are listed as follows:

	Adjustable Range
TB	23 °C (73.4 °F)~43 °C (109.4 °F)

Chapter 7 Managing Patients

7.1 Confirming a Patient

After the user switches the monitor on, the monitor will prompt "**Continue monitoring the current patient or admit new patient?**". Select **Current Patient** to use the current configuration; Select **New Patient** to admit new patient. If the user does not make a selection within 1 minute, **Current Patient** is selected by default.

If the user wants to switch off this function, set **User Maintain** > **Confirm Patient** to **Off**, the monitor will not prompt to confirm a patient. **Current Patient** is selected when the user switches the monitor on.

7.2 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 the **Admission** key on the screen or.
2. Select **Menu** > **Patient Setup** > **New Patient**, 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**, the **Patient Info** window is displayed.
4. 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 characters. Chinese, English, Russian, numbers 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**.
- **Pace**: Choose **On** or **Off** (You must select **On** if your patient has a pacemaker).
- **Date of Birth**: Enter the patient's date of birth.
- **Date of Admission**: Enter the patient's date of admission.
- **Height**: Enter the patient's height, with unit: **cm** or **inch**.
- **Weight**: Enter the patient's weight, with unit: **kg** or **lb**.

The user can set whether a password is required to change the Bed No. and Date of Admission in **Menu** > **Maintenance** > **User Maintain** > **Patient Info. Setup**.

NOTE:

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

2 **For Bed No., user can select English, Chinese, and Russian through switching keyboard language, and select special characters through** 

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7.2.1 Patient Category and Paced Status

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.

The paced setting determines whether the monitor shows pacemaker pulses or not. When **Pace** is set to **Off**, pace pulses are filtered and therefore do not show in the ECG wave.

WARNING

1 **Changing the patient category may change the arrhythmia and NIBP alarm limits. Always check alarm limits to make sure that they are appropriate for your patient.**

2 **For paced patients, you must set Paced to On. If it is incorrectly set to Off, the monitor could mistake a pace pulse for a QRS and fail to give an alarm during asystole.**

7.3 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 Setup** > **Quick Admit**, then a message is displayed to ask the user to confirm to update patient.
3. Click on **No** to cancel this operation; click on **Yes** to continue and the **Quick Admit** window is displayed.
4. Configure **Type** and **Pace** to the correct setting and click **Yes** to finish the quick patient admission operation. If you want to quit the operation, click **No**.

7.4 Barcode Admit

Barcode scanner can recognize patient information directly and quickly, which can provide convenience and reduce mistakes for users.

To admit a patient by barcode,

1. The user can scan the barcode through scanner, then a message is displayed to ask the user to confirm the patient update.
2. Click **No** to cancel this operation; click **Yes**, the **Patient Info** window is displayed and the corresponding patient information is updated according to the identified MRN. If the monitor is connected with the network server through the gateway, the monitor will automatically inquire for patient information from the network server via MRN. As soon as the MRN is successfully found on the network server, the corresponding patient information will be updated to the monitor. Otherwise, prompt information will be displayed to notify the user that network is not available or no patient information is matched. If patient information is modified on the network server, prompt information will also be sent to inform the user of the update.

NOTE:

1 When the monitor is in keyboard interface and patient information interface, admitting patient via barcode scanner is not available.

2 The start and end code should be set before using scanner to update patient, otherwise the barcode can't be recognized normally.

3 Patient information obtained from network server cannot be edited.

7.5 Managing Patient Information

7.5.1 Editing Patient Information

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

If the monitor is equipped with a barcode scanner, the user can scan the patient's barcode to enter the patient's medical record number (MRN). When patient's MRN is modified, the user can click on  to obtain the patient information from network server. Otherwise, only MRN is updated.

NOTE:

Switching patient type will change the current configuration.

7.5.2 Obtaining Patient Information from the Network Server

The user can obtain patient information from the network server to the monitor. To obtain patient information from the network server,

1. Select **Menu** > **Patient Setup** > **Network Admit**.
2. Input the query conditions (**Department**, **Date of Admission**), and then click  . A list including all the patients that meet the query conditions is displayed.
3. Select a patient from the patient list, and click **Admit**. The corresponding patient information in the monitor will be updated after user's confirmation. Click **View** to display the detailed patient information.

NOTE:

The user can load patient information from the network server only when ADT Query is enabled. Default setting is off. Setting path: Maintenance > User Maintain > Network Maintain > ADT Query.

Chapter 8 User Interface

8.1 Setting Interface Style

The user can set the interface based on the requirement, and the set options include the following:

- Sweep of the waveform.
- Parameters needing to be monitored.

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

8.2 Selecting Display Parameters

The user can select the display parameters based on the monitoring and measurement requirements. To select the parameter, please:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu** > **System Setup** > **Module Switch**.
3. Select the required parameters from the popup interface.
4. Exit the menu and the screen will adjust the parameters automatically.

8.3 Changing Waveform Position

The user can exchange the waveform positions of parameter A and parameter B with the following method:

1. Select waveform A and open the setup menu of waveform A.
2. Select **Change** from the popup menu and select the desired label name of waveform B from the pull-down list.

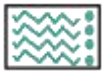
8.4 Changing Interface Layout

Select **Menu** > **Display Setup** to open the **Display Setup** menu on which you can

- Select a function screen based on the clinical requirements by configuring **View Selection**.
- Select the maximum number of waveforms displayed on the screen by configuring **Wave. Num.**.
- Decide whether the control bar is displayed or not displayed on the screen by

setting **Control Bar** to **On** or **Off**.

8.5 Viewing Trend Screen

To view the trend screen, the user can press the shortcut key  on the screen directly or select **Menu** > **Display Setup > View Selection > TrendScreen**.

Select short trend to open **Short Trend Setup** menu, the user can set:

1. **Parameter**.
2. **Interval**: set the interval to **30 min**, **1 h** and **2 h**.

8.6 Viewing OxyCRG Screen

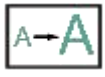
To view the OxyCRG screen, the user can press the shortcut key  on the screen directly or select **Menu** > **Display Setup > View Selection > OxyCRG**. This interface is always used in NICU because the SpO_2, HR and Resp of the neonate are different from those of adults. OxyCRG is in the bottom half part of wave area; it consists of HR trend, SpO_2 trend and RR trend or compressed respiration waveform.

Select OxyCRG waveform to open **OxyCRG Setup** menu, you can set:

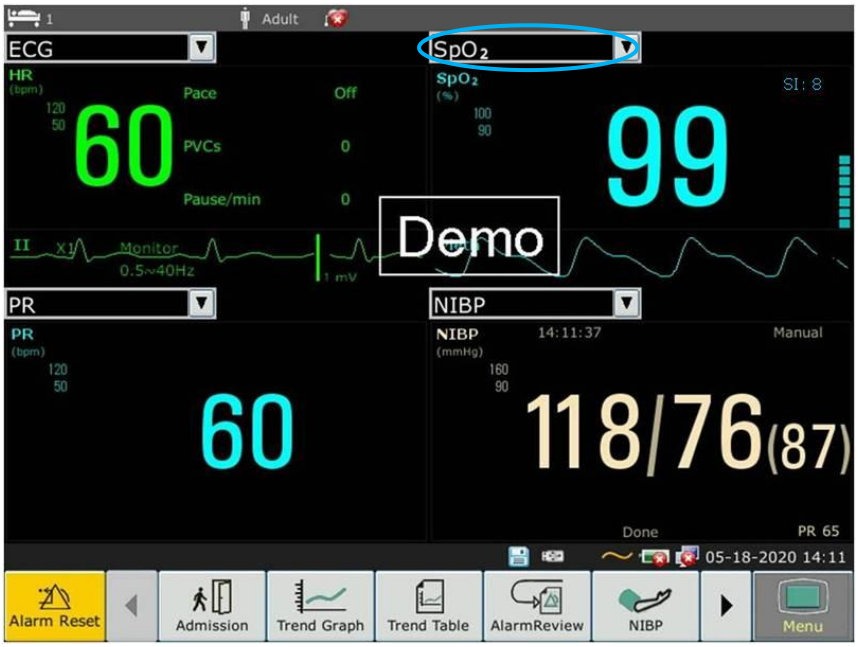
1. **Interval**: set the interval to **1 min**, **2 min** and **4 min**.
2. **Parameter**: to select **RESP** or **RR**.
3. **OxyCRG Review**: user can review the 24 hours OxyCRG parameters including HR, SpO_2, RR. Clicking  or  to left or right move the screen for viewing OxyCRG. Click **Exit** to exit the review interface.

8.7 Viewing Large Font Screen

To open the large font screen, please refer to the following steps:

1. Select the shortcut key  on the screen directly or.
2. Select **Menu** > **Display Setup** > **View Selection > Large Font** to open this interface.

You can view any available parameter by selecting the parameter from the pull-down list on each section.



8.8 Viewing the Vital Screen

To view the vital screen, the user can press the shortcut key  on the screen directly or select **Menu** > **Display Setup > View Selection > Vital**.

8.9 Viewing the Bed View Window

The **Bed View** window allows you to view one waveform, numeric information of all parameters and alarm information from another bed on the same network. The monitor enables a maximum of eight beds to be viewed.

NOTE:

1 **The IP addresses of the monitors configured with bed view function should share the same network segment. The IP addresses of the monitors on the same LAN should be unique from each other; you cannot use the bed view function in the monitors in which an IP address conflict exists.**

2 **In order to use the bed view function without impediment, you need to restart the monitor after you change its IP address.**

3 **To use the bed view function smoothly, make sure the network connection is in good condition.**

4 **In the Bed View window, you cannot view the over-limit alarms of physiological parameters occurring on other beds. Besides, arrhythmia alarms and vital alarms will be indicated only by alarm icons.**

5 The bed view results are for reference only.

8.9.1 Opening the Bed View Window

Before opening the **Bed View** window, make sure the bed view function is configured on your monitor. To open the **Bed View** window, select **Menu** > **Display Setup** and choose **Bed View** in the **View Selection** list.

8.9.2 Settings of the Bed View Window

Click on the **Bed View** window to open the **ViewBed Setup** menu on which you can

- Assign a bed to be viewed by selecting the bed No. in the **Bed No.** list.
- Select the waveform to be displayed on the window in the **Wave Type** list.
- Use the buttons  and  to view more numeric information of parameters in the window.

8.10 Changing Parameter and Waveform Colors

The user can set the display colors of parameter and waveform as desire. To change the display color, please select **Menu > Maintenance > User Maintain**, enter the required password. Then select **Color Setup** to make color changes on parameter and waveform.

8.11 Displaying the Timer

The monitor has the timer function to notify you when a preset time period is expired. To display the timer on the main interface,

1. Select the shortcut key  on the screen directly, or
2. Select **Menu** > **System Setup** > **Module Switch**.
3. Select **Timer** from the popup interface. Exit the menu and the screen will adjust the parameters automatically.

In the timer displaying area, the user can set the timer counting direction. Select **Timer Setup** > **Timing Direction**.

- **Count Down**: to display the remaining time. When the user selects **Count Down**, **Timing Duration** shall be set simultaneously. The timing duration can be set between 0 and 120 hours. Default setting is 5 min. When the remaining time is 30 seconds, the time turns red, prompting you that the timing duration is to expire. When the timing duration expires, the monitor issues a reminder tone. To set the

reminder tone volume, select **Menu** > **System Setup** > **Reminder Volume**.

- **Count Up**: to display the elapsed time.

When the **Timing Direction** is **Count Down**, the user can select **Start**/**Pause**/**Resume** or **Cancel** to start/pause/resume or end the timer; When the **Timing Direction** is **Count Up**, the user can select **Start** or **Cancel** to start or clear the timer.

To turn off the timer displaying, the user can remove the timer in the module switch menu.

NOTE:

1 Timer function shall be used via the touch screen.

2 The user cannot change timer settings when a timer is running.

3 Do not use the timer to schedule critical patient-related tasks.

4 The timer function is not available in privacy mode and standby mode.

8.12 Profile

Select **Menu > Maintenance > User Maintain > Profile**, enter the required password, users can save the current monitor's configuration, delete the saved user configuration and rename it. 12 pieces of user configuration can be saved in the monitor. Users can select as desire.

To set default configuration, select **Menu > Profile**. On the **Profile** menu, users can choose a factory configuration (adult, pediatric or neonate) based on the patient category. The one labeled with ● is current configuration. If there's no labeled configuration, it means the currently used configuration is not one of them.

8.13 Neonatal Configuration*

*Only applicable for X10

Neonatal configuration is exclusively designed for neonate. When it is set to **On**, the patient type is defaulted to be neonate and cannot be changed.

Neonatal configuration is not set by user. Contact the professionals authorized by the manufacturer if needed.

Chapter 9 Monitoring ECG

9.1 Overview

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the monitor as a waveform and a numeric. This chapter also tells you about arrhythmia monitoring and ST monitoring.

9.2 ECG Safety Information

WARNING

1. **Only use the ECG electrodes supplied by the manufacturer when using the monitor for ECG monitoring.**
2. **When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient but not the conductive part or ground.**
3. **Place the electrode carefully and ensure a good contact. Check every day whether there is skin irritation resulted from the ECG electrodes. If yes, replace electrodes every 24 hours or change their sites.**
4. **Store the electrodes in room temperature. Open the electrode package immediately prior to use. Never mix electrode types or brands. This may lead to problem due to impedance difference. When applying the electrodes, avoid bones close to skin, obvious layers of fat and major muscles. Muscle movement can result in electrical interference. Applying electrodes on major muscles, for example on muscles of thorax, may lead to erroneous arrhythmia alarm due to excessive muscle movement.**
5. **Check if the lead connection is correct before monitoring. If you unplug the ECG cable from the socket, the screen will display the error message "ECG Lead OFF" and the auditory alarm is activated.**
6. **If the ECG signal exceeds the measuring range, the monitor will indicates it by a message "ECG Signal Exceeded".**
7. **ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.**
8. **When using Electrosurgery (ES) equipment, do not place an electrode near the grounding plate of the Electrosurgery device: otherwise there will be a great deal of interference with the ECG signal.**
9. **The electrodes should be made of the same metal materials.**

WARNING

10 In order to avoid being burnt, please keep the electrodes far away from the radio knife while using electrosurgical equipment.

11 ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

12 Before outputting signals with defibrillator synchronization or ECG, check if the output is functioning normally.

13 According to AAMI specifications the peak of the synchronized defibrillator discharge should be delivered within 60 ms of the peak of the R wave. The synchronization pulse output on the patient monitors is delayed by a maximum of 35 ms from the R wave peak. Your biomedical engineer should verify that your ECG/Defibrillator combination does not exceed the recommended maximum delay of 60 ms.

14 ECG accessories are not suitable for DIRECT CARDIAC APPLICATION. (Refer to IEC60601-1 for more information about the definition of DIRECT CARDIAC APPLICATION.)

15 Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. When the electrode or lead is loose or fallen, the monitor is easily affected by the transient response of certain types of insulation monitors. The transient monitor signal produced by poor insulation of the line may be very similar to the actual heart waveform, which will prevent the monitor from prompting a heart rate alarm. In order to avoid this, user should check lead wires for damage and ensure good skin contact prior to and during use. Always use fresh electrodes and follow proper skin preparation techniques.

16 The monitor can only be used on one patient at a time. Monitoring more than one patient simultaneously may result in hazards to the patient.

17 Pacemaker Failure: During a complete cardiac block or when pacemaker is unable to pacing/capture, high P-wave (greater than 1/5 of the average height of the R-wave) may be incorrectly counted by the monitor, which leads to a missing asystole.

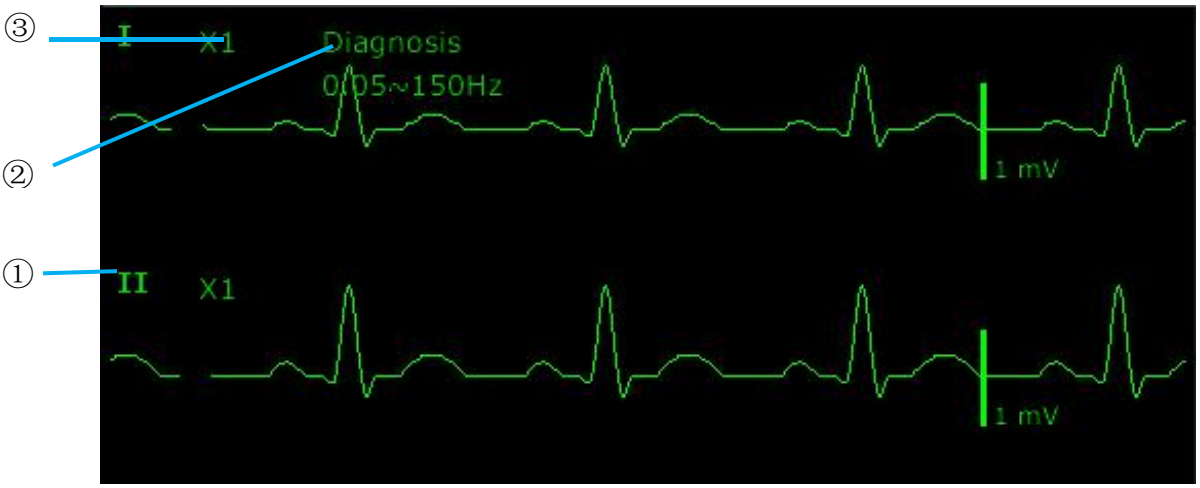
18 The monitor is suitable for use in the presence of electrosurgery. When the monitor is used with HF surgical equipment, user (doctor or nurse) should be cautious about patient safety.

NOTE:

1. **Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.**
2. **IEC/EN60601-1-2 (protection against radiation is 3 V/m) specifies that the electrical field density exceeding 3 V/m may cause measurement error in various frequencies. It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.**
3. **The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.**
4. **If the pacemaker signals are beyond the claimed range, the heart rate may be calculated incorrectly.**
5. **In the default settings of the monitor, the ECG waveforms are the first two waveforms from top in the waveform area.**
6. **For measurements in or near the heart we recommend connecting the monitor to the potential equalization system.**
7. **For protecting environment, the used electrodes must be recycled or disposed of properly.**

9.3 ECG Display

The figure below is for reference only.



The symbol "①"indicates lead name of display waveform: there are other leads for selection, such as **I**, **II**, **III**, **aVR**, **aVF**, **aVL**, **V** (for 5 Electrodes). If you want to change the lead, please refer to Section *Selecting Calculation Lead*.

The symbol "②" indicates Filter setting, there are six options: **Monitor**, **Surgery**, **Diagnosis**, **Enhanced**, **Diagnosis 1**, and **Customized**. If you want to change it, please refer to Section *Changing the ECG Filter Setting*.

The symbol "③" indicates waveform gain: there are several options, such as **X0.125**,

X0.25, **X0.5**, **X1**, **X2**, **X4** and **AUTO**. If you want to change it, please refer to Section *Changing the Size of the ECG Wave*.

9.3.1 Changing the Size of the ECG Wave

If any of the displayed ECG waveform is too small or clipped, you can change the size of it on the screen. First select **ECG Waveform Setup** > **ECG Gain**, then select an appropriate factor from the pop-up box to adjust the ECG waveform.

X0.125: make size of ECG signal waveform of 1mV become 1.25 mm;

X0.25: make size of ECG signal waveform of 1mV become 2.5 mm;

X0.5: make size of ECG signal waveform of 1mV become 5 mm;

X1: make size of ECG signal waveform of 1mV become 10 mm;

X2: make size of ECG signal waveform of 1mV become 20 mm;

X4: make size of ECG signal waveform of 1mV become 40 mm;

AUTO: let the monitor choose the optimal adjustment factor for all the ECG waves.

NOTE:

The effect of ECG wave gain is subject to the size of the wave area. Whichever wave gain is chosen, the ECG wave has to be displayed within the wave area, the exceeded part is clipped.

9.3.2 Changing the ECG Filter Settings

The ECG filter setting defines how ECG waves are smoothed. An abbreviation indicating the filter type is shown underneath the lead label on the monitor display. Filter settings do not affect ST measurement.

To change the filter setting, in the **ECG Setup** menu, select **Filter** and then select the appropriate setting.

– **Monitor**: Use this mode under normal measurement conditions.

– **Surgery**: The filter reduces interference to the signal. It should be used if the signal is distorted by high frequency or low frequency interference. High frequency interference usually results in large amplitude spikes making the ECG signal look irregular. Low frequency interference usually leads to a wandering or rough baseline. In the operating room, the Filter reduces artifacts and interference from electro-surgical units. Under normal measurement conditions, selecting **Surgery** may suppress the QRS complexes too much and thus interfere with the clinical evaluation of the ECG displayed on the monitor.

– **Diagnosis**: Use when undistorted signal is required and its own characteristics can be maintained. The waveform filtered by the bandwidth of 0.05 Hz~150 Hz is displayed so that the actual changes such as R-wave notching or discrete elevation or depression of the ST segments are visible.

– **Enhanced**: It should be used if the signal is distorted by strong interference from high frequency or low frequency. If there is still obviously interference in the signals when select surgery filter mode, it is recommended to choose the enhanced mode. In this mode, QRS wave rhythm information is emphasized, its shape information cannot be considered as diagnostic criteria. Under normal measurement conditions, the selection of this mode may inhibit QRS wave group and interfere ECG analysis.

– **Diagnosis 1**: To meet the filtering requirements of ST analysis, it is used when ST analysis is turned on or when ST analysis results are concerned.

– **Customized**: User can set **High-pass Filter** and **Low-pass Filter** as needed. Cutoff frequency of **High-pass** can be selected as: **0.01 Hz**, **0.05 Hz**, **0.15 Hz**, **0.25 Hz**, **0.32 Hz**, **0.5 Hz** and **0.67 Hz**. Cutoff frequency of **Low-pass Filter** can be selected as: **25 Hz**, **35 Hz**, **45 Hz**, **75 Hz**, **100 Hz**, and **150 Hz**. After **High-pass filter** and **Low-pass Filter** are set, the bandwidth range of high – pass bandwidth to low - pass bandwidth can be formed.

9.4 Selecting Calculation Lead

To set the calculation lead, select **ECG Setup** > **Calc. Lead**, or on the **Normal** display interface, click on the calculation lead waveform area, select **Calc. Lead** from the popup interface to make the appropriate setting. For 3 Electrodes, II, I, and III are selectable; For 5 Electrodes, II, I, III, aVR, aVL, aVF, and V are selectable; For 6 Electrodes, II, I, III, aVR, aVL, aVF and leads corresponding to Va and Vb are selectable; For 10 Electrodes, II, I, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6 are selectable. Normal QRS complex should be:

- The normal QRS should be either completely above or below the baseline and it should not be biphasic. For paced patients, the QRS complexes should be at least twice the height of pace pulses.
- The QRS should be tall and narrow.
- The P-waves and the T-waves should be less than 0.2 mV.

NOTE:

Make sure you have selected the best lead with the best waveform amplitude and highest signal-to-noise ratio. Choosing the best lead is important for heart beat test, heart beat classification and ventricular fibrillation detection.

9.5 Monitoring Procedure

9.5.1 Preparation

The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- Select sites with intact skin, without impairment of any kind.
- Shave hair from sites, if necessary.
- Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).
- Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

9.5.2 Connecting ECG Cables

1. Attach clip or snap to electrodes prior to placement.
2. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.
3. Connect the electrode lead to the patient's cable.

CAUTION

To protect the monitor from damage during defibrillation, for accurate ECG information and to protect against noise and other interference, use only ECG electrodes and cables specified by EDAN.

9.5.3 Selecting Electrode Type

To change the electrode type, please:

1. Select the ECG parameter area, open the **ECG Setup** menu;
2. Set **Electrode Type** to **3 Electrodes**, **5 Electrodes**, **6 Electrodes**, **10 Electrodes** or **AUTO** based on the electrodes used.

9.5.4 Installing Electrodes

NOTE:

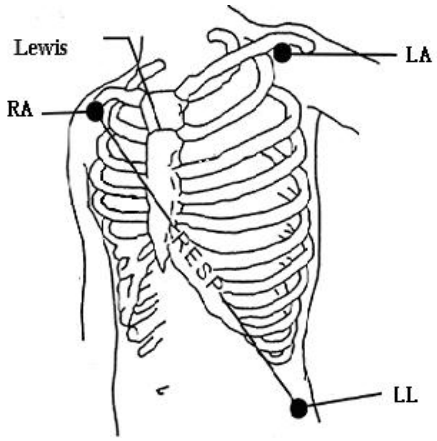
The following table gives the corresponding electrodes names used in Europe and America respectively. (Electrodes names are represented by R, L, F, N, C, C1-C6 in Europe, whose corresponding electrodes names in America are RA, LA, LL, RL, V, V1-V6.)

AHA (American Standard)		IEC (Europe Standard)	
Electrode Labels	Color	Electrode Labels	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/ Red	C1	White/ Red
V2	Brown/ Yellow	C2	White/ Yellow
V3	Brown/ Green	C3	White/ Green
V4	Brown/ Blue	C4	White/ Brown
V5	Brown/ Orange	C5	White/ Black
V6	Brown/ Purple	C6	White/ Purple

3 Electrodes Placement

Take the American standard for example, see the following figure:

- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement: on the left hypogastrium.

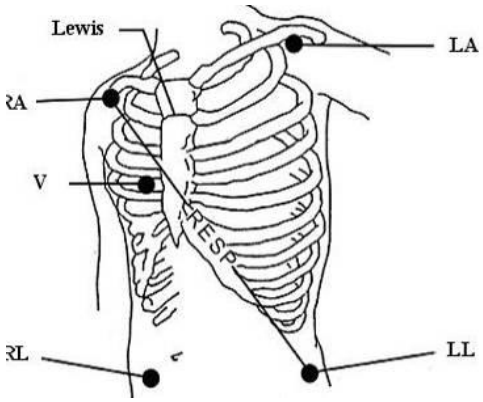


3 Electrodes Placement

5 Electrodes Placement

Take the American standard for example, see the following figure:

- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- RL placement: on the right hypogastrium.
- LL placement: on the left hypogastrium.
- V placement: on the chest, the position depends on your required lead selection.



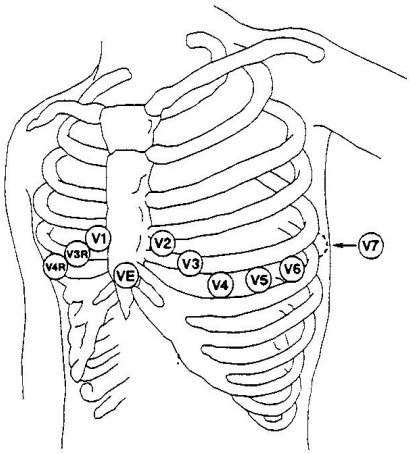
5 Electrodes Placement

NOTE:

To ensure the patient safety, all electrodes must be attached to the patient.

For 5 electrodes, attach the V electrode to one of the indicated positions as below:

- V1 On the 4th intercostal space at the right sterna margin.
- V2 On the 4th intercostal space at the left sterna margin.
- V3 Midway between V2 and V4 electrodes.
- V4 On the 5th intercostal space at the left clavicular line.
- V5 On the left anterior axillary line, horizontal with V4 electrode.
- V6 On the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R On the right side of the chest in positions corresponding to those on the left.
- VE Over the xiphoid position.
- V7 On the 5th intercostal space at the left posterior axillary line of back.
- V7R On the 5th intercostal space at the right posterior axillary line of back.

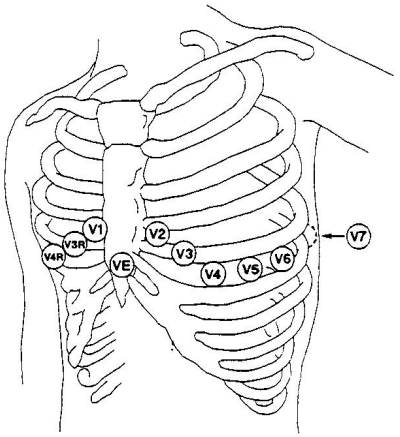


V-Electrode Placement for 5 Electrodes

6 Electrodes Placement

For the placement of 6 electrodes, please use the position of 5 electrodes in the schematic diagram to remove the two thoracic leads. The two thoracic leads Va and Vb can be placed at any two positions from V1 to V6, as shown in the following thoracic leads. To ensure that the label is correct, the selected Va and Vb placements must be set simultaneously in **ECG Setup**.

- V1 On the 4th intercostal space at the right sterna margin.
- V2 On the 4th intercostal space at the left sterna margin.
- V3 Midway between V2 and V4 electrodes.
- V4 On the 5th intercostal space at the left clavicular line.
- V5 On the left anterior axillary line, horizontal with V4 electrode.
- V6 On the left middle axillary line, horizontal with V4 electrode.



V-Electrode Placement for 6 Electrodes

10 Electrodes Placement

In 12-Lead ECG monitoring, the 10 electrodes are placed on the patient's four limbs and chest. The limb electrodes should be placed on the soft skin according to the physician's preference. The picture below shows the conventional 10 electrodes placement.

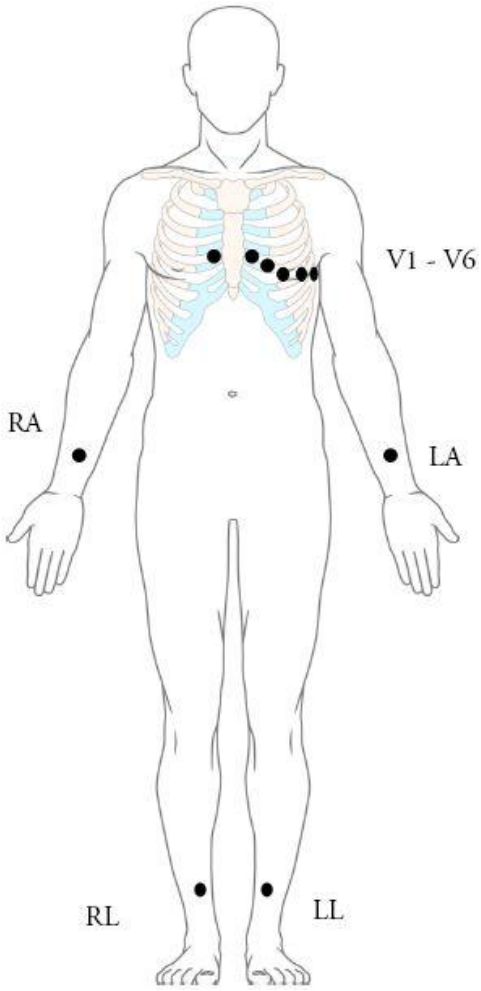
Take the American standard for example; the 10 electrodes should be placed as follows:

Limb electrodes:

- RA and LA: Place arm electrodes on the inside of each arm, between the wrist and the elbow.
- RL and LL: Place leg electrodes inside of each calf, between the knee and the ankle.

Chest electrodes:

- V1: On the 4th intercostal space at the right sterna margin.
- V2: On the 4th intercostal space at the left sterna margin.
- V3: Midway between V2 and V4 electrodes.
- V4: On the 5th intercostal space at the left clavicular line.
- V5: On the left anterior axillary line, horizontal with V4 electrode.
- V6: On the left middle axillary line, horizontal with V4 electrode.



10 Electrodes Placement

Recommended ECG Electrode Placement for Surgical Patients

WARNING

When using Electrosurgery (ES) equipment, leads should be placed in a position in equal distance from Electrosurgery electrotome and the ES grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.

Monitoring ECG leads are mainly used for monitoring the patient's vital signs. When using the patient monitor with other electrosurgery equipment, it is advised to use the counteracting defibrillation ECG lead.

The placement of the ECG leads will depend on the type of surgery that is being performed. For example, in an open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts may affect the

ECG waveform due to the use of ES (Electrosurgery) equipment. To help reduce this you can place the electrodes on the right and left shoulders, the right and left sides near the abdomen, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms. Otherwise the ECG waveform will be too small.

WARNING

ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

NOTE:

1 **If an ECG waveform is not accurate, while the electrodes are tightly attached, try to change the leads displayed on the screen.**

2 **Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.**

9.6 ECG Menu Setup

9.6.1 Setting Alarm Source

To change the alarm source, please select **ECG Setup** > **Alarm Source**, then a pop-up box is displayed:

HR: the monitor considers the HR as HR/PR alarm source;

PR: the monitor considers the PR as HR/PR alarm source;

AUTO: If the Alarm Source is set to **AUTO**, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and valid HR values are available. The monitor will automatically switch to PR as the alarm source if:

−valid HR values can no longer be measured and

−a PR source is switched on and available.

The monitor then uses the pulse rate from the measurement currently active as system pulse. If valid HR values become available again, the monitor automatically uses HR as alarm source.

9.6.2 Setting Beat Source

To change the beat source, select either **ECG Setup** > **Beat Source** or **PR Setup** >

Beat Source. Select from the following options:

HR: HR is HR/PR beat source;

PR: PR is HR/PR beat source;

AUTO: If the Beat Source is set to **AUTO**, the monitor will use HR as the beat source whenever the ECG measurement is switched on, and valid HR values are available. The monitor will automatically switch to PR as the beat source if:

- valid HR values can no longer be measured and
- a PR source is switched on and available.

If an ECG lead becomes available again, the monitor automatically uses HR as beat source and the monitor gives a "Di" tone with a blinking heart ❤ displaying in the HR parameter box when one heartbeat is detected. While a pulse is detected, the monitor gives a "Da" tone.

9.6.3 Smart Lead Off

When **Electrode Type** is **5 Electrodes**, **6 Electrodes** or **10 Electrodes** and **Smart LeadOff** is set to **On**, if the current selected calculation lead cannot detect ECG signal, the monitor automatically switches the corresponding lead as calculation lead, and switches the waveform display of calculation lead at the same time. When ECG electrode is re-connected, and the original calculation lead recover its signals, the monitor automatically switch to the original calculation lead.

To change the smart lead off setting, select **ECG Setup** > **Smart LeadOff**, and select the desired setting.

NOTE:

When Electrode Type is set to AUTO, the smart lead off function will be automatically turned on and cannot be turned off.

9.6.4 ECG Screen Layout

It varies with **Electrode Type**. When **Electrode Type** is set to **3 Electrodes**, **Screen Layout** can be set to **Normal**, and it can display one ECG waveform on the main screen.

When **Electrode Type** is set to **5 Electrodes** or **6 Electrodes**, **Screen Layout** can be set to **Normal**, **Full-Scr** and **Half-Scr**. Select **Normal** to display two ECG waveforms on the main screen; In 5 electrodes, select **Full-Scr** to display seven ECG waveforms which occupy the area of seven waveforms on the main screen; In 6 electrodes, select

Full-Scr to display eight ECG waveforms which occupy the area of eight waveforms on the main screen; In 5 electrodes, select **Half-Scr** to display seven ECG waveforms on the screen, occupying the area of four waveforms; In 6 electrodes, select **Half-Scr** to display eight ECG waveforms on the screen, occupying the area of four waveforms.

When **Electrode Type** is set to **10 Electrodes**, **Screen Layout** can be set to **Normal** and **12 Leads**. Select **Normal** to display two ECG waveforms on the main screen; select **12 Leads** to display 13 ECG waveforms.

When **Electrode Type** is set to **AUTO**, the monitor can automatically identify the electrode type according to the actual connection condition of the electrodes, and provide as much lead data as possible when the condition of the lead signal is satisfied.

NOTE:

1 **If 3 Electrodes is selected in the ECG Setup menu, only Normal can be selected for Screen Layout in the sub-menu.**

2 **In 10 Electrodes display interface, the filter can only be set to Diagnosis.**

3 **If 6 Electrodes is selected in the ECG Setup menu, Va and Vb can be respectively set to either Lead V1 ~ V6, but cannot be set to the same lead, Va is Lead V2 by default, Vb is Lead V5 by default.**

4 **If AUTO is selected in the ECG Setup menu, when the electrodes connected to patient is reduced from 10 electrodes to 3/5/6 electrodes, user can click Update Lead Setup button to enable the monitor to perform lead off alarm according to actual electrodes.**

5 **If AUTO is selected in the ECG Setup menu, Va and Vb cannot be set when the monitor recognizes the 10 electrodes system automatically. Va is fixed as V1 and Vb is fixed as V2.**

6 **After restarting, Screen Layout setting keeps consistent with the previous setting. The user needs to press**  **shortcut key to switch the Full-Scr and Half-Scr to the standard screen.**

9.6.5 Setting Pace Status

It is important to set the paced status correctly when you start monitoring ECG. To change the paced status in the ECG Setup menu, select **Pace** to toggle between **On** or **Off**. When **Pace** is set to **On**:

- Pace Pulse Rejection is switched on. This means that pacemaker pulses are not counted as extra QRS complexes.

–Paced symbol is displayed as | on the main screen. At this time, the artifact is displayed on the screen instead of the actual pacemaker crest. All pacemaker crests are the same, so do not give a diagnostic explanation about the size and shape of the pacemaker crest.

NOTE:

When monitoring a patient with a pacemaker, set Pace to On. If monitoring a patient without a pacemaker, set Pace to Off.

WARNING

1 **For patients with pacemakers, the pace must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected. When changing settings and admitting patients, please make sure the pace mode is always correct.**

2 **External pacing electrodes: When using pacemakers with external pacing electrodes on the patient, the quality of arrhythmia is severely degraded due to the high energy level in the pacemaker pulse. This can cause arrhythmia algorithms can not detect the pacemaker without capturing or asystole.**

Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Be sure to check the paced symbol on the display screen has correctly detected the pacing pulse. Keep pacemaker patients under close observation.

9.6.6 ECG Calibration

This item is used to calibrate ECG waveform. When you select this item from ECG Setup menu again, the ECG waveform calibration ends.

NOTE:

The patients can't be monitored during ECG calibration.

9.6.7 ECG Waveform Settings

To change this speed, select **ECG Waveform Setup** > **Sweep**, then select an appropriate setting from the pop-up list. The bigger the value is, the wider the waveform is.

Select **ECG Waveform Setup** > **Cascade**: Turn on or off ECG cascade. Cascade means the ECG waveforms displayed on the screen all occupy the area of two waveforms.

This function is valid only when **Screen Layout** is set to **Normal**.

9.7 12-Lead ECG Monitoring

In 12-lead display mode, 12 ECG waveforms and one rhythm lead waveform will be shown at the waveform area on the screen. The rhythm lead is for ECG calculation before entering 12-lead display mode. Also, in this mode, the filter mode is set to **Diagnosis** and cannot be changed.

NOTE:

1. **The 12-lead analysis results are for reference only and the clinical significance must be determined by the physician.**
2. **If the ECG signal is too weak, the 12-lead analysis results might be affected.**
3. **SEMIP algorithm is a 12-lead ECG automatic measurement and analysis algorithm. Regarding to the standard's instruction for ECG measurement and analysis of the monitor, please refer to *Smart ECG Measurement and Interpretation Programs User Manual_EDAN2*.**
4. **For 12-lead analysis, the gain selection contains: 1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), AUTO gain.**

9.7.1 Activating 6/10 Electrodes Monitoring

Select **Menu** > **Maintenance** > **User Maintain** > **Other Setups** > **Activate 6/10 Electrodes** in order to get the SN number which is supposed to be supplied to EDAN for a corresponding password. Enter the password on the above-mentioned interface and restart the monitor, and the **6/10 Electrodes** monitoring function will be activated.

NOTE:

If the 6/10 Electrodes monitoring fails to be activated, users can reenter the password and try to activate this function again.

9.7.2 Analysis Function

If your monitor is configured with the 12-lead ECG monitoring function, the monitor can perform automatic analysis function. To perform 12-lead analysis:

1. In the **ECG Setup** menu, set **Electrode Type** to **10 Electrodes** and set **Screen Layout** to **12 Leads**.
2. Select the shortcut key 

on the screen directly.

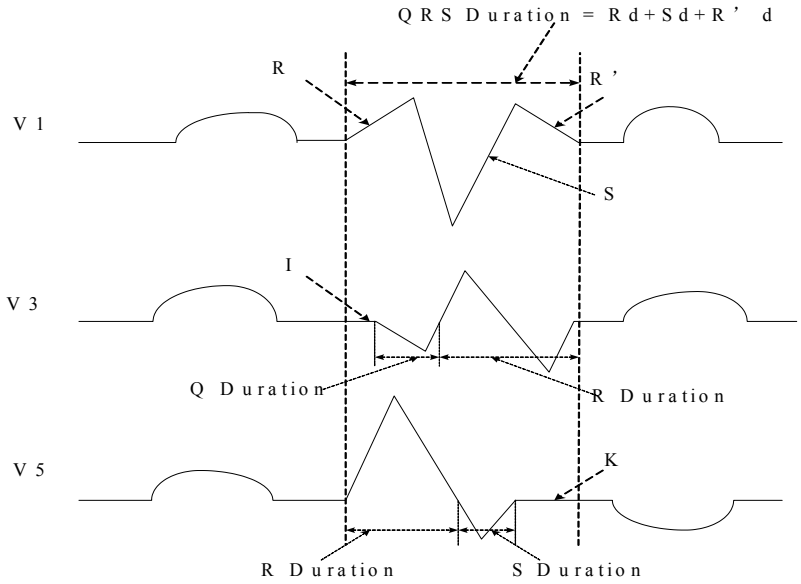
3. The analysis results will be provided in the **Analysis Review** window after approximately 10 seconds.

The measurement function provides the automatic measurement of the common parameters, such as heart rate, PR interval, QRS duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 amplitude and RV5+SV1 amplitude. The interpretation function provides the automatic analysis of hundreds of abnormal cases, such as arrhythmia, AV block, IVCD (Intraventricular Conduction Block), myocardial infarction, ventricular hypertrophy and atrial enlargement, ST-T abnormality and electrical axis deviation.

9.7.3 Waveform Durations and Isoelectric Segments

Between the global onset and offset of the QRS-complex, signal parts with duration of more than 6 ms and amplitude not exceeding 20 μV should be defined as isoelectric segments.

Because the duration of the Q-, R- or S-wave of 12 leads is respectively detected by the ECG algorithm, isoelectric parts (I-waves) after global QRS-onset or before global QRS-offset (K-wave) are excluded in the measurement duration of the respective adjacent waveform.



9.8 ST Segment Monitoring

The monitor performs ST segment analysis on normal and atrial beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numerics and ST templates on the monitor.

ST segment monitoring function is shut off by default. You can switch it to **On** when necessary. When using the ST analysis function, the ST analysis results will be

displayed on the right of the main screen.

NOTE:

1 **ST-segment analysis is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients. For this reason, the recommended and default setting for ST analysis in neonatal and pediatric modes is Off.**

2 **In ST analysis, the obtained ST value and ST template are all unaffected by the selected filter mode. ST algorithm itself uses a dedicated linear filter to ensure the signal is not distorted, and to better ensure the consistent and accurate measurement value and ST template can be obtained in different filter modes. If the doctor wants to observe the waveform to evaluate ST segment result, it is recommended to use the ST template for observation, as it is not affected by the filter mode. If the real-time waveform displayed on the interface is used to evaluate ST segment result, it is recommended to select Diagnosis mode.**

3 **Reliable ST monitoring may be influenced in following situations:**

- **You are unable to get a lead with low noise.**
- **If there is arrhythmia such as atrial fibrillation/flutter, the ECG baseline may be irregular.**
- **The patient is continually performing ventricular paced.**
- **The dominant template cannot be obtained for a long time.**
- **The patient has left bundle branch block.**

When any of above situations happens, ST monitoring should be switched off.

4 **The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.**

5 **If you use ST analysis, you must adjust the ST measurement point when you start the monitor. If the patient's heart rate or ECG waveform changes significantly, this will affect the size of the QT interval, so the ST point must be placed. If the equipotential or ST points are not set correctly, the ST fragments of the artifacts may be depressed or raised. Always ensure that the ST measurement point is suitable for your patient.**

6 **ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.**

7 **ST is calculated with a fixed delay from the R position. Changes in heart rate or the width of QRS may affect ST.**

8 **If the algorithm triggers self-learning (either manually or automatically), the**

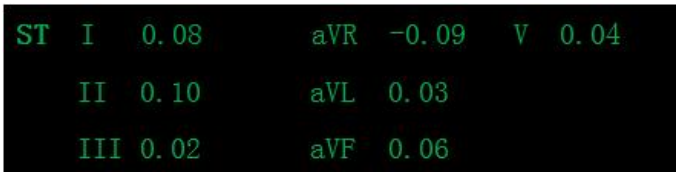
calculation of ST segment will be reinitialized.

9.8.1 Setting ST Analysis

To change ST analysis, please select **ECG Setup** > **ST Analysis**, then select **On** or **Off** from the pop-up list.

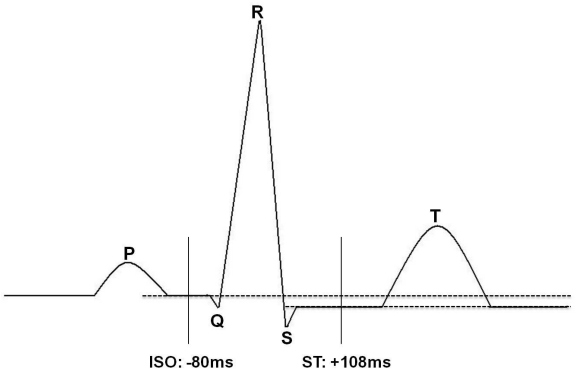
9.8.2 ST Display

Your monitor screen may be configured to look slightly different from the illustrations.



9.8.3 About ST Measurement Points

The ST value for each QRS complex is the vertical difference between the ISO point and the ST point, as shown in the diagram below. The isoelectric (ISO) point provides the baseline, and the ST point is at the midpoint of the ST segment. The J point is where the QRS complex changes its slope; as it is a fixed distance away from the ST point, it can be useful to help you position the ST point correctly.



DEF POINT

The ST and ISO measurement points need to be adjusted when you start monitoring, and if the patient's heart rate or ECG morphology changes significantly. Always ensure that ST measurement points are appropriate for your patient. Abnormal QRS complex is not considered in ST segment analysis.

NOTE:

In DEMO mode, the Analysis Point Setup button is unavailable.

9.8.4 Adjusting ST and ISO Measurement Points

Depending on your monitor's configuration, the ST point can be positioned, too.

These two points can be adjusted by turning the knob. When adjusting ST measurement point, the system will show the ST Measurement Point Window. The system displays the QRS complex template in the window. It is adjustable for the highlight bar in the window. You may select ISO or ST, switch the knob left or right to move the cursor line. When the cursor is at the required position, you may select the base point or the measurement point.

9.8.5 ST Alarm Setup

Select **ECG Setup** > **ST Analysis** > **ST Alarm Setup** to change the ST Alarm Mode:

Real Time: The user can set the alarm switch, alarm level, alarm limit and alarm record separately for each ST or all ST.

Differential: The monitor triggers the alarm according to the change of ST. The user does not need to set alarm for each ST separately, but only need to set alarm switch, alarm level and alarm difference value (-0.1~0.1) for all ST.

When **ST Alarm Mode** is differential, the user needs to select **Delay** to set the ST alarm delay time. **3 seconds** and **5 seconds** are optional, and the default is **3 seconds**. Besides, the Difference and baseline value shall be set, the difference range is 0.01 mv ~0.1 mv, and the baseline range is -1.90 mv ~1.90 mv.

9.8.6 ST View

The ST View displays a complete QRS segment for each ST lead. The color of current ST segment and ST value are consistent with the color of HR. The color of baseline and ST value are yellow. To enter ST view, please select **ST View** in **ST Analysis**.

In the ST View interface, the user can save ST baseline through clicking **Save as Base** when ST values gets stable. If no ST baseline is saved, the monitor automatically saves the baseline when the first valid and complete ST waveform appears.

In the ST View interface, the user can display the current waveform, baseline waveform, or the both by selecting **Real**, **Baseline** or **Real+Base**. The user can also hide or display ST points by selecting **Hide Points** or **Show Points**. Besides, the user can record and print the ST view.

In the ST View interface, the user can save ST segment through clicking **Save ST SEG**. Up to 20 groups of ST segments can be saved. When the 21st ST segment is saved, the earliest ST segment will be deleted.

NOTE:

The ST baseline and ST segment will be cleared in following situations:

1) **Turning off the monitor;**
2) **Changing the electrode type;**
3) **Changing the calculation lead in 3 electrodes;**
4) **Entering or exiting Demo mode;**
5) **Changing the patient type;**
6) **Admitting new patients;**

In order to view the ST value situation of each lead more intuitively, the user can enter into the ST Histogram. The horizontal axis shows the lead name while the vertical axis shows the ST value. And the bar graph is used to display the ST value result. The ST histogram refreshes with ST View synchronously.

9.9 Arrhythmia Monitoring

9.9.1 Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of adult patients in clinics, and detect the changes of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarm information. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting change of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.

ARR Alarms	Occurring Condition
Asystole	No QRS is detected for 4 consecutive seconds.
V-Fib/V-Tach	4 consecutive seconds' fibrillation wave occurs; Or 5 consecutive ventricular beats, and ventricular HR ≥100 bpm.
Run PVCs	3 ≤ the number of consecutive PVCs < 5
Couplet	2 consecutive PVCs
PVC Bigeminy	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.
PVC Trigeminy	A dominant rhythm of N, N, V, N, N, V

ARR Alarms	Occurring Condition
R on T	A type of single PVC under the condition that HR < 100, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).
PVC	Single PVC detected in normal heartbeats, and the number of consecutive single PVC ≥ 4 within 30 s.
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.
Missed Beat	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second;
Irr Rhythm	Consistently irregular heart rhythm
Pacer not Capture	No QRS complex detected in 300 ms after a pace pulse.
Pacer not Pacing	No pace pulse detected in 1.75 times RR interval after a QRS complex.
Vent Brady	5 consecutive ventricular beats, and ventricular HR < 20 bpm.
Vent Rhythm	5 consecutive ventricular beats, and 20 bpm ≤ ventricular HR < 40 bpm.
PVCs High	The measurement value of PVCs is greater than high alarm limit that has been set.
Sustain VT	The duration of ventricular tachycardia rhythm > the threshold value that has been set.
ExtremeTachy	HR > Extreme Tachycardia threshold value that has been set.
ExtremeBrady	HR < Extreme Bradycardia threshold value that has been set.
V-Tach	5 consecutive ventricular beats and ventricular HR ≥ 100 bpm.
Wide QRS Tachy	Meet tachycardia conditions, and QRS wave width ≥ 160 ms.
Non-Sustain VT	3 ≤ The number of consecutive ventricular beats < 5, and ventricular HR ≥ 100 bpm.

ARR Alarms	Occurring Condition
Afib	Atrial fibrillation alarm should meet below two conditions for 1 minute: The RR interval of normal beats must be irregular, and it can be seen that the obvious f or P waves do not exist.
Acc. Vent Rhythm	5 consecutive ventricular beats, and 40 bpm ≤ ventricular HR < 100 bpm.
Pause	No QRS is detected within the heartbeat pause threshold value that has been set.
Pauses/min High	The measurement value of Pause/min is greater than high alarm limit that has been set.
VEB	The delayed ventricular beats detected in normal heartbeats occur more than or equal to 2 times within 30 s.
Multiform PVCs	Different forms of ventricular premature beats are detected in 15 beats.
IPVC	The single ventricular premature beat between 2 sinus beats with normal interval occurs more than or equal to 3 times within 30 s.
PAC Bigeminy	The dominant rhythm of N, A, N, A, N, A, and the rhythm number exceeds the number of threshold value that has been set (N = supraventricular beat, A = atrial beat).
PAC Trigeminy	The dominant rhythm of N, N, A, N, N, A, N, N, A, and the rhythm number exceeds the number of threshold value that has been set.
Low Voltage(Limb)	The signal amplitudes of I, II and III leads shall not exceed alarm threshold value that has been set. PS: this alarm is available for 5, 6 or 10 electrodes only, not available for 3 electrodes.
NOTE: Arrhythmia monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients. For this reason, the recommended and default setting for arrhythmia monitoring in neonatal and pediatric modes is **Off**.	

Selecting an ECG lead for Arrhythmia:

In arrhythmia monitoring, it is important to select the appropriate lead.

For non-paced patients, the guidelines are:

- QRS should be tall and narrow (recommended amplitude > 0.5 mV)
- R wave should be above or below the baseline (but not biphasic)
- T wave should be smaller than 1/3 of the R wave height
- P wave should be smaller than 1/5 of the R wave height.

For paced patients, in addition to above guidelines, the pacemaker signal should also:

- Not wider than normal QRS
- The QRS complexes should be at least twice the height of the pacing pulse
- Large enough to be detected, without repolarization signal

According to Standard IEC 60601-2-27, the minimum detection level of the QRS complex is set to 0.15 mV, to prevent the detection of P-wave or baseline noise as QRS complexes. Adjusting ECG displayed waveform size (gain adjustment) won't influence ECG signals which are used for arrhythmia analysis. If the ECG signal is too small, a false asystole alarm may occur.

Aberrantly-Conducted Beats:

As not recognizing the P waves, the monitoring system is difficult to distinguish between aberrantly-conducted beats and ventricular heartbeat. If the aberrantly-conducted beat is similar to ventricular tachycardia, it may be classified as ventricular. Make sure to select such a lead, the aberrantly-conducted beats have an R wave that is as narrow as possible to minimize the incorrect calls. The ventricular should have a different appearance from "normal heartbeat". Physicians should be more alert to these patients.

Intermittent bundle branch block: bundle branch block or other bundle obstruction phenomenon is a challenge for arrhythmia algorithm. If the QRS wave during the block has a considerable change in morphology compared to the normal QRS of learning, the blocked heartbeat may be misclassified as ventricular tachycardia, resulting in an incorrect chamber alarm. Make sure to select such a lead, which blocks the heartbeat of the R wave as narrow as possible to minimize the wrong classification. Ventricular heartbeat should have a different appearance from "normal heartbeat". Physicians should be more alert to these patients.

NOTE:

1. **Arrhythmia analysis is intended to be used with MFM-CMS 2.65 or above version. Please update MFM-CMS if its version is lower than 2.65.**
2. **Heart rate reading may be affected by cardiac arrhythmias. Do not rely entirely on heart rate alarms when monitoring patients with arrhythmia. Always keep these patients under close surveillance.**
3. **Since the arrhythmia detection algorithm sensitivity and specificity is less than 100%, sometimes there may be some false arrhythmias detected and also some true arrhythmia events may not be detected. This is especially true when the signal is noisy.**
4. **The ventricular HR mentioned above refers to: when the consecutive PVCs number ≥ 3, the algorithm calculates ventricular HR with the average of 2-8 RR intervals. The methods are different from the HR Averaging Method of the**

monitor. Therefore, the ventricular HR values calculated by algorithm may be different from the HR values calculated by HR Averaging Method. The ventricular HR is for judging arrhythmias and is not exactly equal to the HR displayed on the interface.

5 **The ARR analysis results and HR values obtained during ARR analysis and HR calculation are not affected by the selected filter mode. The algorithm itself has independent data-flow processing, which can better ensure the consistent and accurate results in different filter modes.**

6 **Atrial fibrillation alarm should meet below two conditions for 1 minute:**

- **The RR interval of normal beats must be irregular,**
- **It can be seen that the obvious f or P waves do not exist.**

7 **Atrial fibrillation analysis is only applicable to adult patients and should not be performed for PVC or pacing fluctuations.**

8 **Atrial flutter cannot be detected by the atrial fibrillation algorithm because most of their RR intervals are regular.**

9 **In following situations, atrial fibrillation alarm detection error may occur:**

- **Sinus arrhythmia**
- **Atrioventricular block**
- **Frequent ventricular premature beats**
- **Myoelectric interference**
- **Electrode motion artifact**

9.9.2 ARR Analysis Menu

9.9.2.1 Switching ARR Analysis On and Off

To switch ARR Analysis on or off, in the **ECG Setup** menu, select **ARR Analysis** to toggle between **On** and **Off** from the popup interface.

9.9.2.2 ARR Alarm Setup

Select **ECG Setup** > **ARR Analysis** > **ARR Alarm Setup** to change the following ARR alarm settings:

- Separately switch on or off each arrhythmia alarm and set the alarm level.
- Select **All Alarms On/All Alarms Off** to switch on or off all arrhythmia alarms except key ARR alarms.
- Set the threshold of certain arrhythmia alarms. When an arrhythmia exceeds its threshold, an alarm will be triggered.
- Select **Default** to restore the ARR alarm settings to factory defaults.

Confirm the changes to make the settings effective.

V-Fib/V-Tach, **ExtremeTachy**, **ExtremeBrady** and **Vent Brady** are key ARR alarms and they are preset to be on. The user can switch on/off those key ARR alarms only when you have enabled **Key ARR Alarm Switch Authority**. To enable the authority,

1. Select **Menu** > **Maintenance > User Maintain**, and enter the required password.
2. Select **Alarm Setup** and set **Key ARR Alarm Switch Authority** to **On**. If any of key ARR alarms is switched off, the bottom information area will prompt **Key ARR Alarm Off**. Clicking the prompts can view the details.

Asystole and **Sustain VT** alarms are key ARR alarms as well and they are preset to **On** and cannot be turned off.

WARNING

When the ARR 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.

NOTE: Pacer not Capture and Pacer not Pacing alarms are available only when Pace is set to On.

9.9.2.3 Adjustable Range of ARR Alarm Threshold

ARR Alarm	Range
PVCs High	1/min to 99/min
Pause	2 s, 2.5 s, 3 s
ExtremeTachy	Adult: 120 bpm to 300 bpm; Pediatric/neonatal: 120 bpm to 350 bpm
PAC Bigeminy PAC Trigeminy	3/min to 50/min
Pauses/min High	1/min to 20/min
Sustain VT	15 s to 45 s
ExtremeBrady	15 bpm to 60 bpm
Low Voltage(Limb)	0.3 mV to 0.8 mV

NOTE: Both the ARR alarm information and threshold value are displayed when the above ARR alarms are triggered.

9.9.2.4 ARR Selflearning

Pick this item **ARR Selflearn** to start a learning procedure, and **ECG ARR Learning** displayed on the screen.

The ARR selflearning will start automatically in the following status:

- Switching the ARR Analysis from Off to On;
- Changing patient type or electrodes type;
- Connecting or switching calculation leads;
- Changing pacemaker status;
- Exiting DEMO or Standby mode;
- Admitting a patient;
- Switching calibration mode into normal measurement mode;

NOTE:

1 **During the relearning phase of the algorithm, arrhythmia detection may not be available. So you should closely monitor the patient condition during and for several minutes after the learning phase to allow the algorithm to reach optimal detection performance.**

2 **Take care to initiate ARR selflearning only during periods of predominantly normal rhythm and when ECG signal is relatively noise-free. If ARR selflearning takes place during arrhythmia, the ectopics may be incorrectly learned as normal QRS complex. This may result in missed detection of subsequent events of arrhythmia.**

3 **If ARR selflearning is performed during ventricular rhythm, ventricular heartbeats may be erroneously identified as normal QRS complexes. This may lead to missed ventricular tachycardia and ventricular fibrillation events.**

Due to this reason, you should:

1) Take care that ARR selflearning may start automatically;

2) Response to electrodes off information;

3) Always check the correctness of arrhythmia alarm.

9.10 QT Analysis

The QT interval is the time from the beginning of Q wave to the end of T wave. It measured the total duration of the depolarization (QRS duration) and repolarization (ST-T) phases of ventricular action potential. QT analysis can help detect extended QT

interval syndrome.

9.10.1 Measurement Limitations

The following clinical status of the patient may affect the QT analysis, and the inaccurate measurement may but is not limited to the following reasons:

- The T-wave is very flat
- Atrial flutter and atrial fibrillation make T wave is difficult to define
- The end of the T-wave is difficult to define because of the presence of U-waves
- A high heart rate causes the P-wave to encroach on the end of the previous T-wave
- Noise or the QRS wave variation is too big

In these cases, the user should choose a lead with good T wave amplitude and no visible oscillations, and without a dominant U wave or P wave.

In some conditions, such as left or right bundle branch block or cardiac hypertrophy causes broaden QRS complex. If long QTc is observed, verify it to ensure that it is not caused by QRS broadening.

Since normal beats followed by ventricular beats are not included in the analysis, QT measurement could not be carried out when there was bigeminy rhythm.

When the heart rate changes, it may take several minutes for the QT interval to stabilize. In order to obtain reliable QTc calculations, it is important to avoid areas where the heart rate changes.

NOTE:

QT/QTc measurements should always be validated by a qualified clinician.

9.10.2 Switching QT Analysis On and Off

To switch QT Analysis on or off, in the **ECG Setup** menu, select **QT Analysis** to toggle between **On** and **Off** from the popup interface.

9.10.3 QT Display

The following figure is QT display for your reference only. The graphics on your monitor may be slightly different.

9.10.4 Selecting QT Analysis Lead

There are two modes for selection:

All lead: Use all available leads (expect pressurized the limb lead) to produce an overall QT measurement, user can select **ALL** through **ECG Setup** > **QT Analysis** > **Analysis Lead**.

Single lead: QT measurements were performed using all single leads available in the lead (except the pressurized limb lead). User selects any lead in **Analysis Lead** menu to enter into single lead mode.

9.10.5 Selecting Calculation Formula

The monitor uses Bazett formula to correct QT values by default. There are four alternative formulas: **Bazett**, **Fridericia**, **Framingham** and **Hodges**.

Hodges: $QTc = QT + 1.75 \times (HR - 60)$

Bazett: $QTc = QT \times \left(\frac{HR}{60}\right)^{\frac{1}{2}}$

Fridericia: $QTc = QT \times \left(\frac{HR}{60}\right)^{\frac{1}{3}}$

Framingham: $QTc = QT + 154 \times (1 - \frac{60}{HR})$

9.10.6 Setting QT Baseline

To quantitatively express the QTc values change, the user can set a QTc baseline, the baseline is used for calculating ΔQTc value. The user can set the baseline through **ECG Setup > QT Analysis** > **Save Baseline**, and the monitor displays **The Baseline is saved at:** (Time). If no baseline has been set, the first five minute QTc value after the QT measurement begins will be automatically set as the baseline. If a new baseline is set, the previous baseline is discarded. Because ΔQTc alarm is based on the difference of the baseline with the current values, inappropriate baseline settings may lead that no ΔQTc alarm is generated.

NOTE: The QT baseline will be cleared in following situations:

1) **Turning off the monitor;**
2) **Changing the electrode type;**
3) **Changing the calculation lead in 3 electrodes;**
4) **Changing the patient type;**
5) **Admitting new patients;**
6) **Enters or exits Demo mode.**

If QT analysis is needed, please reset the baseline.

9.10.7 QTc Alarm Setup

Select **ECG Setup** > **QT Analysis** > **Alarm Setup** to change the following QT alarm settings:

- Separately switch on or off QTc alarm and ΔQTc alarm and set the alarm level.
- Set the thresholds of QTc alarm and ΔQTc alarm. When QTc value or ΔQTc value exceeds the preset thresholds, an alarm will be triggered.

9.10.8 QT View

To enter QT view, please select **ECG Setup** > **QT Analysis** > **QT View**. In the QT View interface, the color of current QT segment and QT value are consistent with the color of HR. The color of baseline and QT value are yellow.

In the QT View interface, the user can save QT baseline through clicking **Save as Base** when QT values gets stable. If no QT baseline is saved, the monitor automatically saves the baseline when the first five minutes value appears. Besides, the user can record and print the QT view.

9.11 ECG Summary

ECG summary provides ECG statistics of the current patient over the time interval. It allows the user to know the patient's condition of the latest 24 hours. ECG summary contains HR statistics, QT statistics, ST statistics and ARR statistics.

To perform ECG summary, please select **ECG Setup** > **ECG Summary**. The ECG summary interface is default to display HR statistics.

- HR statistics interface: average HR throughout the whole day/daytime/nighttime; maximum HR, minimum HR, and measurement time.
- QT statistics interface: average QT/QTc, maximum QT/QTc, minimum QT/QTc, and measurement time.
- ST statistics interface: maximum ST corresponding to each lead, minimum ST corresponding to each lead, and measurement time.
- ARR statistics interface: Arrhythmia alarm name and alarm times throughout the whole day/daytime/nighttime.

The night time means the period for ECG summary at night time. The night time can be set according to 24 hours format or 12 hours format. The minimum period can be set to 30 minutes. The default start time of night time is 20:00 (PM) and the default end time of night time is 06:00 (AM).

Chapter 10 Monitoring RESP

10.1 Overview

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

10.2 RESP Safety Information

WARNING

1. **If you do not set the Hold High and Hold Low for the respiration correctly in manual detection mode, it may not be possible for the monitor to detect apnea. If you set the Hold High and Hold Low too low, the monitor is more likely to detect cardiac activity, and to falsely interpret cardiac activity as respiratory activity in the case of apnea.**
2. **Respiration measurements cannot detect all underexposure sudden events, nor can they distinguish between central, obstructive and mixed respiratory asphyxial events. It only prompts alarm in a predetermined time if the last breath is detected and the next breath is not detected, so it cannot be used for diagnostic purposes.**
3. **If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3 V/m), field strengths above 3 V/m may cause erroneous measurements at various frequencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.**
4. **Cardiogenic artifact in impedance respiration monitoring may make it difficult to detect breaths or may otherwise be counted as breaths. In some instances, the breath rate may also correspond to the heart rate making it difficult to determine if the signal is due to breathing or the cardiac cycle. Do not rely on RESP monitoring as the sole method for detecting cessation of breathing. Follow hospital guidelines and best clinical practices for apnea detection including monitoring additional parameters that indicate the patient's oxygenation status, such as $EtCO_2$ and SpO_2.**
5. **For the diagnosis of apnea, especially in premature infants and infants, the safety and effectiveness of respiration measurements have not been validated.**
6. **Respiration measurement cannot be performed when ESU is used.**

WARNING

7 **To monitor the respiration, only non-ESU-proof accessories can be used. This is because the internal impedance of the ESU-proof accessories required to be used for electrosurgical operation is too large.**

8 **In manual detection mode, after changing the gain of the respiration wave, be sure to check the setting of hold high and hold low.**

9 **Some implantable pacemakers can adjust their triggering frequency according to the "minute ventilation rate." Impedance respiration measurements may cause these pacemakers to react incorrectly. To prevent this, turn off the respiration measurement.**

10 **RESP Apnea alarm is based on inadequate thoracic impedance change.**

11 **When ECG electrode is placed on patient's limb, the impedance respiration may be unreliable.**

12 **RESP Apnea alarm should not be used or relied upon while the patient is unattended.**

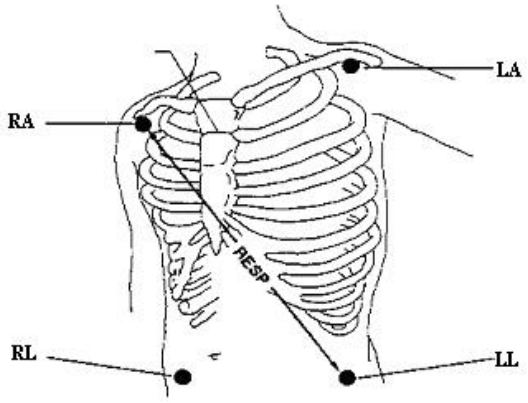
NOTE:

The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.

10.3 Electrode Placement for Monitoring RESP

Correct patient skin preparation techniques for electrode placement are important for RESP measurement: you will find this information in the chapter on ECG.

The RESP signal is always measured between two of the ECG electrodes. There are two standard ECG leads for selection: I lead (RA and LA) and II lead (RA and LL).



Electrodes Placement for 5 Electrodes

10.4 Cardiac Overlay

Cardiac activity that affects the RESP waveform is called cardiac overlay. It happens when the RESP electrodes pick up impedance changes caused by the rhythmic blood flow. Correct electrode placement can help to reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes. This is particularly important for neonates.

10.5 Chest Expansion

Some patients, especially neonates, expand their chests laterally. In these cases it is best to place the two respiratory electrodes in the right mid-axillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the respiratory wave.

10.6 Abdominal Breathing

Some patients with restricted chest movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.

NOTE:

Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

10.7 Setting RR Source

Set **RR Source** to **SpO_2**, **ECG** or **Auto** in RESP Setup menu. The RR source is displayed in the RESP parameter area.

When it is set to **Auto**, the monitor automatically selects the RR source with the following priority: ECG > SpO_2.

10.8 Selecting RESP Lead

To change RESP lead, in the **RESP Setup** menu, select **RESP Lead** to pick up the appropriate lead from the pop-up list.

10.9 Changing Hold Type

To change the calculation mode, in the **RESP Setup** menu, set **Hold Type** to **Manual** or **AUTO**. When it is set to the **AUTO** mode, **Hold High** and **Hold Low** are unavailable, and the monitor can calculate the respiration rate automatically. When it is set to the

Manual mode, you can adjust the broken lines in RESP area by the **Hold High** and **Hold Low** items.

10.10 Changing the Size of the Respiration Wave

Select the RESP waveform area to open the **RESP Waveform Setup** menu:

- Select **AMP**, and choose an appropriate value. The bigger the value is, the higher the waveform amplitude will be.
- Select **Sweep**: select an appropriate setting from the pop-up list.

10.11 Changing the Apnea Delay

The RESP Apnea alarm is a high priority red alarm used to detect apnea. The apnea delay time defines the time period between the point where the monitor cannot detect any respiration activity and the indication of the apnea delay. Users should set it cautiously.

1. In the **RESP Setup** menu, select **Apnea Alm**.
2. Select the appropriate setting from the popup list.

Chapter 11 Monitoring SpO_2

11.1 Overview

SpO_2 is used to measure arterial blood oxygen saturation, which is the percentage of oxyhemoglobin in the arterial blood. SpO_2 parameter can also provide pulse rate (PR), respiratory rate (RR) and a plethysmogram wave (Pleth).

11.2 SpO_2 Safety Information

WARNING

1. **Do not use the SpO_2 sensors if the packaging or the sensor is damaged and return them to the vendor.**
2. **If the SpO_2 sensor cannot work properly, please reconnect the sensor or change a new one.**
3. **Correct and proper sensor application: if the sensor is too loose, it might compromise the optical alignment, and even cause the sensor to fall off. If the sensor is too tight, (such as the application site is too large or becomes too large due to edema), excessive pressure and local tissue ischemia, hypoxia and lack of nutrition may occur on the application site. Prolonged and continuous monitoring may increase the risk of skin irritations or lacerations. To avoid these damages, users should periodically check surrounding skin of application site according to the patient's condition and pressure sensor, inspect if there is sign of stress-related damage in surrounding tissue, and regularly change the application site. For the patients whose fluid is easy to transfer and/or the patients with systemic or localized edema, users should inspect the skin and change application site more frequently.**
4. **Use only EDAN permitted sensors and extension cables with the monitor. Other sensors or extension cables may cause improper monitor performance and/or minor personal injury.**
5. **High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the high limit alarm off.**
6. **When serious arrhythmia is present, the SpO_2 pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO_2) value.**
7. **Misapplied sensor or sensor that becomes partially dislodged may cause either over or under reading of actual arterial oxygen saturation.**

WARNING

8 **Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and patient conditions.**

9 **Inaccurate RR measurements may be caused by:**

- **Low arterial perfusion.**
- **Motion induced artifact.**
- **Severe anemia.**
- **Arrhythmia**

10 **RR does not provide an alarm when the patient is breathing poorly or has apnea. The function is not suitable for use as an apnea monitor.**

11 **The Respiratory rate monitoring is not applicable to neonate patients. When monitoring respiratory rate, the patient should be quiet, motionless and calm.**

NOTE:

1 **Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line. When measuring SpO_2 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 **SpO_2 waveform is not directly proportional to the pulse volume.**

4 **The device is calibrated to display functional oxygen saturation.**

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

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

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

8 The first RR is measured within 30 seconds.

11.3 Measuring SpO_2

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

Measurement Procedure

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient.

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:

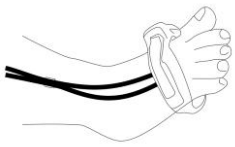
- Check the sensor outside and inside. To inspect the inside, gently open the sensor cavity and check splits on or next to the transparent silicone that covers the optical elements.
- Any sensor showing signs of damage or alteration must not be used for further patient monitoring; instead, dispose of 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 ring finger of the non-dominate hand is preferred. Alternatively, the other fingers on the non-dominate hand may be used.
- The big toe or long toe (next to the big 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. Adjust the finger to ensure that the pad of the finger completely covers the sensor detection 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).

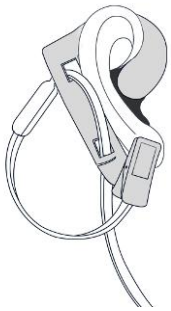
Applying Neonatal Finger (or Toe) Wrap Sensors:

- 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 part on top of the ear; reinforce it to prevent falling off or 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 SpO_2 socket.

WARNING

1 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.

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

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

11.5 Assessing the Validity of a SpO_2 Reading

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

Generally, the quality of the SpO_2 pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO_2 values also reflects the signal quality. Different from varying SpO_2 readings caused by physiological factors, unstable SpO_2 readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO_2 readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

1 The SpO_2 accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. SpO_2 measurements are statistically distributed; only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies are composed of healthy men and women from age 18 to 50, 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 SpO_2 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 Pulsatile Strength

Pulsatile Strength can be set to **Perfusion Index** or **Signal Intensity** in **SpO_2 Setup** menu:

- **Perfusion Index** (**PI**) gives a percentage for the pulsatile signal to the non-pulsatile signal at the monitoring site. PI reflects the perfusion level at the monitoring site, which can also indicate arterial pulse signal strength. PI below 0.1% indicates the low perfusion at the monitoring site. Reposition the sensor or find a better site.
- **Signal Intensity** (**SI**) is a numeric value indicating the arterial pulse signal intensity, which can be used to assess the SpO_2 signal intensity. SI is indicated by a value ranging from 0 to 10. The bigger the value is, the better the signal quality will be. The signal quality is at its maximum when the value reaches 10. When SI is below 2, it indicates the poor signal quality at the monitoring site; you need to reposition the sensor or find a better site.

The PI or SI value will be displayed in the SpO_2 parameter area.

NOTE:

When the Pulsatile Strength is displayed as PI, the pulsatile strength value sent by the monitor to the MFM-CMS is still SI.

11.8 Measuring SpO_2 and NIBP Simultaneously

While measuring SpO_2 and NIBP on the same limb simultaneously, the user can set **NIBP Simul** to **On** in **SpO_2 Setup** menu to lock the SpO_2 alarm status until the NIBP measurement ends. The alarm occurred before entering NIBP Simul will not disappear. If **NIBP Simul** is set to **Off**, low perfusion caused by NIBP measurement may lead to inaccurate SpO_2 readings and therefore cause false physiological alarms.

11.9 Setting Pitch Tone

If tone modulation is on, the PR sound lowers when the SpO_2 level drops. In the **SpO_2 Setup** menu, select pitch tone to toggle between **On** and **Off**.

11.10 Setting Sensitivity

The different sensitivity indicates different refresh frequency. **High** indicates the refresh frequency of SpO_2 value is the most frequent. To change the sensitivity, please follow the steps:

1 Select the **SpO_2 Setup** menu;

2 Select **Sensitivity** on the interface and select the desired sensitivity from the popup list.

11.11 Setting Sensor Light Intensity Display

In the **SpO_2 Setup** menu, select sensor light intensity to toggle between **On** and **Off**. The default setting is **Off**. When it is set to **On**, the sensor light intensity icon will be displayed in the SpO_2 parameter area to indicate five different levels of intensity.

11.12 RR (Respiratory Rate)*

* Only applicable to the EDAN SpO_2 module.

Respiratory rate can be determined by plethysmography. This method can be used to measure the number of breaths per minute (rpm) for adults and pediatrics according to the cyclic changes of Pleth or PPG, so as to establish the respiratory rate measurement.

Optical, pleth-based measurements (SpO_2 and RR) can be affected by the following:

- Improper sensor application or use of incorrect sensor.
- NIBP cuff applied to the same arm as the sensor site.
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous congestion.
- Abnormal venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg position).
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Moisture, birthmarks, skin discoloration, nail aberration, deformed fingers, or foreign objects in the light path.
- Elevated levels of bilirubin.
- Physiological conditions that can significantly shift the oxygen disassociation curve.
- A physiological condition that may effect vasomotor tone or changes in vasomotor tone.

Inaccurate RR measurements may be caused by:

- Low arterial perfusion.
- Motion induced artifact.
- Severe anemia.
- Arrhythmia

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 SpO_2 signal or any arterial pressure.

12.2 Setting PR Source

The monitor provides PR source options. You can select SpO_2 or arterial pressure labels as the PR source in the **PR Source** list on the **PR Setup** menu.

12.3 Setting PR Volume

Select **PR Setup** > **PR Volume**, 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 of pulse has positive correlation with measurement value.

12.4 Selecting the Active Alarm Source

In most cases, the HR and PR numerics are identical. In order to avoid simultaneous alarms on HR and PR, the monitor uses either HR or PR as its active alarm source. To change the alarm source, select **PR Setup** > **Alarm Source**, then a pop-up box is displayed:

- **HR**: if you want HR to be the active alarm source.
- **PR**: if you select PR as the active alarm source. Be aware that if you select PR as the alarm source, ECG HR alarms are inactivated.
- **AUTO**: If the Alarm Source is set to Auto, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and valid HR values are available. The monitor will automatically switch to PR for the alarm source if:
  - valid HR values can no longer be measured and
  - a PR source is switched on and available.

The monitor uses the pulse rate from the currently active measurement as system pulse. If valid HR values become available again, the monitor automatically uses HR as alarm source.

Chapter 13 Monitoring NIBP

13.1 Overview

This monitor uses the oscillometric method for measuring NIBP.

iCUFS algorithm: 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.

iFAST algorithm: During the cuff inflation, oscillometric devices detect the change of pulsation amplitude due to the cuff pressure change. The pulsations increase in amplitude and reach a maximum (which approximates to the mean pressure). The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures. Oscillometric devices terminate the NIBP measurement and deflate quickly once the systolic pressure is determined.
The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ISO 81060-2) 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.

When selecting the patient type on the patient admitting interface, it is recommended to choose **Adult** for patients greater than 21 years of age, **Pediat** for patients greater than 3 through 21 years of age and **Neonat** for patients from birth through 3 years of age.

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. **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.**

WARNING

4 **Use clinical judgment to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**

5 **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.**

6 **Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.**

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

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

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

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 the 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.
- **Auto** – continually repeated measurements (between 1 and 480 minute adjustable interval). The interval can be user defined, and the default interval of user defined is 2.5 minutes. After the first measurement starts manually, the monitor will automatically measure NIBP as preset interval. When the measurement interval is set to 5 min, 10 min, 15 min, 30 min, 60 min, 90 min, 120 min, 180 min, 240 min, 360 min and 480 min, the system will automatically adjust the next measurement time. Here’s an example.

Auto Measurement Interval	Current Time	Next Measurement Time
5 min	12:02	12:05, 12:10, 12:15, 12:20, and so forth.
10 min	12:02	12:10, 12:20, 12:30, 12:40, and so forth.
15 min	12:02	12:15, 12:30, 12: 45, 13:00, and so forth.
30 min	12:02	12:30, 13:00, 13:30, 14:00, and so forth.
60 min	12:02	13:00, 14:00, 15:00, 16:00, and so forth.
90 min	12:02	13:00, 14:30, 16:00, 17:30, and so forth.
120 min	12:02	13:00, 15:00, 17:00, 19:00, and so forth.
180 min	12:02	13:00, 16:00, 19:00, 22:00, and so forth.
240 min	12:02	13:00, 17:00, 21:00, 1:00, and so forth.
360 min	12:02	13:00, 19:00, 1:00, 7:00, and so forth.
480 min	12:02	13:00, 21:00, 5:00, 13:00, and so forth.

When the completion time of manual measurement to the first hourly time is less than or equal to 30 seconds, the measurement will not be performed at the first hourly time, and the first automatic measurement will be delayed to the next hourly time.

- **Continuous**- the measurement will run consecutively in five minutes, then the monitor enters manual mode.
- **Sequence**- after the first measurement starts manually, NIBP measurements run automatically according to the preset phase and interval. The phase can be selected as **4**, **5** and **6**. The interval can be set as **1 min**, **2 min**, **3 min**, **4 min**, **5 min**, **10 min**, **15 min**, **30 min**, **60 min**, **90 min**, **120 min**, **180 min**, **240 min**, **360 min**, and **480 min**. The user can also set the measurement times in each phase, there are several selections: **Off**, **1**, **2**, **3**, **4**, **5**, **6**, **7**, **8**, **9**, **10**, **11**, **12**, **13**, **14**, **15**, **16**, **17**, **18**, **19**, **20**, **21**, **22**, **23**, **24**, **25**, **26**, **27**, **28**, **29**, **30** and **Continuous**.

WARNING

Prolonged non-invasive blood pressure measurements in Auto, Continuous or Sequence 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

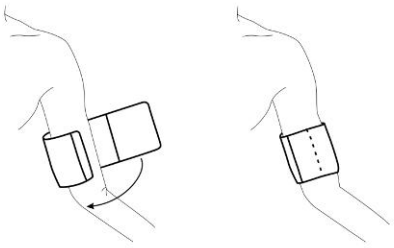
To obtain accurate measurements, the following operating steps need to be observed:

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;
- 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 or leg and follow the instructions below.



Cuff Usage

- Ensure that the cuff is completely deflated.

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

3. Check whether the patient type is appropriately selected. Access the **Patient Setup** menu from **Menu**. Turn the knob to select the required patient **Type** in the **Patient Info.** menu.
4. Select a measurement mode in the **NIBP Setup** menu. Refer to Section ***Operation Prompts*** for details.
5. Set the **NIBP unit** in **User Maintain** (mmHg, cmH_2O or kPa, 1 mmHg = 0.133 kPa, 1 mmHg=1.36 cmH_2O).
6. Press the button on the front panel or shortcut key on the screen to start a measurement.

7. 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.**

13.5.1 Operation Prompts

1. Manual Measuring

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Manual**. Then press the button on the front panel or shortcut key on the screen to start a manual measurement.

2. Automatical Measurement

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Auto**, then press the button on the front panel or shortcut key on the screen to start the automatical measurement according to the selected time interval. Press the button or shortcut key to exit in advance.

During the idle period of measurement process, press the button on the front panel or shortcut key on the screen at any time to start a manual measurement. Then press the button on the front panel or shortcut key on the screen to stop manual measurement and the system continues to execute auto measurement program according to the selected time interval.

3. Continuous measurement

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

4. Sequence measurement

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Sequence**, then click **Sequence**, in **Sequence Measurement Setup**, set the **Phase Counts**, **Times** and **Interval** to start a sequence measurement.

5. Stopping continuous measurement

During continuous measurement, press the button on the front panel or shortcut key on the screen at any time to stop continuous measurement.

13.6 NIBP Multi-Review Window

To set the display of NIBP measurements, select **NIBP Setup** > **Review**:

- When it is set to **On**, a window for NIBP measurements will be displayed at the waveform area on the main interface, and the size of this window varies depending on the numbers of displayed waveforms.
- When it is set to **Off**, the window is unavailable on the screen.

13.7 Resetting NIBP

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 Maintain** menu to activate self-test procedure, and thus restore the system from abnormal performance.

13.8 Selecting NIBP Algorithm

The EDAN NIBP module supports two measurement algorithms: iCUFS and iFAST. iCUFS measurement is applicable to adults, pediatrics and neonates. iFAST measurement shortens the blood pressure measurement time and rapidly outputs values, which is applicable to adults and pediatrics. It is also intended for use with pregnant, including pre-eclamptic patients.

To set the NIBP algorithm, select **User Maintain** > **NIBP Maintain** and set **NIBP Algorithm** to **iCUFS** or **iFAST**.

13.9 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.

13.10 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 **User Maintain > NIBP Maintain**.
5. Select **Leakage Test**. Then the prompt **Leak. Test Running** will appear indicating that the system has started the leakage test.

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

6. If the alarm information **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.

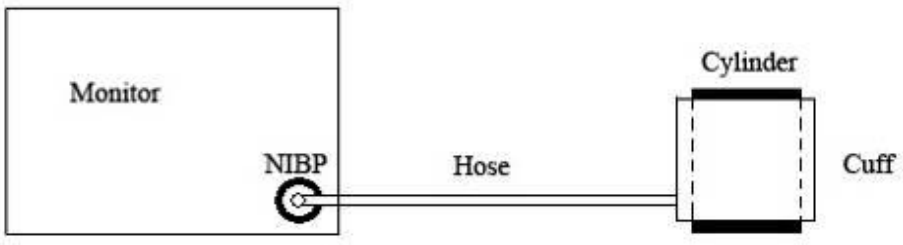


Diagram of NIBP Air Leakage Test

13.11 Setting Inflation Mode

To change the inflation mode:

1. Select **NIBP Setup** > **Inflation Mode**;

2. Choose **Manual** or **AUTO** from the pull-down list.
   - If **Manual** is 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.

13.12 Cleaning Mode

The cleaning mode can remove the dust and foreign matters in the air valve to ensure the accuracy of NIBP measurement. To start the cleaning mode, please select **User Maintain** > **NIBP Maintain** > **Cleaning Mode**, the monitor displays: **Be sure the cuff is disconnected from monitor**, after confirmation and clicking **Start Cleaning** button, cleaning mode starts. The cleaning mode lasts three minutes. In this mode, the monitor displays **Cleaning in progress**, the remaining time of cleaning mode and cuff value are also displayed. When the counting down finishes, the monitor exits cleaning mode automatically, if the user needs to exit the cleaning mode in advance, please click **Stop** button.

When the air pressure is abnormal, the monitor will automatically turn off the cleaning mode and display the prompt message: **Cleaning failed**.

NOTE:

Cleaning mode is only available when the patient type is adult.

13.13 Assisting Venipuncture

The user can use the NIBP cuff to cause a pressure close to diastolic pressure, so as to block the venous blood vessel and therefore help venipuncture. To assist venipuncture:

1. Select **NIBP Setup** > **Venipuncture**;
2. Select the appropriate **Cuff Pressure** according to the patient type;
3. Select **Start**, the monitor displays: **Venipuncture Starting**.
4. Wait until the monitor prompts **In venipuncture process**. If an abnormal alarm occurs before it, no follow-up operation can be carried out. Restart the procedure after checking if necessary;
5. Puncture vein and draw blood sample;
6. Select **Stop** to deflate the cuff. If you do not deflate the cuff, the cuff automatically deflates when the venipuncture time expires (170 seconds for adult and pediatric patient, 85 seconds for neonatal patient).

During venipuncture, pay attention to the cuff pressure and the countdown displayed in the NIBP numerics area. When the remaining time is 30 seconds, the monitor issues a reminder tone and the countdown displays in red, prompting the user that the venipuncture time is to expire.

NOTE:

1 **Only when the monitor exits Venipuncture menu, the user can do other operations.**

2 **When the monitor is in DEMO mode, privacy mode, standby mode, continuous measurement process, manual measurement process, sequence measurement process or auto measurement process, Assisting Venipuncture function is not available.**

13.14 NIBP Summary

NIBP summary provides NIBP statistics of the current patient over the time scale. It allows the user to know the patient's condition over the latest 24 hours.

To perform NIBP summary, please select **NIBP Setup** > **NIBP Summary**. NIBP summary interface provides the following information:

- NIBP data throughout the whole day/daytime/nighttime (average SYS/DIA/MAP, maximum SYS/DIA/MAP, minimum SYS/DIA/MAP, and measurement time).
- The normal SYS/DIA, the percentage of SYS and DIA within the normal range, below the normal range, and above the normal range throughout the whole day.
- The night time duration. The night time can be set according to 24 hours format or 12 hours format. The minimum period can be set to 30 minutes. The default start time of night time is 20:00 (PM) and the default end time of night time is 06:00 (AM).

Chapter 14 Monitoring TEMP

14.1 Overview

Body temperature is measured by means of a thermistor probe (a semiconductor whose resistance changes with temperature) that is applied to the skin or to the rectum.

Two TEMP probes can be used simultaneously to measure two TEMP values and get the temperature difference.

14.2 TEMP Safety Information

WARNING

1. **Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable of the channe1 from the socket, and then the screen will display the error message TEMP T1 Sensor Off and the auditory alarm is activated. It is the same to the other channel.**
2. **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.**
3. **Temperature probes do not need any probe covers; please remember to disinfect the reusable probe after each use on a patient.**

NOTE:

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

14.3 Selecting TEMP Sensor Type

The user can choose the TEMP sensor type as the temperature signal source.

To configure the TEMP sensor type, select **Menu** > **Maintenance** > **User Maintain** > **Other Setups**, and set **TEMP Sensor** to **YSI-10K** or **YSI-2.252K**.

14.4 Switching T1/T2 On/Off

In **Menu** > **System Setup** > **Module Switch**, T1 or T2 can be switched on/off separately and won't be affected by each other.

14.5 TEMP Monitoring Setup

With a reusable TEMP probe you can plug the probe directly into the monitor. Apply the TEMP probes securely to the patient. Switch on the monitor.

It takes 5 minutes for the body temperature to stabilize.

14.6 Selecting a Temperature for Monitoring

Select the temperature label according to the measurement site. The label is a unique identifier for each type of temperature.

To select the label,

1. Click the TEMP parameter area to enter **TEMP Setup** menu.
2. Select the appropriate label from the list for **T1** and **T2**.

Label	Description
Tskin	Skin temperature
Trect	Rectal temperature

14.7 Calculating Temp Difference

The monitor can calculate and display the difference between two temperature values by subtracting the second value from the first. The difference is labeled TD.

14.8 External TD-1261 TEMP Module via E-Link

To Connect TD-1261 to the monitor, please follow below steps:

1. Turn on the monitor and TD-1261.

2. Set **User Maintain** > **E-Link** to **On**.

3. Select **Common Function** > **E-Link** > **Available Device** on the monitor.

4. Choose the name of TD-1261 and Click **Connect** to pair the monitor and TD-1261.

When the monitor displays the icon of 

, it means the connection is successful.

 means the connection is not successful.

Click the **Measure** key on the TD-1261, the measurement result will be displayed on the monitor for 30 minutes.

For more operation and specification of TD-1261 TEMP, please refer to the corresponding manufacturer's instruction manual.

Chapter 15 Monitoring IBP

15.1 Overview

IBP is measured by means of a catheter inserted directly into the circulatory system. A pressure transducer connected to the catheter converts the mechanical force exerted by the blood into an electrical signal, which is displayed graphically as pressure versus time on a monitor screen or numerically on digital display.

The monitor measures direct blood pressure of one selected blood vessel through two channels, and displays waveforms and pressure of measured direct blood pressure (SYS, DIA and MAP).

15.2 IBP Safety Information

WARNING

1. **The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.**
2. **Disposable IBP transducer or domes should not be reused.**
3. **If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.**
4. **The longest duration of IBP arterial catheterization is 7 days.**
5. **All invasive procedures have risks to the patient. Use aseptic technique and follow catheter manufacturer's instructions.**
6. **Mechanical shock to the invasive blood pressure transducer may cause severe shifts in zero and calibration, and then cause erroneous readings.**
7. **Zeroing or and calibration are required after replacing the transducer or cable.**

NOTE:

1. **Use only the pressure transducer listed in the IBP Accessories**
2. **If measuring intracranial pressure (ICP) on a sitting patient, adjust the transducer on the same level with the top of the patient's ear. Incorrect leveling may lead incorrect values.**
3. **Confirm you set correct alarm limit for labels, the alarm limit you set are stored for its label only. Changing label may change the alarm limit.**
4. **Don't perform IBP calibration when a patient is being monitored.**

5 **When using high frequency ventilation, make sure that the ventilator catheter is not connected to or indirectly connected to the arterial catheter at zero pressure. This can lead to less pressure variations, thus interfere the zeroing process.**

6 **Please use the accessory of the same model from the same manufacturer.**

15.3 Monitoring Procedures

Preparatory steps for IBP measurement:

1. Plug the pressure cable into the corresponding socket and switch on the monitor.
2. Prepare the flush solution.
3. Flush through the system, exhaust all air from the tube, and ensure that the transducer and stopcocks are free of air bubbles.
4. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.
5. Position the transducer so that it is at the same level with the patient's heart, approximately mid-axillary line.
6. For the label name selection, please refer to Selecting a Pressure for Monitoring.
7. To zero the transducer, please refer to Zeroing the Pressure Transducer.

WARNING

If there are air bubbles in the tube system, you should flush the system with the solution again. The bubbles may cause erroneous pressure readings.

15.3.1 Selecting a Pressure for Monitoring

Tell the monitor which pressure you want to monitor by selecting its pressure label. The label is a unique identifier for each type of pressure. When you choose a label, the monitor uses that label's stored settings, for example color, wave scale and alarm settings. The label also determines which algorithm is used to process the pressure signal, so an incorrect label can lead to incorrect pressure values. To select the label, please refer to the following table:

Label	Description
ART	Arterial blood pressure
PA	Pulmonary artery pressure

Label	Description
CVP	Central venous pressure
ICP	Intracranial pressure
LAP	Left atrial pressure
RAP	Right atrial pressure
P1-P2	Alternative non-specific pressure labels

NOTE:

The pressure option is only valid when the label is P1/P2 and does not take effect under other labels.

15.3.2 Zeroing the Pressure Transducer

To avoid inaccurate pressure readings, the monitor requires a valid zero. Zero the transducer in accordance with your hospital policy (at least once per day). You must perform a zero:

- When you use a new transducer or tubing;
- Every time you reconnect the transducer cable to the monitor;
- If you think the monitor's pressure readings are not correct.

When using a pressure module, the zero information is stored in the module.

The zeroing procedure is listed as below:

1. Turn off the stopcock to the patient.
2. Vent the transducer to atmospheric pressure, to compensate for the static and atmospheric pressure exerted on the transducer.
3. In the setup menu for the pressure, select **Zero**. **Channel: XX** or **Zero All**. (**XX** stands for the IBP label name). After confirmation, the user can zero the pressure of certain channel or pressure of all channels. After zeroing, the interface displays the result and last calibration time.
4. When you see the message **Zero Ok**, please close the stopcock to atmospheric pressure, and open the stopcock to the patient.

15.3.3 Troubleshooting the Pressure Zeroing (Taking Art for Example)

Message	Corrective Action
Art Sensor Off, Fail!	Make sure that transducer is not off, and then proceed zeroing.
Unable to Calibrate in Demo Mode	Make sure that the monitor is not in DEMO mode. Contact service technician if necessary.
Pressure out of normal range, Fail.	Make sure that the stopcock is vented to atmosphere. If the problem persists, please contact service technician.
Pulsatile Pressure Zero Fail.	Make sure that the transducer is vented to air, not connected to a patient, and try again.

15.3.4 IBP Calibration

IBP is not user-calibrated. Calibration should be performed by a qualified service professional as frequently as dictated by your Hospital Procedures Policy.

15.4 Changing the IBP Waveform Ruler

The top, middle and bottom rulers are available for each channel of IBP waveform. Users can adjust the top, middle or bottom rulers manually:

1. Open the menu **Wave Setup** of IBP by clicking on the IBP waveform area.
2. Select a suitable ruler from the options **TopRuler**, **MidRuler** and **BotRuler**.

15.5 IBP Waveform Overlapping

The monitor can display IBP overlapped waveforms. To set IBP waveform overlapping:

1. Select **Menu** > **Maintenance** > **User Maintain** > **Other Setups**, and set **IBP Wave Overlapping** to **On** or **Off**.
2. Click the IBP waveform area to show the IBP **Wave Setup** menu.
3. Select **Add IBP Waves** and then select the IBP waves for overlapping from the pop-up list. A maximum of four overlapping waveforms can be displayed.
4. After exiting the interface, the main screen will display the overlapped IBP waves. The flashing label is the main label of the waveform area.

Click the IBP overlapping waveform area on the main screen, and then select **Setup Rulers**. The user can select a suitable ruler for the overlapped waveforms from the options **TopRuler** and **BotRuler**.

15.6 Measuring PAWP

PAWP, Pulmonary Artery Wedge Pressure, used to assess the cardiac function, is obtained by introducing a balloon-tipped pulmonary artery flotation catheter into the pulmonary artery. When the catheter is in one of the smaller pulmonary arteries, the inflated balloon occludes the artery allowing the monitor to record changes in the intrathoracic pressures that occur throughout the respiration cycle. The user can view the PAWP measurement result via connected MFM-CMS.

15.6.1 Measurement Procedures

Pulmonary Artery Wedge Pressure (PAWP) values are affected by fluid status, myocardial contractility, valve and pulmonary circulation integrity. The most accurate PAWP values are obtained at the end of the respiration cycle when the intrathoracic pressure is fairly constant. You can use the respiration waveform as a reference when assessing the PAWP waveform, to ensure constant measurement timing relative to the respiratory cycle.

To start the measurement:

1. On the standard screen interface, select the PA parameter window to enter its setup menu. Then, select **Setup** > **PAWP Activate** to open the PAWP measurement window.
2. Prepare and check the accessories according to your hospital policy.
3. Wedge the flotation catheter into the pulmonary artery. Then inflate the balloon and pay attention to PA waveform changes on the screen.
4. After obtaining a stable PAWP waveform, press **Freeze** to freeze the waveform. In freeze status, you can adjust the PAWP scale to an appropriate position by selecting **Measure** and moving the cursors up and down according to the clinical experience. Select **Confirm** to store the PAWP, CVP, HR values. To review the frozen waveform, press **s Browse** and rotate the rotary knob clockwise or counter-clockwise as desired. If you need to review the stored PAWP, CVP, HR values, select **PAWP Review**.
5. Deflate the balloon when the monitor prompts you "**Please deflate the balloon!**".
6. If you need to start a new measurement, select **Remeasure**.
7. Click on **Exit** or select **Setup** > **PAWP Exit** to exit.

WARNING

1 **Prolonged inflation can cause pulmonary hemorrhage, infarction or both. Inflate the balloon for the minimum time necessary to get an accurate measurement.**

2 **If the PAWP (mean) is greater than the PA (systolic), deflate the balloon and report the incident in accordance with hospital policy, because the pulmonary artery could be accidently ruptured, and the PAWP value derived will not reflect the patient's hemodynamic state, but will merely reflect the pressure in the catheter or balloon.**

3 **The pressure receiver in the catheter records the pressure change that occurs only at the front of the obstruction.**

4 **Due to the short measurement delay, do not use sidestream CO_2 as a direct reference to determine the end point of the breath in the pressure curve.**

5 **If the balloon is not inflated but the pulmonary artery floating catheter enters the wedge position, the pulmonary artery pressure waveform becomes wedge-shaped. Follow the standard steps to take appropriate action to correct this situation.**

6 **PAWP measurement is not applicable to pediatric and neonate patients.**

15.7 Calculating CPP

CPP is calculated by subtracting MAP and ICP, it means: CPP=MAP-ICP.

15.7.1 Calculation Procedures

To start CPP calculation:

1. Click the ICP parameter area to enter into **ICP Options** interface, select **Setup** to enter into **ICP Setup > CPP Source**; CPP source is defaulted as the currently opened artery, it can be selected as **Art**, **P1** or **P2**. If there is more than one arterial pressure at the same time, the priority level should be: Art > P1 > P2.
2. Take P1 as example: if P1 is selected as CPP Source, when MAP and ICP are both measured, ICP area will display CPP and its value as below picture, unit is same as ICP. Invalid CPP will display "-?-". CPP will be closed if exit ICP parameter.

15.8 Calculating PPV

Pulse Pressure Variation (PPV) is calculated from the specific arterial pressure values, which reflects the variation between the maximal pulse pressure and the minimum pulse pressure in 30 seconds. Pulse pressure is affected by left ventricular-stroke volume, arterial resistance and arterial compliance.

WARNING

1 **The clinical value of the derived PPV information must be determined by a physician. According to recent scientific literature, the PPV information is restricted to sedated patients who receive controlled mechanical ventilation and without arrhythmia. Whether the calculation results in other situations are clinically significant, applicable and reliable must be determined by a physician.**

2 **In below situations, the calculated PPV value may be inaccurate:**

- **the respiration rate is lower than 8 rpm**
- **the tidal volume during ventilation is lower than 8 ml/kg**
- **patients have acute right ventricular functional disorder (pulmonary heart disease)**

3 **PPV measurement has been validated only for adult patients.**

PPV is calculated according to the following equation:

PPV= (PPmax − PPmin)/(PPmax + PPmin)/2) * 100%

To select an arterial pressure as PPV source:

1. Click the PPV parameter area to enter **PPV Setup** menu.
2. Select **Art**, **P1**, **P2**, or **AUTO** as **PPV Source**.

Only when P1 and P2 are arterial pressure can they be selected as PPV source. When it is set to **AUTO** and if there is more than one arterial pressure at the same time, the priority level should be: Art > P1 > P2.

NOTE:

PPV results will not be recorded.

Chapter 16 Monitoring CO_2

16.1 Overview

The monitor provides the sidestream and mainstream methods for CO_2 monitoring. EDAN EtCO_2 module is used for sidestream measuring.

The principle of CO_2 measurement is primarily based on the fact that CO_2 molecule can absorb 4.3μm infrared ray. Absorption intensity is proportional to CO_2 concentration of patient sample, the CO_2 concentration will compute according to the detecting CO_2 absorption intensity of patient sample.

Sidestream measurement takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a remote CO_2 sensor. You can measure Sidestream CO_2 using the monitor's built-in CO_2 measurement. Respiration rate is calculated by measuring the time interval between detected breaths.

16.2 CO_2 Safety Information

WARNING

1. **Do not use the device in the environment with flammable anesthetic gas.**
2. **The device should be used by trained and qualified medical personnel authorized by EDAN.**
3. **Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the CO_2 measurement.**
4. **The monitor will be damaged if any pipeline from the CO_2 module's air tube /the air inlet /the air outlet is plugged by water or other materials.**
5. **The accuracy of the CO_2 measurement will be affected by the following reasons: the airway was highly obstructed; the leakage of air way connection or quick variation of environment temperature.**
6. **Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.**
7. **When using mechanical ventilation, gas compensation should be well set. Inappropriate setting may cause incorrect measurement result.**
8. **Do not place the sensor cables or tubing in any manner that may cause entanglement or strangulation.**
9. **EDAN EtCO_2 module is equipped with automatic air pressure compensation, and manual setting is not required.**

WARNING

10 Leakage in the respiratory system or sampling system may result in a significant low display of the $EtCO_2$ value. Always keep all components connected firmly and check for leaks according to standard clinical procedures.

11 Don't measure CO_2 while nebulized medications are being delivered.

12 The CO_2 module temporally stops measuring during zeroing.

13 Do not use the $EtCO_2$ monitor for diagnostic purpose.

14 CO_2 APNEA alarm is based on detection of breaths within a configured time frame.

15 CO_2 APNEA alarm should not be used or relied upon while the patient is unattended.

16 The $EtCO_2$ reading is not always closely related to the $paCO_2$ value, especially in neonatal patients, and patients with pulmonary disease, with pulmonary embolism or inappropriate ventilation.

17 Disconnect the water trap from the holder or set Work Mode to Standby when the module is not in use. Setting path: CO_2 Setup > Work Mode > Standby.

NOTE:

1 After the low battery alarm appears, please do not start the CO_2 measurement, or the monitor may turn off for the low capacity of battery.

2 For disposal of hospital waste such as accumulated fluids, calibration gases, sampled gases, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

3 If the measurement or sensor fails, stop measurement before the qualified service personnel solves the problem.

4 The cumulative use time for the sampling line in a single patient should be less than 30 days.

16.3 Monitoring Procedures

16.3.1 Zeroing

EDAN $EtCO_2$ module itself has automatic zero function, only when the measurement is abnormal or measurement results are doubtful, the user can perform manual zero as following steps:

1. Wait until the monitor's warm-up message disappears; keep the monitor away

from CO_2 source.

2. In the **CO_2 Setup** menu, set **Work Mod**e to **Measure**.
3. Select **Zero Calibration** in **CO_2 Setup** menu.
4. After the zeroing calibration is completed, the zeroing message disappears, and the CO_2 monitoring can be performed.

NOTE:

The zeroing function will be inactivated when EDAN EtCO_2 module related technical alarms or apnea alarm are generated or no respiration was detected for more than 30 s.

16.3.2 Hiding the Invalid Display after Zeroing the CO_2 Module

Within 30 s after the zero calibration starts, the monitor displays **Zero Recovering** and invalid CO_2 value. Valid data will reappear 30 seconds after the zero calibration is started. The user can hide the display of **Zero Recovering** and show CO_2 values. To hide the display of **Zero Recovering**, follow these steps:

1. Select **Menu** > **Maintenance** > **User Maintain**, and input the password;
2. Select **Gas Maintenance** and switch off **Zero Recovery for 30s**.

NOTE:

CO_2 values displayed within 30 s after the zero calibration is started should be interpreted cautiously.

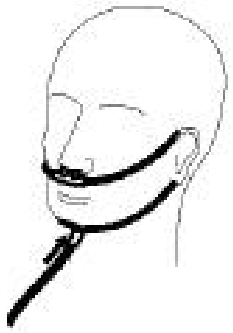
16.3.3 Sidestream CO_2 Module

16.3.3.1 Measurement Steps

1. Fix the water trap to the water trap holder on the left side of the monitor. Confirm it is well fixed.

2. Connect the sampling cannula or the sampling line to the water trap.

3. Set **Work Mode** to **Measure**.
4. For intubated patients, an airway adapter is required. For non-intubated patients, place the nasal cannula or the sampling mask onto the patient.



Place the Nasal Cannula

CAUTION

1 **The water trap collects water drops condensed in the sampling line and therefore prevents them from entering the module. If the water trap is nearly filled, you should replace it to avoid blocking the airway.**

2 **Based on a sample gas temperature of 37 °C, a room temperature of 23 °C and sample relative humidity of 100%, the water trap will be filled after approximately 90 hours with the flowrate of 100 ml/min, approximately 130 hours with the flowrate of 70 ml/min, and approximately 180 hours with the flowrate of 50 ml/min. In clinical practice, the water trap can be used for a longer time before it is filled. It is recommended to replace the water trap once every month.**

3 **When replacing the water trap or suspecting the measurement value, please check if the O-rings of the water trap holder are normal and well installed. If the O-rings get damaged or loose, contact EDAN's service staff.**

4 **To prevent the module from abnormal work, please ensure the water trap detection button is not mistakenly touched.**

5 **Please replace and discard the water trap when blocking. Don't reuse it, otherwise the reading is not accurate and even the device may be damaged.**

6 **The sample gas flowrate 50 ml/min is only applicable to patients whose respiratory rate ranges from 0 rpm to 40 rpm.**

NOTE: To avoid patient cross infection, do not connect the exhaust tube to the ventilator circuit. If the sampled gas is returned to the breathing system, always use the bacterial filter of the sample gas return kit.

16.3.3.2 Removing Exhaust Gases from the System

WARNING

Do not connect the exhaust tube to the ventilator circuit, connect the outlet to a scavenging system, cross infection can occur if sampling gas is returned to the breathing system. When using the sidestream CO_2 measurement on patients who are receiving or have recently received anesthetics, please avoid exposing medical staff to anesthetics.

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the sidestream sensor at the outlet connector.

16.4 Setting CO_2 Corrections

Temperature, water vapor in the patient's breath, barometric pressure, and the proportions of O_2, N_2O and Helium in the mixture all influence CO_2 absorption. If values seem inaccurately high or low, check that the monitor is using the appropriate corrections.

The following items are available in the **CO_2 Other Setup** menu: **N_2O Compen.**, **O_2 Compens.**, **Anest. Agent**, **Vapor Compen.** and **Pump Rate**. The concentration of compensated gas should be set based on the current gas concentration which is supplied for patient. As for O_2 and N_2O, make the supplied gas concentration multiply to its volume to get the concentration. For instance, supply 100% O_2, and its volume is 60%, then O_2 compensation is: 100%*60%=60%. AG concentration is decided by anaesthesia apparatus. After settings, the interface will display a dialog box: **Confirm to change the settings?** And the detailed settings are displayed under the warning. Click **Yes** to confirm, and click **No** to cancel the settings.

NOTE: Make sure compensation value is correctly set, otherwise the measurement accuracy may be affected.

16.5 Setting Apnea Delay

This determines the time limit after which the monitor gives an alarm if the patient stops breathing.

1. Select **CO_2 Setup** > **Apnea Alm**;
2. Choose the apnea alarm time from the pop-up list.

WARNING

Safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of prematurity and apnea of infancy, has not been established.

16.6 Setting CO_2 Waveform

Open the menu **CO_2 Waveform Setup** by clicking on the CO_2 waveform area:

- Choose **Mode** and set it to **Curve** or **Filled** from the pop-up list;
- Choose **Sweep** and select a suitable setting from the pop-up list. The bigger the value is, the wider the waveform will be.

16.7 Intubation Mode

Intubation mode is suitable for CO_2 monitoring. During general anesthesia, the monitor can be set to intubation mode to eliminate unnecessary alarms. In intubation mode, CO_2-related physiological alarm including **CO_2 APNEA** will be turned off.

To enter intubation mode, follow these steps:

1. Click **Intubation Mode** in **CO_2 Setup**;
2. Select **Duration** in **Intubation Mode**, there are two selections: **3 min** and **5 min**. The default setting is **3 min**.
3. Click **Start**, the monitor will start the intubation mode. During the intubation mode, the monitor will display the intubation mode and remaining time in the form of text.

When countdown finishes or clicking **End** in **Intubation Mode** menu, the monitor will exit the intubation mode; After exiting intubation mode, the monitor will respond the physiological alarm related to CO_2.

NOTE:

The intubation mode is not available when CO_2 module is in Standby mode.

Chapter 17 Monitoring C.O.

17.1 Overview

The cardiac output (C.O.) measurement invasively measures cardiac output and other hemodynamic parameters by using the Thermodilution method. The Thermodilution method is to inject a cold solution into the blood circulation system and measure the temperature changes caused by the cold solution through the thermistor of the pulmonary artery floating catheter, and the C.O. value is calculated by using the temperature dilution curve.

As C.O. is a variable value, a series of measurements must be carried out to obtain a reliable and average C.O. value. Always use the average of multiple measurements for therapy decisions. The monitor can save a maximum of 6 measurement results.

17.2 C.O. Safety Information

WARNING

1. **Make sure that appurtenance applied is in conformity with relevant Medical Device Safety Requirements.**
2. **Appurtenance should be avoided from contact with conductive metal body when being connected or applied.**
3. **All invasive procedures involve risks to the patient. Use aseptic technique and follow catheter manufacturer's instructions.**
4. **The C.O. measurement results may be incorrect during electrosurgery.**
5. **C.O. floating catheter shall be removed or reinserted after 3 days.**

NOTE:

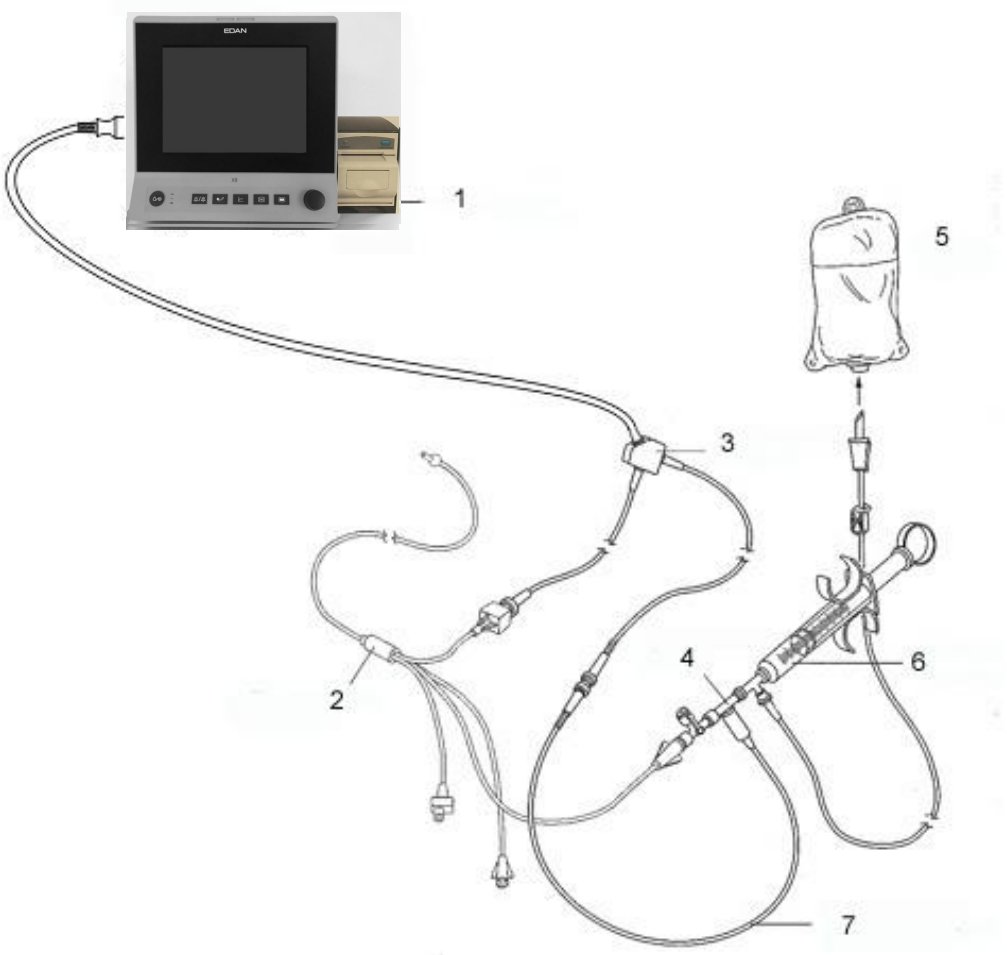
1. **Please set injection switch well. The calculation of the cardiac output is based on the state of the injection switch at the end of the measurement. Therefore, after the selection of the injection switch is completed, don’t change until the measurement is completed.**
2. **Please start C.O. measurement after blood temperature is stable, otherwise the measurement may fail.**
3. **To replace the catheter thermistor, please enter the catheter computation coefficient into the Constant item according to the instruction.**
4. **C.O. measurement is not applicable to pediatric and neonate patients.**

17.3 C.O. Monitoring

Preparing Measurement:

1. Plug the C.O. interface cable into the C.O. socket and turn on the monitor.

2. Attach the injective probe connector and catheter thermistor connector to the appropriate parts of the cardiac output interface cable.



1: Monitor; 2: Thermodilution Catheter; 3: Cardiac Output Cable; 4: Injectate Sensor Housing; 5: Injectate; 6: Delivery System; 7: In-line injectate Temperature probe.

C.O. Sensor Connection

3. Open the patient information window to confirm the patients' height and weight.

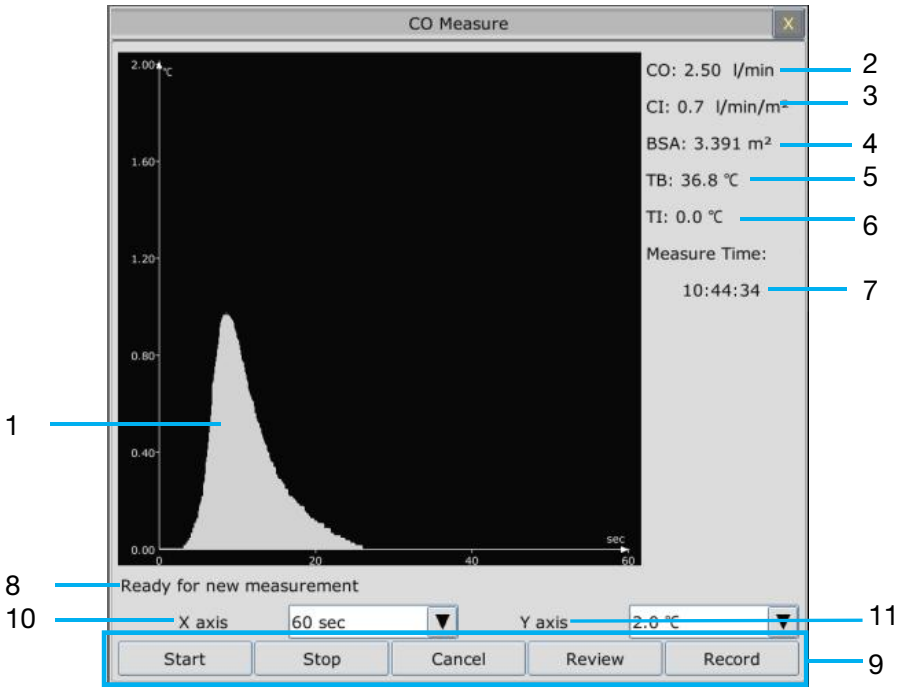
4. In C.O. Setup menu, set:

- **C.O. Constant**: The computation constant is associated with catheter and injectate volume. When the catheter is changed, please adjust **Constant** in the **C.O. Setup** menu based on product description provided by the manufacturer. After user's confirmation, the setup takes effect.
- **INJ. TEMP Source**: Select **Auto** or **Manual** from the list, when set as **Manual**, the

system directly displays the injectate temperature from INJ. TEMP. Ensure INJ. TEMP is correct, otherwise the C.O. measurement may be affected. When set as **Auto**, the system obtains the injectate temperature through sampling.

Performing C.O. Measurement

1. Pick the **C.O. Measure** item in the **C.O. Option** menu.



1	Measurement curve	10	**X axis**: Change the Scale X (time) value. Two modes are available: 0 s to 30 s, 0 s to 60 s. If you start measurement in the 0 s to 30 s mode, it will be switched to 0 s to 60 s mode automatically if the measurement cannot finish within 30 seconds. After the switch, no further adjustment can be made to the Scale X.
2	Cardiac Output		
3	Cardiac Index		
4	Body Surface Area		
5	Blood Temperature		
6	Injectate Temperature	11	**Y axis**: Change the scale Y (temperature) value. Three modes are available: 0 °C to 0.5 °C, 0 °C to 1 °C, 0 °C to 2.0 °C. Adjust the scale by the temperature differences. A smaller scale results in a larger curve.
7	Start time of the measurement		
8	Prompt message area		
9	Function keys		

The functional keys on the C.O. measure window are explained in the following table:

Start: Start a measurement

Stop: If the blood temperature cannot resume in a considerably long time, the measurement could not stop automatically. Use this button to stop the measurement and display the C.O., CI calculation result.

Cancel: Cancel the processing measurement or cancel the result after measurement.

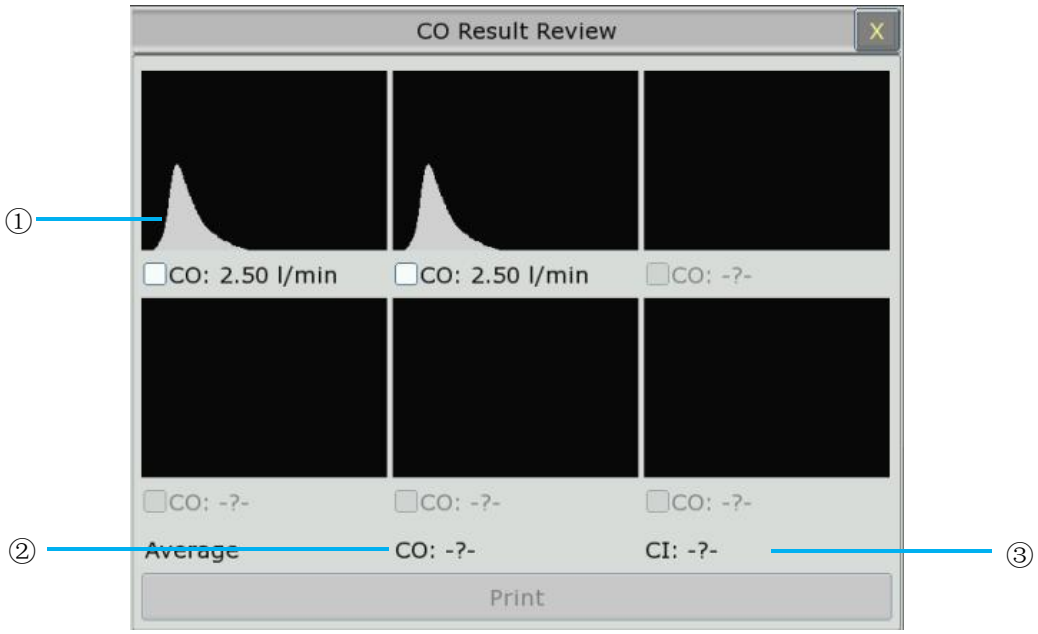
Record: Print out the curve.

Review: Enter the **Review** window

2. Measurement should be taken when the message "**Ready for new measurement**" appears on the screen. Press the **Start** button, and then start injection. The thermodilution curve, current blood temperature and the injectate temperature are displayed during the measurement. Curve drawing will stop automatically when the measurement finishes, and the C.O. and CI (2 and 3 in the above figure) will be calculated and displayed on the screen. The monitor will display C.O. in the parameter area and the start measurement time (7 in the above figure).

To ensure the accuracy of the measurement, it is suggested that a reasonable interval should take place between two consecutive measurements. The length of the interval can be set in the C.O. Setup menu (Time unit: second). The interval time counter is displayed on the screen. The next measurement cannot be performed until the time reduces to zero and a message **Ready for new measurement** appears. The adjustable range of **Interval** is: 5 to 300 seconds.
Repeat this procedure until you have completed the measurements you want.

A maximum of six measurements can be saved. If you perform additional measurements, the earliest measurement will be automatically deleted when a seventh curve is saved. In C.O. review window, select required curves from the 6 measurement curves, and the monitor will automatically calculate and respectively display the average values of C.O. and C.I. as following:



Window for C.O. Edit

◆ Contents displayed in the window:

①	Six curves of the six measurements and C.O. value
②	Average value of C.O.
③	Average value of CI

WARNING

1 **Make sure that the computational constant for the measurement is appropriate to the catheter used.**

2 **Before a C.O. measurement is initiated, check the accuracy of patient setup. The calculation of C.O. is related to the patient height, weight, and catheter computation coefficient; therefore, incorrect input will lead to error in calculation.**

NOTE:

1 **The blood temperature alarm will not function during C.O. measurement. It will resume automatically when the measurement is over.**

2 **It is strongly recommended that the user must push the injector within four seconds after pressing the Start button.**

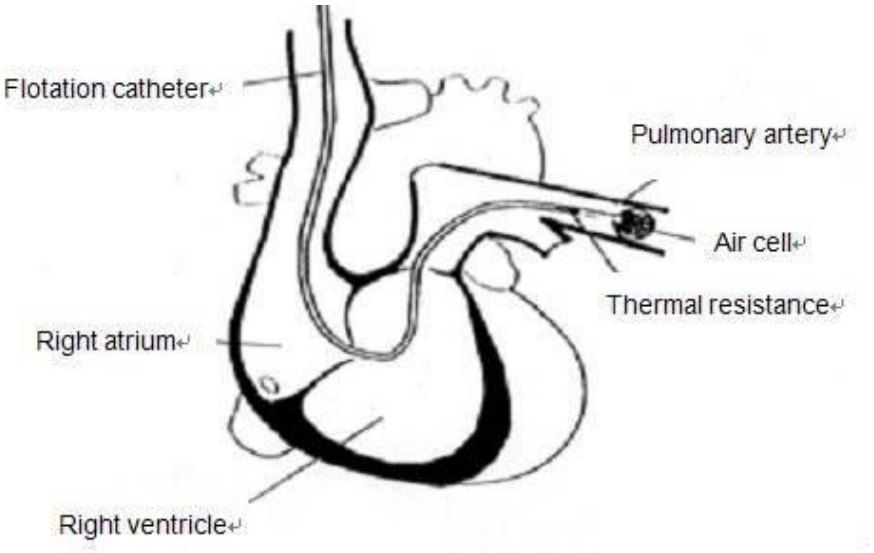
3 **It is strongly recommended that you wait at least 1 minute (or longer depending on the patient's clinical condition) before starting the next measurement.**

17.4 Blood Temperature Monitoring

Blood temperature monitoring can function when C.O. measurement is not taken. The blood temperature is measured by the thermistor situated in the distal end of the flotation catheter in the pulmonary artery.

The blood temperature alarm function will not work during the C.O. measurement. When the measurement ends, the function will automatically resume.

The current blood temperature is displayed in the C.O. parameter area.



Thermodilution Catheter Site

Chapter 18 Freeze

18.1 Overview

When monitoring a patient, the user may freeze the waveforms and examine them. Generally, the user can review a frozen waveform of a maximum of 120 seconds. The freeze function of this monitor has the following features:

- Freeze status can be activated on any operating screen.
- Once entering the Freeze status, the system exits all other operating menus. Besides, the system freezes all waveforms in the Waveform area of the Basic Screen, and also freezes Full Lead ECG waveforms and extra waveforms on the Full Lead ECG interface (if any). Nevertheless the Parameter area refreshes normally.
- The frozen waveforms can be reviewed and recorded.

18.2 Entering/Exiting Freeze Status

18.2.1 Entering Freeze Status

In the Non-Freeze status, press the button on the control panel of the monitor or select the shortcut key to exit the current menu. Press the button or select the shortcut key again, freeze status is entered and the popup **Freeze** menu is displayed. In Freeze status, all waveforms are frozen and will no longer be refreshed.

18.2.2 Exiting Freeze Status

In the Freeze status, executing any of the following operations will command the system to exit the Freeze status:

- Exit the **Freeze** menu;
- Press the button on the control panel or select the shortcut key again;
- Execute any operation that may trigger the adjustment of the screen or the display of a new menu.

After exiting Freeze status, the system will clear screen waveforms and resume displaying real-time waveforms. In the Screen Refresh mode, the system will sweep the waveforms from left to right in the Waveform Area.

Press the button on the control panel or select the shortcut key, and the **Freeze** menu will appear on the bottom part of the screen. At the same time, the system freezes the waveforms.

NOTE:

Pressing the  button or select the shortcut key  repeatedly over a short period of time may result in discontinuous waveforms on the screen.

18.3 Setting Freeze Duration

By setting the freeze duration, the monitor can exit freeze status automatically after certain period. To set the freeze duration:

1. On the **Freeze** menu, select **Duration**.
2. Select the desired setting from the pop-up list. None/1/2/3/4/5/10/15/20/30/60 min are optional. When **None** is selected, exit freeze status manually based on the actual situation.

18.4 Reviewing Frozen Waveform

By moving the frozen waveform, you may review a waveform of 120 seconds before it is frozen. For a waveform of less than 120 seconds, the remaining part is displayed as a straight line. Select **Time** on the **Freeze** menu and use the up/down arrow keys to move the frozen waves so that you can review the other parts of the frozen waves not displayed on the current screen.

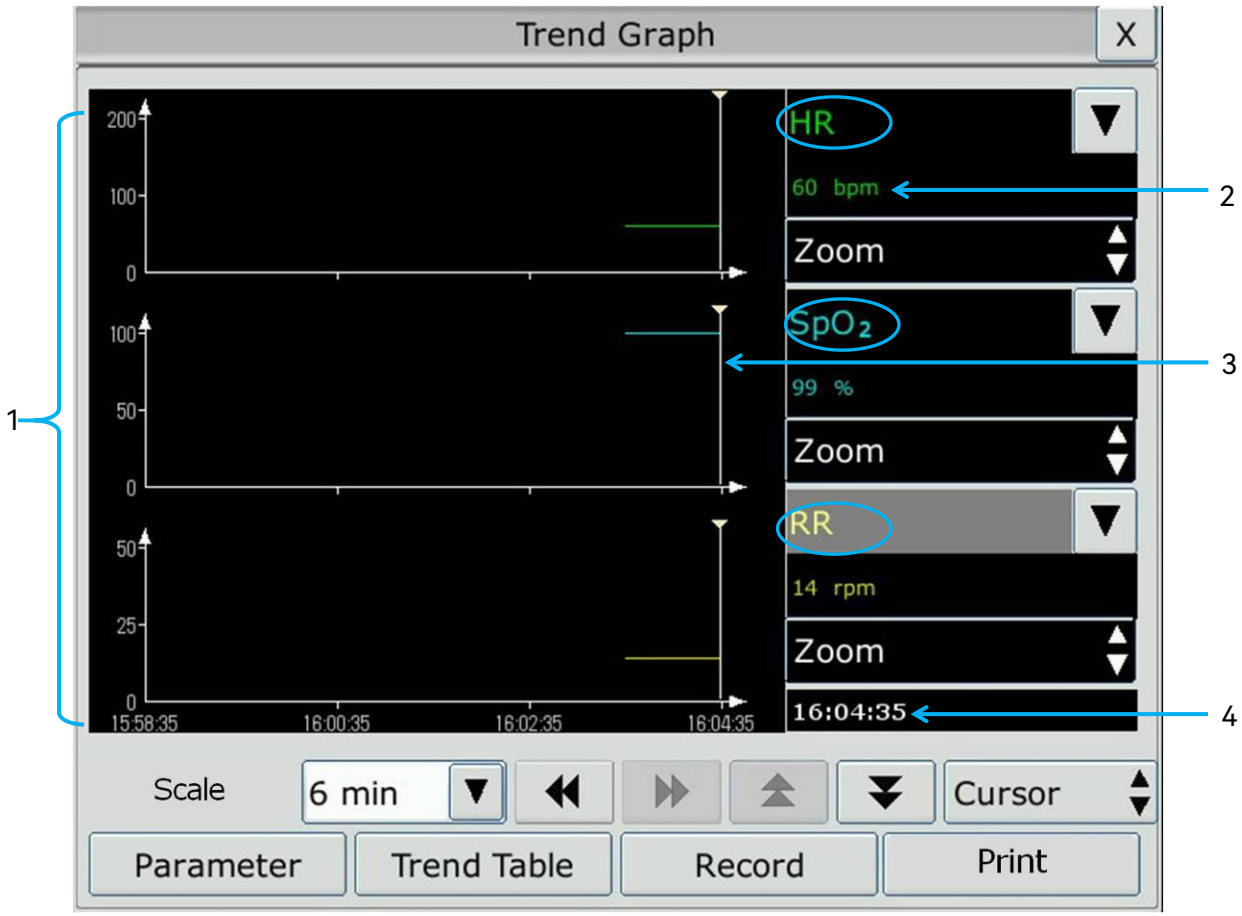
Chapter 19 Review

The monitor provides 120-hour trend data of all parameters, storage of 1200 NIBP measurement results, 200 alarm events, 200 arrhythmia events, 24 hours OxyCRG and 50 sets of 12-lead analysis results. This chapter gives detailed instruction for review of all data.

19.1 Trend Graph Review

To review the trend graph, please press the **Trend Graph** 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, other trends are displayed as continuous curves.



1 Trend curve area

2 Trend data: displays measurement values at the cursor indicated time.

3 Cursor

4 Cursor time

In the trend graph review window:

- Select **Parameter** and you can choose the required parameters to be displayed in the trend graph.
- To display a different parameter's trend, you can either:
  - Select ▼ beside the parameter name and choose the desired parameter from the pop-up list (as shown in red circle above).
  - Press the symbols ⏫ and ⏬ to switch parameters in batch.
- Select **Zoom** to adjust the trend scale. Once the trend scale on the trend graph review interface is adjusted, the trend scale of the corresponding parameter in **TrendScreen** of the main interface will also change.
- Select **Scale** to change the length of trend data displayed on the current screen. **6 min**, **12 min**, **30 min**, **1 h**, **2 h**, **4 h**, **6 h**, **12 h**, **24 h**, **36 h** and **48 h** 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 **Trend Table** to switch to the trend table interface.
- Select **Record** to print out the currently displayed trends by the recorder.
- Select **Print** to print out the trend graph report by the printer.

19.2 Trend Table Review

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

In the trend table review window:

- Select **Parameter** and you can choose the required parameters to be displayed in the trend table.
- 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 **Trend Graph** to switch to the trend graph interface.

- Select **Record** to print out the currently displayed trends by the recorder.
- Select **Record All** after setting **Start Time** and **End Time**, then all the trends for that period will be printed out by the recorder.
- Select **Print** to print out the trend table report by the printer.

NOTE:

When the interval is selected as 3 min, 5 min, 10 min, 15 min, 30 min or 60 min, the latest measurement values are displayed in the right of the trend table.

19.3 NIBP Review

To review the NIBP measurement data, please press the **NIBP Review** key  on the screen or select **Menu** > **Review** > **NIBP Review**.

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.
- Select **Print** to print out the NIBP review report by the printer.

19.4 Alarm Review

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

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.
- Select **Record** to print out the alarm events by the recorder.
- Select **Print** to print out the alarm event report by the printer.

NOTE:

1. **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.**
2. **When the alarm system is powered down, the log is maintained. The time of powering down will not be recorded in the system log.**
3. **A total loss of power has no impact on the stored log.**

19.5 ARR Review

To review the ARR alarm event, please press the **ARR Review** key  on the screen or select **ECG Setup** > **ARR Analysis** > **ARR Review** or **Menu > Review > ARR Review**.

In the ARR review window, the latest arrhythmia events are displayed. Select  and  to browse more ARR alarm events. You may select an alarm event and access the alarm review interface to get more information. On the alarm review interface, you can:

- Right or left shift the waveform to review the complete 8-second waveform.
- Select **Record** and output the arrhythmia waveform by the recorder.
- According to the actual clinical needs, select another name from the pull-down list of **Rename** for the arrhythmia event. Confirm the changes to make the settings take effect.
- Select **Delete** to remove a specific arrhythmia event.
- Select **Alarm List** or **Exit** to get back to the arrhythmia review interface.

NOTE:

1 **If there are more than 200 arrhythmia events, the monitor will only keep the recent ones.**

2 **The name of arrhythmia event will be shown on the alarm status area.**

3 **The renaming is only available for the ARR alarm event of the current patient, not for that of the history patient.**

19.6 12-Lead Analysis Review

To review the 12-lead analysis result, please press the **Analysis Review** key  on the screen or select **Menu** > **Review** > **Analysis Review**.

In the 12-lead analysis review window:

- The user can switch between results and waveforms. Select **Waveform** to review the analysis waveforms and **Result** to review the analysis results.
- Select **Delete** to delete the analysis results displayed on the current screen.
- Select  and  to browse more analysis results or waveforms.
- Select **Record** to print out the analysis results by the recorder.
- Select **Print** to print out the analysis report by the printer.

19.7 ST Segment Review

To review the ST segment, please press the **ECG Setup** > **ST Analysis** > **ST Segment Review**. In the ST segment review window,

- The user can select the specific lead waveform to review.
- The user can select the ST segment to review. There are 20 groups of segments at the most, user can review one ST segment, and can also review all overlapped ST segments.
- The color of ST waveform is consistent with the color of ECG. When only one ST segment is reviewed, this segment is highlighted, the ST value and saved time of the ST Segment is displayed, at the same time, the color of other segments becomes dark.

Chapter 20 Calculation

The monitor provides calculation and record function and titration table. Calculations are patient data that are not directly measured but calculated by the monitor.

The monitor can perform drug calculation, hemodynamic calculation, oxygenation calculation, ventilation calculation and renal function calculation, and also support record function.

NOTE:

1 **The drug calculation function acts only as a calculator. The patient weights in Drug Dose menu and in Patient Information menu are independent of each other. Therefore changing the Weight in Drug Dose menu will not change the weight in the Patient Information menu.**

2 **The calculation results are for reference only and the calculation significance must be determined by the physician.**

WARNING

The correctness of the input parameters and the suitability of the calculated results should be carefully verified. EDAN is not liable for any consequences arising from input or operation errors.

20.1 Drug Calculation

20.1.1 Calculation Procedures

1. The drug calculation window is displayed by selecting **Menu** > **Common Function** > **Calculation** > **Drug Dose**.
2. Select the right pull-down box of the **Drug** option and select the required drug name among the 15 drugs which are listed as follows. And the drug name of **Drug A**, **Drug B**, **Drug C**, **Drug D** and **Drug E** can be defined by the user.
   - Drug A, Drug B, Drug C, Drug D and Drug E
   - Aminophylline
   - Dobutamine
   - Dopamine
   - Epinephrine
   - Heparin
   - Isuprel

- Lidocaine
- Nipride
- Nitroglycerin
- Pitocin

3. The system generates values that can't be treated the calculation results. The user must enter the correct parameter value based on the doctor's instruction.
4. Manually enter the value of patient weight or directly obtain the value from the monitor by selecting **Get Info**.
5. Enter the correct parameter value.
6. Confirm whether the calculation result is correct.

The following formulas are applied to dose calculation:

Concentration = Amount / Volume

Inf. Rate = Dose / Concentration

Duration = Amount / Dose

Dose = Inf. Rate × Concentration

Dose (weight based) = Inf. Rate × Concentration / Weight

Drip Rate (GTT/min) = Inf. Rate (ml/hr) / 60 × Drop Factor (GTT/ml)

20.1.2 Calculation Unit

Each drug has the fixed unit or unit series to calculate. Among the same unit series, the unit binary varies with the entered parameter value.

The calculation units of the drugs are listed as follows:

Drug	Unit
Drug A, Drug B, Drug C, Aminophylline, Dobutamine, Dopamine, Epinephrine, Isuprel, Lidocaine, Nipride, Nitroglycerin	g, mg, mcg
Drug D, Pitocin, Heparin	Ku, mu, Unit
Drug E	mEq

When defining a drug, select Drug A, Drug B, Drug C, Drug D, and Drug E based on the unit series.

NOTE:

1 The drug calculation is displayed as invalid value before the user edits the drug

name and patient weight, and the user can't enter any value.

2 **Drip Rate and Drop Factor are invalid in the neonatal mode.**

20.1.3 Titration Table

After completing the drug calculation, the user can open the **Titration** on the **Drug Dose** interface.

The user can change the following items in the titration table:

- Basic
- Step
- Dose Type

The data in the titration table will vary with the changes above. And the user can perform the following:

- Select  and  to observe more data.
- Record the data displayed in the current window by selecting **Record**.

20.2 Hemodynamic Calculation

20.2.1 Calculation Procedure

1. The hemodynamic calculation interface is displayed by selecting **Menu** > **Common Function** > **Calculation** > **Hemodynamics**.
2. Manually enter the values required on this interface. You can also directly obtain the values of HR, C.O., PA MAP, CVP, and PAWP if they are available from the monitor by selecting **Get Info**.
3. Select **Calculate** to output parameter value.

20.2.2 Input Parameters

Items	Unit	English Full Name/Description
PAWP	mmHg	Pulmonary artery wedge pressure
CVP	mmHg	Central venous pressure
C.O.	L/min	Cardiac output
HR	bpm	Heart rate
EDV	ml	End-diastolic volume
AP MAP	mmHg	Mean Artery Pressure

PA MAP	mmHg	Pulmonary artery mean pressure
PAP	mmHg	Pulmonary artery pressure
Height	cm	/
Weight	kg	/

20.2.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
CI	L/min/m^2	Cardiac index	CI (L/min/m^2) = C.O. (L/min)/BSA (m^2)
BSA	m^2	Body surface area	BSA (m^2) = Weight$^{0.425}$ (kg) × Height$^{0.725}$ (cm) × 0.007184
SV	ml	Stroke volume	SV (ml) = C.O. (L/min)/HR (bpm) × 1000
SVI	ml/m^2	Stroke volume index	SVI (ml/m^2) = SV (ml)/BSA (m^2)
SVR	DS/cm^5	Systemic vascular resistance	SVR (DS/cm^5) = 80 × [AP MAP (mmHg) - CVP (mmHg)]/C.O. (L/min)
SVRI	DS·m^2/cm^5	Systemic vascular resistance index	SVRI (DS·m^2/cm^5) = SVR (DS/cm^5) × BSA (m^2)
PVR	DS/cm^5	Pulmonary vascular resistance	PVR (DS/cm^5) = 80 × [PA MAP (mmHg) - PAWP (mmHg)]/C.O. (L/min)
PVRI	DS·m^2/cm^5	Pulmonary vascular resistance index	PVRI (DS·m^2/cm^5) = PVR (DS/cm^5) × BSA (m^2)
LCW	kg·m	Left cardiac work	LCW (kg·m) = 0.0136 × [AP MAP (mmHg) - PAWP (mmHg)] × C.O. (L/min)
LCWI	kg·m/m^2	Left cardiac work index	LCWI (kg·m/m^2) = LCW (kg·m)/BSA (m^2)
RCW	kg·m	Right cardiac work	RCW (kg·m) = 0.0136 × [PA MAP (mmHg) - CVP (mmHg)] × C.O. (L/min)

Items	Unit	English Full Name/Description	Formula
RCWI	kg·m/m^2	Right cardiac work index	RCWI (kg·m/m^2) = RCW (kg·m)/BSA (m^2)
LVSW	g·m	Left ventricular stroke work	LVSW (g·m) = 0.0136 × [AP MAP (mmHg) – PAWP (mmHg)] × SV (ml)
LVSWI	g·m/m^2	Left ventricular stroke work index	LVSWI (g·m/m^2) = LVSW (g·m)/BSA (m^2)
RVSW	g·m	Right ventricular stroke work	RVSW (g·m) = 0.0136 × [PA MAP (mmHg) – CVP (mmHg)] × SV (ml)
RVSWI	g·m/m^2	Right ventricular stroke work index	RVSWI (g·m/m^2) = RVSW (g·m)/BSA (m^2)
EF	%	Ejection fraction	EF (%) = SV (ml)/EDV (ml) × 100

20.3 Oxygenation Calculation

20.3.1 Calculation Procedure

1. Select **Menu** > **Common Function** > **Calculation** > **Oxygenation**.
2. Manually enter the values required on this interface. You can also directly obtain the values of patient height, patient weight, C.O. and FiO_2 if they are available from the monitor by selecting **Get Info**.
3. Select **Calculate** to output parameter value.

20.3.2 Input Parameters

Items	Unit	English Full Name/Description
FiO_2	%	Percentage fraction of inspired oxygen
PaO_2	mmHg	Partial pressure of oxygen in the arteries
$PaCO_2$	mmHg	Partial pressure of carbon dioxide in the arteries
SaO_2	%	Arterial oxygen saturation
PvO_2	mmHg	Partial pressure of oxygen in venous blood
SvO_2	%	Venous oxygen saturation

Items	Unit	English Full Name/Description
Hb	g/L	Hemoglobin
RQ	/	Respiratory quotient
ATMP	mmHg	Atmospheric pressure
C.O.	L/min	Cardiac output
Height	cm	/
Weight	kg	/

20.3.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
BSA	m^2	Body surface area	BSA (m^2) = Weight$^{0.425}$ (kg) × Height$^{0.725}$ (cm) × 0.007184
VO_2	ml/min	Oxygen consumption	VO_2 (ml/min) = Ca-vO_2 (ml/L) × C.O. (L/min)
Ca-vO_2	ml/L	Arterial venous oxygen content difference	Ca-vO_2 (ml/L) = CaO_2 (ml/L) - CvO_2 (ml/L)
O_2ER	%	Oxygen extraction ratio	O_2ER (%) = VO_2 (ml/min)/DO_2 (ml/min) × 100
DO_2	ml/min	Oxygen transport	DO_2 (ml/min) = CaO_2 (ml/L) × C.O. (L/min)
PAO_2	mmHg	Partial pressure of oxygen in the alveoli	PAO_2 (mmHg) = [ATMP (mmHg) - 47 mmHg] × FiO_2 (%)/100 - $PaCO_2$ (mmHg) × [FiO_2 (%)/100 + (1 - FiO_2 (%)/100)/RQ]
$AaDO_2$	mmHg	Alveolar-arterial oxygen difference	$AaDO_2$ (mmHg) = PAO_2 (mmHg) - PaO_2 (mmHg)
CcO_2	ml/L	Capillary oxygen content	CcO_2 (ml/L) = Hb (g/L) × 1.34 + 0.031 × PAO_2 (mmHg)
$AaDO_2/PaO_2$	/	$AaDO_2/PaO_2$	$AaDO_2/PaO_2$ = [PAO_2 (mmHg) - PaO_2 (mmHg)]/PaO_2 (mmHg)
DO_2I	ml/min/m^2	Oxygen delivery index	DO_2I (ml/min/m^2) = DO_2 (ml/min)/BSA (m^2)
VO_2I	ml/min/m^2	Oxygen consumption index	VO_2I (ml/min/m^2) = VO_2 (ml/min)/BSA (m^2)

Items	Unit	English Full Name/Description	Formula
CaO_2	ml/L	Arterial oxygen content	CaO_2 (ml/L) = 100 ×1.34 × Hb (g/L) × SaO_2 (%)/100 + 0.031 × PaO_2 (mmHg)
CvO_2	ml/L	Venous oxygen content	CvO_2 (ml/L) = 100 ×1.34 × Hb (g/L) × SvO_2 (%)/100 + 0.031 × PvO_2 (mmHg)
CvO_2	ml/L	Venous oxygen content	CvO_2 (ml/L) = 100 ×1.34 × Hb (g/L) × SvO_2 (%)/100 + 0.031 × PvO_2 (mmHg)

20.4 Ventilation Calculation

20.4.1 Calculation Procedure

1. Select **Menu** > **Common Function** > **Calculation** > **Ventilation**.
2. Manually enter the values required on this interface. You can also directly obtain the values of FiO_2, RR, PIP and PEEP if they are available from the monitor by selecting **Get Info**.
3. Select **Calculate** to output parameter value.

20.4.2 Input Parameters

Items	Unit	English Full Name/Description
FiO_2	%	Percentage fraction of inspired oxygen
RR	rpm	Respiratory rate
VT	ml	Tidal volume
$PaCO_2$	mmHg	Partial pressure of carbon dioxide in the arteries
PaO_2	mmHg	Partial pressure of oxygen in the arteries
RQ	/	Respiratory quotient
$PeCO_2$	mmHg	Partial pressure of mixed expiratory CO_2
ATMP	mmHg	Atmospheric pressure

20.4.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
PAO_2	mmHg	Partial pressure of oxygen in the alveoli	PAO_2 (mmHg) = [ATMP (mmHg) - 47 mmHg] × FiO_2 (%)/100 - $PaCO_2$ (mmHg) × [FiO_2 (%)/100 + (1 - FiO_2 (%)/100)/RQ]
$AaDO_2$	mmHg	Alveolar-arterial oxygen difference	$AaDO_2$ (mmHg) = PAO_2 (mmHg) - PaO_2 (mmHg)
$AaDO_2/PaO_2$	/	$AaDO_2/PaO_2$	$AaDO_2/PaO_2$ = [PAO_2 (mmHg) - PaO_2 (mmHg)]/PaO_2 (mmHg)
MV	L/min	Minute volume	MV (L/min) = VT (ml) × RR (rpm)/1000
VD	ml	Volume of physiological dead space	VD (ml) = [($PaCO_2$ (mmHg) - $PeCO_2$ (mmHg) × VT (ml)]/$PaCO_2$ (mmHg)
VD/VT	%	Physiological dead space in percent of tidal volume	VD/VT (%) = [$PaCO_2$ (mmHg) - $PeCO_2$ (mmHg)]/$PaCO_2$ (mmHg) × 100
VA	L/min	Alveolar volume	VA (L/min) = [VT(ml) - VD(ml)] × RR (rpm)/1000

20.5 Renal Function Calculation

20.5.1 Calculation Procedure

1. Select **Menu** > **Common Function** > **Calculation** > **Renal Function**.
2. Manually enter the values required on this interface.
3. Select **Calculate** to output parameter value.

20.5.2 Input Parameters

Items	Unit	English Full Name/Description
URK	mmol/L	Urine potassium
URNa	mmol/L	Urinary sodium
Urine	ml/24h	Urine

Items	Unit	English Full Name/Description
Posm	mOsm/kgH_2O	Plasm osmolality
Uosm	mOsm/kgH_2O	Urine osmolality
SerNa	mmol/L	Serum sodium
SCr	μmol/L	Serum creatinine
UCr	μmol/L	Urine creatinine
BUN	mmol/L	Blood urea nitrogen
UUN	mmol/L	Urine urea nitrogen

20.5.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
URNaEx	mmol/24h	Urine sodium excretion	URNaEx (mmol/24h) = URNa (mmol/L) × Urine (ml/24h)/1000
URKEx	mmol/24h	Urine potassium excretion	URKEx (mmol/24h) = URK (mmol/L) × Urine (ml/24h)/1000
Na/K	%	Sodium potassium ratio	Na/K (%) = URNa (mmol/L)/URK (mmol/L) × 100
CNa	ml/24h	Clearance of sodium	CNa (ml/24h) = URNa (mmol/L) × Urine (ml/24h)/SerNa (mmol/L)
CCr	ml/min	Creatinine clearance rate	CCr (ml/min) = UCr (μmol/L) × Urine (ml/24h)/[SCr (μmol/L) × 24 × 60]
CUUN	ml/min	Urine urea nitrogen clearance rate	CUUN (ml/min) = UUN (mmol/L) × Urine (ml/24h)/[BUN (mmol/L) × 24 × 60]
FENa	%	Fractional excretion of sodium	FENa (%) = [URNa (mmol/L) × SCr (μmol/L)]/[Ucr (μmol/L) × SerNa (mmol/L)] × 100
FEUr	%	Fractional Excretion of Urea	FEUr (%) = [SCr (μmol/L) × UUN (mmol/L)]/[UCr (μmol/L) × BUN (mmol/L)] × 100
Cosm	ml/min	Osmolar clearance	Cosm (ml/min) = [Uosm (mOsm/kgH_2O) × Urine (ml/24h)]/[Posm (mOsm/kgH_2O) × 24 × 60]
CH_2O	ml/24h	Free water clearance	CH_2O (ml/24h) = Urine (ml/24h) – Uosm (mOsm/kgH_2O) × Urine (ml/24h)/Posm (mOsm/kgH_2O)

Items	Unit	English Full Name/Description	Formula
U/P osm	/	Urine to plasma osmolality ratio	U/P osm = Uosm (mOsm/kgH_2O)/Posm (mOsm/kgH_2O)
BUN/SCr	/	Blood urea nitrogen creatinine ratio	BUN/SCr = [BUN (mmol/L)/SCr (μmol/L)] × 1000
U/SCr	/	Urine-serum creatinine ratio	U/SCr = UCr (μmol/L)/SCr (μmol/L)

Chapter 21 Warning-Score System

User can use warning-score system to get an early warning score based on measurement value or input value of each vital sign. Warning-score system includes NEWS (National Early Warning Score System) and MEWS (Modified Early Warning Score) system.

NOTE:

1 **The score results are for reference only and the score significance must be determined by the physician.**

2 **MEWS and NEWS are applicable to adults only.**

21.1 Warning-Score Interface

The interface includes NEWS and MEWS sub-interface.

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

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

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

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

NOTE:

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

21.2 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**, **SpO_2**, **Oxygen**, **Age** and **Consciousness** manually, if auto score is selected, user only needs to input **Consciousness** manually, **HR/PR**, **TEMP**, **SYS**, **RR** and other value will be obtained automatically, and then click **Start to Score**. The monitor will calculate and display score result.

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

21.3 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:

NEWS	Severity Level	Color
NEWS=0	Non-urgent	Green
1<NEWS<4	Observing	Yellow
5<NEWS<6	Warning	Amber
One single parameter's score value=3 points		
NEWS≥7	Critical	Red

MEWS	Severity Level	Color
0	Non-urgent	Green
1≤MEWS≤3	Observing	Yellow
4≤MEWS≤6	Warning	Amber
One single parameter's score value=3 points		
MEWS>7	Critical	Red

NOTE: The score result can be displayed on the main screen through ticking the Display on Main Screen in Score Interface.

21.4 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. To check the trend table, click **Trend Table** button in Warning-Score interface. NEWS and MEWS can respectively support 1200 groups of trend review at least.

NOTE:

Trend table is cleared after admitting new patients, entering or exiting Demo mode.

Chapter 22 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

22.1 Performance of the Recorder

- Waveform record is printed at the rate of 12.5 mm/s, 25 mm/s or 50 mm/s.
- 48 mm record width and 50 mm record paper width.
- It can record up to three waveforms.
- 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.

22.2 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	Select at least one Rec waveform in **Recorder Setup** (A maximum of three waveforms can be selected), select **Continual** in **R-T Rec Time**. Press  shortcut key on the screen to start the recording. Press the shortcut again to stop recording.
8-second real-time recording/20-second real-time recording	Select at least one Rec waveform in **Recorder Setup** (A maximum of three waveforms can be selected), select **8 s** or **20 s** in **R-T Rec Time**, set **Record Interval** as needed, press  shortcut key on the screen to start the recording. Press the shortcut again to stop recording or when R-T Rec time ends, the monitor stops recording automatically. The runtime for each wave is 8 seconds or 20 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**. The default recording time is 8s.
Trend graph recording	Select **Menu > Review > Trend Graph**, click **Record** to start recording.
Trend table recording	Select **Menu > Review > Trend Table**, click **Record** to start recording.
NIBP review recording	Select **Menu > Review > NIBP Review**, click **Record** to start recording.
Arrhythmia review recording	Select **Menu > Review > ARR Review**, select one arrhythmia alarm and click **Record** to start recording.
Alarm review recording	Select **Menu > Review > Alarm Review**, select one alarm and click **Record** to start recording.

Recording Type	Description/ Procedure
Drug calculation titration recording	Select **Menu > Common Function > Calculation > Drug Dose > Titration**, click **Record** to start recording.
Hemodynamic Calculation result recording	Select **Menu > Common Function > Calculation > Hemodynamics**, click **Record** to start recording.
Oxygenation Calculation result recording	Select **Menu > Common Function > Calculation > Oxygenation**, click **Record** to start recording.
Ventilation Calculation result recording	Select **Menu > Common Function Calculation > Ventilation**, click **Record** to start recording.
Renal Function Calculation result recording	Select **Menu > Common Function > Calculation > Renal Function**, click **Record** to start recording.
12-lead analysis recording	Select **ECG Setup > 12-L Review**, click **Record** to start recording.
C.O. measurement recording	Select **C.O. Option > C.O. Measure**, click **Record** to start recording.
Frozen waveform recording	In the **Freeze** window, click **Record** to start recording.
ST View recording	In the **ST View** window, click **Record** to start recording.
QT View recording	In the **QT View** window, click **Record** to start recording.

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 into standby mode.

NOTE:

1 You can also use the shortcut key  on the screen to manually start or stop

recording.

2 **For waveforms with sweep of 6.25 mm/s, after entering freeze status, the recording speed will automatically be adjusted to 12.5 mm/s. Users can modify the recording speed according to their actual needs. The options are 12.5 mm/s, 25 mm/s and 50 mm/s.**

22.3 Recorder Operations and Status Messages

22.3.1 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.

22.3.2 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.

22.3.3 Paper Out

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

22.3.4 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.

22.3.5 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  is pressed.

2 Do not touch the thermo-sensitive print head when performing continuous recording.

Chapter 23 Printing Patient Reports

Patient reports can be printed out by an HP series laser printer connected with the monitor.

NOTE: Use the printer HP Laser Jet P2055dn, HP LaserJet Pro 400 M401n and HP LaserJet 600 M602, which are tested to be compatible with the monitor.

23.1 Printer Settings

You can configure the printer settings on the monitor before printing out patient reports. Click the shortcut key  or select **Menu** > **System Setup** > **Printer Setup**, and you can

- Assign a locally networked printer by selecting it from the **Printer** list.
- Search all available printers networked with the monitor by clicking **Search Printer**.
- Enable or disable double side printing by setting **DoubleSide Print** to **On** or **Off**.

The reports will be printed out on A4 paper and with single side by default.

NOTE:

1 **You need to search all available printers on the local network for the first time you use a networked printer.**

2 **Make sure the IP of the printer and the IP of the monitor share the same network segment.**

3 **Do not click Search Printer during printing patient reports, or the printer might stop the current print job.**

4 **When a printer simultaneously received print jobs from several networked monitors, a print job conflict may occur. Check the use status of the monitors and the printers on the same network prior to use and avoid print job conflicts.**

5 **Make sure there is no lack of paper before printing patient reports, or the alarm Printer Unavailable will be triggered.**

23.2 Starting and Stopping Report Printing

You can print out ten types of patient reports following the procedure below:

Report Type	Procedure
Trend graph report	In the **Trend Graph** window, click **Print** to start printing.
Trend table report	In the **Trend Table** window, click **Print** to start printing.
Alarm waveform report	In the **Alarm Review** window, click **Print** to start printing.
NIBP review report	In the **NIBP Review** window, click **Print** to start printing.
Arrhythmia review report	In the **ARR Review** window, click **Print** to start printing.
12-lead analysis report	In the **Analysis Review** window, click **Print** to start printing.
12-lead analysis waveform report	In the **12-Lead Analysis Waveform Review** window, click **Print** to start printing.
Drug calculation titration report	In the **Titration** window, click **Print** to start printing.
Oxygenation calculation report	In the **Oxygenation** window, click **Print** to start printing.
Ventilation calculation report	In the **Ventilation** window, click **Print** to start printing.
Renal function calculation report	In the **Renal Function** window, click **Print** to start printing.
C.O. measurement report	In the **C.O. Measure** window, click **Print** to start printing.
Hemodynamics report	In the **Hemodynamics** window, click **Print** to start printing.
ST View	In the **ST View** window, click **Print** to start printing.
QT View	In the **QT View** window, click **Print** to start printing.

To stop the current print job, click **Stop Printing** in the windows mentioned above.

NOTE: You can only start one print job at a time. Before starting a new print job, you have to stop the current print job or wait until the current print job is completed.

Chapter 24 Other Functions

24.1 Nurse Call

The monitor provides dedicated nurse call port which is connected to nurse call system through the nurse call cable to perform the nurse call function. You should activate the function following the steps below:

1. Select **Menu** > **Maintenance** > **User Maintain**, and input the password;
2. Select **Other Setups** > **Aux Output**;
3. Choose **On** in the **Nurse Call** list.

NOTE:

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

24.2 Analog Output and Defibrillator Synchronization

The monitor provides analog output signals to accessory equipment. Also, if a defibrillator is connected to the monitor, a defibrillator synchronization pulse can be output. You should activate the function following the steps below:

1. Select **Menu** > **Maintenance** > **User Maintain**, and input the password;
2. Select **Other Setups** > **Aux Output**;
3. Choose **Analog Output** or **Defibrillation** in the **Aux Output** list.

24.3 Storing Data in the Storage Device

24.3.1 Data Stored in the Storage Device

Refer to Section *Data Management* for more information about single patient data volume.

You can choose to **Keep Storing** or **Stop Storing** by selecting **Menu** > **Common Function** > **Data Store** > **if one patient data full**. When the single patient data reach the maximum, the monitor will keep storing or stop storing as selected.

If you choose **Keep Storing**, as soon as the single patient data is full, the earliest data will be replaced by the latest one. When the remaining storage space is less than 15 M, the earliest patient data in the storage space will be deleted in order to store the latest data.

If you choose **Stop Storing**, the monitor will stop data storing and the latest data cannot be stored when the single patient data reach the maximum. For instance, if all

the patient data (such as the trend graph, trend table, NIBP measurements, arrhythmia event, alarm event and 12-lead analysis) except waveforms reach the maximum, the monitor will stop storing, while only the waveforms keep storing until they are full. When the remaining storage space is less than 10 M, the monitor will stop storing new data, prompting insufficient storage space. The default setting of **if one patient data full** is **Stop Storing**.

The monitor can detect the storage space threshold. Select **Menu** > **Common Function** > **Data Store** and set **Threshold Detection** to **On**. When the removable device is newly inserted and selected as storage device, and its remaining storage space is less than 300 M, the monitor will not store data, prompting **The space in U disk is less than 300 M. Please clean it up.** The user needs to clean up the space manually till the remaining space is more than 300 M, thus the monitor will keep storing data. When this removable device is read-only and its space is insufficient, the monitor only provides alarm of **Read-only storage device**.

NOTE:

1 **The storage time varies according to the patient's parameter data volume. When the single patient data storage reaches 240 hours, the monitor will automatically create a new folder for continuous data store. If you chose Keep Storing, when the storage space is insufficient, the earliest folder will be deleted and new folder will be created.**

2 **Threshold Detection is only applicable to the removable devices.**

3 **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.**

24.3.2 Activating/ Deactivating Data Storing

To activate/ deactivate the data storing function, select **Menu** > **Maintenance** > **User Maintain** > **Other Setups**, and set **Data Store** to **On** or **Off**.

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

- No storage devices are selected.
- There is no enough space in the storage device for storing data.
- The removable device is read-only.
- The storage device is damaged.
- The data storing function is deactivated.

- The monitor is switched off.
- The power supply is off.

24.3.3 Selecting a Storage Device

To configure the storage device, select **Menu** > **Common Function** > **Data Store**. The initial default storage device is **Internal Storage**. When the monitor has no internal storage device, the storage device displays **Null**.

When user switches the storage device from an internal device to a removable device or switches from one removable device to another removable device, the user password is required.

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.

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.**

24.3.4 Reviewing Data Stored in the Storage Device

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, 12-lead analysis and waveform.

24.3.4.1 Reviewing Full Disclosure Waveform

Select **Menu** > **Review** > **History Patient** > **Full Wave.** to enter the full disclosure review interface. Select **Wave Setup** to set the desired waveform (Maximum: 1) to be displayed on the full disclosure review interface.

24.3.5 Deleting Data Stored in the Storage Device

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.

24.3.6 Exporting Data Stored in the Internal Storage Device

To export data of one patient from the internal storage device to the removable device, choose the patient from the list after selecting **Menu** > **Review** > **History Patient**, and then click **Export Current Data** on the **Review** menu.

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

NOTE:

When exporting data from the internal storage device, the user password is required, and the monitor will prompt Attention! Private information included in the data. If password is correct, the data will be successfully exported into the selected removable device, otherwise, the data export fails, and the interface displays: Wrong Password.

24.3.7 Formatting the Internal Storage Device

To format the internal storage device, select **Menu** > **Maintenance** > **User Maintain** > **Other Setups** > **Format internal storage device**. Further confirmation is required. After Formatting, the monitor displays result including **Format Succeeded** or **Format Failed**, **Please Retry**!

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.**

24.3.8 Ejecting a Removable Device

Before unplugging a removable device from the monitor, you need to select **Menu** > **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.

Chapter 25 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.

25.1 Battery Safety Information

WARNING

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

2 **The lithium battery can only be used for this device.**

3 **The lithium battery can only be charged in this device.**

4 **Do not reverse the lithium battery polarity.**

5 **Do not connect the positive (+) and negative (-) terminals with metal objects such as lead wire, which can result in short circuits.**

6 **The cycle life of the lithium battery is 300 times. The service life of the lithium battery may shorten if it is used inappropriately. It is recommended to replace the lithium battery after 300 charge-discharge cycles, or it may cause safety risks such as heat and liquid leakage, and risks such as failure or decline of performance.**

7 **Do not heat or throw the lithium battery into a fire.**

8 **Do not immerse, throw, or wet the lithium battery in water, beverages or other liquids.**

9 **Do not use or leave lithium battery at high temperature (charging>45 ℃, discharging>60 ℃, such as in direct sunlight or in a very hot car), otherwise it may cause overheat, fire, malfunction to the lithium battery, shorten the service life of the lithium battery, or damage the lithium battery.**

10 **Do not place the lithium battery near microwave equipment or other cooking devices. If the lithium battery is heated or subjected to strong electromagnetic radiation, liquid leakage, heat, smoke, fire, etc. may occur.**

11 **Do not hit with a hammer, step on, throw or drop to cause strong shock.**

WARNING

12 Do not weld the lithium battery directly.

13 Do not use a lithium battery of other specifications.

14 Do not use a lithium battery with serious scratch or deformation.

15 Keep lithium batteries out of the reach of children.

16 Power off the device, remove and stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage, or it may cause safety accidents such as heat, smoke, and fire.

17 Do not touch a leaking lithium battery. If the liquid leaked from the lithium battery gets into eyes, do not rub the eyes. Wash them well with clean water and see a doctor immediately.

18 When the device is running on lithium battery power, do not replace the lithium battery during operation of the device.

19 High internal temperature may also cause the lithium battery unable to be charged. Keep the device at room temperature and move it away from heat sources or out of direct sunlight. The lithium battery will resume charging when the temperature is within range again.

20 Lithium batteries should be charged, used and stored in places far away from static electricity.

21 Lithium 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 lithium batteries, please contact your local Civic Office, or the shop where you purchased the product.

25.2 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 fully powered, or when AC power is applied.

25.3 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: 76%~100%.

 Remaining battery power: 51%~75%

 Remaining battery power: 26%~50%

 Remaining battery power: 4%~25%

 Batteries are almost depleted and need to recharge immediately.

 No battery is installed.

 Battery error

25.4 Charging the Battery

To charge the battery, please follow the procedure:

1. Load the battery into the device and connect the device to the mains power. The battery indicator illuminates in yellow when battery is being charged.
2. Charge the battery until it is full, the battery indicator is not illuminated and the battery power indicator is filled.

NOTE:

It is recommended to charge the battery when the device is switched off so as to improve the charging efficiency and save charging time.

25.5 Maintaining the Battery

The performance of rechargeable batteries may deteriorate over time. It is recommended to check and maintain the batteries regularly every 3 months.

1. Disconnect the patient from the device and stop all measurement.
2. Switch off the device, connect it to mains power, install the battery and fully charge it.
3. Disconnect the device from mains power, switch on the device and let the device run until there is no battery power left and the device shuts off.
4. Reconnect the device to mains power and charge the battery until it is full for use or charge to 40%~60% for storage.

NOTE:

1. **Do not use the device on a patient during the battery maintenance.**

2. **Do not interrupt the battery maintenance process.**

25.6 Storing the Battery

Remove the lithium battery and store it at a cool and dry environment if the lithium battery or the device is not used for a long time. Charge the batteries to 40%-60% for storage. Check and maintain the batteries regularly every 3 months. For more information, please refer to Section *Maintaining the Battery*.

NOTE:

1. **When storing batteries, make sure that the battery terminals do not come into contact with metallic objects.**
2. **The service life of the battery will be shortened if it is stored at high temperature for a long time. Storing batteries in a cool place can slow down the aging process. The ideal storage temperature is 15 ℃.**

25.7 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. If you suspect that the battery may have failed, check the battery performance.

Refer to Step 1~Step 3 in Section *Maintaining the Battery* and record the running time of the battery which reflects the battery performance directly. If the running time is obviously less than the specified time in the specification, the battery may have reached its service life or malfunctioned, please change the battery or contact the service personnel. If the running time meets the specification, then the battery can continue to be used normally.

25.8 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.

Chapter 26 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.

26.1 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.

26.2 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.

NOTE:

Automated cleaning/disinfection to the equipment and accessories is prohibited.

26.3 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:

- Mild near neutral detergent
- Ethanol (75%)
- 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.

26.3.1 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 after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the monitor to ensure that there is no damage.

26.3.2 Cleaning the Reusable Accessories

26.3.2.1 Cleaning the ECG Cable Assembly

1. Remove ECG cables from the monitor.
2. Remove all residual foreign matters from the surface of ECG cables using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the cable assembly 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 cable assembly to air dry.
7. If the ECG cables are not visually clean after cleaning please repeat the cleaning steps through step 3 to step 6.
8. Inspect the ECG cables to ensure that there is no damage.

26.3.2.2 Cleaning the Blood Pressure Cuff

Cleaning the Cuff:

1. Remove 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 after cleaning, please repeat the cleaning steps through step 3 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.

26.3.2.3 Cleaning the SpO_2 Sensor

1. Remove SpO_2 sensors from the monitor.
2. Remove all residual foreign matters from the surface of SpO_2 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 SpO_2 sensors, including cables, are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 7.
9. Inspect the SpO_2 sensors, including cables, to ensure that there is no damage.

26.3.2.4 Cleaning the IBP/C.O. Cables

1. Remove IBP/C.O. cables from the monitor.
2. Remove all residual foreign matters from the surface of IBP/C.O. cables using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the cables 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 cables to air dry.
7. If the IBP/C.O. cables are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the IBP/C.O. cables to ensure that there is no damage.

26.3.2.5 Cleaning the TEMP Sensor

1. Remove TEMP sensors 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 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 to air dry.
7. If the TEMP sensors are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the TEMP sensors to ensure that there is no damage.

26.4 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 disinfecting the monitor and reusable accessories are:

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

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.

WARNING

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

CAUTION

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

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

CAUTION

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.**

26.4.1 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 *Cleaning the Monitor* 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 manufacture'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 manufacture'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.

26.4.2 Disinfecting the Reusable Accessories

26.4.2.1 Disinfecting the ECG Cable Assembly

1. Remove ECG cables from the monitor.

2. Clean and dry the ECG cables according to the methods in section *Cleaning the ECG Cable Assembly* prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the cable assembly with a soft cloth dampened with the disinfectant solution.
5. Wipe off the disinfectant solution with a dry cloth after disinfection.
6. Leave the cable assembly to air dry for at least 30 minutes.
7. Inspect the ECG cables to ensure that there is no damage.

26.4.2.2 Disinfecting the Blood Pressure Cuff

Disinfecting the Cuff:

1. Remove 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 *Cleaning the Blood Pressure Cuff* 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 *Cleaning the Blood Pressure Cuff* for more information.

NOTE:

Prolonged use of disinfectant may cause discoloration of the cuff.

26.4.2.3 Disinfecting the SpO_2 Sensor

1. Remove SpO_2 sensors from the monitor.
2. Clean and dry the SpO_2 sensor according to the methods in section *Cleaning the SpO_2 Sensor* 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 SpO_2 sensors, including cables, to ensure that there is no damage.

26.4.2.4 Disinfecting the IBP/C.O. Cables

1. Remove IBP/C.O. cables from the monitor.
2. Clean and dry the IBP/C.O. cables according to the methods in section *Cleaning the IBP Cables/ C.O. Cable* prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the cables with a soft cloth dampened with the disinfectant solution.
5. Wipe off the disinfectant solution with a dry cloth after disinfection.
6. Leave the cables to air dry for at least 30 minutes.
7. Inspect the IBP/C.O. cables to ensure that there is no damage.

26.4.2.5 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. Remove TEMP sensors from the monitor.
2. Clean and dry the TEMP Sensor according to the methods in section *Cleaning the TEMP Sensor* 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 sensors to ensure that there is no damage.

26.5 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.

26.6 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. SpO_2 sensors and NIBP Cuffs.

26.7 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 27 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's qualified service professionals.**
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.**

27.1 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 insulation meets requirement.
- If the device and accessories have damage.
- Specified accessories.
- If the alarm system can work properly.
- If the recorder can work properly and the paper meets the requirement.
- Battery performance
- If all monitoring functions are in good conditions.
- If the grounding resistance and leakage current meet requirement.

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

27.2 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 28 Warranty and Service

28.1 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.

NOTE:

The products marked with this symbol apply to the European WEEE directive. This symbol Indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning of your equipment.

28.2 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.

Chapter 29 Accessories

You can order accessories from EDAN supplies at www.edan.com 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.**

3 **IBP and C.O. sterilized accessories are already sterilized, refer to the package labeling for detailed method. Do not use a sterilized accessory if its packaging is damaged.**

NOTE:

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

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

29.1 ECG Accessories

Part Number	Accessories
ECG Cable	
01.57.471380	3-lead, 12-pin, Defib-proof, AHA, Snap
01.57.471388	3-lead, 12-pin, ESU-proof, AHA, Snap
01.57.471378	3-lead, 12-pin, Defib-proof, AHA, Clip
01.57.471386	3-lead, 12-pin, ESU-proof, AHA, Clip
01.57.471379	3-lead, 12-pin, Defib-proof, IEC, Snap
01.57.471387	3-lead, 12-pin, ESU-proof, IEC, Snap

Part Number	Accessories
01.57.471377	3-lead, 12-pin, Defib-proof, IEC, Clip
01.57.471385	3-lead, 12-pin, ESU-proof, IEC, Clip
01.57.471226	5-lead, 12-pin, ESU-proof, Adult/pediatric
01.57.471227	ECG trunk cable, 5-lead, 12-pin, ESU-proof, AHA/IEC, 5.0 m, reusable
01.57.471228	5-lead, 12-pin, Defib-proof, Adult/pediatric
01.57.471229	5-lead, 12-pin, Defib-proof, Adult/pediatric, Extended
01.13.036620	5-lead, Clip, AHA, Adult/pediatric, Extended
01.13.036621	5-lead, Clip, AHA, Adult/pediatric
01.13.036622	5-lead, Snap, AHA, Adult/pediatric, Extended
01.13.036623	5-lead, Snap, AHA, Adult/pediatric
01.13.036624	5-lead, Clip, IEC, Adult/pediatric, Extended
01.13.036625	5-lead, Clip, IEC, Adult/pediatric
01.13.036626	5-lead, Snap, IEC, Adult/pediatric, Extended
01.13.036627	5-lead, Snap, IEC, Adult/pediatric
01.57.471979	6-lead, 12-pin, Defib-proof, Adult/pediatric
01.57.471980	6-lead, Clip, AHA, Adult/pediatric
01.57.471981	6-lead, Snap, AHA, Adult/pediatric
01.57.471982	6-lead, Clip, IEC, Adult/pediatric
01.57.471983	6-lead, Snap, IEC, Adult/pediatric
01.57.040203	12-lead, Snap, IEC, Adult/pediatric
01.57.471163	12-lead, Clip, IEC, Adult/pediatric
01.57.109101	12-lead, Snap, AHA, Adult/pediatric
01.57.471169	12-lead, Clip, AHA, Adult/pediatric

Part Number	Accessories
01.57.471072	12-lead, 12-pin, Defib-proof, AHA, Adult/pediatric
01.57.471168	12-lead, 12-pin, Defib-proof, IEC, Adult/pediatric
01.57.471461	3-lead, Clip, IEC, 1.0 m, Reusable
01.57.471462	ECG limb wires, 3-lead, snap, IEC, 1.0 m, reusable
01.57.471463	3-lead, Clip, AHA, 1.0 m, Reusable
01.57.471464	ECG limb wires, 3-lead, snap, AHA, 1.0 m, reusable
01.57.471465	5-lead, 12-pin, Defib-proof, Clip, IEC, 3.4 m, Reusable
01.57.471466	5-lead, 12-pin, Defib-proof, Clip, AHA, 3.4 m, Reusable
01.57.471467	5-lead, 12-pin, Defib-proof, Snap, IEC, 3.4 m, Reusable
01.57.471468	5-lead, 12-pin, Defib-proof, Snap, AHA, 3.4 m, Reusable
01.57.471473	5-lead, 12-pin, ESU-proof, Clip, IEC, 3.4 m, Reusable
01.57.471474	5-Lead, 12-pin, ESU-proof, Clip, AHA, 3.4 m, Reusable
01.57.471475	5-Lead, 12-pin, ESU-proof, Snap, IEC, 3.4 m, Reusable
01.57.471476	5-lead, 12-pin, ESU-proof, Snap, AHA, 3.4 m, Reusable
01.57.471481	3-lead, 12-pin, ESU-proof, AHA/IEC, 2.7 m, Reusable
01.57.471482	3-lead, 12-pin, ESU-proof, AHA/IEC, 5.0 m, Reusable
01.57.471483	3-lead, 12-pin, Defib-proof, AHA/IEC, 2.7 m, Reusable
01.57.471484	3-lead, 12-pin, Defib-proof, AHA/IEC, 5.0 m, Reusable
01.57.471196	3-lead, Snap, AHA, Neonate
01.57.471198	3-lead, Clip, AHA, Neonate
01.57.471195	3-lead, Snap, IEC, Neonate
01.57.471197	3-lead, Clip, IEC, Neonate
01.57.471194	3-lead, 12-pin, Defib-proof, Neonate

Part Number	Accessories
ECG Electrode	
01.57.471861	Disposable ECG Electrodes
01.57.471858	Disposable ECG Electrodes
01.57.471862	Disposable ECG Electrodes
01.57.471859	Disposable ECG Electrodes
01.57.471897	Disposable ECG Electrodes
01.57.471898	Disposable ECG Electrodes
01.57.471276	Disposable ECG Electrodes
01.57.471056	Disposable ECG Electrodes
01.57.471057	Disposable ECG Electrodes
01.57.471060	Disposable ECG Electrodes
01.57.472011	Disposable ECG Electrodes
01.57.472012	Disposable ECG Electrodes
01.57.472013	Disposable ECG Electrodes

29.2 SpO_2 Accessories

Part Number	Accessories
SpO_2 Sensor	
02.57.225029	7-pin SH1 Adult Reusable SpO_2 Sensor /adult, 2.5 m
02.01.210120	SH1 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	SpO_2 Sensor, Ear Clip, Adult/Pediatric, 1 m, reusable
01.57.471235	SHD-A SpO_2 Sensor, adult, disposable

Part Number	Accessories
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
SpO_2 Extension Cable	
01.57.471068	SpO_2 Extension cable, 2 m
01.57.471789	7-pin SpO_2 adapter cable/SpO_2 Extension cable, 4.0 m

29.3 NIBP Accessories

Part Number	Accessories
NIBP Cuff	
01.57.471326	NIBP Cuff, E5, Infant, 10-15 cm, reusable
01.57.471327	NIBP Cuff, E6, Small child, 13-17 cm, reusable
01.57.471328	NIBP Cuff, E7, Child, 16-21.5 cm, reusable
01.57.471329	NIBP Cuff, E8, Small adult, 20.5-28 cm, reusable
01.57.471330	NIBP Cuff, E9, Adult, 27-35 cm, reusable
01.57.471331	NIBP Cuff, E10, Large adult, 34-43 cm, reusable
01.57.471396	NIBP Cuff, E11,Thigh, 42-54 cm, reusable
01.57.471323	NIBP Cuff, Neonate, 10 cm-15 cm, reusable
01.57.471324	NIBP Cuff, Neonate, 6 cm-11 cm, reusable
01.57.471157	NIBP Cuff, neonatal #1, 3-6 cm, disposable
01.57.471158	NIBP Cuff, neonatal #2, 4-8 cm, disposable
01.57.471159	NIBP Cuff, neonatal #3, 6-11 cm, disposable
01.57.471160	NIBP Cuff, neonatal #4, 7-13 cm, disposable
01.57.471161	NIBP Cuff, neonatal #5, 8-15 cm, disposable

Part Number	Accessories
NIBP Tube	
01.59.473007	NIBP Hose/3.0 m,Φ7.2 mm*Φ3.6 mm, TPU 85A, gray

29.4 TEMP Accessories

Part Number	Accessories
Temperature Probe	
01.15.040225	Temperature Probe/Skin, adult, 3 m, reusable
01.15.040226	Temperature Probe/Skin, adult, 3 m, reusable
01.15.040227	Temperature Probe/rectal/oral, adult, 3 m, reusable
01.15.040228	Temperature Probe, rectal/oral, adult, 3 m, reusable
01.15.040253	Temperature Probe/Skin, neonatal/Infant, 3 m, reusable
01.15.040254	Temperature Probe/rectal/oral, neonatal/Infant, 3 m, reusable
01.15.040255	Temperature Probe/Skin, neonatal/Infant, 3 m, reusable
01.15.040256	Temperature Probe/rectal/oral, neonatal/Infant, 3 m, reusable

29.5 IBP Accessories

Part Number	Accessories
IBP Transducer	
01.57.471070	IBP Pressure transducer interface cable/Interface model BD
01.57.471172	IBP Pressure transducer interface cable/EDWARD type interface
01.57.471173	IBP Pressure transducer interface cable/Hospira type interface
01.57.471166	IBP Pressure transducer interface cable/the UTAH type interface
01.57.471836	IBP Pressure transducer interface cable/12 pin,B.Braun type interface
01.57.40121	IDTX Enhanced SPU Transducer/BD DT-4812

Part Number	Accessories
01.57.471664	Disposable Pressure Transducer
01.57.471665	Disposable Pressure Transducer
01.57.471666	Disposable Pressure Transducer
IBP Cable	
01.57.471971	12 pin, dual channel, IBP cable (BD)
01.57.471972	12 pin, dual channel, IBP cable (EDWARD)
01.57.471973	12 pin, dual channel, IBP cable (HOSPIRA)
01.57.471974	12 pin, dual channel, IBP cable (UTAH)
01.57.471975	12 pin, dual channel, IBP cable (B.Braun)

29.6 CO_2 Accessories

Part Number	Accessories
01.57.471034	L-type tee
02.01.210520	Dewatering Cup(Single Patient Use, Adult/Pediatric 10 ml)
01.57.471275	CO_2 Sampling Line with Male Luer Lock, 2.0 m
01.57.471282	All Purpose Sampling Cannula without filter (Non Sterile). Size: Adult
01.57.471283	All Purpose Sampling Cannula without filter (Non Sterile). Size: Infant
01.57.471284	All Purpose Sampling Cannula without filter (Non Sterile). Size: Neonate
01.57.471285	Duo Flow O_2+CO_2 Sampling Cannula (Non Sterile). Size: Adult
01.57.471286	Duo Flow O_2+CO_2 Sampling Cannula (Non Sterile). Size: Child
01.57.471287	Capnomask O_2+CO_2 Sampling Cannula (Non Sterile). Size: Adult
01.57.471288	Capnomask O_2+CO_2 Sampling Cannula (Non Sterile). Size: Child

29.7 C.O. Accessories*

*Only applicable to X12.

Part Number	Accessories
01.57.471071	Cardiac output cable
01.13.40119	In-line Injection temperature probe (BD 684056-SP4042)
01.57.40120	In-line Injection temperature probe housing (BD 680006-SP5045)
01.57.40121	IDTX Enhanced SPU Transducer/BD DT-4812
01.57.100175	Control Syringe (Medex MX387)

NOTE:

The Thermodilution Catheter is required when measuring C.O.. Swan-Ganz catheter manufactured by Edwards Lifesciences Corporation, has been validated to be compatible with the monitor. Refer to Edwards for more details.

29.8 Other Accessories

Part Number	Accessories
01.13.036638	Power cable, length 1.8 m, VDE
01.13.037122	Power cable, length 1.8 m, American standard, medical grade
01.57.078035	Recorder paper
01.23.068023	Linear Barcode Scanner
02.04.241690	Patient monitor mounting arm assembly kit (X8/X10, big basket)
02.04.101976	Rolling Stand Basket (in the bottom)
02.04.241699	Patient monitor mounting arm assembly kit (M3/iM50)
83.60.262076	MT-206 Trolley (Metal wheels, X8/X10)
83.60.262081	MT-206 Trolley (Plastic wheels, X8/X10)
01.13.114214	Potential Equalization Conductor
01.18.052245	Netac USB flash disk (U208, 4G, USB2.0)
02.01.210633	Unicode recorder, Serial/parallel port

Part Number	Accessories
01.17.102659	SD Memory Card (32 GB, Class 10)
01.21.064380	Rechargeable Lithium-Ion Battery, 2550 mAh, 10.8 V
01.21.064381	Rechargeable Lithium-Ion Battery, 5100 mAh, 10.8 V
02.01.211226	Patient monitor mounting arm assembly kit
02.01.211225	Patient monitor mounting arm assembly kit
02.04.241697	Patient monitor mounting arm assembly kit (iM60/iM70)
02.04.241688	Patient monitor mounting arm assembly kit (X12, with basket)
02.01.211227	Trolley adapter assembly kit (X12)
02.04.101984	M3 Trolley Adaptor Kit
83.60.262078	MT-206 Trolley (Metal wheels, X12)
83.60.262083	MT-206 Trolley (plastic wheels, X12)
83.60.262072	MT-206 (S) Trolley (X8/X10)
83.60.262073	MT-206 (S) Trolley (X12)

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	CF
Ingress Protection	IPX1
Disinfection/sterilization method	Refer to Chapter Care and Cleaning for details.
Working system	Continuous operation equipment
Compliant with Standards	IEC 60601-1; IEC 60601-1-2; EN 60601-1; EN 60601-1-2; IEC 80601-2-49.

A.2 Physical Specifications

A.2.1 Size and Weight

Product	Size	Weight	
X8	236±2 mm (W)×236±2 mm (H)×147±2 mm (D)	< 2.4 kg	Standard configurations, no battery or accessories
X10	261±2 mm (W)×246±2 mm (H)×146±2 mm (D)	< 2.8 kg	
X12	306±2 mm (W)×309±2 mm (H)×151±2 mm (D)	< 3.5 kg	

A.2.2 Function Configuration

Product	Configuration
X8	ECG (3 electrodes), ECG (5 electrodes), RESP, TEMP (T1), SpO_2, NIBP ECG (6 electrodes), ECG (10 electrodes), CO_2, Wi-Fi, Recorder
X10	ECG (3 electrodes), ECG (5 electrodes), RESP, TEMP (T1, T2), SpO_2, NIBP ECG (6 electrodes), ECG (10 electrodes), IBP, CO_2, Wi-Fi, Recorder
X12	ECG (3 electrodes), ECG (5 electrodes), RESP, TEMP (T1, T2), SpO_2, NIBP ECG (6 electrodes), ECG (10 electrodes), IBP, CO_2, C.O., Wi-Fi, Recorder

A.2.3 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 ºF ~104 ºF) When the battery is charged: +0 °C to +35 °C (32 ºF~95 ºF)	
Transport and Storage	-20 °C to +55 °C (-4 ºF ~131 ºF)	
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	
	X8	Current=1.0 A-0.5 A;
	X10/X12	Current=1.4 A-0.7 A.

A.2.4 Display

Product	Display	Messages
X8	Display screen: 8-inch color TFT, supporting touch screen Resolution: 800×600 A maximum of 13 waveforms	One power LED Two alarm LED One charge LED

Product	Display	Messages
X10	Display screen: 10.1-inch color TFT, supporting touch screen Resolution: 800×480 A maximum of 13 waveforms	
X12	Display screen: 12.1-inch color TFT, supporting touch screen Resolution: 800×600 A maximum of 13 waveforms	

A.2.5 Battery Specification

Operating Time	2550 mAh (standard)	≥ 4 h
	5100 mAh (optional)	≥ 8 h
Condition	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, brightness set to “1”.	
Charge Time	2550 mAh (standard)	≤ 3.5 h, 90% charge
	5100 mAh (optional)	≤ 6.5 h, 90% charge
Condition	Environment temperature: 20 °C ~30 °C. And the monitor is off.	
Charge/Discharge Cycle	300 times	

A.2.6 Recorder

Record Width	48 mm
Record Paper Width	50 mm
Paper Speed	12.5 mm/s, 25 mm/s, 50 mm/s
Trace	3
Recording types	Continuous real-time recording 8 seconds real-time recording 20 seconds real-time recording

	Time recording Alarm recording Trend graph recording Trend table recording NIBP review recording Arrhythmia review recording Alarm review recording Drug calculation titration recording Hemodynamic Calculation result recording 12-lead analysis recording C.O. measurement recording ST view recording QT view recording

A.2.7 Data Management

Data Review

Trend graph/trend table review	3 hrs, at 1 Second Resolution 120 hrs, at 1 min. Resolution
Alarm/Monitoring Event data	Up to 200 sets
NIBP Measurement Review	1200 sets
Arrhythmia events	Up to 200 sets
12-lead analysis Review	Up to 50 sets

Refer to Chapter *Review* for more information about data review.

Data Storage

A single piece of patient data maximally contains the following information:

Trend graph and trend table	240 hours, resolution: 1 min
NIBP measurement review	1200 sets
Alarm review	200 sets
Arrhythmia event	200 sets

12-lead analysis review	50 sets
Full disclosure Waveforms	3 electrodes/5 electrodes/6 electrodes: 48 hours 10 electrodes: 35 hours

The following storage capacity for 1 G extended space is for reference:

Continuous parameter data	720 hours, resolution: 1 min
NIBP data	At least 68000 sets
Physiological alarm event	At least 4500 sets
Arrhythmia event	At least 4500 sets
Full disclosure waveforms	30 hours

Refer to Section *Storing Data in the Storage Device* for more information about storing data in the storage medium.

A.3 Wi-Fi (Optional)

A.3.1 Wi-Fi Technical Specifications

IEEE	802.11a/b/g/n
Frequency Band	2.4 GHz ISM band & 5 G ISM band
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Maximum Transmit Power (±2 dBm)	2.4 G: 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 G: 10 dBm for 802.11a OFDM 9 dBm for 802.11n OFDM

A.3.2 Wi-Fi Performance Specifications

System Capacity and Resistance to Wireless Interference	When the following conditions are present, ■ Quantity of the monitors supported by a single AP: ≤ 8. ■ Each monitor can communicate with MFM-CMS. ■ Each monitor supports bed view function, which allows users to view its information from another bed or view other bed's information from its screen. ■ The AP signal strength of the monitor should be stronger than -65 dBm. ■ When the distance between the interfering devices and the monitor is more than 30 cm, and there are a co-channel interference Wi-Fi network (at least -85 dBm weaker than the monitor's network) and an adjacent-channel Wi-Fi network (at least -50 dBm weaker than the monitor's network) at the same time. Note: Excluding the Wi-Fi devices, the interfering devices include but are not limited to: ◆ 2.4 G or 5G wireless devices (excluding Wi-Fi devices) ◆ Cellular mobile communication networks ◆ Microwave ovens ◆ Interphones ◆ Mobile phones ◆ ESU equipment The wireless network function of all monitors works normally and meets the following requirements: ■ Total delay time for data transmission from

	the monitors to MFM-CMS: ≤ 2 s. ■ Total delay time of data transmission from one monitor to other monitors: ≤ 2 seconds. ■ Effective time of alarm reset configured on another monitor ≤ 2 s. ■ Effective time for monitor-related settings configured on the MFM-CMS: ≤ 2 s. ■ No communication loss between all the monitors.
Wi-Fi Network Stability	When the following conditions are present, ■ Quantity of the monitors supported by a single AP: ≤ 8. ■ Each monitor can communicate with MFM-CMS. ■ Each monitor supports bed view function, which allows users to view its information from another bed or view other bed's information from its screen. ■ The AP signal strength of the monitor should be stronger than -65 dBm. The following requirements must be met: ■ Within 24 hours, the time percentage of failing to transmit data from any monitor to the MFM-CMS does not exceed 0.1%. When the connected 8 monitors roam for 30 times, the time percentage of failing to transmit data from any monitor to the MFM-CMS does not exceed 0.1%.
Distinct Vision Distance	The distinct vision distance between the monitor and the AP: ≥ 50 meters.

A.4 ECG

Complies with IEC 60601-2-25, IEC 60601-2-27.

Lead Mode	3 Electrodes: I, II, III 5 Electrodes: I, II, III, aVR, aVL, aVF, V 6 Electrodes: I, II, III, aVR, aVL, aVF, and leads corresponding to Va Vb. 10 Electrodes: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Electrode Standard	AHA, IEC
☆Display Sensitivity (Gain Selection)	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/mV (×4), AUTO gain
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
Bandwidth (-3dB) (Output amplitude relative to that for a 5 Hz sinusoidal input signal)	Diagnosis: 0.05 Hz to 150 Hz Diagnosis 1: 0.05 Hz to 40 Hz Monitor: 0.5 Hz to 40 Hz Surgery: 1 Hz to 20 Hz Enhanced: 2 Hz ~18 Hz Customized: High-pass Filter and Low-pass Filter (Refer to *Changing the ECG Filter Settings*)
☆CMRR (Common Mode Rejection Ratio)	Diagnosis: > 95 dB Diagnosis 1: > 105 dB (when Notch is turned on) Monitor: > 105 dB Surgery: > 105 dB Enhanced: > 105 dB Customized: > 105 dB (Low-pass Filter < 40 Hz) > 95 dB (Low-pass Filter > 40 Hz)
Hum Filter	In diagnosis, Diagnosis 1, monitor, surgery, enhanced and customized modes: 50 Hz/60 Hz (Hum filter can be turned on or off manually)
☆Differential Input Impedance	> 5 MΩ

☆Input Signal Range	±10 mV PP
☆Accuracy of Signal Reproduction	An error of ≤ ±20 % of the nominal value of the output or ±100 μV, whichever is greater. The total error and frequency response comply with IEC 60601-2-27: 2011, Sect. 201.12.1.101.1.
☆Electrode Offset Potential Tolerance	± 800 mV
Auxiliary Current (Leads off detection)	Active electrode: < 100 nA Reference electrode: < 900 nA
☆Recovery Time After Defibrillation	< 5 s (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)
Leakage Current of Patient	< 10 μA
Scale Signal	1 mV PP, accuracy is ±5%
☆System Noise	< 30 μV_{P-P}
☆Multichannel Crosstalk	≤ 5% of the input signal Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.5.
☆Frequency and Impulse Response	Frequency response: Input a 5 Hz, 1 mV sine wave signal, and the output signal amplitude remains within the range of 71 % to 110 % at 0.67 Hz and 40 Hz. Input a 1 Hz, 1.5 mV 200 ms triangular wave input signal, and the output shall be within 11.25 mm~15 mm. Impulse response: Displacement value: ≤ 0.1 mV Slope: ≤ 0.3 mV/s following the end of the pulse. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.8.
Sampling Frequency	1000 Hz
Sampling Channel Switch Time	< 80 μS

A/D Precision	24 Bits (Minimum resolution: 0.077uV/LSB)
☆ESU Protection	Cut mode: 300 W Coagulation mode: 100 W Restore time: ≤ 10 s
Electrosurgical Interference Suppression	Test according to ANSI/AAMI EC13:2002, Sect. 5.2.9.14. Complied with ANSI/AAMI EC13:2002, Sect. 4.2.9.14.
Minimum Input Slew Rate (Lead II)	> 2.5 V/s
☆Baseline Reset Time	< 3 s
Pace Pulse (without overshoot)	
☆Pulse Indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to2.0 ms Ascending time: 10 μs to 100 μs
☆Pulse Rejection	Pulse is rejected if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.13 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs
Pace Pulse Detecting Lead: one among I, II, III, AVR, AVL, AVF, V1, V2, V3,V4, V5, V6	
Heart Rate	
HR Calculation	
☆Range	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm
☆Accuracy	±1% or 1 bpm, whichever is greater
Resolution	1 bpm
Sensitivity	≥ 300 μVPP

☆QRS Detection Range	The detection range has exceeded the requirement described in the standard: Width: 70 ms~120 ms for adult, 40 ms~120 ms for Pediatric/neonate. Amplitude: 0.5 mv~5 mv In adult mode, these two signals are not responded: 1. when QRS amplitude of 0.15 mV or less is applied; 2. when QRS duration of 10 ms and QRS amplitude of 1 mV or less is applied. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.15.
PVC	
Range	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min
Resolution	1 PVCs/min
Pauses/min	
Range	ADU/PED/NEO: (0 to 30) pauses/min
Resolution	1 pause/min
ST value	
Range	-2.0 mV to +2.0 mV
Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.
Resolution	0.01 mV
QT measurement	
Range	200 ms ~ 800 ms
Resolution	4 ms
Accuracy	± 30 ms
QTc measurement	
Range	200ms ~ 800 ms

Resolution	1 ms
ΔQTc measurement	
Range	-600 ms ~ 600 ms
Resolution	1 ms
HR Averaging Method	
Method 1	Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.
Method 2	If each of three consecutive RR intervals is greater than 1200 ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
Normal	Adult: 0.5 s < RR interval for 5 consecutive QRS complex < 1.5 s. Pediatric/neonatal: 0.375 s < RR interval for 5 consecutive QRS complex < 1 s.
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.
Range of Ventricular Rhythm	
V-Tach	5 consecutive ventricular beats and ventricular HR ≥ 100 bpm.
Vent Rhythm	5 consecutive ventricular beats, and 20 bpm ≤ ventricular HR < 40 bpm.
Vent Brady	5 consecutive ventricular beats, and ventricular HR < 20 bpm.
Acc. Vent Rhythm	5 consecutive ventricular beats, and 40 bpm ≤ ventricular HR < 100 bpm.

<table>
<tr><td colspan="4">Maximum Start-up Alarm Time for Tachycardia</td></tr>
<tr><td>Ventricular Tachycardia
1 mV 206 bpm</td><td colspan="3">Gain 0.5: 10 s
Gain 1.0: 10 s
Gain 2.0: 10 s</td></tr>
<tr><td>Ventricular Tachycardia
2 mV 195 bpm</td><td colspan="3">Gain 0.5: 10 s
Gain 1.0: 10 s
Gain 2.0: 10 s</td></tr>
<tr><td>Response Time of Heart Rate Meter to Change in HR</td><td colspan="3">HR range: 80 bpm to 120 bpm
Range : Within 11 s
HR range: 80 bpm to 40 bpm
Range : Within 11 s</td></tr>
<tr><td>☆Tall T-wave Rejection</td><td colspan="3">Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude</td></tr>
<tr><td>Accuracy of Heart Rate Meter and Response to Irregular Rhythm</td><td colspan="3">Complied with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4), the HR value after 20 seconds of stabilization is displayed as follows:
Ventricular bigeminy: 80 bpm±1 bpm
Slow alternating ventricular bigeminy: 60 bpm±1 bpm
Rapid alternating ventricular bigeminy: 120 bpm±1 bpm
Bidirectional systoles: 91 bpm±1 bpm</td></tr>
<tr><td>Time to Alarm for Heart Rate alarm conditions</td><td colspan="3">Asystole alarm: ≤ 10 s
HR low alarm: ≤ 10 s
HR high alarm: ≤ 10 s</td></tr>
<tr><td rowspan="8">Arrhythmia analyses</td><td>Asystole</td><td>V-Fib/V-Tach</td><td>Couplet</td></tr>
<tr><td>Vent Rhythm</td><td>PVC Bigeminy</td><td>PVC Trigeminy</td></tr>
<tr><td>Tachy</td><td>R on T</td><td>PVC</td></tr>
<tr><td>Irr Rhythm</td><td>Brady</td><td>Missed Beat</td></tr>
<tr><td>Pacer not Pacing</td><td>Vent Brady</td><td>Pacer not Capture</td></tr>
<tr><td>VEB</td><td>Run PVCs</td><td>Acc. Vent Rhythm</td></tr>
<tr><td>IPVC</td><td>Non-Sustain VT</td><td>Multiform PVCs</td></tr>
<tr><td>Pauses/min High</td><td>Pause</td><td>Afib</td></tr>
</table>

	PAC Bigeminy	PVCs High	Low Voltage(Limb)
	ExtremeBrady	PAC Trigeminy	Wide QRS Tachy
	Sustain VT	ExtremeTachy	V-Tach
12-Lead ECG Synchronization Analysis	Average parameters of heart beat		
	Heart rate (bpm)		
	Time limit of P wave (ms)		
	PR interval (ms)		
	QRS interval (ms)		
	QT/QTC (ms)		
	P-QRS-T AXIS		

A.5 RESP

Method	Impedance between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is Lead II.
Calculation Type	Manual, Automatic
Baseline Impedance Range	200 Ω to 2500 Ω (with ECG cables of 1 KΩ resistance)
Measuring Sensitivity	Within the baseline impedance range: 0.3 Ω
Waveform Bandwidth	0.2 Hz to 2.5 Hz (-3 dB)
Respiration Excitation Waveform	Sinusoid, 45.6 kHz (±10%), < 350 μA
☆RR Measuring Range	
☆Adult	0 rpm to120 rpm
☆Neo/Ped	0 rpm to150 rpm
Resolution	1 rpm
☆Accuracy	
☆Adult	6 rpm to 120 rpm: ±2 rpm 0 rpm to 5 rpm: not specified

☆Neo/Ped	6 rpm to 150 rpm: ±2 rpm 0 rpm to 5 rpm: not specified		
☆Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5		
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s		
☆Apnea Delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.		
☆RR Measuring Range	☆Range	From ECG	0 rpm ~ 120 rpm (Adult) 0 rpm ~ 150 rpm (Pediatric/Neonate)
		From SpO_2	4 rpm ~ 70 rpm
	☆Accuracy	From ECG	±2 rpm; Undefined (0 rpm~6 rpm)
		From SpO_2	Arms ≤ 3 rpm, mean error [-1,1] rpm Arms accuracy is a statistical calculation of the difference between the measurement value and the reference measurement value.

A.6 NIBP

Complies with IEC 80601-2-30

Technique	Oscillometry
Mode	Manual, Auto, Continuous, Sequence

Measuring Interval in AUTO Mode (unit: minutes)	1/2/2.5/3/4/5/10/15/30/60/90/120/180/240/360/480 and User Define
Continuous	5 min, interval is 5 s
Measuring Parameter	SYS, DIA, MAP, PR
Pressure Unit	kPa, mmHg, cmH_2O
☆Measuring Range	
☆Adult Mode	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg
☆Pediatric Mode	SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg
☆Neonatal Mode	SYS: 25 mmHg to 140 mmHg DIA: 10 mmHg to 115 mmHg MAP: 15 mmHg to 125 mmHg
☆Alarm Type	SYS, DIA, MAP, PR (NIBP)
☆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	iCUFS measurement: 20 s to 35 s (depend on HR/motion disturbance) (measured with E9 cuff, default inflation value, PR is set as 80 bpm and systolic pressure within 100~120 mmHg,) iFAST measurement: 15 s (depend on SYS, arm circumstance and HR/motion disturbance) (measured with E8 cuff, PR is set as 80 bpm and systolic pressure within 100~120 mmHg)

Dual Independent Channel Overpressure Protection	
Adult	(297±3) mmHg
Pediatric	(245±3) mmHg
Neonatal	(147±3) mmHg
Pre-inflation Pressure	
Adult Mode	Range: 80/100/120/140/150/160/180/200/220/240 mmHg
Pediatric Mode	Range: 80/100/120/140/150/160/180/200 mmHg
Neonatal Mode	Range: 60/70/80/100/120 mmHg
Venipuncture pressure	
Adult	Default: 60 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 110 mmHg, 120 mmHg
Pediatric	Default: 40 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg
Neonatal	Default: 30 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg

A.7 SpO_2

Complies with ISO 80601-2-61.

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)

Sensor	
Red Light	(660±3) nm
Infrared Light	(905±10) nm
Emitted Light Energy	< 15 mW
Sensor Light Intensity Display	5 levels
SI	
Measuring Range	0-10, invalid SI value is -?-.
Resolution	1
PI	
Measuring Range	0.00-20%, invalid PI value is -?-.
Resolution	1% (10% to 20%) 0.1% (1.0% to 9.9%) 0.01% (0.00% to 0.99%)

NOTE:

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

A.8 TEMP

Complies with ISO 80601-2-56.

Technique	Thermal resistance
Position	Skin, oral cavity, rectum
Measure Parameter	T1, T2, TD (the absolute value of T2 minus T1)
Channel	X8: 1 X10/X12: 2
Sensor Type	YSI-10K and YSI-2.252K
Unit	°C, °F
Measuring Range	0 °C to 50 °C (32 ºF to 122 ºF)
Resolution	0.1 °C (0.1 ºF)
☆Accuracy	±0.3 °C (±0.54 ºF)

	[±0.1 °C (±0.18 ºF), exclude sensor error]
Refresh Time	Every 1 s to 2 s
Temperature Calibration	At an interval of 5 to 10 minutes
Measuring Mode	Direct Mode
Transient Response Time	≤ 30 s

TD-1261

☆Measuring range	32 ℃ to 43 ℃ (89.6 ℉ to 109.4 ℉)
Accuracy	Meet the accuracy requirement specified in ASTM E1965-98 ±0.2 °C (±0.4 °F) (36 °C ~39 °C) ± 0.3 ° C (± 0.5 ℉) (34 ° C~35.9 ° C) and (39.1 °C~42.2 °C)
Clinical bias	0.10
Limits of agreement	-0.43~0.63
Clinical repeatability	0.08

A.9 PR

	Measuring range	Accuracy	Resolution
PR (SpO_2)	25 bpm to 300 bpm	± 2 bpm	1 bpm
PR (NIBP)	40 bpm to 240 bpm	± 3 bpm or 3.5%, whichever is greater	1 bpm
PR (IBP)	20 bpm to 300 bpm	30 bpm to 300 bpm: ± 2 bpm or ± 2%, whichever is greater; 20 bpm to 29 bpm: undefined	1 bpm

A.10 IBP

Only applicable to X10 and X12.

Complies with IEC 60601-2-34.

Technique	Direct invasive measurement

Channel			2 channels
IBP Measure	☆Measuring Range	Art	(0 to +300) mmHg
		PA/PAWP	(-6 to +120) mmHg
		CVP/RAP/LAP/ICP	(-10 to +40) mmHg
		P1/P2	(-50 to +300) mmHg
	Resolution		1 mmHg
	☆Accuracy (not including sensor)		± 2 % or ±1 mmHg, whichever is greater ICP: 0 mmHg to 40 mmHg: ± 2 % or ±1 mmHg, whichever is greater; -10 mmHg to -1 mmHg: undefined
Pressure Unit			kPa, mmHg, cmH_2O
Pressure sensor			
Sensitivity			5 μV/V/mmHg
Impedance Range			300 Ω to 3000 Ω
Filter			DC~ 12.5 Hz; DC~ 40 Hz
Zero			Range: ± 200 mmHg
Pressure Calibration Range		IBP (excluding ICP)	80 mmHg to 300 mmHg
		ICP	10 mmHg to 40 mmHg
Volume Displacement			7.4 x 10^4 mm^3 / 100 mmHg

A.11 CO_2

Complies with ISO 80601-2-55.

Intended Patient	Adult, pediatric, neonatal	
Measure Parameters	$EtCO_2$, $FiCO_2$, AwRR	
Unit	mmHg, %, kPa	
☆Measuring	$EtCO_2$	0 mmHg to 150 mmHg (0 % to 20%)

<table>
<tr><td rowspan="2">Range</td><td>$FiCO_2$</td><td colspan="2">0 mmHg to 50 mmHg</td></tr>
<tr><td>AwRR</td><td colspan="2">2 rpm to 150 rpm</td></tr>
<tr><td rowspan="3">Resolution</td><td>$EtCO_2$</td><td colspan="2">1 mmHg</td></tr>
<tr><td>$FiCO_2$</td><td colspan="2">1 mmHg</td></tr>
<tr><td>AwRR</td><td colspan="2">1 rpm</td></tr>
<tr><td rowspan="6">☆Accuracy</td><td rowspan="5">$EtCO_2$</td><td>± 2 mmHg, 0 mmHg to 40 mmHg</td><td rowspan="4">Typical conditions:
Ambient temperature: (25 ± 3) °C
Barometric pressure: (760 ± 10) mmHg
Balance gas: N_2
Sample gas flowrate: 100 ml/min</td></tr>
<tr><td>± 5% of reading, 41 mmHg to 70 mmHg</td></tr>
<tr><td>± 8% of reading, 71 mmHg to 100 mmHg</td></tr>
<tr><td>± 10% of reading, 101 mmHg to 150 mmHg</td></tr>
<tr><td>± 12% of reading or ± 4 mmHg, whichever is greater</td><td>All conditions</td></tr>
<tr><td>AwRR</td><td colspan="2">± 1 rpm</td></tr>
<tr><td>Drift of Measure Accuracy</td><td colspan="3">Meets the requirements of the measure accuracy</td></tr>
<tr><td>Sample Gas Flowrate</td><td colspan="3">50 ml/min, 70 ml/min or 100 ml/min (default), accuracy: ±15 ml/min</td></tr>
<tr><td>Warm-up Time</td><td colspan="3">Display reading within 20 s; reach to the designed accuracy within 2 minutes.</td></tr>
<tr><td rowspan="3">Rise Time</td><td colspan="3">< 400 ms (with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)</td></tr>
<tr><td colspan="3">< 500 ms (with 2 m gas sampling tube, sample gas flowrate: 70 ml/min)</td></tr>
<tr><td colspan="3">< 1000 ms (with 2 m gas sampling tube, sample gas flowrate: 50 ml/min)</td></tr>
<tr><td rowspan="2">Response Time</td><td colspan="3">< 4 s
(with 2 m gas sampling tube, sample gas flowrate: 100 ml/min/70 ml/min)</td></tr>
<tr><td colspan="3">< 5.5 s (with 2 m gas sampling tube, sample gas flowrate: 50 ml/min)</td></tr>
<tr><td>Work Mode</td><td colspan="3">Standby (default), measure</td></tr>
</table>

O_2 Compensation	Range: 0% to 100% Resolution: 1% Default: 16%	
N_2O Compensation	Range: 0% to 100% Resolution: 1% Default: 0%	
AG Compensation	Range: 0% to 20% Resolution: 0.1% Default: 0%	
Humidity Compensation Method	ATPD (default), BTPS	
Barometric Pressure Compensation	Automatic (The change of barometric pressure will not add additional errors to the measurement values.)	
Zero Calibration	Support	
Calibration	Support (It is recommend to be operated by trained personal.)	
☆Alarm	$EtCO_2$, $FiCO_2$, AwRR	
☆Apnea delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.	
Data Sample Rate	100 Hz	
$EtCO_2$ Change[1]	AwRR ≤ 80 rpm, meet the accuracy mentioned above; AwRR > 80 rpm, $EtCO_2$ descends 8%; AwRR > 120 rpm, $EtCO_2$ descends 10%;	with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)
	AwRR ≤ 60 rpm, meet the accuracy mentioned above; AwRR > 60 rpm, $EtCO_2$ descends 8%; AwRR > 90 rpm, $EtCO_2$ descends 10%; AwRR > 120 rpm, $EtCO_2$ descends 15%;	with 2 m gas sampling tube, sample gas flowrate: 70 ml/min)

	AwRR ≤ 20 rpm, meet the accuracy mentioned above; AwRR > 20 rpm, $EtCO_2$ descends 8%; AwRR > 40 rpm, not applicable;	with 2 m gas sampling tube, sample gas flowrate: 50 ml/min)

Note 1: Use a test device equivalent to EN ISO 80601-2-55 fig 201.101 to measure at 1:2 I/E ratio. Respiration rate accuracy is determined by frequency of device, and end-tidal reading change refers to the nominal value.

Interfering Gas Effects:

Gas	Gas Level (%)	Quantitative Effect/Comments
Nitrous oxide	60%	None
Halothane	4%	None
Enflurane	5%	None
Isoflurane	5%	None
Sevoflurane	5%	None
Xenon	Not applicable	Not applicable
Hehelium	Not applicable	Not applicable
Metered dose inhaler propellants	Not applicable	Not applicable
Desflurane	15%	None
Ethanol	0.1%	None
Isopropanol	0.1%	None
Acetone	0.1%	None
Methane	1%	None

NOTE:

Respiration Rate accuracy was verified by using a solenoid test setup to deliver a square wave of known CO_2 concentration to the device. 5% and 10% CO_2 concentrations were used. Respiration rate was varied over the range of the device. Pass/Fail criteria was comparison of the respiratory rate output from the sensor to the frequency of the square wave.

A.12 C.O.

Only applicable to X12.

Technique	Thermodilution Technique
Measure Parameters	C.O., TB, TI
Measuring Range	
C.O.	0.1 L/min to 20 L/min
TB	23 °C to 43 °C (73.4 ºF to 109.4 ºF)
TI	-1 °C to 27 °C (30.2 ºF to 80.6 ºF)
Resolution	
C.O.	0.01 L/min
TB, TI	0.1 °C (+0.1 ºF)
Accuracy	
C.O.	±5% or ± 0.2 L/min, whichever is greater
TB	±0.1 °C (±0.18 ºF) (not including sensor)
TI	±0.1 °C (±0.18 ºF) (not including sensor)

NOTE:

At least 90% of the C.O. data should reside inside the bounded region, and the lower 95% confidence interval should not exceed 85%.

A.13 Interfaces

A.13.1 Analog Output (Optional)

Bandwidth (-3 dB; reference frequency: 10 Hz)	Monitor: 0.5 Hz to 40 Hz Diagnosis/Diagnosis 1: 0.05 Hz to 40 Hz Surgery: 1 Hz to 20 Hz Enhanced: 2 Hz ~18 Hz Customized: When Low-pass Filter < 40 Hz, Bandwidth is High-pass Filter ~ Low-pass Filter; When Low-pass Filter > 40 Hz, Bandwidth is High-pass ~40 Hz.

Maximum Transmission Delay (Diagnosis Mode)	500 ms
Sensitivity	1 V/1 mV ±10%
PACE Rejection/ Enhancement	No PACE Rejection or Enhancement
Waveform Display	Consistent with the calculation leads.
Compliant with Standard and Directive	Complies with the requirements in terms of short circuit protection and leakage current in EN60601-1.
Output Impedance	< 500 Ω
Interface Type	PS2 connector

NOTE:

While using analog output, set the calculation lead as following:

1) In 3 Electrodes mode, set to Lead I, Lead II, or Lead III.

2) In 5 Electrodes mode, set to Lead I, Lead II, Lead III or Lead V.

3) In 6 Electrodes mode, set to I, II, III, and leads corresponding to Va, Vb.

4) In 10 Electrodes mode, set to Lead I, Lead II, Lead III or Lead V1~V6.

A.13.2 Defibrillator Synchronization (Optional)

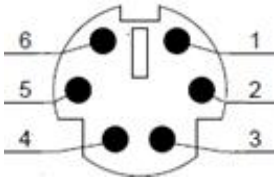
Output Impedance	< 500 Ω
Maximum Time Delay	35 ms (R-wave peak to leading edge of pulse)
Waveform	Rectangular wave
Amplitude	High level: 3.5 V to 5.5 V, providing a maximum of 1 mA output current; Low level: < 0.5 V, receiving a maximum of 5 mA input current
Minimum Required R-wave Amplitude	0.3 mV
Pulse Width	100 ms±10%
Limited Current	15 mA rating

Rising and Falling Time	< 1 ms
Interface Type	PS2 connector

A.13.3 Nurse Call (Optional)

Drive Mode	Voltage output
Power Supply	≤ 12.6 VDC, 200 mA Max.
Interface Signal	12 V power supply and PWM waveform
Interface Type	PS2 connector

PS2 connector Definition for Analog Output/Defibrillator Synchronization/Nurse Call

	PIN.NO.	Signal name	Signal Description
	1	ANALOG_OUT	Analog out signal
	2	GND	Ground
	3	SYS_OUT	Defibrillator Synchronization signal
	4	+12V	Nurse call power
	5	GND	Ground
	6	NURSE_OUT	Nurse call control signal

A.13.4 USB Interfaces

Number of USB Interfaces	Standard: 2
Drive Mode	HOST interface, USB 2.0 protocol
Power Supply	5 VDC±5%, 500 mA Max.
Interface Type	USB A-type port

A.13.5 VGA Interface (Optional)

Number of VGA Interface	1
Horizontal Refreshing Rate	(30-94) KHZ
Video Signal	0.7 Vpp @ 75 Ohm, HSYNC/VSYNC signal TTL
Interface Type	DB-15 female receptacle

A.13.6 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		
X8 X10 and X12 are intended for use in the electromagnetic environment specified below. The customer or the user of X8/X10/X12 should assure that they are used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	X8 X10 and X12 use 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	X8 X10 and X12 are 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 X8 X10 and X12 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) X8 X10 and X12 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			
X8 X10 and X12 are intended for use in the electromagnetic environment specified below. The customer or the user of X8 X10 and X12 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 X8 X10 and X12 requires continued operation during power mains interruptions, it is recommended that X8 X10 and X12 be powered from an uninterruptible power supply or a battery.
IMMUNITY to proximity magnetic fields	Test frequency: 30 KHz; 65 A/m, Modulation: Pulse modulation, 2.1 KHz Test frequency: 134.2 KHz; 7.5 A/m, Modulation: Pulse modulation, 50 KHz Test frequency: 13.56 MHz;	Test frequency: 30 KHz; 65 A/m, Modulation: Pulse modulation, 2.1 KHz Test frequency: 134.2 KHz; 7.5 A/m, Modulation: Pulse modulation, 50 KHz Test frequency: 13.56 MHz;	-
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

B.3 Electromagnetic Immunity

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">X8 X10 and X12 are intended for use in the electromagnetic environment specified below. The customer or the user of X8 X10 and X12 should assure that they are used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC/EN 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC/EN 61000-4-6

Radiated RF
IEC/EN 61000-4-3</td><td>3 V_{rms}
150 kHz to 80 MHz
6Vrms[c] in ISM bands between

0.15 MHz and 80 MHz

3 V/m
80 MHz to 2.7 GHz

See Table 1</td><td>3 V_{rms}
150 kHz to 80 MHz
6Vrms[c] in ISM bands between

0.15 MHz and 80 MHz

3 V/m
80 MHz to 2.7 GHz

Comply with Table 1</td><td>Portable and mobile RF communications equipment should be used no closer to any part of X8 X10 and X12, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2\sqrt{P}$ 150 KHz to 80 MHz
$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz
$d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, 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</td></tr>
</table>

			the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which X8 X10 and X12 are used exceeds the applicable RF compliance level above, X8 X10 and X12 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating X8 X10 and X12.

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

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

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

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

5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
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 X8 X10 and X12

X8 X10 and X12 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of X8 X10 and X12 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and X8 X10 and X12 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
Pace	Off

C.2 Alarm Default Settings

Alarm Settings	
Pause Time	120 s
Sensor Off Alarm	Off
Alarm Latch	Off

C.3 ECG Default Settings

ECG Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
Pace	Off		
Electrode Type	5 Electrodes		
Screen Layout	Normal		
Filter	Monitor		
Smart Lead Off	Off		

Heart Volume	3		
ST Analysis	ADU	PED	NEO
ST Analysis	Off	Off	Off
Alarm Switch	Off		
Alarm Level	Medium		
Alarm Record	Off		
Alarm High Limit (ST-X)	0.2		
Alarm Low Limit (ST-X)	-0.2		
QT Analysis	Off		
QTc	500	480	460
ΔQTc	60		
X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6.			
	ADU	PED	NEO
ARR Analysis	On	Off	Off
ARR Alarm Settings	Alarm Switch	Alarm Level	Alarm Record
Asystole	On (non-adjustable)	High (non-adjustable)	Off
V-Fib/V-Tach	On	High (non-adjustable)	Off
R on T	On	Medium	Off
PVC	Off	Low	Off
Couplet	On	Low	Off
Run PVCs	On	Low	Off
PVC Bigeminy	On	Medium	Off
PVC Trigeminy	On	Low	Off
Tachy	On	Medium	Off
Brady	On	Medium	Off

Missed Beat	Off	Low	Off
Irr Rhythm	Off	Low	Off
Pacer not Capture	On	Medium	Off
Pacer not Pacing	On	Medium	Off
Vent Brady	On	High (non-adjustable)	Off
Vent Rhythm	On	Medium	Off
Sustain VT	On (non-adjustable)	High (non-adjustable)	Off
ExtremeTachy	On	High (non-adjustable)	Off
ExtremeBrady	On	High (non-adjustable)	Off
V-Tach	On	High (non-adjustable)	Off
Wide QRS Tachy	On	Medium	Off
Non-Sustain VT	On	Medium	Off
Afib	On	Medium	Off
Acc. Vent Rhythm	On	Low	Off
Pause	On	Medium	Off
Pauses/min High	On	Medium	Off
PVCs High	On	Medium	Off
VEB	Off	Low	Off
Multiform PVCs	Off	Low	Off
IPVC	Off	Low	Off
PAC Bigeminy	Off	Low	Off
PAC Trigeminy	Off	Low	Off
Low Voltage(Limb)	Off	Low	Off
ARR Analysis Threshold Value			
Low Voltage(Limb)	0.5 mV		

Pause	3 s		
Sustain VT	30 s		
PAC Bigeminy	8/min		
Pauses/min High	8/min		
PVCs High	10/min		
PAC Trigeminy	16/min		
ExtremeTachy	160	180	200
ExtremeBrady	30	50	60

C.4 RESP Default Settings

RESP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	30	30	100
Alarm Low Limit	8	8	30
Apnea delay	20 s		
Calculation Type	Auto		
Resp Type	II		
Sweep	12.5 mm/s		
Amplitude	1		

C.5 SpO_2 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
Pitch Tone	On		
Sweep	12.5 mm/s		
SpO_2 Desat Limit	80%		

C.6 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	Auto		

C.7 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
Venipuncture pressure	60	40	30

Inflation value	160	140	100
Unit	mmHg		
Measure Mode	Manual		

C.8 TEMP Default Settings

TEMP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (T1)	39.0	39.0	39.0
Alarm Low Limit (T1)	36.0	36.0	36.0
Alarm High Limit (T2)	39.0	39.0	39.0
Alarm Low Limit (T2)	36.0	36.0	36.0
Alarm High Limit (TD)	2.0	2.0	2.0
Unit	°C		

C.9 IBP Default Settings

IBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Unit	mmHg		
Filter	12.5 Hz		
	SYS, DIA, MAP	SYS, DIA, MAP	SYS, DIA, MAP
Alarm High Limit (ART, P1, P2)	160, 90, 110	120, 70, 90	90, 60, 70
Alarm Low Limit (ART, P1, P2)	90, 50, 70	70, 40, 50	55, 20, 35
Alarm High Limit (PA)	35, 16, 20	60, 4, 26	60, 4, 26

Alarm Low Limit (PA)	10, 0, 0	24, -4, 12	24, -4, 12
	MAP	MAP	MAP
Alarm High Limit (CVP, RAP, LAP, ICP)	10	4	4
Alarm Low Limit (CVP, RAP, LAP, ICP)	0	0	0

C.10 CO_2 Default Settings

CO_2 Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Standby		
Unit	mmHg		
Apnea delay	20 s		
O_2 Compensate	16%		
N_2O Compensate	0%		
Water vapor Compensate	Off		
Flow rate	100%		
Anes Agent	0.0%		
Alarm High Limit ($EtCO_2$)	50	50	45
Alarm Low Limit ($EtCO_2$)	25	25	30
Alarm High Limit ($FiCO_2$)	4	4	4
Alarm High Limit (AwRR)	30	30	100
Alarm Low Limit (AwRR)	8	8	30
Sweep	6.25 mm/s		
Amplitude	Low		

C.11 C.O. Default Settings

C.O. Settings	ADU
Alarm Switch	On
Alarm Record	Off
Alarm Level	Medium
Alarm High Limit (TB)	40.0
Alarm Low Limit (TB)	30.0
Injective Temperature Source	Auto
Temperature Unit	°C
Interval	30
Constant	0.542

D Abbreviations

Abbr	English Full Name/Description
AC	Alternating current
Acc. Vent Rhythm	Accelerated Idioventricular Rhythm
Adu	Adult
Afib	Atrial fibrillation
AG	Anaesthesia gas
Art	Arterial
aVF	Left foot augmented electrode
aVL	Left arm augmented electrode
aVR	Right arm augmented electrode
AwRR	Airway respiration rate
BC	Burst count
BIS	Bispectral index
BP	Blood pressure
BTPS	Body temperature and pressure, saturated
Brady	Bradycardia
CCU	Cardiac care unit
CI	Cardiac index
C.O.	Cardiac output
CISPR	International Special Committee on Radio Interference
CMS	Central monitoring system
CO_2	Carbon dioxide
COHb	Carboxyhemoglobin
Couplet	Ventricular couplets
CVP	Central venous pressure
DC	Direct current
Des	Desflurane

Abbr	English Full Name/Description
Dia	Diastolic
DoS	Denial of Service
DDoS	Distributed Denial of Service
ECG	Electrocardiogram
EEC	European Economic Community
EEG	Electroencephalogram
EMC	Electromagnetic compatibility
EMG	Electromyelogram
EMI	Electromagnetic interference
Enf	Enflurane
ER	Emergency room
ESU	Electrosurgical unit
Et	End-tidal
$EtCO_2$	End-tidal carbon dioxide
EtN_2O	End-tidal nitrous oxide
Eto	Ethylene oxide
EtO_2	End-tidal oxygen
ExtremeTachy	Extreme Tachycardia
ExtremeBrady	Extreme Bradycardia
FCC	Federal Communication Commission
FDA	Food and Drug Administration
Fi	Fraction of inspired
$FiCO_2$	Fraction of inspired carbon dioxide
FiN_2O	Fraction of inspired nitrous oxide
FiO_2	Fraction of inspired oxygen
Hal	Halothane
Hb	Hemoglobin
Hb-CO	Carbon mono-xide hemoglobin

Abbr	English Full Name/Description
HR	Heart rate
IBP	Invasive blood pressure
ICG	Impedance cardiography
ICP	Intracranial pressure
ICU	Intensive care unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
IPVC	Inserted Premature Ventricular Contraction
Irr Rhythm	Irregular Rhythm
Iso	Isoflurane
LA	Left arm
LAP	Left atrial pressure
LCD	Liquid crystal display
LED	Light emitting diode
LL	Left leg
Low Voltage(Limb)	Low QRS Voltage
MAP	Mean arterial pressure
MDD	Medical Device Directive
MetHb	Methemoglobin
MRI	Magnetic resonance imaging
Multiform PVCs	Multiformed Premature Ventricular Contractions
N/A	Not applicable
N_2	Nitrogen
N_2O	Nitrous oxide
Neo	Neonate
NICU	Neonatal intensive care unit
NIBP	Non-invasive blood pressure

Abbr	English Full Name/Description
O_2	Oxygen
OR	Operating room
OxyCRG	Oxygen cardio-respirogram
PA	Pulmonary artery
PAC Bigeminy	Premature Atrial Contraction (PAC) Bigeminy
PAC Trigeminy	Premature Atrial Contraction (PAC) Trigeminy
PACU	Post-anaesthesia care unit
PAWP	Pulmonary artery wedge pressure
Ped	Pediatric
Pleth	Plethysmogram
PR	Pulse rate
PVC	Premature ventricular contraction
R	Right
RA	Right arm
RAP	Right atrial pressure
Resp	Respiration
RHb	Reduced hemoglobin
RL	Right leg
RM	Respiration mechanics
RR	Respiration Rate
Run PVCs	Run premature Ventricular Contractions
SEF	Spectral edge frequency
Sev	Sevoflurane
SpO_2	Pulse Oxygen Saturation
Sustain VT	Sustained Ventricular Tachycardia
SQI	Signal quality indicator
SR	Suppression ratio
SYS	Systolic pressure
Tachy	Tachycardia

Abbr	English Full Name/Description
TB	Blood Temperature
TD	Temperature difference
TEMP	Temperature
TP	Total power
USB	Universal serial bus
Vent Brady	Ventricular Bradycardia
Vent Rhythm	Ventricular Rhythm
V-Fib/V-Tach	Ventricular Fibrillation/Ventricular Tachycardia
Wide QRS Tachy	Wide QRS Tachycardia

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